AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 76 Monday,
No. 137 July 18, 2011

Pages 41993–42468

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.ofr.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.fdsys.gov*, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Printing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpo@custhelp.com.*

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Printing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 76 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Printing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC	
Subscriptions:	
Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**
Single copies/back copies:	
Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**
FEDERAL AGENCIES	
Subscriptions:	
Paper or fiche	**202–741–6005**
Assistance with Federal agency subscriptions	**202–741–6005**

Printed on recycled paper.

Contents

Federal Register

Vol. 76, No. 137

Monday, July 18, 2011

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this page for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

5 CFR
831.....41993
841.....41993
842.....41993

6 CFR
5 (3 documents) 42003, 42004, 42005

7 CFR
989.....42006
1210.....42009
1260.....42012
Proposed Rules:
800.....42067
930.....42072

10 CFR
Proposed Rules:
20.....42074

12 CFR
204.....42015
217.....42015
230.....42015

14 CFR
33.....42020
39 (4 documents) 42024, 42029, 42031, 42033

17 CFR
Proposed Rules:
240.....42396

26 CFR
1 (2 documents) 42036, 42038
Proposed Rules:
1.....42076

33 CFR
165.....42048

38 CFR
Proposed Rules:
3.....42077

40 CFR
9.....42052
63.....42052
97.....42055
300.....42055
Proposed Rules:
52.....42078

42 CFR
Proposed Rules:
410.....42170
411.....42170
416.....42170
419.....42170
489.....42170
495.....42170

48 CFR
Ch. 10.....42056

50 CFR
Proposed Rules:
229.....42082
665.....42082
679.....42099

Rules and Regulations

Federal Register
Vol. 76, No. 137
Monday, July 18, 2011

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 831, 841 and 842

RIN 3206–AL69

Customs and Border Protection Officer Retirement

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is amending its regulations, to reflect changes in the retirement benefits available to customs and border protection officers under the Civil Service Retirement System (CSRS) and the Federal Employees' Retirement System (FERS). These rules incorporate amendments to CSRS and FERS retirement law pursuant to section 535 of the Department of Homeland Security Appropriations Act, 2008. The Act provides early retirement and enhanced annuity benefits for customs and border protection officers employed by the United States Department of Homeland Security under CSRS and FERS; requires an increase in the percentage rate of withholdings from the basic pay of customs and border protection officers; and establishes mandatory retirement of customs and border protection officers at age 57.

DATES: Effective July 18, 2011.

FOR FURTHER INFORMATION CONTACT: Patrick Jennings, (202) 606–0299.

SUPPLEMENTARY INFORMATION: On October 1, 2010, after consultation with the Department of Homeland Security, OPM published (at 75 FR 60645) proposed regulations and requested comments concerning section 535 of the Department of Homeland Security Appropriations Act, 2008 (the Act), Division E of the Consolidated Appropriations Act, 2008, Public Law 110–161 (approved December 26, 2007), 112 Stat. 1844, at 2075, which enacted new human resource management provisions applicable to specified Customs and Border Protection employees. Section 535 of the Act provides that individuals defined as ''customs and border protection officers'' will be prospectively added as a new group with special human resource management provisions essentially similar to those applicable to other special retirement groups including law enforcement officers, nuclear materials couriers, and firefighters. The principal elements of those structures include: (1) A maximum entry age (to maintain a young and vigorous workforce and to permit a career to be completed by mandatory retirement age); (2) early optional retirement eligibility; (3) enhanced annuity provisions (to make a shorter career economically feasible); (4) mandatory retirement (generally at age 57, but with agency authority to extend to age 60), and (5) higher employer and employee retirement contribution rates. The effective date of section 535 is July 6, 2008.

In addition to the provisions that will be continuing and that apply to individuals employed as customs and border protection officers, section 535 of the Act also includes unique provisions applicable to individuals who are customs and border protection officers on its effective date. These incumbents will not be subject to mandatory retirement, but are eligible for partial annuity computation credit for future service as a customs and border protection officer.

Covered Individuals

The same definition is applicable to both FERS and CSRS:

> [T]he term ''customs and border protection officer'' means an employee in the Department of Homeland Security (A) who holds a position within the GS–1895 job series (determined applying the criteria in effect as of September 1, 2007) or any successor position, and (B) whose duties include activities relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry, including any such employee who is transferred directly to a supervisory or administrative position in the Department of Homeland Security after performing such duties (as described in subparagraph (B)) in 1 or more positions (as described in subparagraph (A)) for at least 3 years.

This definition, while similar to the statutory definition of ''law enforcement officer,'' contains important differences that distinguish it from that definition. For the first time in a special retirement coverage definition, there is specific reference to a Federal occupational series—the Customs and Border Protection job series (GS–1895). Two points are significant in this regard. First, only positions in this series are eligible for ''primary'' coverage. Second, in addition to position classification, there is an additional requirement that the duties of the specific position must include specified activities. Thus, not all positions in the GS–1895 job series will meet the requirements for primary coverage, although it is probable that those that are not eligible for primary coverage will generally meet the requirements for secondary (supervisory or administrative) coverage.

The provision for extending coverage to ''any successor position'' is also novel. Primary coverage is based upon the GS–1895 series as of September 1, 2007, and it is possible that position classification standards and/or the manner in which positions are described may be changed in the future. The logical interpretation is that this is intended to provide authority for coverage should positions with the same elements currently classified in the GS–1895 series be assigned to another series at some time in the future so long as they would have been covered under the GS–1895 series as it existed on September 1, 2007.

Secondary coverage is not limited to positions in the GS–1895 series. However, section 535 of the Act permits secondary coverage using language equivalent to that applicable to other special retirement groups (*i.e.,* law enforcement officers, firefighters, etc.). Thus, as in the law enforcement officer retirement regulations, secondary coverage will generally be limited to continuous employment in supervisory and/or administrative positions that could not be performed by individuals without prior experience in a customs and border protection officer primary position.

As with other special retirement groups, the final authority on position coverage for retirement purposes is OPM, although coverage determinations are delegated to the Department of Homeland Security. Statutorily, OPM is

also the final authority on position classification, the other aspect of retirement coverage eligibility.

Incumbent Employees

Section 535 of the Act has provisions concerning mandatory retirement and annuity computation that are applicable to individuals who, depending upon the provision, were first appointed as a customs and border protection officer prior to the effective date, or are customs and border protection officers on the effective date.

Mandatory retirement: Sections 831.1608(c) and 842.1006(d) of the rule address the provisions of section 535(e)(2)(A) of the Act, which provide that mandatory retirement ''shall not apply to an individual first appointed as a customs and border protection officer before the effective date'' of July 6, 2008. Unlike another provision of section 535 (i.e., section 535(e)(2)(C)), section 535(e)(2)(A) does not specify that the individual has to be a customs and border protection officer on the effective date. Thus, an individual previously appointed as a customs and border protection officer before July 6, 2008, but not so employed on that date would not be subject to mandatory retirement upon returning to customs and border protection officer employment following that break in service.

Prior service and secondary coverage: Sections 831.1604(b) and 842.1003(c) of the rule address the provisions of section 535(e)(2)(B) of the Act, which provide special rules for treatment of pre-enactment customs and border protection officer service. These special rules are relevant to secondary customs and border protection officer coverage determinations. Section 535 of the Act is explicit that its provisions are prospective, stating in section 535(e)(2)(B)—

(B) TREATMENT OF PRIOR CBPO SERVICE.—

(i) GENERAL RULE.—Except as provided in clause (ii), nothing in this section or any amendment made by this section shall be considered to apply with respect to any service performed as a customs and border protection officer before the effective date under paragraph (1).

(ii) EXCEPTION.—Service described in section 8331(31) or 8401(36) of title 5, United States Code (as amended by this section) rendered before the effective date under paragraph (1) may be taken into account to determine if an individual who is serving on or after such effective date then qualifies as a customs and border protection officer by virtue of holding a supervisory or administrative position in the Department of Homeland Security.

The meaning of clause (ii) is that if an individual is in a secondary (supervisory or administrative) position on July 6, 2008, that individual's eligibility to be a customs and border protection officer will be determined by looking back at the individual's employment history to determine whether the requirements for coverage would have been met if the provisions of 535 had been in effect during the earlier employment history.

There is one potential issue in this regard resulting from the fact that the GS–1895 series dates back only to July of 2004, and that standard is the one in effect on September 1, 2007. Thus, a cursory reading of this provision could be interpreted to mean that only if there has been three years of post-July 2004 primary service actually classified in the GS–1895 series followed by a direct transfer to a secondary position can an individual in a secondary position be found to be a customs and border protection officer on July 6, 2008. This would permit such coverage only if an individual transferred into a secondary position on or after July 1, 2007. This would mean that some customs and border protection officers in secondary supervisory and administrative customs and border protection officer positions on July 6, 2008, would not be entitled to retirement coverage under the law when the law went into effect.

Despite the lack of relevant legislative history, such a rigid interpretation would be inconsistent with the statutory scheme. There is however an alternative interpretation yielding a reasonable result, which OPM has adopted for this rule. Prior to the establishment of the GS–1895 series, it was preceded by three precursor position series; GS–1816, Immigration Inspection, GS–1890, Customs Inspection, and GS–1801, Canine Enforcement Officer. Most positions classified under those series would now be classified under the GS–1895 series.

Accordingly, for purposes of evaluating whether pre-July 2004 service is qualifying as primary service, positions classified prior to July 2004 in the GS–1816, GS–1890, or GS–1901 series should be considered as meeting the requirement of being a ''position within the GS–1895 job series (determined applying the criteria in effect as of September 1, 2007).'' However, merely being in one of those three series does not mean that the position was a primary position. The additional requirements relating to the type of work performed must also be satisfied.

Proportional Annuity Computation

Sections 831.1612(c) and 842.1009(c) of the rule address the unique provisions of section 535(e)(2)(C) of the Act, which provide for proportional annuity computations that are applicable only to individuals who are customs and border protection officers on July 6, 2008, based on an appointment to a customs and border protection officer prior to that date. Unlike the mandatory retirement exemption, the provisions of section 535(e)(2)(C) of the Act do not apply to a previously appointed customs and border protection officer who is not employed as a customs and border protection officer on July 6, 2008. A previously employed customs and border protection officer who returns after July 6, 2008, would not be eligible, nor would a U.S. Customs and Border Protection employee not in a customs and border protection officer position on July 6, 2008. Under the provisions of section 535(e)(2)(C), individuals do not receive credit for pre-July 6, 2008, service counted towards special retirement eligibility or computation. However, they are eligible to have post-July 5, 2008 customs and border protection officer service credited in their annuity computation at a higher rate even though they may not meet the requirements for special customs and border protection officer retirement. Service in other special retirement categories such as law enforcement officer or firefighter cannot be added to customs and border protection officer service for use in a proportional annuity computation.

Thus, a customs and border protection officer employed on July 6, 2008, and covered by CSRS would have all full months of customs and border protection officer service computed using an annual multiplier of 2.5 percent per year of such service up to 20 years. A customs and border protection officer employed on July 6, 2008, and covered by FERS would have all full months of customs and border protection officer service computed using an annual multiplier of 1.7 percent per year of such service up to 20 years.

Elections

Sections 831.1612(a) and 842.1009(a) of the rule address the provisions of section 535(e)(3) of the Act, which require that individuals who are customs and border protection officers on December 26, 2007, must be given the right to elect to be covered by or excluded from its provisions when it becomes effective on July 6, 2008. For such incumbents, section 535 provides a substantial lifetime annuity increase in return for a small increase in retirement contributions deducted from

pay. Incumbents on July 6, 2008, are exempt from mandatory retirement. Although the Department of Homeland Security has already provided affected employees with the opportunity to elect to be excluded from the customs and border protection officer provisions, the proposed rule describes the terms of the election opportunity provided by the Department of Homeland Security in the event that there is any question about an employee's election opportunity in the future.

Current Law Enforcement Officers

Sections 831.1612(b) and 842.1009(b) of the rule address the provisions of section 535(e)(5) of the Act, which specifies that nothing in section 535 or any amendment made by it shall be considered to afford any election or to otherwise apply with respect to anyone who as of December 25, 2007, was a law enforcement officer employed by U.S. Customs and Border Protection.

Technical and Conforming Amendments to Existing Regulations

The rule makes various technical and conforming amendments to 5 CFR §§ 831.502, 841.403, 841.503, 842.208, 842.403, 842.801, and 842.901 to add references to customs and border protection officers. Section 831.502 is also being reissued in its entirety to correct typographical errors in the existing paragraph designations.

Comments

We received several comments regarding the proposed rule and they are addressed below. We have not addressed comments we received that were aimed at substantive benefit and procedural issues outside the scope of the regulations.

One commenter asked for an extension until November 3, 2010, to submit comments on the proposed rule because he had not immediately known that the proposed rule had been published. The proposed rule, with a request for comments, was published in the **Federal Register** and posted on Regulations.gov. This process provided adequate notice to the public of the proposed rule and of OPM's request for comments on the rule. The reasons provided by the commenter for asking for an extension are insufficient and would unnecessarily delay the publication of the final rule. The same commenter noted that the regulations make a distinction between primary and secondary positions. This commenter asked why the distinction is being made since ''previous experience in a primary position is required.'' This commenter also asked that the provisions of § 831.1607 be waived or phased-in over a period of time for current officers. Section 831.1607(a) provides in part that the Department of Homeland Security deduct and withhold an additional 0.5% an employee's base pay, as required under 5 U.S.C. 8334(a), when the employee is entitled to retirement coverage as a customs and border protection officer. With regard to primary and secondary positions, the regulations follow the general structure of the retirement regulations of other special groups such as law enforcement officers, firefighters, and nuclear materials couriers. All of these regulations draw a distinction between primary (or rigorous) positions and secondary positions, and the proposed rule incorporates substantially similar provisions. The distinction between primary and secondary provisions is based on the statutory distinction between front-line positions and secondary positions in all of the definitions for special groups. With regard to 5 U.S.C. 8334(a), OPM has no authority to waive or phase-in the statute.

Several commenters objected to the requirement at § 831.1604(a)(2) and § 842.1003(b)(2) of the proposed rule which provides that an employee have at least three years of experience in a primary customs and border protection officer position to continue to be covered as a customs and border protection officer upon direct transfer to a secondary supervisory or administrative position (the 3-year experience requirement). This requirement is included in the statutory definition of ''customs and border protection officer'' at 5 U.S.C. 8331(31) and § 8401(36). OPM has permitted as much flexibility as possible under the law in permitting prior service in occupational series that were precursor series to the GS–1895 series to count toward the 3-year experience requirement at § 831.1604(a)(2) and § 842.1003(b)(2). These special rules are provided at §§ 831.1604(b) and 842.1003(c) of the rules (see *Prior service and secondary coverage* above).

Another commenter indicated that the proposed rule improperly limited precursor series to the Customs and Border Protection Series (GS–1895) only to the Immigration Inspector Series (GS–1816), Customs Inspector Series (GS–1890), and Canine Enforcement Officer Series (GS–1801). This commenter also stated that given the similarity between the statutory definition of customs and border protection officer and the statutory definitions for other special groups such as law enforcement officers and firefighters, that only the duties of a position (i.e., activities relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry) should be considered when the 3-year experience requirement is applied. First, the regulations do not limit precursor series to the Customs and Border Protection Series (GS–1895) to only the Immigration Inspector Series (GS–1816), Customs Inspector Series (GS–1890), and Canine Enforcement Officer Series (GS–1801). Sections 831.1604(b)(1)(i) and 842.1003(c)(1)(i) provide that in addition to the Immigration Inspector Series (GS–1816), Customs Inspector Series (GS–1890), and Canine Enforcement Officer Series (GS–1801), a precursor series to the GS–1895 series includes ''any other series which the agency head determines were predecessor series to the Customs and Border Protection Series (GS–1895), and that would have been classified under the GS–1895 series had it then existed.'' Second, OPM cannot adopt an approach to the 3-year experience requirement that disregards the statutory reference to the GS–1895 series in favor of an approach which considers only the duties performed by an employee. The statutory definition of customs and border protection officer clearly requires that customs and border protection officer retirement coverage in a supervisory or administrative position in the Department of Homeland Security is only permitted when an employee is transferred directly to such a position after performing duties relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry *in one or more positions classified within the GS–1895 job series.* Thus, work experience in a position classified within the GS–1895 job series is one of the conditions that must be satisfied for an employee to continue customs and border protection officer retirement coverage in a supervisory or administrative position. As discussed above, the inclusion of the reference to the GS–1895 job series in the customs and border protection officer definition is the first time in history of special retirement coverage definitions that a specific reference to a Federal occupational series has been included in a definition. Although the regulations are flexible in that they permit service in precursor series to the Customs and Border Protection Series (GS–1895) to be used to satisfy the 3-year experience requirement, the requirement that an employee have experience in the GS–1895 job series to continue customs and border protection officer retirement coverage in a supervisory or

administrative position cannot be disregarded.

Two commenters asked that the proposed rule be changed to allow service as a law enforcement officer to be used to satisfy the requirements for special coverage in a customs and border protection officer position. One commenter, noted that 5 U.S.C. 8336(c) and 8412(d) provide that ''any combination'' of service as a law enforcement officer, firefighter, nuclear materials courier, customs and border protection officer, etc., can be used to meet the service requirements for entitlement to an immediate retirement under those sections. This commenter stated that service as a law enforcement officer, firefighter, nuclear materials courier, customs and border protection officer, etc., is therefore interchangeable for other purposes as well. This commenter also asked whether a 38-year-old employee with 10 years of service as a customs and border protection officer could transfer to a law enforcement officer position. Law enforcement officer, firefighter, nuclear materials courier, customs and border protection officer, and other types of special service are each defined by the different duties. The duties of a law enforcement officer (investigation, apprehension, or detention of individuals suspected or convicted of offenses against the criminal laws of the United States) and the duties of a customs and border protection officer (activities relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry) are entirely different. Each type of special group service is a unique career field and positions within each group are classified under a separate occupational series. Experience in one occupation is not equivalent with experience in another occupation. In fact, one policy goal of special retirement coverage is to encourage career service by an employee in the particular occupation chosen by the employee. However, it is possible for an employee to move, within certain limits, from one of the special group occupations to another without a loss of special retirement coverage. Changing careers is easier for an employee to do early in his or her career, and there should be no obstacle to a 38-year-old employee with 10 years of service as a customs and border protection officer moving to a primary law enforcement officer position. In this situation, an agency would be within its discretion to adjust the usual law enforcement officer maximum entry age (age 37) for the employee by 10 years (i.e., to age 47) because the employee already has 10 years of service creditable towards entitlement under 5 U.S.C. 8412(d) (assuming the employee is covered by FERS). If the employee remained continuously employed as a law enforcement officer, he would have 29 years of combined customs and border protection officer service and law enforcement officer service when he reached age 57, and would be subject to mandatory separation by virtue of the ''any combination of such service'' clause of § 8412(d). The second commenter asked that service in a ''CBPO (Enforcement) (CBPOE) position, or in the predecessor Senior Immigration Inspector position'' be considered as service in a primary customs and border protection officer for purposes of transferring to a secondary position because employees in these positions were law enforcement officers under subchapter III of chapter 83 and chapter 84 of title 5, United States Code, before the enactment of section 535 of the Act. As discussed above, the duties of a law enforcement officer and customs and border protection officer are not equivalent. Furthermore, section 535(e)(5) of the Act clearly provides that nothing in section 535 or any amendment made by it shall be considered to afford any election or to otherwise apply with respect to anyone who as of December 25, 2007, was a law enforcement officer employed by U.S. Customs and Border Protection. Law enforcement officer experience cannot be used to meet the 3-year customs and border protection officer experience requirement under § 831.1604 and § 842.1003(b) of the regulations.

One commenter asserted that § 831.1605 of the proposed rule is inconsistent with the existing CSRS law enforcement officer regulations at 5 CFR 831.906(e) and the court's decision in *Hall* v. *Department of the Treasury,* 264 F.3d 1050 (Fed. Cir. 2001). This commenter also asserted that § 831.1605 of the proposed rule ''engraft the more restrictive FERS regulations [at 5 CFR 842.906]'' onto the CSRS customs and border protection officer regulations. Section § 831.1605 of the proposed rule is not inconsistent with the court's decision in *Hall.* In the section of the court's decision where it discussed 5 CFR 831.906(e), it merely cited the provisions at § 831.906(e) and determined that the Treasury had waived its timeliness defense under § 831.906(e) when it decided the merits of Mr. Hall's complaint without addressing the question of timeliness. *Hall,* 264 F.3d at 1061. The court's decision in *Hall* does not require OPM to use the rule at § 831.906(e) for other special groups. The rule at § 831.1605 of the proposed rule is based on § 831.805(c) of subpart H of title 5, Code of Federal Regulations—the regulations pertaining to CSRS nuclear materials courier retirement coverage. Although § 831.1605 of the proposed rule is different from 5 CFR 831.906(e), it provides a reasonable amount of flexibility for the consideration of untimely requests. If an employee in a position not subject to the one-half percent higher withholding rate of 5 U.S.C. 8334(c) fails to seek a determination from the Department of Homeland Security within 6 months after entering the position, or after any significant change in the position, that his or her position is properly covered by the higher withholding rate, the agency head's determination that the service was not so covered at the time of the service is presumed to be correct. This presumption may be rebutted by a preponderance of the evidence that the employee was unaware of his or her status or was prevented by cause beyond his or her control from requesting that the official status be changed at the time the service was performed. Furthermore, because the presumption is a defense to an untimely request, the Department of Homeland Security may decide not to assert the presumption of correctness as a defense. In other words, the Department of Homeland Security may waive the defense by addressing the merits of the employee's claim, as occurred in *Hall.*

One commenter asked that the deadline for past service credit requests at § 831.1606(c) be changed to after the date of publication of the final rule. We agree. The date at § 831.1606(c) was arrived at during the drafting of the proposed rule. At the time, the June 30, 2011 date was in the future. We have changed the date to June 30, 2012.

Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation will only affect retirement payments to retired employees, spouses, former spouses, and insurable interest survivors.

List of Subjects in 5 CFR Parts 831, 841 and 842

Administrative practice and procedure, Air traffic controllers,

Alimony, Claims, Disability benefits, Firefighters, Government employees, Income taxes, Intergovernmental relations, Law enforcement officers, Pensions, Reporting and recordkeeping requirements, Retirement.

Office of Personnel Management.

John Berry,

Director.

For the reasons discussed in the preamble, OPM is amending 5 CFR parts 831, 841, and 842, as set forth below:

PART 831—RETIREMENT

■ 1. The authority citation for part 831 is revised to read as follows:

Authority: 5 U.S.C. 8347; Sec. 831.102 also issued under 5 U.S.C. 8334; Sec. 831.106 also issued under 5 U.S.C. 552a; Sec. 831.108 also issued under 5 U.S.C. 8336(d)(2); Sec. 831.114 also issued under 5 U.S.C. 8336(d)(2), and Sec. 1313(b)(5) of Pub. L. 107–296, 116 Stat. 2135; Sec. 831.201(b)(1) also issued under 5 U.S.C. 8347(g); Sec. 831.201(b)(6) also issued under 5 U.S.C. 7701(b)(2); Sec. 831.201(g) also issued under Secs. 11202(f), 11232(e), and 11246(b) of Pub. L. 105–33, 111 Stat. 251; Sec. 831.201(g) also issued under Sec. 7(b) and (e) of Pub. L. 105–274, 112 Stat. 2419; Sec. 831.201(i) also issued under Secs. 3 and 7(c) of Pub. L. 105–274, 112 Stat. 2419; Sec. 831.204 also issued under Sec. 102(e) of Pub. L. 104–8, 109 Stat. 102, as amended by Sec. 153 of Pub. L. 104–134, 110 Stat. 1321; Sec. 831.205 also issued under Sec. 2207 of Pub. L. 106–265, 114 Stat. 784; Sec. 831.206 also issued under Sec. 1622(b) of Pub. L. 104–106, 110 Stat. 515; Sec. 831.301 also issued under Sec. 2203 of Pub. L. 106–265, 114 Stat. 780; Sec. 831.303 also issued under 5 U.S.C. 8334(d)(2) and Sec. 2203 of Pub. L. 106–235, 114 Stat. 780; Sec. 831.502 also issued under 5 U.S.C. 8337, and Sec. 1(3), E.O. 11228, 3 CFR 1965–1965 Comp. p. 317; Sec. 831.663 also issued under 5 U.S.C. 8339(j) and (k)(2); Secs. 831.663 and 831.664 also issued under Sec. 11004(c)(2) of Pub. L. 103–66, 107 Stat. 412; Sec. 831.682 also issued under Sec. 201(d) of Pub. L. 99–251, 100 Stat. 23; Sec. 831.912 also issued under Sec. 636 of Appendix C to Pub. L. 106–554, 114 Stat. 2763A–164; Subpart P also issued under Sec. 535(d) of Title V of Division E of Pub. L. 110–161, 121 Stat. 2042; Subpart V also issued under 5 U.S.C. 8343a and Sec. 6001 of Pub. L. 100–203, 101 Stat. 1330–275; Sec. 831.2203 also issued under Sec. 7001(a)(4) of Pub. L. 101–508, 104 Stat. 1388–328.

■ 2. Revise 831.502 to read as follows:

§ 831.502 Automatic separation; exemption.

(a) When an employee meets the requirements for age retirement on any day within a month, he is subject to automatic separation at the end of that month. The department or agency shall notify the employee of the automatic separation at least 60 days in advance of the separation. If the department or agency fails through error to give timely notice, the employee may not be separated without his consent until the end of the month in which the notice expires.

(b) The head of the agency, when in his or her judgment the public interest so requires, may exempt a law enforcement officer, firefighter, nuclear materials courier, or customs and border protection officer from automatic separation until that employee becomes 60 years of age.

(c) The Secretary of Transportation and the Secretary of Defense, under such regulations as each may prescribe, may exempt an air traffic controller having exceptional skills and experience as a controller from automatic separation until that controller becomes 61 years of age.

(d) When a department or agency lacks authority and wishes to secure an exemption from automatic separation for one of its employees other than a Presidential appointee, beyond the age(s) provided by statute, i.e., age 60 for a law enforcement officer, firefighter, nuclear materials courier, or customs and border protection officer, and age 61 for an air traffic controller, the department or agency head shall submit a recommendation to that effect to OPM.

(1) The recommendation shall contain:

(i) A statement that the employee is willing to remain in service;

(ii) A statement of facts tending to establish that his/her retention would be in the public interest;

(iii) The period for which the exemption is desired, which period may not exceed 1 year; and,

(iv) The reasons why the simpler method of retiring the employee and immediately reemploying him or her is not being used.

(2) The recommendation shall be accompanied by a medical certificate showing the physical fitness of the employee to perform his or her work.

(e) OPM may approve an exemption only before the automatic separation date applicable to the employee. For this reason, the department or agency shall forward the recommendation to OPM at least 30 days before this separation date.

■ 3. Add subpart P to part 831 to read as follows:

Subpart P—Customs and Border Protection Officers

Sec.

Subpart P—Customs and Border Protection Officers

§ 831.1601 Applicability and purpose.

(a) This subpart contains regulations of the Office of Personnel Management (OPM) to supplement 5 U.S.C. 8336(c), which establishes special retirement eligibility for customs and border protection officers employed under the Civil Service Retirement System; 5 U.S.C. 8331(3)(C) and (G), pertaining to basic pay; 5 U.S.C. 8334(a)(1) and (c), pertaining to deductions, contributions, and deposits; 5 U.S.C. 8335(b), pertaining to mandatory retirement; and 5 U.S.C. 8339(d), pertaining to computation of annuity.

(b) The regulations in this subpart are issued pursuant to the authority given to OPM in 5 U.S.C. 8347 to prescribe regulations to carry out subchapter III of chapter 83 of title 5 of the United States Code, and in 5 U.S.C. 1104 to delegate authority for personnel management to the heads of agencies, and pursuant to the authority given the Director of OPM in Section 535(d) of the Department of Homeland Security Appropriations Act, 2008, Division E of Public Law 110–161, 121 Stat. 1844, at 2075.

§ 831.1602 Definitions.

In this subpart—

Agency head means the Secretary of the Department of Homeland Security. For purposes of an approval of coverage under this subpart, agency head is also deemed to include the designated representative of the Secretary of the Department of Homeland Security (DHS), except that the designated representative must be a department headquarters-level official who reports directly to the Secretary of the Department of Homeland Security, or to the Deputy Secretary of the Department of Homeland Security, and who is the sole such representative for the entire department. For the purposes of a denial of coverage under this subpart, agency head is also deemed to include the designated representative of the Secretary of the Department of Homeland Security at any level within the Department of Homeland Security.

Customs and border protection officer means an employee in the Department

of Homeland Security occupying a position within the Customs and Border Protection Officer (GS–1895) job series (determined applying the criteria in effect as of September 1, 2007) or any successor position, and whose duties include activities relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry. Also included in this definition is an employee engaged in this activity who is transferred directly to a supervisory or administrative position in the Department of Homeland Security after performing such duties in 1 or more positions within the GS–1895 job series (determined applying the criteria in effect as of September 1, 2007), or any successor position, for at least 3 years.

First-level supervisors are employees classified as supervisors who have direct and regular contact with the employees they supervise. First-level supervisors do not have subordinate supervisors. A first-level supervisor may occupy a primary position or a secondary position if the appropriate definition is met.

Primary position means a position classified within the Customs and Border Protection Officer (GS–1895) job series (determined applying the criteria in effect as of September 1, 2007) or any successor position whose duties include the performance of work directly connected with activities relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry.

Secondary position means a position within the Department of Homeland Security that is either—

(1) Supervisory; i.e., a position whose primary duties are as a first-level supervisor of customs and border protection officers in primary positions; or

(2) Administrative; i.e., an executive, managerial, technical, semiprofessional, or professional position for which experience in a primary customs and border protection officer position is a prerequisite.

§ 831.1603 Conditions for coverage in primary positions.

(a) An employee's service in a position that has been determined by the employing agency head to be a primary customs and border protection officer position is covered under the provisions of 5 U.S.C. 8336(c).

(b) An employee who is not in a primary position, nor covered while in a secondary position, and who is detailed or temporarily promoted to a primary position is not covered under the provisions of 5 U.S.C. 8336(c) for any purpose under this subpart.

§ 831.1604 Conditions for coverage in secondary positions.

(a) An employee's service in a position that has been determined by the employing agency head to be a secondary position is covered under the provisions of 5 U.S.C. 8336(c) if all of the following criteria are met:

(1) The employee is transferred directly (i.e., without a break in service exceeding 3 days) from a primary position to a secondary position; and

(2) The employee has completed 3 years of service in a primary position, including a position for which no CSRS deductions were withheld; and

(3) If applicable, the employee has been continuously employed in secondary positions since transferring from a primary position without a break in service exceeding 3 days, except that a break in employment in secondary positions which begins with an involuntary separation (not for cause), within the meaning of 8336(d)(1) of title 5, United States Code, is not considered in determining whether the service in secondary positions is continuous for this purpose.

(b) For the purpose of applying the criteria at paragraphs (a)(1) through (3) of this section to evaluate transfers, service, and employment periods that occurred before September 1, 2007—

(1) A primary position is deemed to include:

(i) A position whose duties included the performance of work directly connected with activities relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry that was classified within the Immigration Inspector Series (GS–1816), Customs Inspector Series (GS–1890), Canine Enforcement Officer Series (GS–1801), or any other series which the agency head determines were predecessor series to the Customs and Border Protection Series (GS–1895), and that would have been classified under the GS–1895 series had it then existed; and

(ii) A position within the Customs and Border Protection Series (GS–1895) whose duties included the performance of work directly connected with activities relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry.

(2) A secondary position is deemed to include:

(i) A first-level supervisor of an employee in a position described at paragraph (b)(1)(i) or (b)(1)(ii) of this section; or

(ii) An executive, managerial, technical, semiprofessional, or professional position for which experience in a position described at paragraph (b)(1)(i) or (b)(1)(ii) of this section is a mandatory prerequisite.

(c) An employee who is not in a primary position, nor covered while in a secondary position, and who is detailed or temporarily promoted to a secondary position is not covered under the provisions of 5 U.S.C. 8336(c) for any purpose under this subpart.

§ 831.1605 Evidence.

(a) An agency head's determination under §§ 831.1603(a) and 831.1604(a) must be based solely on the official position description of the position in question and any other official description of duties and qualifications.

(b) If an employee is in a position not subject to the one-half percent higher withholding rate of 5 U.S.C. 8334(c), and the employee does not, within 6 months after entering the position or after any significant change in the position, formally and in writing seek a determination from the employing agency that his position is properly covered by the higher withholding rate, the agency head's determination that the service was not so covered at the time of the service is presumed to be correct. This presumption may be rebutted by a preponderance of the evidence that the employee was unaware of his or her status or was prevented by cause beyond his or her control from requesting that the official status be changed at the time the service was performed.

§ 831.1606 Requests from individuals.

(a) An employee who requests credit for service under 5 U.S.C. 8336(c) bears the burden of proof with respect to that service, and must provide the employing agency with all pertinent information regarding duties performed.

(b) An employee who is currently serving in a position that has not been approved as a primary or secondary position, but who believes that his or her service is creditable as service in a primary or secondary position may request the agency head to determine whether or not the employee's current service should be credited and, if it qualifies, whether it should be credited as service in a primary or secondary position. A written request for current service must be made within 6 months after entering the position or after any significant change in the position.

(c) A current or former employee (or the survivor of a former employee) who believes that a period of past service in an unapproved position qualifies as service in a primary or secondary position and meets the conditions for credit may request the agency head to determine whether or not the

employee's past service should be credited and, if it qualifies, whether it should be credited as service in a primary or secondary position. A written request for past service must be made no later than June 30, 2012.

(d) The agency head may extend the time limit for filing under paragraph (b) or (c) of this section when, in the judgment of such agency head, the individual shows that he or she was prevented by circumstances beyond his or her control from making the request within the time limit.

§ 831.1607 Withholdings and contributions.

(a) During the service covered under the conditions established by § 831.1603 and § 831.1604, the Department of Homeland Security will deduct and withhold from the employee's base pay the amount required under 5 U.S.C. 8334(a) for such positions and submit that amount, together with agency contributions required by 5 U.S.C. 8334(a), to OPM in accordance with payroll office instructions issued by OPM.

(b) If the correct withholdings and/or Government contributions are not submitted to OPM for any reason whatsoever, the Department of Homeland Security must correct the error by submitting the correct amounts (including both employee and agency shares) to OPM as soon as possible. Even if the Department of Homeland Security waives collection of the overpayment of pay under any waiver authority that may be available for this purpose, such as 5 U.S.C. 5584, or otherwise fails to collect the debt, the correct amount must still be submitted to OPM without delay as soon as possible.

(c) Upon proper application from an employee, former employee or eligible survivor of a former employee, the Department of Homeland Security will pay a refund of erroneous additional withholdings for service that is found not to have been covered service. If an individual has paid to OPM a deposit or redeposit, including the additional amount required for covered service, and the deposit or redeposit is later determined to be erroneous because the service was not covered service, OPM will pay the refund, upon proper application, to the individual, without interest.

(d) The additional employee withholding and agency contribution for covered or creditable service properly made as required under 5 U.S.C. 8334(a)(1) or deposited under 5 U.S.C. 8334(c) are not separately refundable, even in the event that the employee or his or her survivor does not qualify for a special annuity computation under 5 U.S.C. 8339(d).

(e) While an employee who does not hold a primary or secondary position is detailed or temporarily promoted to a primary or secondary position, the additional withholdings and agency contributions will not be made. While an employee who does hold a primary or secondary position is detailed or temporarily promoted to a position which is not a primary or secondary position, the additional withholdings and agency contributions will continue to be made.

§ 831.1608 Mandatory separation.

(a) Except as provided in paragraph (c) of this section, the mandatory separation provisions of 5 U.S.C. 8335(b) apply to customs and border protection officers appointed in primary and secondary positions. A mandatory separation under section 8335(b) is not an adverse action under part 752 of this chapter or a removal action under part 359 of this chapter. Section 831.502 provides the procedures for requesting an exemption from mandatory separation.

(b) In the event an employee is separated mandatorily under 5 U.S.C. 8335(b), or is separated for optional retirement under 5 U.S.C. 8336(c), and OPM finds that all or part of the minimum service required for entitlement to immediate annuity was in a position which did not meet the requirements of a primary or secondary position and the conditions set forth in this subpart, such separation will be considered erroneous.

(c) The customs and border protection officer mandatory separation provisions of 5 U.S.C. 8335(b) do not apply to an individual first appointed as a customs and border protection officer before July 6, 2008.

§ 831.1609 Reemployment.

An employee who has been mandatorily separated under 5 U.S.C. 8335(b) is not barred from reemployment in any position except a primary position after age 60. Service by a reemployed annuitant is not covered by the provisions of 5 U.S.C. 8336(c).

§ 831.1610 Review of decisions.

(a) The final decision of the agency head issued to an employee as the result of a request for determination filed under § 831.1606 may be appealed to the Merit Systems Protection Board under procedures prescribed by the Board.

(b) The final decision of the agency head denying an individual coverage while serving in an approved secondary position because of failure to meet the conditions in § 831.1604(a) may be appealed to the Merit Systems Protection Board under procedures prescribed by the Board.

§ 831.1611 Oversight of coverage determinations.

(a) Upon deciding that a position is a customs and border protection officer position, the agency head must notify OPM (Attention: Associate Director, Retirement Services, or such other official as may be designated) stating the title of each position, occupational series, position description number (or other unique identifier), the number of incumbents, and whether the position is primary or secondary. The Director of OPM retains the authority to revoke the agency head's determination that a position is a primary or secondary position.

(b) The Department of Homeland Security must establish and maintain a file containing all coverage determinations made by the agency head under § 831.1603 and § 831.1604, and all background material used in making the determination.

(c) Upon request by OPM, the Department of Homeland Security will make available the entire coverage determination file for OPM to audit to ensure compliance with the provisions of this subpart.

(d) Upon request by OPM, the Department of Homeland Security must submit to OPM a list of all covered positions and any other pertinent information requested.

§ 831.1612 Elections of Retirement Coverage, exclusions from retirement coverage, and proportional annuity computations.

(a) *Elections of coverage.* (1) The Department of Homeland Security must provide an employee who is a customs and border protection officer on December 26, 2007, the opportunity to elect not to be treated as a customs and border protection officer under section 535(a) and (b) of the Department of Homeland Security Appropriations Act, 2008, Public Law 110–161, 121 Stat. 2042.

(2) An election under this paragraph (a) is valid only if made on or before June 22, 2008.

(3) An individual eligible to make an election under this paragraph who fails to make such an election on or before June 22, 2008, is deemed to have elected to be treated as a customs and border protection officer for retirement purposes.

(b) *Exclusion from coverage.* The provisions of this subpart and any other

specific reference to customs and border protection officers in this part do not apply to employees who on December 25, 2007, were law enforcement officers under subpart I of this part or subpart H of part 842 within U.S. Customs and Border Protection. These employees cannot elect to be treated as a customs and border protection officer under paragraph (a) of this section, nor can they be deemed to have made such an election.

(c) *Proportional annuity computation.* The annuity of an employee serving in a primary or secondary customs and border protection officer position on July 6, 2008, must, to the extent that its computation is based on service rendered as a customs and border protection officer on or after that date, be at least equal to the amount that would be payable—

(1) To the extent that such service is subject to the Civil Service Retirement System, by applying section 8339(d) of title 5, United States Code, with respect to such service; and

(2) To the extent such service is subject to the Federal Employees' Retirement System, by applying section 8415(d) of title 5, United States Code, with respect to such service.

PART 841—FEDERAL EMPLOYEES RETIREMENT SYSTEM—GENERAL ADMINISTRATION

■ 4. The authority citation for part 841 continues to read as follows:

Authority: 5 U.S.C. 8461; Sec. 841.108 also issued under 5 U.S.C. 552a; subpart D also issued under 5 U.S.C. 8423; Sec. 841.504 also issued under 5 U.S.C. 8422; Sec. 841.507 also issued under section 505 of Pub. L. 99–335; subpart J also issued under 5 U.S.C. 8469; Sec. 841.506 also issued under 5 U.S.C. 7701(b)(2); Sec. 841.508 also issued under section 505 of Pub. L. 99–335; Sec. 841.604 also issued under Title II, Pub. L. 106–265, 114 Stat. 780.

■ 5. Revise § 841.403(c) to read as follows:

§ 841.403 Categories of employees for computation of normal cost percentages.

* * * * *

(c) Law enforcement officers, members of the Supreme Court Police, firefighters, nuclear materials couriers, customs and border protection officers, and employees under section 302 of the Central Intelligence Agency Retirement Act of 1964 for Certain Employees.

* * * * *

■ 6. Revise § 841.503(b) to read as follows:

§ 841.503 Amounts of employee deductions.

* * * * *

(b) The rate of employee deductions from basic pay for FERS coverage for a Member, law enforcement officer, firefighter, nuclear materials courier, customs and border protection officer, air traffic controller, member of the Supreme Court Police, Congressional employee, or employee under section 302 of the Central Intelligence Agency Act of 1964 for Certain Employees is seven and one-half percent of basic pay, minus the percent of tax which is (or would be) in effect for the payment, for the employee cost of social security.

* * * * *

PART 842—FEDERAL EMPLOYEES RETIREMENT SYSTEM—BASIC ANNUITY

■ 7. The authority citation for part 842 is revised to read as follows:

Authority: 5 U.S.C. 8461(g); Secs. 842.104 and 842.106 also issued under 5 U.S.C. 8461(n); Sec. 842.104 also issued under Secs. 3 and 7(c) of Pub. L. 105–274, 112 Stat. 2419; Sec. 842.105 also issued under 5 U.S.C. 8402(c)(1) and 7701(b)(2); Sec. 842.106 also issued under Sec. 102(e) of Pub. L. 104–8, 109 Stat. 102, as amended by Sec. 153 of Pub. L. 104–134, 110 Stat. 1321–102; Sec. 842.107 also issued under Secs. 11202(f), 11232(e), and 11246(b) of Pub. L. 105–33, 111 Stat. 251, and Sec. 7(b) of Pub. L. 105–274, 112 Stat. 2419; Sec. 842.108 also issued under Sec. 7(e) of Pub. L. 105–274, 112 Stat. 2419; Sec. 842.109 also issued under Sec. 1622(b) of Public Law 104–106, 110 Stat. 515; Sec. 842.208 also issued under Sec. 535(d) of Title V of Division E of Pub. L. 110–161, 121 Stat. 2042; Sec. 842.213 also issued under 5 U.S.C. 8414(b)(1)(B) and Sec. 1313(b)(5) of Pub. L. 107–296, 116 Stat. 2135; Secs. 842.304 and 842.305 also issued under Sec. 321(f) of Pub. L. 107–228, 116 Stat. 1383, Secs. 842.604 and 842.611 also issued under 5 U.S.C. 8417; Sec. 842.607 also issued under 5 U.S.C. 8416 and 8417; Sec. 842.614 also issued under 5 U.S.C. 8419; Sec. 842.615 also issued under 5 U.S.C. 8418; Sec. 842.703 also issued under Sec. 7001(a)(4) of Pub. L. 101–508, 104 Stat. 1388; Sec. 842.707 also issued under Sec. 6001 of Pub. L. 100–203, 101 Stat. 1300; Sec. 842.708 also issued under Sec. 4005 of Pub. L. 101–239, 103 Stat. 2106 and Sec. 7001 of Pub. L. 101–508, 104 Stat. 1388; Subpart H also issued under 5 U.S.C. 1104; Sec. 842.810 also issued under Sec. 636 of Appendix C to Pub. L. 106–554 at 114 Stat. 2763A–164; Sec. 842.811 also issued under Sec. 226(c)(2) of Public Law 108–176, 117 Stat. 2529; Subpart J also issued under Sec. 535(d) of Title V of Division E of Pub. L. 110–161, 121 Stat. 2042.

■ 8. Revise the section heading, and paragraphs (a)(1) and (2) of § 842.208 to read as follows:

§ 842.208 Firefighters, customs and border protection officers, law enforcement officers, members of the Capitol or Supreme Court Police, and nuclear materials couriers.

(a) * * *

(1) After completing any combination of service as a firefighter, customs and border protection officer, law enforcement officer, member of the Capitol or Supreme Court Police, or nuclear materials courier totaling 25 years; or

(2) After becoming age 50 and completing any combination of service as a firefighter, customs and border protection officer, law enforcement officer, member of the Capitol or Supreme Court Police, or nuclear materials courier totaling 20 years.

* * * * *

■ 9. Revise § 842.403 (b)(2)(ii) to read as follows:

§ 842.403 Computation of basic annuity.

* * * * *

(b) * * *

(2) * * *

(ii) Is not a customs and border protection officer, a Member, Congressional employee, military reserve technician, law enforcement officer, firefighter, nuclear materials courier, or air traffic controller.

■ 10. Revise 842.801 to read as follows:

§ 842.801 Applicability and purpose.

(a) This subpart contains regulations of the Office of Personnel Management (OPM) to supplement—

(1) 5 U.S.C. 8412(d) and (e), which establish special retirement eligibility for law enforcement officers, members of the Capitol Police and Supreme Court Police, firefighters, nuclear materials couriers, customs and border protection officers, and air traffic controllers employed under the Federal Employees Retirement System (FERS);

(2) 5 U.S.C. 8422(a), pertaining to deductions;

(3) 5 U.S.C. 8423(a), pertaining to Government contributions; and

(4) 5 U.S.C. 8425, pertaining to mandatory retirement.

(b) The regulations in this subpart are issued pursuant to the authority given to OPM in 5 U.S.C. 8461(g) to prescribe regulations to carry out the provisions of 5 U.S.C. chapter 84, in 5 U.S.C. 1104 to delegate authority for personnel management to the heads of agencies and pursuant to the authority given the Director of OPM in section 535(d) of the Department of Homeland Security Appropriations Act, 2008, Public Law 110–161, 121 Stat. 2042.

■ 11. Revise 842.901 to read as follows:

§ 842.901 Applicability and purpose.

(a) This subpart contains regulations of the Office of Personnel Management (OPM) to supplement—

(1) 5 U.S.C. 8412(d) and (e), which establish special retirement eligibility

for law enforcement officers, members of the Capitol Police and Supreme Court Police, firefighters, nuclear materials couriers, customs and border protection officers, and air traffic controllers employed under the Federal Employees Retirement System (FERS);

(2) 5 U.S.C. 8422(a), pertaining to deductions;

(3) 5 U.S.C. 8423(a), pertaining to Government contributions; and

(4) 5 U.S.C. 8425, pertaining to mandatory retirement.

(b) The regulations in this subpart are issued pursuant to the authority given to OPM in 5 U.S.C. 8461(g) to prescribe regulations to carry out the provisions of 5 U.S.C. chapter 84, in 5 U.S.C. 1104 to delegate authority for personnel management to the heads of agencies and pursuant to the authority given the Director of OPM in section 535(d) of the Department of Homeland Security Appropriations Act, 2008, Division E of Public Law 110–161, 121 Stat. 1844.

■ 12. Add subpart J to part 842 to read as follows:

Subpart J—Customs and Border Protection Officers

Subpart J—Customs and Border Protection Officers

§ 842.1001 Applicability and purpose.

(a) This subpart contains regulations of the Office of Personnel Management (OPM) to supplement—

(1) 5 U.S.C. 8412(d) and (e), which establish special retirement eligibility for law enforcement officers, members of the Capitol Police and Supreme Court Police, firefighters, nuclear materials couriers, customs and border protection officers, and air traffic controllers employed under the Federal Employees Retirement System (FERS);

(2) 5 U.S.C. 8422(a), pertaining to deductions;

(3) 5 U.S.C. 8423(a), pertaining to Government contributions; and

(4) 5 U.S.C. 8425, pertaining to mandatory retirement.

(b) The regulations in this subpart are issued pursuant to the authority given to OPM in 5 U.S.C. 8461(g) to prescribe regulations to carry out the provisions of 5 U.S.C. chapter 84, in 5 U.S.C. 1104 to delegate authority for personnel management to the heads of agencies and pursuant to the authority given the Director of OPM in section 535(d) of the Department of Homeland Security Appropriations Act, 2008, Division E of Public Law 110–161, 121 Stat. 1844.

§ 842.1002 Definitions.

As used in this subpart:

Agency head means the Secretary of the Department of Homeland Security. For purposes of an approval of coverage under this subpart, agency head is also deemed to include the designated representative of the Secretary of Department of Homeland Security, except that the designated representative must be a department headquarters-level official who reports directly to the Secretary of Homeland Security, or to the Deputy Secretary of Homeland Security, and who is the sole such representative for the entire department. For the purposes of a denial of coverage under this subpart, agency head is also deemed to include the designated representative of the Secretary of Department of Homeland Security at any level within the Department of Homeland Security.

Customs and border protection officer means an employee in the Department of Homeland Security occupying a position within the Customs and Border Protection Officer (GS–1895) job series (determined applying the criteria in effect as of September 1, 2007) or any successor position and whose duties include activities relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry. Also included in this definition is an employee engaged in this activity who is transferred directly to a supervisory or administrative position in the Department of Homeland Security after performing such duties in 1 or more positions within the GS–1895 job series (determined applying the criteria in effect as of September 1, 2007), or any successor position, for at least 3 years.

Employee means an employee as defined by 5 U.S.C. 8401(11).

First-level supervisors are employees classified as supervisors who have direct and regular contact with the employees they supervise. First-level supervisors do not have subordinate supervisors. A first-level supervisor may occupy a primary position or a secondary position if the appropriate definition is met.

Primary position means a position classified within the Customs and Border Protection Officer (GS–1895) job series (determined applying the criteria in effect as of September 1, 2007) or any successor position whose duties include the performance of work directly connected with activities relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry.

Secondary position means a position within the Department of Homeland Security that is either—

(1) Supervisory; i.e., a position whose primary duties are as a first-level supervisor of customs and border protection officers in primary positions; or

(2) Administrative; i.e., an executive, managerial, technical, semiprofessional, or professional position for which experience in a primary customs and border protection officer position is a prerequisite.

§ 842.1003 Conditions for coverage.

(a) *Primary positions.* (1) An employee's service in a position that has been determined by the employing agency head to be a primary customs and border protection officer position is covered under the provisions of 5 U.S.C. 8412(d).

(2) An employee who is not in a primary position, nor covered while in a secondary position, and who is detailed or temporarily promoted to a primary position is not covered under the provisions of 5 U.S.C. 8412(d) for any purpose under this subpart.

(3) A first-level supervisor position may be determined to be a primary position if it satisfies the conditions set forth in § 842.1002.

(b) *Secondary positions.* An employee's service in a position that has been determined by the employing agency head to be a secondary position is covered under the provisions of 5 U.S.C. 8412(d) if all of the following criteria are met:

(1) The employee, while covered under the provisions of 5 U.S.C. 8412(d) as a customs and border protection officer, is transferred directly (i.e., without a break in service exceeding 3 days) from a primary position to a secondary position; and

(2) The employee has completed 3 years of service in a primary position, including service for which no FERS deductions were withheld; and

(3) If applicable, the employee has been continuously employed in secondary positions since transferring from a primary position without a break in service exceeding 3 days, except that a break in employment in secondary positions which begins with an involuntary separation (not for cause), within the meaning of 8414(b)(1)(A), is not considered in determining whether the service in secondary positions is continuous for this purpose.

(c) For the purpose of applying the criteria at paragraph (b)(1) through (3) of this section to evaluate transfers, service, and employment periods that occurred before September 1, 2007—

(1) A primary position, covered under the provisions of 5 U.S.C. 8412(d), is deemed to include:

(i) A position whose duties included the performance of work directly connected with activities relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry that was classified within the Immigration Inspector Series (GS–1816), Customs Inspector Series (GS–1890), Canine Enforcement Officer Series (GS–1801), or any other series which the agency head determines were predecessor series to the Customs and Border Protection Series (GS–1895), and that would have been classified under the GS–1895 series had it then existed; and

(ii) A position within the Customs and Border Protection Series (GS–1895) whose duties included the performance of work directly connected with activities relating to the arrival and departure of persons, conveyances, and merchandise at ports of entry.

(2) A secondary position is deemed to include:

(i) A first-level supervisor of an employee in a position described at paragraph (c)(1)(i) or (c)(1)(ii) of this section; or

(ii) A executive, managerial, technical, semiprofessional, or professional position for which experience in a position described at paragraph (c)(1)(i) or (c)(1)(ii) of this section is a mandatory prerequisite.

(d) An employee who is not in a primary position, nor covered while in a secondary position, and who is detailed or temporarily promoted to a secondary position is not covered under the provisions of 5 U.S.C. 8412(d) for any purpose under this subpart.

§ 842.1004 Evidence.

(a) The agency head's determination under § 842.1003(a) that a position is a primary position must be based solely on the official position description of the position in question, and any other official description of duties and qualifications. The official documentation for the position must establish that it satisfies the requirements defined in § 842.1002.

(b) A determination under § 842.1003(b) must be based on the official position description and any other evidence deemed appropriate by the agency head for making the determination.

(c) If an employee is in a position not subject to the one-half percent higher withholding rate of 5 U.S.C. 8422(a)(3), and the employee does not, within 6 months of entering the position formally and in writing seek a determination from the employing agency that his or her service is properly covered by the higher withholding rate, the agency head's determination that the service was not so covered at the time of the service is presumed to be correct. This presumption may be rebutted by a preponderance of the evidence that the employee was unaware of his or her status or was prevented by cause beyond his or her control from requesting that the official status be changed at the time the service was performed.

§ 842.1005 Withholding and contributions.

(a) During service covered under the conditions established by § 842.1003(a) or (c), the Department of Homeland Security will deduct and withhold from the employee's base pay the amounts required under 5 U.S.C. 8422(a) and submit that amount to OPM in accordance with payroll office instructions issued by OPM.

(b) During service described in paragraph (a) of this section, the Department of Homeland Security must submit to OPM the Government contributions required under 5 U.S.C. 8423(a) in accordance with payroll office instructions issued by OPM.

(c) If the correct withholdings and/or Government contributions are not timely submitted to OPM for any reason whatsoever, including cases in which it is finally determined that past service of a current or former employee was subject to the higher deduction and Government contribution rates, the Department of Homeland Security must correct the error by submitting the correct amounts (including both employee and agency shares) to OPM as soon as possible. Even if the Department of Homeland Security waives collection of the overpayment of pay under any waiver authority that may be available for this purpose, such as 5 U.S.C. 5584, or otherwise fails to collect the debt, the correct amount must still be submitted to OPM as soon as possible.

(d) Upon proper application from an employee, former employee or eligible survivor of a former employee, the Department of Homeland Security will pay a refund of erroneous additional withholdings for service that is found not to have been covered service. If an individual has paid to OPM a deposit or redeposit, including the additional amount required for covered service, and the deposit is later determined to be erroneous because the service was not covered service, OPM will pay the refund, upon proper application, to the individual, without interest.

(e) The additional employee withholding and agency contributions for covered service properly made are not separately refundable, even in the event that the employee or his or her survivor does not qualify for a special annuity computation under 5 U.S.C. 8415(d).

(f) While an employee who does not hold a primary or secondary position is detailed or temporarily promoted to such a position, the additional withholdings and agency contributions will not be made.

(g) While an employee who holds a primary or secondary position is detailed or temporarily promoted to a position that is not a primary or secondary position, the additional withholdings and agency contributions will continue to be made.

§ 842.1006 Mandatory separation.

(a) Except as provided in paragraph (d) of this section, the mandatory separation provisions of 5 U.S.C. 8425 apply to customs and border protection officers, including those in secondary positions. A mandatory separation under 5 U.S.C. 8425 is not an adverse action under part 752 of this chapter or a removal action under part 359 of this chapter.

(b) Exemptions from mandatory separation are subject to the conditions set forth under 5 U.S.C. 8425. An exemption may be granted at the sole discretion of the head of the employing agency or by the President in accordance with 5 U.S.C. 8425(c).

(c) In the event that an employee is separated mandatorily under 5 U.S.C. 8425, or is separated for optional retirement under 5 U.S.C. 8412(d) or (e), and OPM finds that all or part of the minimum service required for entitlement to immediate annuity was in a position that did not meet the requirements of a primary or secondary position and the conditions set forth in this subpart or, if applicable, in part 831 of this chapter, such separation will be considered erroneous.

(d) The customs and border protection officer mandatory separation provisions of 5 U.S.C. 8425 do not apply to an individual first appointed as a customs and border protection officer before July 6, 2008.

§ 842.1007 Review of decisions.

(a) The final decision of the agency head denying an individual's request for approval of a position as a primary or secondary customs and border

protection officer position made under § 842.1003(a) may be appealed to the Merit Systems Protection Board under procedures prescribed by the Board.

(b) The final decision of the agency head denying an individual coverage while serving in an approved secondary position because of failure to meet the conditions in § 842.1003(b) may be appealed to the Merit Systems Protection Board under procedures prescribed by the Board.

§ 842.1008 Oversight of coverage determinations.

(a) Upon deciding that a position is a customs and border protection officer, the Department of Homeland Security must notify OPM (Attention: Associate Director, Retirement Services, or such other official as may be designated) stating the title of each position, the occupational series of the position, the number of incumbents, whether the position is primary or secondary, and, if the position is a primary position, the established maximum entry age, if one has been established. The Director of OPM retains the authority to revoke the agency head's determination that a position is a primary or secondary position.

(b) The Department of Homeland Security must establish and maintain a file containing all coverage determinations made by the agency head under § 842.1003(a) and (b), and all background material used in making the determination.

(c) Upon request by OPM, the Department of Homeland Security will make available the entire coverage determination file for OPM to audit to ensure compliance with the provisions of this subpart.

(d) Upon request by OPM, the Department of Homeland Security must submit to OPM a list of all covered positions and any other pertinent information requested.

§ 842.1009 Elections of retirement coverage, exclusions from retirement coverage, and proportional annuity computations.

(a) *Election of coverage.* (1) The Department of Homeland Security must provide an individual who is a customs and border protection officer on December 26, 2007, with the opportunity to elect not to be treated as a customs and border protection officer under section 535(a) and (b) of the Department of Homeland Security Appropriations Act, 2008, Public Law 110–161, 121 Stat. 2042.

(2) An election under this paragraph is valid only if made on or before June 22, 2008.

(3) An individual eligible to make an election under this paragraph who fails to make such an election on or before June 22, 2008, is deemed to have elected to be treated as a customs and border protection officer for retirement purposes.

(b) *Exclusion from coverage.* The provisions of this subpart and any other specific reference to customs and border protection officers in this part do not apply to employees who on December 25, 2007, were law enforcement officers, under subpart H of this part or subpart I of part 831, within U.S. Customs and Border Protection. These employees cannot elect to be treated as a customs and border protection officer under paragraph (a) of this section, nor can they be deemed to have made such an election.

(c) *Proportional annuity computation.* The annuity of an employee serving in a primary or secondary customs and border protection officer position on July 6, 2008, must, to the extent that its computation is based on service rendered as a customs and border protection officer on or after that date, be at least equal to the amount that would be payable—

(1) To the extent that such service is subject to the Civil Service Retirement System, by applying section 8339(d) of title 5, United States Code, with respect to such service; and

(2) To the extent such service is subject to the Federal Employees' Retirement System, by applying section 8415(d) of title 5, United States Code, with respect to such service.

[FR Doc. 2011–18006 Filed 7–15–11; 8:45 am]

BILLING CODE 6325–63–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2011–0037]

Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security Transportation Security Administration—023 Workplace Violence Prevention Program System of Records

AGENCY: Privacy Office, DHS.

ACTION: Final rule.

SUMMARY: The Department of Homeland Security is issuing a final rule to amend its regulations to exempt portions of a newly established system of records titled, ''Department of Homeland Security/Transportation Security Administration—023 Workplace Violence Prevention Program System of Records'' from certain provisions of the Privacy Act. Specifically, the Department exempts portions of the ''Department of Homeland Security/ Transportation Security Administration—023 Workplace Violence Prevention Program System of Records'' from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: *Effective Date:* This final rule is effective July 18, 2011.

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Ted Calhoun, Office of Law Enforcement, TSA–18, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6018; e-mail *Ted.Calhoun@dhs.gov.* For privacy issues please contact: Mary Ellen Callahan (703–235–0780), Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

Background

The Department of Homeland Security (DHS) Transportation Security Administration (TSA) published a notice of proposed rulemaking (NPRM) in the **Federal Register**, 75 FR 7978, February 23, 2010, proposing to exempt portions of the DHS/TSA–023 Workplace Violence Prevention Program system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements. The DHS/ TSA–023 Workplace Violence Prevention Program system of records notice (SORN) was published concurrently in the **Federal Register**, 75 FR 8096, February 23, 2010, and comments were invited on both the NPRM and SORN.

Public Comments

DHS/TSA received one comment on the NPRM and no comments on the SORN.

NPRM

DHS/TSA received one comment from the public that supported the proposed rule. No other substantive or significant comments were received.

SORN

TSA received no comments on the SORN.

After consideration of the public comment received, the Department will implement the rulemaking as proposed.

List of Subjects in 6 CFR Part 5

Freedom of information; Privacy.

For the reasons stated in the preamble, DHS amends Chapter I of Title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

■ 1. The authority citation for Part 5 continues to read as follows:

Authority: 6 U.S.C. 101 *et seq.;* Pub. L. 107–296, 116 Stat. 2135; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

■ 2. Add at the end of Appendix C to Part 5, the following new paragraph ''56'':

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

56. The DHS/TSA–023 Workplace Violence Prevention Program System of Records consists of electronic and paper records and is used by the TSA in the administration of its Workplace Violence Prevention Program, an internal TSA program designed to prevent and respond to workplace violence. The DHS/TSA–023 Workplace Violence Prevention Program System of Records is a repository of information held by TSA in connection with its several and varied missions and functions, including, but not limited to: The enforcement of civil and criminal laws; investigations, inquiries, and proceedings there under. The DHS/TSA–023 Workplace Violence Prevention Program System of Records contains information collected by TSA, and may contain personally identifiable information collected by other federal, state, local, tribal, foreign, or international government agencies. The Secretary of Homeland Security has exempted portions of this system from the following provisions of the Privacy Act, subject to the limitations set forth in (c)(3); (d); (e)(1), (e)(4)(G); (e)(4)(H); (e)(4)(I); and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2). Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

(b) From subsection (d) (Access to Records) because access to the records contained in this system of records could inform the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS or another agency. Access to the records could permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension. Amendment of the records could interfere with ongoing investigations and law enforcement activities and would impose an unreasonable administrative burden by requiring investigations to be continually reinvestigated. In addition, permitting access and amendment to such information could disclose security-sensitive information that could be detrimental to homeland security.

(c) From subsection (e)(1) (Relevancy and Necessity of Information) because in the course of investigations into potential violations of federal law, the accuracy of information obtained or introduced occasionally may be unclear, or the information may not be strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of unlawful activity.

(d) From subsections (e)(4)(G), (e)(4)(H), and (e)(4)(I) (Agency Requirements) and (f) (Agency Rules), because portions of this system are exempt from the individual access provisions of subsection (d) for the reasons noted above, and therefore DHS is not required to establish requirements, rules, or procedures with respect to such access. Providing notice to individuals with respect to existence of records pertaining to them in the system of records or otherwise setting up procedures pursuant to which individuals may access and view records pertaining to themselves in the system would undermine investigative efforts and reveal the identities of witnesses, and potential witnesses, and confidential informants.

Mary Ellen Callahan,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2011–17938 Filed 7–15–11; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2011–0050]

Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security Federal Emergency Management Agency—011 Training and Exercise Program Records System of Records

AGENCY: Privacy Office, DHS.

ACTION: Final rule.

SUMMARY: The Department of Homeland Security is issuing a final rule to amend its regulations to exempt portions of a newly established system of records titled, ''Department of Homeland Security Federal Emergency Management Agency—011 Training and Exercise Program Records System of Records'' from certain provisions of the Privacy Act. Specifically, the Department exempts portions of the ''Department of Homeland Security Federal Emergency Management Agency—011 Training and Exercise Program Records System of Records'' from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: *Effective Date:* This final rule is effective July 18, 2011.

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Dr. Lesia Banks (202–646–3323), Acting Privacy Officer, Federal Emergency Management Agency, Department of Homeland Security, Washington, DC 20478. For privacy issues please contact: Mary Ellen Callahan (703–235–0780), Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

Background

The Department of Homeland Security (DHS) Federal Emergency Management Agency (FEMA) published a notice of proposed rulemaking (NPRM) in the **Federal Register**, 76 FR 18954, April 6, 2011, proposing to exempt portions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements. The system of records is the DHS/FEMA—011 Training and Exercise Program Records System of Records. The DHS/FEMA—011 Training and Exercise Program Records system of records notice (SORN) was published concurrently in the **Federal Register**, 76 FR 19107, April 6, 2011, and comments were invited on both the NPRM and SORN.

Public Comments

DHS did not receive comments on the NPRM or SORN. The Department will implement the rulemaking as proposed.

List of Subjects in 6 CFR Part 5

Freedom of information; Privacy.

For the reasons stated in the preamble, DHS amends Chapter I of Title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

■ 1. The authority citation for Part 5 continues to read as follows:

Authority: 6 U.S.C. 101 et seq.; Public Law 107–296, 116 Stat. 2135; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

■ 2. Add at the end of Appendix C to Part 5, the following new paragraph ''55'':

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

55. The DHS/FEMA–011 Training and Exercise Program Records System of Records consists of electronic and paper records and will be used by FEMA. The DHS/FEMA–011 Training and Exercise Program Records System of Records consists of electronic and paper records and will be used by DHS and its components and offices to maintain records about individual training, including enrollment and participation information, information pertaining to class schedules, programs, and instructors, training trends and needs, testing and examination materials, and assessments of training efficacy. The data will be collected by employee name or other unique identifier. The collection and maintenance of this information will assist DHS in meeting its obligation to train its personnel and contractors in order to ensure that the agency mission can be successfully accomplished. The DHS/FEMA–011 General Training and Exercise Program Records System of Records contains information that is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information collected by other Federal, State, local, tribal, foreign, or international government agencies. The Secretary of Homeland Security has exempted this system from the following provisions of the Privacy Act, subject to limitations set forth in 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I); and (f) pursuant to 5 U.S.C. 552a (k)(6) where it states: ''For testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service the disclosure of which would compromise the objectivity or fairness of the testing or examination process.''

Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

(b) From subsection (d) (Access to Records) because access to the records contained in this system of records could inform the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS or another agency. Access to the records could permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension. Amendment of the records could interfere with ongoing investigations and law enforcement activities and would impose an unreasonable administrative burden by requiring investigations to be continually reinvestigated. In addition, permitting access and amendment to such information could disclose security-sensitive information that could be detrimental to homeland security.

(c) From subsection (e)(1) (Relevancy and Necessity of Information) because in the course of investigations into potential violations of federal law, the accuracy of information obtained or introduced occasionally may be unclear, or the information may not be strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of unlawful activity.

(d) From subsections (e)(4)(G), (e)(4)(H), and (e)(4)(I) (Agency Requirements) and (f) (Agency Rules), because portions of this system are exempt from the individual access provisions of subsection (d) for the reasons noted above, and therefore DHS is not required to establish requirements, rules, or procedures with respect to such access. Providing notice to individuals with respect to existence of records pertaining to them in the system of records or otherwise setting up procedures pursuant to which individuals may access and view records pertaining to themselves in the system would undermine investigative efforts and reveal the identities of witnesses, and potential witnesses, and confidential informants.

Mary Ellen Callahan,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2011–17940 Filed 7–15–11; 8:45 am]

BILLING CODE 9110–17–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2011–0056]

Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security Office of Operations Coordination and Planning–002 National Operations Center Tracker and Senior Watch Officer Logs Records System of Records

AGENCY: Privacy Office, DHS.

ACTION: Final rule.

SUMMARY: The Department of Homeland Security is issuing a final rule to amend its regulations to exempt portions of a newly established system of records titled, ''Department of Homeland Security Office of Operations Coordination and Planning –002 National Operations Center Tracker and Senior Watch Officer Logs Records System of Records'' from certain provisions of the Privacy Act. Specifically, the Department exempts portions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: *Effective Date:* This final rule is effective July 18, 2011.

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Michael Page (202–357–7626), Privacy Point of Contact, Office of Operations Coordination and Planning, Department of Homeland Security, Washington, DC 20528. For privacy issues please contact: Mary Ellen Callahan (703–235–0780), Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

Background

The Department of Homeland Security (DHS) Office of Operations Coordination and Planning (OPS) published a notice of proposed rulemaking (NPRM) in the **Federal Register**, March 8, 2011, 76 FR 12745, proposing to exempt portions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements. The system of records is the DHS/OPS–002 National Operations Center Tracker and Senior Watch Officer Logs Records System of Records. The DHS/OPS–002 National Operations Center Tracker and Senior

Watch Officer Logs Records system of records notice (SORN) was published concurrently in the **Federal Register**, March 8, 2011, 76 FR 12609, and comments were invited on both the NPRM and SORN.

Public Comments

No comments were received on the NPRM or SORN. The Department will implement the rulemaking as proposed.

List of Subjects in 6 CFR Part 5

Freedom of information; Privacy.

For the reasons stated in the preamble, DHS amends Chapter I of Title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

■ 1. The authority citation for Part 5 continues to read as follows:

Authority: 6 U.S.C. 101 *et seq.;* Public Law 107–296, 116 Stat. 2135; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

■ 2. Add at the end of Appendix C to Part 5, the following new paragraph ''57'':

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

57. The DHS/OPS–002 National Operations Center Tracker and Senior Watch Officer Logs Records System of Records consists of electronic and paper records and will be used by DHS and its components. The DHS/OPS–002 National Operations Center Tracker and Senior Watch Officer Logs Records System of Records is a repository of information held by DHS in connection with its several and varied missions and functions, including, but not limited to the enforcement of civil and criminal laws; investigations, inquiries, and proceedings there under; national security and intelligence activities; and protection of the President of the U.S. or other individuals pursuant to Section 3056 and 3056A of Title 18. The DHS/OPS–002 National Operations Center Tracker and Senior Watch Officer Logs Records System of Records contains information that is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information collected by other federal, state, local, tribal, foreign, or international government agencies. The Secretary of Homeland Security is exempting this system from the following provisions of the Privacy Act, subject to limitations set forth in 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I); and (f) pursuant to 5 U.S.C. 552a(k)(1), (k)(2), and (k)(3). Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

(b) From subsection (d) (Access to Records) because access to the records contained in this system of records could inform the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS or another agency. Access to the records could permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension. Amendment of the records could interfere with ongoing investigations and law enforcement activities and would impose an unreasonable administrative burden by requiring investigations to be continually reinvestigated. In addition, permitting access and amendment to such information could disclose security-sensitive information that could be detrimental to homeland security.

(c) From subsection (e)(1) (Relevancy and Necessity of Information) because in the course of investigations into potential violations of federal law, the accuracy of information obtained or introduced occasionally may be unclear, or the information may not be strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of unlawful activity.

(d) From subsections (e)(4)(G), (e)(4)(H), and (e)(4)(I) (Agency Requirements) and (f) (Agency Rules), because portions of this system are exempt from the individual access provisions of subsection (d) for the reasons noted above, and therefore DHS is not required to establish requirements, rules, or procedures with respect to such access. Providing notice to individuals with respect to existence of records pertaining to them in the system of records or otherwise setting up procedures pursuant to which individuals may access and view records pertaining to themselves in the system would undermine investigative efforts and reveal the identities of witnesses, and potential witnesses, and confidential informants.

Mary Ellen Callahan,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2011–17939 Filed 7–15–11; 8:45 am]

BILLING CODE 9110–09–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 989

[Docket No. AMS–FV–11–0013; FV11–989–1 FR]

Raisins Produced From Grapes Grown In California; Increase in Desirable Carryout Used To Compute Trade Demand

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule increases the desirable carryout used to compute the yearly trade demand for Natural (sun-dried) Seedless (NS) raisins covered under the Federal marketing order for California raisins (order). The order regulates the handling of raisins produced from grapes grown in California and is administered locally by the Raisin Administrative Committee (committee). This rule increases the amount of tonnage available early in the season when volume regulation is implemented, and is expected to help the industry meet its market needs.

DATES: *Effective Date:* July 19, 2011.

FOR FURTHER INFORMATION CONTACT: Terry Vawter, Senior Marketing Specialist, or Kurt J. Kimmel, Regional Manager, California Marketing Field Office, Fruit and Vegetable Programs, AMS, USDA, 2202 Monterey Street, Suite 102B, Fresno, California 93721; *Telephone:* (559) 487–5901, *Fax:* (559) 487–5906; or *E-mail: Terry.Vawter@ams.usda.gov* or *Kurt.Kimmel@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Laurel May, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; Telephone (202) 720–2491; *Fax:* (202) 720–8938; or *E-mail: Laurel.May@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement and Order No. 989 (7 CFR part 989), both as amended, regulating the handling of raisins produced from grapes grown in California, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction in equity to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule increases the desirable carryout used to compute the yearly trade demand for NS raisins regulated under the order. ''Trade demand'' is computed based on a formula specified in the order, and is used to determine volume regulation percentages for each crop year, if necessary. ''Desirable carryout,'' one component of this formula, is the amount of tonnage carried in from the prior crop year which is considered necessary to meet market needs, before raisins from the new crop year are available.

Currently, the desirable carryout for NS raisins is defined as: The total shipments of free tonnage during August and September of each of the past 5 crop years, converted to a natural condition basis, dropping the high and low figures, and dividing the remaining sum by three, or 60,000 natural condition tons, whichever is higher. This rule increases the desirable carryout to 85,000 natural condition tons, with no further calculations required. This action was unanimously recommended by the committee at a meeting held on February 23, 2011.

It should be noted that the desirable carryout for raisin varieties other than NS are not impacted by this change.

The order provides authority for volume regulation designed to promote orderly marketing conditions, stabilize prices and supplies, and improve producer returns. When volume regulation is in effect, a certain percentage of the California raisin crop may be sold by handlers to any market (free tonnage) while the remaining percentage must be held by handlers in a reserve pool (reserve) for the account of the committee.

Reserve raisins are disposed of through certain programs authorized under the order. For instance, reserve raisins may be sold by the committee to handlers for free use or to replace part of the free tonnage raisins they exported; used in diversion programs; carried over as a hedge against a short crop the following year; or disposed of in other outlets not competitive with those for free tonnage raisins, such as government purchase, distilleries, or animal feed. Funds generated from sales of reserve raisins are also used to support handler sales to export markets. Net proceeds from sales of reserve raisins are ultimately distributed to the reserve pool's equity holders, primarily producers.

Section 989.54 of the order prescribes procedures to be followed in establishing volume regulation and includes methodology used to calculate volume regulation percentages. Trade demand is based on a computed formula specified in this section, and is also part of the formula used to determine volume regulation percentages. Trade demand is equal to 90 percent of the prior year's shipments, adjusted by the carrying and desirable carryout inventories.

At one time, § 989.54(a) also specified actual tonnages for desirable carryout for each varietal type regulated. However, in 1989, these tonnages were suspended from the order, and flexibility was added so that the committee could adopt other methods for arriving at a desirable carryout in the order's rules and regulations. The current formula has allowed the committee to periodically adjust the desirable carryout to better reflect changes in marketing conditions, as they have since 1989, most recently in 2000 and 2002.

The formula for desirable carryout has been specified since 1989 in § 989.154. Initially, the formula was established so that desirable carryout was based on shipments for the first 3 months of the prior crop year—August, September, and October (the crop year runs from August 1 through July 31). The formula has been changed over the years because the committee believed that an excessive supply of raisins was available early in a new crop year, which contributed to unstable market conditions.

However, given recent worldwide shortages of NS raisins, a favorable monetary exchange rate, and the extremely low inventory carried in by the industry at the beginning of the 2010–11 crop year, the committee determined that the current trade demand formula would not provide enough raisins to meet market demands when volume regulation is implemented, especially in the early part of the crop year when supplies can be tight. Thus, the committee recommended increasing the desirable carryout component of the formula. This change also allows desirable carryout of NS raisins to more accurately reflect the amount of NS raisins that handlers actually hold in inventory at the end of a crop year, or about 100,000 tons.

The Committee's Recommendation

At a meeting on February 23, 2011, the committee reviewed the desirable carryout level. Most committee members believe that the supply of free tonnage raisins on the market has become tight, and the carryout balance has resulted in market shortages and missed marketing opportunities in the early part of the season. The following table illustrates handler inventories for NS raisins have generally been declining in recent years, with the exception of 2009–10.

CARRYOUT INVENTORY OVER PAST 6 YEARS

[Natural condition tons]

Crop year	NS carryout inventory
2010–11	83,143
2009–10	126,824
2008–09	106,249
2007–08	105,430
2006–07	111,444
2005–06	114,792

Committee staff estimated that this change to the desirable carryout level would increase the 2011–12 trade demand for NS raisins by 15,000 tons. Increasing the trade demand will increase the free tonnage percentage, making more free tonnage available to handlers for immediate use. The effect of increased free tonnage would be to decrease any reserve pool which might be established.

NS raisins are the major commercial varietal type of raisin produced in California. With the exception of the 1998–99, 2003–04, and 2010–11 crop years, volume regulation has been implemented for NS raisins every year since 1983.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 28 handlers of California raisins who are subject to regulation under the order and approximately 3,000 raisin producers in the regulated area. The Small Business Administration (13 CFR 121.201) defines small agricultural service firms as those having annual receipts of less than $7,000,000, and small agricultural producers are defined as those having annual receipts of less than $750,000.

Based upon shipment data and other information provided by the committee, it may be concluded that a majority of producers and approximately 18 handlers of California raisins may be classified as small entities.

This rule increases the desirable carryout used to compute the yearly trade demand for raisins regulated under the order. ''Trade demand'' is computed based on a formula specified under § 989.54(a) of the order. It is also part of another formula used to determine volume regulation percentages for each crop year, if necessary. ''Desirable carryout,'' one component of this formula, is the amount of tonnage from the prior crop year needed during the first part of the next crop year to meet market needs, before new crop raisins are available. Currently, the desirable carryout for Natural (sun-dried) Seedless (NS) raisins is defined as: The total shipments of free tonnage during August and September of each of the past 5 crop years, converted to a natural condition basis, dropping the high and low figures, and dividing the remaining sum by three, or 60,000 natural condition tons, whichever is higher.

This rule increases the desirable carryout to 85,000 natural condition tons, with no calculations required. This action was unanimously recommended by the committee at a meeting held on February 23, 2011.

The desirable carryout level applies uniformly to all handlers in the industry, whether small or large, and there are no known additional costs incurred by small handlers. As previously mentioned, increasing the desirable carryout will increase the trade demand and free tonnage percentage, thus making more raisins available to handlers early in the season. This action is expected to provide more raisins at the beginning of each crop year to meet early demand, thereby improving market conditions at a time period when optimum shipments are advantageous—in time for the holidays. Holiday shipments begin in August, before new-crop raisins are available, and continue through October, and have traditionally been the highest shipment period, as buyers prepare for increased holiday sales of raisins and goods containing raisins.

The committee has an appointed subcommittee, the Administrative Issues Subcommittee (subcommittee), which periodically holds public meetings to discuss changes to the order and other issues. The subcommittee met on February 1, 2011, and discussed desirable carryout, considering a number of alternative levels of desirable carryout. While there was no opposition to increasing the desirable carryout, some industry members supported making the NS desirable carryout 90,000 natural condition tons, while some suggested that 80,000 natural condition tons was a good alternative. Still others suggested that the ideal number might be closer to 100,000 natural condition tons, in keeping with the average of the last several years' actual inventory carried in at the beginning of the crop year, 106,000 natural condition tons. The 85,000 natural condition tons ultimately recommended was a compromise reached during subcommittee deliberations of the alternatives.

On February 23, 2011, the subcommittee met again and further discussed desirable carryout before recommending to the full committee that the desirable carryout be increased for NS raisins from the current formula or 60,000 natural condition tons, whichever is greater, to simply 85,000 natural condition tons. Ultimately, the full committee adopted the subcommittee's recommendation, and unanimously recommended the change to USDA.

This final rule would impose no additional reporting or recordkeeping requirements on either small or large raisin handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

AMS is committed to complying with the E–Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

In addition, the subcommittee's meetings on February 1, 2011, and February 23, 2011; and the committee's meeting on February 23, 2011, were public meetings, widely publicized throughout the raisin industry. All interested persons were invited to attend the meetings and encouraged to participate in the industry's deliberations.

A proposed rule concerning this action was published in the **Federal Register** on May 13, 2011 (76 FR 27921). Copies of the rule were provided to all committee members and raisin handlers. Finally, the rule was made available through the Internet by USDA and the Office of the Federal Register. A 30-day comment period ending June 13, 2011, was provided to allow interested persons to respond to the proposal. There were two comments received during the comment period, both in support of the proposed rule. Accordingly, no changes will be made to the rule as proposed.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at the following Web site: *http://www.ams.usda.gov/fv/MarketingOrdersSmallBusinessGuide* Any questions about the compliance guide should be sent to Laurel May at the previously-mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant matters presented, including information and recommendation submitted by the committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

It is further found that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because handlers are aware of this change, which was unanimously recommended at at least one public meeting. In addition, this rule needs to be in effect in time for the beginning of the new crop year, which is August 1, 2011.

List of Subjects in 7 CFR Part 989

Grapes, Marketing agreements, Raisins, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 989 is amended as follows:

PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 989 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. In § 989.154, the first sentence of paragraph (a) is revised to read as follows:

§ 989.154 Marketing policy computations.

(a) *Desirable carryout levels.* The desirable carryout level to be used in computing and announcing a crop year's marketing policy for Natural (sun-dried) Seedless raisins shall be 85,000 natural condition tons.

* * * * *

Dated: July 11, 2011.

Rayne Pegg,

Administrator, Agricultural Marketing Service.

[FR Doc. 2011–17788 Filed 7–15–11; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1210
[Document Number AMS–FV–10–0093]

Watermelon Research and Promotion Plan; Redistricting and Importer Representation

AGENCY: Agricultural Marketing Service, USDA

ACTION: Final rule.

SUMMARY: This rule changes the boundaries of all seven districts under the Watermelon Research and Promotion Plan (Plan) to reapportion the producer, handler, and importer memberships on the National Watermelon Promotion Board (Board). In addition, the Board is adding two importer seats based on the quantity of watermelon imports in the past three years. These changes are based on a review of the production and assessments paid in each district and the amount of watermelon import assessments, which the Plan requires at least every five years. As a result of these changes, the importer seats will increase from six to eight. Therefore, the total Board membership will increase from 35 to 37 members. In addition, a new Code of Federal Regulation section is added to reflect the importer representation on the Board.

DATES: Effective July 19, 2011.

FOR FURTHER INFORMATION CONTACT: Jeanette Palmer, Marketing Specialist, Research and Promotion Branch, Fruit and Vegetable Programs, AMS, U.S. Department of Agriculture, Stop 0244, 1400 Independence Avenue, SW., Room 0632–S, Washington, DC 20250–0244; telephone: (888) 720–9917; facsimile: (202) 205–2800; or electronic mail: *Jeanette.Palmer@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under the Watermelon Research and Promotion Plan [7 CFR part 1210]. The Plan is authorized under the Watermelon Research and Promotion Act (Act) [7 U.S.C. 4901–4916].

Executive Orders 12866

The Office of Management and Budget has waived the review process required by Executive Order 12866 for this action.

Executive Order 12988

In addition, this rule has been reviewed under Executive Order 12988, Civil Justice Reform. The rule is not intended to have retroactive effect.

The Act allows producers, producer-packers, handlers, and importers to file a written petition with the Secretary of Agriculture (Secretary) if they believe that the Plan, any provision of the Plan, or any obligation imposed in connection with the Plan, is not established in accordance with the law. In any petition, the person may request a modification of the Plan or an exemption from the Plan. The petitioner will have the opportunity for a hearing on the petition. Afterwards, an Administrative Law Judge (ALJ) will issue a decision. If the petitioner disagrees with the ALJ's ruling, the petitioner has 30 days to appeal to the Judicial Officer, who will issue a ruling on behalf of the Secretary. If the petitioner disagrees with the Secretary's ruling, the petitioner may file, within 20 days, an appeal in the U.S. District Court for the district where the petitioner resides or conducts business.

Regulatory Flexibility Act and Paperwork Reduction Act

In accordance with the Regulatory Flexibility Act [5 U.S.C. 601–612], AMS has examined the economic impact of this rule on the small producers, handlers, and importers that would be affected by this rule.

The Small Business Administration defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than $750,000 and small agricultural service firms (handlers and importers) as those having annual receipts of no more than $7 million. Under these definitions, the majority of the producers, handlers, and importers that would be affected by this rule would be considered small entities. Producers of less than 10 acres of watermelons are exempt from this program. Importers of less than 150,000 pounds of watermelons per year are also exempt.

USDA's National Agricultural Statistics Service (NASS) data for the 2010 crop year was about 310 hundredweight (cwt.) of watermelons were produced per acre. The 2010 grower price published by NASS was $12.00 per hundredweight. Thus, the value of watermelon production per acre in 2010 averaged about $3,720 (310 cwt. × $12.00). At that average price, a producer would have to farm over 202 acres to receive an annual income from watermelons of $750,000 ($750,000 divided by $3,720 per acre equals 202). Accordingly, as previously noted, a majority of the watermelon producers would be classified as small businesses.

Based on the Board's data, using an average of freight on board (f.o.b.) price of $.0164 per pound and the number of pounds handled in 2010, none of the watermelon handlers had receipts over the $7.5 million threshold. Therefore, the watermelon handlers would all be considered small businesses. A handler would have to ship over 457 million pounds of watermelons to be considered large (457,317,073 times $.0164 f.o.b. equals $7,500,000).

According to the Board, there are approximately 950 producers, 230 handlers, and 137 importers who are required to pay assessments under the program.

Based on the watermelon import assessments received for the year 2010, the United States imported watermelons worth over $260 million dollars. The largest imports of watermelon came from Mexico which accounted for 93 percent of the total in 2010. Other suppliers of imported watermelon are Guatemala at 3 percent and Honduras at 1 percent. The remaining 3 percent of imported watermelon came from Canada, Netherlands, Nicaragua, Nigeria, and Panama.

The Board's assessment records show imports for the years 2007, 2008, and 2009 at $681,565, $783,249, and $742,363 respectively. Based on this data, the three-year average annual imports for watermelon total $735,725 (2,207,177 divided by 3). This represents approximately 29 percent of the total assessments paid to the Board. Currently there are 6 importers on the Board representing 17 percent of the

total members. Accordingly, two importer seats should be added to the Board. The new Board membership distribution would be 14 producers, 14 handlers, 8 importers, and 1 public member which would bring the percentage of seats for importers to 22 percent of the total seats on the Board.

Nominations and appointments to the Board are conducted pursuant to sections 1210.321 of the Plan. The Plan requires producers to be nominated by producers, handlers to be nominated by handlers, and importers to be nominated by importers. This would not change. Because some current members are in States or counties which would be moved to other districts under this rule, one producer member vacancy in the new District 2, one handler member vacancy in the new Districts 3, and one producer member vacancy in the new District 7 would result with this change. Nomination meetings will be held in the new districts to fill these vacancies.

Appointments to the Board are made by the Secretary from a slate of nominated candidates. The nominees for the two producer, one handler and two importer positions will be submitted to the Secretary for appointment to the Board.

The overall impact is favorable because the new district boundaries provide more equitable representation for the producers, handlers, and importers who pay assessments in the various districts.

The Board chose the realignment scenario that kept the States together. For instance, California is currently divided into two districts and the Board has realigned California so that all the counties in California are located in one district. The new realignment would also give Georgia and Texas their own respective districts. The other States will be divided up to reflect their watermelon production levels and grouped together for the four remaining districts.

The Board considered several alignments of the districts in an effort to provide balanced representation for each district. The Board selected the alignment described in this rule as it provides proportional representation on the Board of producers, handlers, and importers. The addition of two importers would allow for more importers representation on the Board's decision making and also potentially provide an opportunity to increase diversity on the Board.

In accordance with the Office of Management and Budget (OMB) regulation [5 CFR part 1320] which implements the Paperwork Reduction Act of 1995 [44 U.S.C. Chapter 35], the background form, which represents the information collection and recordkeeping requirements that are imposed by the Plan have been approved previously under OMB number 0505–0001.

The Plan requires that two nominees be submitted for each vacant position. With regard to information collection requirements, adding two importers to the Board means that four additional importers will be required to submit background forms to USDA in order to be considered for appointment to the Board. However, serving on the Board is optional, and the burden of submitting the background form would be offset by the benefits of serving on the Board. The estimated annual cost of providing the information by four importers would be $33 or $8.25 per importer. The additional minimal burden will be included in the existing information collection package under OMB number 0505–0001.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Background

Under the Plan, the Board administers a nationally coordinated program of research, development, advertising, and promotion designed to strengthen the watermelon's position in the market place and to establish, maintain, and expand markets for watermelons. This program is financed by assessments on producers growing 10 acres or more of watermelons, handlers of watermelons, and importers of 150,000 pounds of watermelons or more per year. The Plan specifies that handlers are responsible for collecting and submitting both the producer and handler assessments to the Board, reporting their handling of watermelons, and maintaining records necessary to verify their reporting(s). Importers are responsible for payment of assessments to the Board on watermelons imported into the United States through the U.S. Customs Service and Border Protection. This action will not have any impact on the assessment rates paid by producers, handlers, and importers.

Membership on the Board consists of two producers and two handlers for each of the seven districts established by the Plan, at least one importer, and one public member. The Board currently consists of 35 members: 14 producers, 14 handlers, 6 importers, and 1 public member.

The seven current districts were established in 2006. They are:

District 1—The Florida counties of Brevard, Broward, Charlotte, Citrus, Collier, Dade, DeSoto, Flagler, Glades, Hardee, Hendry, Hernando, Highlands, Hillsborough, Indian River, Lake, Lee, Manatee, Martin, Marion, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pasco, Pinellas, Polk, Putnam, Sarasota, Seminole, St. Johns, St. Lucie, Sumter, and Volusia.

District 2—The Florida counties of Alachua, Baker, Bay, Bradford, Calhoun, Clay, Columbia, Dixie, Duval, Escambia, Franklin, Gadsden, Gilchrist, Gulf, Hamilton, Holmes, Jackson, Jefferson, Lafayette, Leon, Levy, Liberty, Madison, Nassau, Okaloosa, Santa Rosa, Suwannee, Taylor, Union, Wakulla, Walton, Washington, and the Georgia counties Early, Baker, Miller, Mitchell, Colquitt, Thomas, Grady, Decatur, Seminole, and the States of Alabama, Arkansas, Louisiana, Mississippi, North Carolina, Oklahoma, Tennessee, and Virginia.

District 3—The Georgia counties not included in District two and the State of South Carolina.

District 4—The States of North Dakota, South Dakota, Nebraska, Kansas, Minnesota, Iowa, Illinois, Missouri, Michigan, Indiana, Ohio, Kentucky, West Virginia, Maryland, New Hampshire, Maine, New Jersey, New York, Pennsylvania, Massachusetts, Rhode Island, Delaware, Vermont, Wisconsin, Connecticut, and Washington, DC.

District 5—The States of Alaska, Hawaii, Nevada, Oregon, and Washington and all of the counties in the state of California except for those California counties included in District Seven.

District 6—The counties in the state of Texas, except for those counties in Texas included in District Seven.

District 7—The counties in the state of Texas; Dallam, Sherman, Hanaford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, Hemphill, Oldham, Potter, Carson, Gray, Wheeler, Deaf Smith, Randall, Armstrong, Donley, Collingsworth, Parmer, Castro, Swisher, Briscoe, Hall, Childress, Bailey, Lamb, Hale, Floyd, Motley, Cottle, Cochran, Hockley, Lubbock, Crosby, Dickens, King, Yoakum, Terry, Lynn, Garza, Kent, Stonewall, the States of New Mexico, Arizona, Utah, Colorado, Idaho, Montana, and Wyoming, and the following counties in California; San Bernardino, Riverside, San Diego, and Imperial.

Pursuant to section 1210.320(c) of the Plan, the Board shall review the seven districts every five years to determine whether realignment of the districts is necessary. When making a review, the Plan specifies that the Board should consider factors such as the most recent three years of USDA production reports

or Board assessment reports if USDA production reports are unavailable, shifts and trends in quantities of watermelons produced, and any other relevant factors. Any realignment should be recommended by the Board at least six months prior to the date of the call for nominations and should become effective at least 30 days prior to this date.

Pursuant to section 1210.320(e) of the Plan, the Secretary shall review importer representation every five years. According to the Plan, the Secretary shall review a three-year average of watermelon import assessments and adjust, to the extent practicable, the number of importers on the Board.

The Board appointed a subcommittee to begin reviewing the U.S. districts and to determine whether realignment was necessary based on production and assessment collections in the current districts. During the review, as prescribed by the Plan, the subcommittee reviewed USDA's Annual Crop Summary reports for 2007 through 2009, which provided figures for the top 17 watermelon producing States, and the Board's assessment collection records for 2007 through 2009. Both sets of data showed similar trends in production among the various States. However, the Board used the assessment reports because USDA's Annual Crop Summary reports were available for only 17 of the 34 States in which watermelons are produced.

The subcommittee recommended to the Board that the boundaries of all seven districts be changed in order to provide for a better distribution of production among producers and handlers in the districts.

The subcommittee also considered the assessments of watermelon imports paid to the Board. The Board's assessment records show imports for the years 2007, 2008, and 2009 at $681,565, $783,249, and $742,363 respectively. Based on this data, the three-year average annual imports for watermelon total $735,725 (2,207,177 divided by 3). The average annual percentage of assessments paid by importers represents almost 29 percent of the Board's assessment income. In contrast to the 2006 realignment, the importer's assessment collection represented 20 percent of the Board's assessment income. Because there was a 9 percent increase in the assessments on imports, the Board recommended an increase in the number of importers on the Board. USDA has evaluated information concerning importer assessments and has determined that the number of importer representatives on the Board should be increased by two members. Therefore, the number of importer Board members would increase from six to eight.

Section 1647(3)(A) of the Act authorizes the Board to have at least one or more importer representative to serve on the Board. However, there is no section in the Plan that identifies the number of importers on the Board. Section 1210.502 is currently reserved and will be used to reflect importer representation on the Board.

The realignment was approved by the Board at its November 13, 2010, meeting. Under the realignment, each district would represent, on average, 16 percent of total U.S. production. The composition of the Board would increase to a total of 37 members: 14 producers, 14 handlers, 8 importers, and 1 public member.

Therefore, this rule realigns the districts as follows:

District 1—The Florida counties of Brevard, Broward, Charlotte, Collier, Dade, Desoto, Glades, Hardee, Hendry, Highlands, Hillsborough, Indian River, Lake, Lee, Manatee, Martin, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pasco, Pinellas, Polk, Sarasota, Seminole, St. Lucie, and Volusia.

District 2—The Florida counties of Alachua, Baker, Bay, Bradford, Calhoun, Citrus, Clay, Columbia, Dixie, Duval, Escambia, Flagler, Franklin, Gadsden, Gilchrist, Gulf, Hamilton, Hernando, Holmes, Jackson, Jefferson, Lafayette, Leon, Levy, Liberty, Madison, Marion, Nassau, Okaloosa, Putnam, Santa Rosa, St. Johns, Sumter, Suwannee, Taylor, Union, Wakulla, Walton, and Washington, and the States of North Carolina and South Carolina.

District 3—The State of Georgia.

District 4—The States of Alabama, Connecticut, Delaware, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Virginia, Vermont, Wisconsin, West Virginia, and Washington, DC.

District 5—The State of California.

District 6—The State of Texas.

District 7—The States of Alaska, Arkansas, Arizona, Colorado, Hawaii, Idaho, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Washington, and Wyoming.

Under this realignment: (1) The Florida counties of Citrus, Flagler, Hernando, Marion, Putnam, St. Johns and Sumter are moved from District 1 to District 2; (2) Alabama, Tennessee, and Virginia are moved from District 2 to District 4; (3) Arkansas, Louisiana, Mississippi, and Oklahoma are moved from District 2 to District 7; (4) Georgia counties Early, Baker, Miller, Mitchell, Colquitt, Thomas, Grady, Decatur, and Seminole are moved from District 2 to District 3, (5) South Carolina moved from District 3 to District 2; (6) Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota are moved from District 4 to District 7; (7) Alaska, Hawaii, Nevada, Oregon, and Washington are moved from District 5 to District 7; (8) The following counties in the State of Texas: Armstrong, Bailey, Briscoe, Carson, Castro, Childress, Cochran, Collingsworth, Cottle, Crosby, Dallam, Deaf Smith, Dickens, Donley, Floyd, Garza, Gray, Hale, Hall, Hanaford, Hartley, Hemphill, Hockley, Hutchinson, Kent, King, Lamb, Lipscomb, Lubbock, Lynn, Moore, Motley, Ochiltree, Oldham, Parmer, Potter, Randall, Roberts, Sherman, Stonewall, Swisher, Terry, Wheeler, and Yoakum are moved from District 7 to District 6; (9) the following counties in California: San Bernardino, Riverside, San Diego, and Imperial are moved from District 7 to District 5.

Due to the re-alignment of districts, the following vacancies are created: one producer vacancy in District 2; one handler vacancy in District 3, one producer vacancy in District 7; and two importer vacancies. Current Board members would be affected because their States or counties would be moved to other districts. Nomination meetings will be held as soon as possible in the new districts to fill the vacancies.

A 30-day comment period was provided to allow interested persons to respond to the proposal which was published in the **Federal Register** on May 5, 2011 [76 FR 25619]. Copies of the rule were made available through the Internet by USDA and the Office of the Federal Register. The comment period ended June 6, 2011. Two comments were received by the deadline.

Two favorable comments were received. One commenter agreed with the Board's recommendation to realign the district boundaries. The other commenter supported the Board's recommendation to add two importers to the Board based on the 29 percent of assessments paid by importers to the Board. The number of importer members would increase from six to eight importer members on the Board.

After consideration of all relevant material presented, the Board's recommendation, and other information, it is hereby found that this rule is consistent with and will effectuate the purpose of the Act.

Pursuant to 5 U.S.C. 553, it also found that good cause exists for not postponing the effective date of this action until one day after publication in the **Federal Register** because the Board's term of office begins January 1, 2012, and this rule will allow the upcoming nominations and appointments to be conducted in a timely manner for the new members to be appointed to the Board so they can begin serving during the next term of office.

List of Subjects in 7 CFR Part 1210

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Reporting and recordkeeping requirements, Watermelon promotion.

For the reasons set forth in the preamble, Part 1210, Chapter XI of Title 7 is amended as follows:

PART 1210—WATERMELON RESEARCH AND PROMOTION PLAN

■ 1. The authority citation for 7 CFR Part 1210 continues to read as follows:

Authority: 7 U.S.C. 4901–4916 and 7 U.S.C. 7401.

Subpart C—Rules and Regulations

■ 2. Section 1210.501 is revised to read as follows:

§ 1210.501 Realignment of districts.

Pursuant to § 1210.320(c) of the Plan, the districts shall be as follows:

(a) *District 1*—The Florida counties of Brevard, Broward, Charlotte, Collier, Dade, Desoto, Glades, Hardee, Hendry, Highlands, Hillsborough, Indian River, Lake, Lee, Manatee, Martin, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pasco, Pinellas, Polk, Sarasota, Seminole, St. Lucie, and Volusia.

(b) *District 2*—The Florida counties of Alachua, Baker, Bay, Bradford, Calhoun, Citrus, Clay, Columbia, Dixie, Duval, Escambia, Flagler, Franklin, Gadsden, Gilchrist, Gulf, Hamilton, Hernando, Holmes, Jackson, Jefferson, Lafayette, Leon, Levy, Liberty, Madison, Marion, Nassau, Okaloosa, Putnam, Santa Rosa, St. Johns, Sumter, Suwannee, Taylor, Union, Wakulla, Walton, and Washington, and the States of North Carolina and South Carolina.

(c) *District 3*—The State of Georgia.

(d) *District 4*—The States of Alabama, Connecticut, Delaware, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Virginia, Vermont, Wisconsin, West Virginia, and Washington, DC.

(e) *District 5*—The State of California.

(f) *District 6*—The State of Texas.

(g) *District 7*—The States of Alaska, Arkansas, Arizona, Colorado, Hawaii, Idaho, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Washington, and Wyoming.

■ 3. Section 1210.502 is added to read as follows:

§ 1210.502 Importer members.

Pursuant to § 1210.320(d) of the Plan, there are eight importer representatives on the Board based on the proportionate percentage of assessments paid by importers to the Board.

Dated: July 12, 2011.

Rayne Pegg,

Administrator.

[FR Doc. 2011–17882 Filed 7–15–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1260

[No. AMS–LS–10–0086]

Beef Promotion and Research; Reapportionment

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule adjusts representation on the Cattlemen's Beef Promotion and Research Board (Board), established under the Beef Promotion and Research Act of 1985 (Act), to reflect changes in cattle inventories and cattle and beef imports that have occurred since the most recent Board reapportionment rule became effective in October 2008. These adjustments are required by the Beef Promotion and Research Order (Order) and will result in a decrease in Board membership from 106 to 103, effective with the U.S. Department of Agriculture's (USDA) appointments for terms beginning early in the year 2012.

DATES: Effective July 19, 2011.

FOR FURTHER INFORMATION CONTACT: Craig Shackelford, Marketing Programs Branch, on 202/720–1115, fax 202/720–1125, or by e-mail at *craig.shackelford@ams.usda.gov.*

SUPPLEMENTARY INFORMATION:

Executive Order 12866

The Office of Management and Budget has waived the review process required by Executive Order 12866 for this action.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect.

Section 11 of the Act provides that nothing in the Act may be construed to preempt or supersede any other program relating to beef promotion organized and operated under the laws of the United States or any State. There are no administrative proceedings that must be exhausted prior to any judicial challenge to the provisions of this rule.

Regulatory Flexibility Act and Paperwork Reduction Act

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA)(5 U.S.C. 601–612), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic effect of this action on small entities and has determined that this final rule will not have a significant economic impact on a substantial number of small entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened.

In the February 2010 publication of ''Farms, Land in Farms, and Livestock Operations,'' USDA's National Agricultural Statistics Service (NASS) estimates that in 2009 the number of operations in the United States with cattle totaled approximately 950,000. The majority of these operations that are subject to the Order may be classified as small entities.

The final rule imposes no new burden on the industry. It only adjusts representation on the Board to reflect changes in domestic cattle inventory and cattle and beef imports. The adjustments are required by the Order and will result in a decrease in Board membership from 106 to 103.

Background and Final Action

The Board was initially appointed August 4, 1986, pursuant to the provisions of the Act (7 U.S.C. 2901–2911) and the Order issued thereunder. Domestic representation on the Board is based on cattle inventory numbers, and importer representation is based on the conversion of the volume of imported cattle, beef, or beef products into live animal equivalencies.

Section 1260.141(b) of the Order provides that the Board shall be composed of cattle producers and importers appointed by the Secretary of Agriculture (Secretary) from

nominations submitted by certified producer organizations. A producer may only be nominated to represent the unit in which that producer is a resident.

Section 1260.141(c) of the Order provides that at least every 3 years and not more than every 2 years, the Board shall review the geographic distribution of cattle inventories throughout the United States and the volume of imported cattle, beef, and beef products and, if warranted, shall reapportion units and/or modify the number of Board members from units in order to reflect the geographic distribution of cattle production volume in the United States and the volume of cattle, beef, or beef products imported into the United States.

Section 1260.141(d) of the Order authorizes the Board to recommend to USDA modifications to the number of cattle per unit necessary for representation on the Board.

Section 1260.141(e)(1) provides that each geographic unit or State that includes a total cattle inventory equal to or greater than 500,000 head of cattle shall be entitled to one representative on the Board. Section 1260.141(e)(2) provides that States that do not have total cattle inventories equal to or greater than 500,000 head shall be grouped, to the extent practicable, into geographically-contiguous units, each of which have a combined total inventory of not less than 500,000 head. Such grouped units are entitled to at least one representative on the Board. Each unit that has an additional 1 million head of cattle within a unit qualifies for additional representation on the Board as provided in § 1260.141(e)(4). As provided in § 1260.141(e)(3), importers are represented by a single unit, with the number of Board members based on a conversion of the total volume of imported cattle, beef, or beef products into live animal equivalencies.

The initial Board appointed in 1986 was composed of 113 members. Reapportionment, based on a 3-year average of cattle inventory numbers and import data, reduced the Board to 111 members in 1990 and 107 members in 1993 before the Board was increased to 111 members in 1996. The Board was decreased to 110 members in 1999, 108 members in 2001, 104 members in 2005, and increased to 106 members in 2009. This final rule will decrease the number of Board members from 106 to 103 with appointments for terms effective early in 2012.

The current Board representation by States or units was based on an average of the January 1, 2005, 2006, and 2007, inventory of cattle in the various States as reported by NASS. Current importer representation was based on a combined total average of the 2005, 2006, and 2007 live cattle imports as published by USDA's Foreign Agricultural Service and the average of the 2004, 2005, and 2006 live animal equivalents for imported beef products.

In considering reapportionment, the Board reviewed cattle inventories as well as cattle, beef, and beef product import data for the period of January 1, 2008, to January 1, 2010. The Board recommended that a 3-year average of cattle inventories and import numbers should be continued. The Board determined that an average of the January 1, 2008, 2009, and 2010, cattle inventory numbers would best reflect the number of cattle in each State or unit since publication of the last reapportionment rule published in 2008 (73 FR 60097).

The Board recommended the use of a combined total of the average of the 2008, 2009, and 2010, cattle import data and the average of the 2007, 2008, and 2009, live animal equivalents for imported beef products. The method used to calculate the total number of live animal equivalents was the same as that used in the previous reapportionment of the Board. The live animal equivalent weight was changed in 2006 from 509 pounds to 592 pounds.

The final rule decreases the number of representatives on the Board from 106 to 103. Kansas, Nebraska, Nevada, and the Southeast Region will each lose one Board seat. Montana will gain a Board seat. The importers will lose two Board seats. The Southeast Region will be expanded to include Alabama, permitting the new unit three Board members. California and Nevada will be combined to form a Southwest unit.

The States and units affected by the reapportionment plan and the current and revised member representation per unit are as follows:

State/unit	Current representation	Revised representation
Alabama	1	0
Kansas	7	6
Nebraska ..	7	6
Nevada	1	0
California ...	5	0
Southeast ..	3	[1] 3
Importers ...	9	7
Montana	2	3
Southwest Unit	N/A	[2] 6

[1] Lost one seat but added a seat with Alabama joining the unit.

[2] California and Nevada.

On April 4, 2011, USDA published in the **Federal Register** (76 FR 18422) for public comment a proposed rule providing for the adjustment in Board membership. Comments were due to USDA by May 4, 2011.

USDA received five comments concerning the proposed rule for Board reapportionment. One commenter raised a number of points regarding the Board and the beef industry as a whole that are not pertinent to the proposal and therefore are not addressed. The commenter also suggested that the membership of the Board be limited to one member per State and that importers should not have members on the Board. Section 5 of the Act and section 1260.141 of the Order contain provisions that determine the structure of the Board based on cattle inventory. Therefore, USDA has not adopted this suggestion.

One commenter suggested that Checkoff collections would be a more appropriate value to use for apportioning Board seats and that Board seats could be determined by each State's total checkoff collections, less the amount returned to other States under the existing State-of-origin rules. Section 5 of the Act and Section 1260.141 of the Order contain provisions that determine the structure of the Board based on cattle inventory. Therefore, USDA has not adopted this suggestion.

One commenter offered support for the proposed rule but also suggested that USDA go further and ensure that Board representation reflect the diversity of interests of all ranchers, representing all sizes and make-ups of operations, and include representation from a multitude of organizations at both the State and national level as well as non-affiliated ranchers. Section 5 of the Act and Section 1260.141 of the Order contain provisions that determine the structure of the Board based on cattle inventory. Therefore, USDA has not adopted this suggestion. However, the Secretary of Agriculture remains committed to ensuring that the Board reflects diversity in the size of operations, experience of members, methods of production and distribution, marketing strategies, and other distinguishing factors that will bring different perspectives and ideas to the table. This communication has been distributed to all organizations that nominate members to the Board.

Two commenters stated their preference that California and Nevada not be combined, but understood that section 1260.141 of the Order provides for the action. The commenters further suggested that the Southwest Unit be dissolved when Nevada cattle numbers increase to appropriate levels. Section 1260.141 of the Order provides that at least every 3 years and not more than

every 2 years, the Board shall review the geographic distribution of cattle inventories throughout the United States and the volume of imported cattle, beef, and beef products and, if warranted, shall reapportion units and/or modify the number of Board members from units in order to reflect the geographic distribution of cattle production volume in the United States and the volume of cattle, beef, or beef products imported into the United States. This comment is consistent with the provisions of the Order and will be considered in future proposals. The commenters also made a number of suggestions regarding the nomination of members within the proposed Southwest Unit. These suggestions are beyond the scope of the proposed rule and are not considered in the final rule.

It is found that good cause exists to make this rule effective less than 30 days after the date of publication in the **Federal Register** because this rule should be in effect as soon as possible for the Board appointments that will be effective early in the year 2012.

List of Subjects in 7 CFR Part 1260

Administrative practice and procedure, Advertising, Agricultural research, Imports, Marketing agreement, Meat and meat products, Reporting and recordkeeping requirements.

For reasons set forth in the preamble, 7 CFR part 1260 is amended as follows:

PART 1260—BEEF PROMOTION AND RESEARCH

■ 1. The authority citation for 7 CFR part 1260 continues to read as follows:

Authority: 7 U.S.C. 2901–2911 and 7 U.S.C. 7401.

■ 2. In § 1260.141, paragraph (a) and the table immediately following it, are revised to read as follows:

§ 1260.141 Membership of Board.

(a) Beginning with the 2011 Board nominations and the associated appointments effective early in the year 2012, the United States shall be divided into 37 geographical units and, 1 unit representing importers, for a total of 38 units. The number of Board members from each unit shall be as follows:

CATTLE AND CALVES [1]

State/unit	1,000 head	Directors
1. Arizona	983	1
2. Arkansas	1,837	2
3. Colorado	2,650	3
4. Florida	1,710	2
5. Idaho	2,153	2
6. Illinois	1,200	1
7. Indiana	873	1
8. Iowa	3,933	4
9. Kansas	6,317	6
10. Kentucky	2,333	2
11. Louisiana	873	1
12. Michigan	1,080	1
13. Minnesota	2,407	2
14. Mississippi	957	1
15. Missouri	4,217	4
16. Montana	2,583	3
17. Nebraska	6,350	6
18. New Mexico	1,540	2
19. New York	1,410	1
20. North Carolina	833	1
21. North Dakota	1,763	2
22. Ohio	1,270	1
23. Oklahoma	5,417	5
24. Oregon	1,290	1
25. Pennsylvania	1,607	2
26. South Dakota	3,733	4
27. Tennessee	2,040	2
28. Texas	13,500	14
29. Utah	820	1
30. Virginia	1,530	2
31. Wisconsin	3,367	3
32. Wyoming	1,327	1
33. Northwest	.....	1
Alaska	15	.....
Hawaii	151	.....
Washington	1,070	.....
Total	1,236	.....
34. Northeast	.....	1
Connecticut	50	.....
Delaware	21	.....
Maine	88	.....
Massachusetts	44	.....
New Hampshire	38	.....
New Jersey	37	.....
Rhode Island	5	.....
Vermont	267	.....

CATTLE AND CALVES [1]—Continued

State/unit	1,000 head	Directors
Total	550	
35. Mid-Atlantic		1
Maryland	192	
West Virginia	400	
Total	592	
36. Southeast		3
Alabama	1,253	
Georgia	1,100	
South Carolina	385	
Total	2,738	
37. Southwest		6
California	5,283	
Nevada	450	
Total	5,733	
38. Importer [2]	6,887	7

[1] 2008, 2009, and 2010 average of January 1 cattle inventory data.
[2] 2007, 2008, and 2009 average of annual import data.

* * * * *

Dated: July 12, 2011.

Rayne Pegg,

Administrator, Agricultural Marketing Service.

[FR Doc. 2011–17885 Filed 7–15–11; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

12 CFR Parts 204, 217, and 230

Regulations D, Q, and DD

[Docket No. R–1413]

RIN 7100–AD 72

Prohibition Against Payment of Interest on Demand Deposits

AGENCY: Board of Governors of the Federal Reserve System (Board)

ACTION: Final rule.

SUMMARY: The Board is publishing a final rule repealing Regulation Q, Prohibition Against Payment of Interest on Demand Deposits, effective July 21, 2011. Regulation Q was promulgated to implement the statutory prohibition against payment of interest on demand deposits by institutions that are member banks of the Federal Reserve System set forth in Section 19(i) of the Federal Reserve Act (''Act''). Section 627 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act'') repeals Section 19(i) of the Federal Reserve Act effective July 21, 2011. The final rule implements the Dodd-Frank Act's repeal of Section 19(i). The final rule also repeals the Board's published interpretation of Regulation Q and removes references to Regulation Q found in the Board's other regulations, interpretations, and commentary.

DATES: *Effective Date:* July 21, 2011.

FOR FURTHER INFORMATION CONTACT: Sophia H. Allison, Senior Counsel (202/452–3565), Legal Division, or Joshua S. Louria, Financial Analyst (202/263–4885), Division of Monetary Affairs; for users of Telecommunications Device for the Deaf (TDD) only, contact (202/263–4869); Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

I. Prohibition Against Payment of Interest on Demand Deposits

Section 19(i) of the Federal Reserve Act (''Act'') (12 U.S.C. 371a) generally provides that no member bank ''shall, directly or indirectly, by any device whatsoever, pay any interest on any deposit which is payable on demand. * * *'' Section 19(i) was added to the Act by Section 11 of the Banking Act of 1933 (48 Stat. 162, 181). Section 324 of the Banking Act of 1935 (49 Stat. 684, 714) amended Section 19(a) of the Act to authorize the Board, ''for the purposes of this section, to define the terms 'demand deposits', 'gross demand deposits,' 'deposits payable on demand' [and] to determine what shall be deemed to be a payment of interest, and to prescribe such rules and regulations as it may deem necessary to effectuate the purposes of this section and prevent evasions thereof. * * *'' The Board promulgated Regulation Q on August 29, 1933 to implement Section 19(i) of the Act. Section 627 of the Dodd-Frank Act repeals Section 19(i) of the Act in its entirety, effective July 21, 2011.

II. Request for Public Comment

On April 14, 2011, the Board published in the **Federal Register** a request for comment on its proposal to repeal Regulation Q effective July 21, 2011 (76 FR 20892, Apr. 14, 2011). In its request for comment, the Board also sought comment on all aspects of the proposal, and also sought comment on four specific issues related to the proposal:

1. Does the repeal of Regulation Q have significant implications for the balance sheets and income of depository institutions? What are the anticipated effects on bank profits, on the allocation of deposit liabilities among product offerings, and on the rates offered and fees assessed on demand deposits, sweep accounts, and compensating balance arrangements?

2. Does the repeal of Regulation Q have any implications for short-term funding markets such as the overnight federal funds market and Eurodollar markets, or for institutions such as institution-only money market mutual funds that are active investors in short-term funding markets?

3. Is the repeal of Regulation Q likely to result in strong demand for interest-bearing demand deposits?

4. Does the repeal of Regulation Q have any implications for competitive burden on smaller depository institutions?

The comment period closed on May 16, 2011.

III. Public Comments

a. Summary

The Board received a total of 62 comments on the proposed rule. Of these, 45 comments were received from 40 banks,[1] 6 comments were received from trade associations, 4 comments were received from other types of entities, and 7 comments were received from individuals. Of the comments received on the proposed rule, 6 comments were in favor of the proposed rule, 54 comments were opposed to the proposed rule, and 2 comments neither supported nor opposed the proposed rule but commented on other aspects of the proposal. A number of commenters specifically addressed one or more of the four specific questions the Board asked in the proposed rule separately from their general comments on the proposed rule.

b. Comments in Favor of the Proposed Rule

One financial group expressed support for the proposed rule, stating that the commenter looked forward to a fair and competitive market that is no longer manipulated through regulation by lobbyists for money market funds and large banks. Another commenter, an individual, opined that the proposal ''repeals an arbitrary and basically non-functioning rule'' and would ''allow more transparency and competition in this arena'' that ''will force banks to innovate and to lower costs.'' This commenter asserted that the repeal would ''lead to more simplicity in deposit offerings and to less rationale for current workarounds'' such as NOW accounts.

A trade association commented that the repeal could result in a more stable source of capital for banks and provide financial professionals with another competitive investment alternative. This commenter also opined that taxes on interest paid would increase revenues for the U.S. Treasury, and asserted that ''there inherently will be new economic dynamics that must be considered when negotiating fees and rates.'' This commenter further asserted that this would ''force financial professionals and corporate treasurers to consider how to effectively rebalance their deposit portfolios in light of the new products and rates structures,'' and that they would have ''another option in terms of liquidity.'' This commenter expected demand for interest-bearing demand deposits to increase after the repeal.

One bank commented in support of the proposal because ''price controls should not be the subject of government regulation.'' This commenter suggested that the repeal would enable the bank to compete for corporate demand deposits without having to sweep them into other off-balance-sheet investments. Another bank commented favorably on the repeal, arguing that Regulation Q ''has been pretty much hollowed out and therefore rendered irrelevant through the years.''

c. Comments Opposed to the Proposed Rule

Most of the comments received opposed the repeal of Regulation Q. Several commenters indicated that they believe that the repeal would have ''devastating'' effects on smaller and community banks. Commenters also indicated that they expect many detrimental effects for institutions from the repeal, including increased cost of funding, the addition of increased interest rate risk to institution balance sheets, increased expenses, decreased net interest margins, decreased earnings, decreased profits, and the ''potential to place many banks in a liability sensitive position.'' Commenters also expected detrimental effects for institutions' customers, including decreased credit availability, increased costs of credit, and increased fees and costs of services. A number of commenters argued that the repeal comes at a time when the banking industry in general, and the community banking industry in particular, is already stressed and facing challenges to continued viability and profitability, as well as increased regulatory burden, particularly with new interchange fee regulations. Some commenters contended that there is currently little demand for loans, and that without loan demand the increased cost of funds represented by paying interest on demand deposits would result in decreased income. One commenter argued that the payment of interest on balances maintained in accounts at Federal Reserve Banks is not sufficient to offset the cost of paying interest on demand deposits.

A number of commenters asserted that the interest-free demand deposit base is the primary franchise builder for community banks and the largest source of fixed-rate funding. One commenter argued that such deposits ''are the lifeblood of community banks'' who lend this money back into the local market at competitive rates to promote local lending for housing, consumer lending and small business lending. Commenters argued that smaller institutions, as they lose their demand deposit base, would have to access other short-term funding sources, which would increase costs in those markets. Commenters also argued that the repeal would increase the concentration of financial assets in the banking sector as funds move out of investments such as money market mutual funds into interest-bearing demand deposits, making nonbank money markets less liquid, less robust, less efficient, and more expensive. One commenter further argued that the outflow of funds from money market mutual funds into interest-bearing demand deposits would damage the commercial paper market, since money market mutual funds are major purchasers of commercial paper. Another commenter argued that the repeal would harm the market for municipal bonds, because community banks would be no longer able to buy fixed-rate bank-qualified municipal bonds.

Several commenters stated that they expect larger and ''too big to fail'' banks, which they believe already have a competitive advantage, to draw commercial demand depositors away from smaller and community banks with expensive marketing programs and offers of higher interest rates with which smaller institutions cannot compete. Some commenters asserted that these customers, once drawn away to larger banks, will suffer decreases in service levels compared to what they received from smaller banks because the business model of smaller banks focuses on relationships and service levels. One commenter asserted that the repeal of Regulation Q would not enable smaller and community banks to compete with larger institutions because, according to the commenter, community banks mostly compete with one another and not with larger institutions. Other commenters asserted that troubled banks would be likely to try to ''buy'' demand deposits by offering unsustainably high interest rates, placing the banking system at risk for more bank failures and increasing costs to the FDIC's bank insurance fund. One commenter argued that large banks that are funded with off-balance-sheet sources in order to avoid FDIC insurance premiums would see the repeal as a way to ''buy'' domestic deposits, ''robbing'' local communities of needed capital.

Some commenters asserted that the movement of funds from non-interest-

[1] More than one person from the same institution submitted comments in some cases.

bearing demand deposits into interest-bearing demand deposits would take such deposits outside of the unlimited FDIC insurance coverage currently available for non-interest-bearing transaction accounts. One commenter argued that the unlimited insurance for such accounts created moral hazard by reducing depositor incentives to monitor institutions and by encouraging institutions to engage in riskier behavior secure in the knowledge that their demand depositors will not move. This commenter argued that the repeal of Regulation Q will increase these risks because depositors could move freely from interest-bearing to non-interest-bearing demand deposits in times of stress, thereby creating effective unlimited insurance on all demand deposits.

Several commenters argued that the effects of the repeal may be less visible in a low interest rate environment but would be more pronounced as interest rates begin to rise. Some commenters argued that the repeal would threaten the viability of many institutions in a rising rate environment. Another commenter argued that the effect would be magnified by the combination of rising interest rates and the expiration of the FDIC's program of unlimited insurance for non-interest-bearing transaction accounts in 2012.

Some comments opposed to the repeal asserted that the provision that became Section 627 of the Dodd-Frank Act was inserted into the bill late in the process, and was not debated or heard in the House or Senate Committees. A few commenters questioned the stated rationale for interest on demand deposits as benefitting small businesses. These commenters asserted that a typical small business maintains on average about $10,000 in a demand deposit, which even at a two percent interest rate would still earn the small business only $200 in one year. One of these commenters asserted that banks would have to increase fees to make up for the increased cost associated with paying interest on demand deposits, eroding the $200-per-year figure to approximately $100 per year. This commenter argued that $100 or $200 per year was not sufficient to permit such businesses to grow or create jobs.

Several commenters argued that the Board should not repeal Regulation Q, or should delay the effective date of the repeal until studies of the impact of the repeal, including safety and soundness effects, could be conducted and considered. Some commenters suggested that the Board advocate before the Congress for a repeal of Section 627 of the Dodd-Frank Act (the provision that repeals the statutory prohibition against payment of interest on demand deposits), and some contended that the Board simply should retain or reinstate Regulation Q. One commenter, noting that the Board would no longer have statutory authority to retain Regulation Q after July 21, 2011, asserted that the Board nevertheless has the authority to issue a policy statement prohibiting the payment of interest on demand deposits until the banking agencies studied the safety and soundness implications of the repeal and determined that it was safe and sound to permit payment of such interest. Another commenter argued that the repeal of Regulation Q would create systemic risk and that the Board should use its systemic risk authority under the Dodd-Frank Act to prevent the repeal from taking effect. Another commenter suggested a two-stage process, repealing the regulation in the first phase, and then starting a second phase of twelve to eighteen months within which the existing interpretations of Regulation Q would remain in effect to give the FDIC the opportunity to consider whether to adopt some or all of them.

A few commenters argued that, instead of repealing Regulation Q, the Board should amend Regulation D to provide for a non-reservable interest-bearing ''money market deposit account'' that would allow up to twenty-four preauthorized or automatic transfers per month. Commenters also asserted that funds moving into interest-bearing demand deposits from non-reservable deposits such as time deposits, or from other non-deposit sources would be subject to a reserve requirement of up to ten percent, which they stated would reduce the availability of such funds for lending or other investment.

d. Comments Addressing Four Specific Questions Raised in the Proposed Rule

1. Does the repeal of Regulation Q have significant implications for the balance sheets and income of depository institutions? What are the anticipated effects on bank profits, on the allocation of deposit liabilities among product offerings, and on the rates offered and fees assessed on demand deposits, sweep accounts, and compensating balance arrangements?

A financial group commented that the ''playing field will be leveled between big banks and community banks'' and that the proposed rule would ''provide an opportunity to pursue large balance commercial clients that in the past would not consider a smaller institution.'' This group commented that the cost of funds ''will be considerably less than consumer core deposits,'' and that ''in spite of the cannibalization of some current deposits'' the net effect would be beneficial. This commenter also asserted that ''we will no longer have to pay vendors for sweeps'' and that customers would be able to choose between receiving earnings credits and direct payments of interest. This commenter further asserted that there would be no impact on that institution's fees but that the repeal would enable smaller institutions to compete with larger institutions for ''large balance clients'' because previously ''large balance clients'' always had sufficient earnings credits to offset fees and the large institutions holding those balances were able to use in-house sweeps programs. Smaller institutions, according to this commenter, were not able to price competitively for such programs because of the vendor costs for sweeps programs, ''the 'Too Big To Fail' concept'' and the fact that earnings credits are not valuable beyond what can be used to pay for fees.

A trade association commented that the anticipated effects of the repeal on bank profits, allocation of deposit liabilities, and rates offered is closely tied to the bank's local market and interest rate environment. Specifically, this association commented that in small markets with little competition for deposits, banks may elect neither to pay interest nor to offer earnings credits following the repeal. This commenter asserted that many banks in markets with high competition for deposits believed that the cost difference between paying direct interest or offering an interest substitute would not be significant in a low interest rate environment. This commenter asserted that, in a high interest rate environment, banks will be under increased pressure to offer interest which would result in higher costs of funds and decreased net interest margins. This commenter also asserted that ''the banking industry's best defense against interest rates spiraling to exceptionally high and unsustainable levels are more account options, including interest, earnings credits, premiums, bonuses, and hybrid accounts.'' This commenter further asserted that the effect of the repeal on correspondent banks should be negligible.

2. Does the repeal of Regulation Q have any implications for short-term funding markets such as the overnight federal funds market and Eurodollar markets, or for institutions such as institution-only money market mutual funds that are active investors in short-term funding markets?

A financial group commented that ''[a]ny changes would be limited'' and would have no long-term effects on such markets. This group commented that off-balance-sheet sweeps would be moved back on balance sheet and that ''deposits for the first time will actually have market competition which will be good for the company, good for the bank, consumers, and overall good for the market.'' This commenter also asserted that ''[t]he only complainers will be those that monopolize the business today due to regulation, but they will adjust [by] either paying more or [downsizing].''

A bank commented that the demand for short-term funding markets will likely increase, which will increase cost of accessing those markets which will increase bank borrowing costs and have a negative impact on profitability.

3. Is the repeal of Regulation Q likely to result in strong demand for interest-bearing demand deposits?

A financial group commented that the repeal of Regulation Q is likely to result in strong demand for interest-bearing demand deposits and that ''this is very good for the bank and the business clients'' and that they expect to see ''significant growth in this product category in number of accounts and balances.''

4. Does the repeal of Regulation Q have any implications for competitive burden on smaller depository institutions?

Many of the comments described above discussed the implications of the repeal of Regulation Q for competitive burden on smaller depository institutions. A financial group commented that the repeal of Regulation Q would not have any implications ''to any significant degree'' for competitive burden on smaller depository institutions and that the repeal ''provides the best opportunity we have seen in decades to pursue business clients.'' This commenter asserted that only the smaller institutions that would be negatively affected by the repeal ''are those very small institutions in non-competitive markets which have benefitted having no large banks compete for funds.'' A bank contended that the repeal of Regulation Q will add to the profitability challenges of smaller institutions that have a better track record of serving the communities in which they operate than larger institutions do.

A trade association commented that the repeal would increase competition for typically high-balance business accounts and that costs of funds would increase as such accounts become more difficult to attract and more expensive to retain. This commenter asserted that troubled financial institutions needing liquidity or deposits will aggressively market exceptionally high interest rates which may place community banks at a disadvantage. This commenter also asserted that the repeal would improve parity between FDIC-insured institutions and credit unions in a high interest rate environment because credit unions ''pay interest on business checking and are moving aggressively into the small business-banking niche.'' The commenter further asserted that the repeal ''may assist banks of all sizes and charter types to attract funds previously placed outside of the traditional banking system'' and that this ''reintermediation of corporate money will be more noticeable when interest rates increase.''

e. Responses to the Public Comments

Many of the comments opposed to the repeal of Regulation Q suggested implicitly or explicitly that the Board should not repeal Regulation Q or should delay the repeal of Regulation Q. As stated in the Board's Notice of Proposed Rulemaking, however, the Board will no longer have the authority to retain Regulation Q after July 21, 2011. Accordingly, the Board does not have the discretion to retain the regulation, nor does the Board have the authority to postpone the effective date of the repeal beyond July 21, 2011. While the Board may use its safety and soundness authority to regulate interest paid by the smaller group of state-chartered member banks (but not all member banks, as under Regulation Q), the implementation of Section 627 of the Dodd-Frank Act does not appear to present issues of systemic risk or safety and soundness. In particular, the ability to pay interest on demand deposits should enhance clarity in the market for transaction accounts and potentially eliminate many of the complicated procedures implemented by depository institutions to pay implicit interest on demand deposits. Interest-bearing demand deposits could attract funds from other areas of the financial system and increase the funding possibilities of the banking sector. Additionally, the repeal of Regulation Q will become effective during a period of exceptionally low interest rates. In such an environment, all short-term money market rates are near zero, suggesting that even for those institutions that chose to pay interest on demand deposits, the rate paid will likely also be close to zero. Near-zero money market rates will likely continue for an extended period, so depository institutions and their customers should be able to adjust in a gradual and orderly manner to the new environment.

Similarly, it would be contrary to the purpose of Regulation D to define ''savings deposit'' to include an account from which up to 24 convenient transfers or withdrawals per month are permitted, as some commenters requested. The Board is required by Section 19(b) of the Act to impose reserve requirements on transaction accounts. Section 19(b)(1)(C) of the Act defines ''transaction account'' as a deposit or account on which the depositor is permitted ''to make withdrawals by negotiable or transferrable instrument, payment orders of withdrawal, telephone transfers, or other similar items for the purpose of making payments or transfers to third persons or others.'' [2] Section 19 was intended to distinguish transaction accounts, which are reservable, from savings deposits, which are not reservable. Allowing 24 convenient transfers per month would allow such transfers every business day of the month, and allow a savings deposit to function in a manner indistinguishable from a transaction account.

IV. Final Regulatory Flexibility Analysis

In accordance with Section 3(a) of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* (RFA), the Board is conducting this final regulatory flexibility analysis incorporating comments received during the public comment period. An initial regulatory flexibility analysis was included in the Board's notice of proposed rulemaking in accordance with Section 3(a) of the RFA. In its notice of proposed rulemaking, the Board requested comments on all aspects of the proposal, and specifically requested comment on whether the repeal of Regulation Q pursuant to Section 627 of the Dodd-Frank Act would have any implications for competitive burden on smaller depository institutions.

1. Statement of the need for and the objectives of the final rule. The Board is repealing Regulation Q, which implements the statutory prohibition set forth in Section 19(i) of the Act,

[2] 12 U.S.C. 461(b)(1)(C).

effective July 21, 2011. The repeal implements Section 627 of the Dodd-Frank Act, which repeals Section 19(i) of the Act effective July 21, 2011. Accordingly, the repeal of Regulation Q effective July 21, 2011, is mandatory.

2. Summary of significant issues raised by public comments in response to the Board's IRFA, the Board's assessment of such issues, and a statement of any changes made as a result of such comments. As noted in the **SUPPLEMENTARY INFORMATION**, a majority of commenters asserted that the final rule would have numerous deleterious effects on small member banks. As also noted in the **SUPPLEMENTARY INFORMATION,** however, the legal authority pursuant to which the Board promulgated Regulation Q will cease to exist on July 21, 2011. Accordingly, the Board does not have the discretion to retain the regulation beyond July 21, 2011, nor does the Board have the authority to postpone the effective date of the repeal beyond that date. As further noted in the **SUPPLEMENTARY INFORMATION**, the Board does not believe that the final rule presents issues of systemic risk or safety and soundness sufficient to warrant action by the Board on those bases. Accordingly, the Board made no changes in the final rule as a result of the analysis of the public comments.

3. Description of and estimate of small entities affected by the final rule. The final rule will affect all national banks and all state-chartered member banks. Those institutions may choose after July 21, 2011 to pay interest on demand deposits that they hold for their customers. A financial institution is generally considered ''small'' if it has assets of $175 million or less.[3] There are currently approximately 2,956 member banks (national banks and state-chartered member banks) that have assets of $175 million or less. These institutions are not required to offer demand deposits to their customers or to pay interest on those deposits. The Board expects the final rule to have a positive impact on all such entities because it eliminates an obsolete regulatory provision and because it provides member banks with the option of offering interest-bearing demand deposits following the repeal of Regulation Q.

4. Projected reporting, recordkeeping, and other compliance requirements. The Board believes that the final rule will not have any impact on reporting, recordkeeping, and other compliance requirements for member banks.

5. Steps taken to minimize the economic impact on small entities; significant alternatives. No significant alternatives to the final rule were suggested that could be accomplished without Congressional action. Although some commenters suggested that the Board issue a policy statement delaying the implementation of the statutory repeal, the Board does not believe that it has the authority to extend the statutory effective date through a policy statement that would contravert the clear Congressional intent to repeal the prohibition against the payment of interest on demand deposits effective July 21, 2011.

[3] U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, available at *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf.*

V. Paperwork Reduction Act Analysis

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), the Board reviewed the final rule under the authority delegated to the Board by the Office of Management and Budget (OMB). No collections of information pursuant to the PRA are contained in the final rule; however, there will be clarifications to the instructions of several regulatory reporting requirements. The Board estimates that the clarifications would have a negligible effect on the burden estimates for the existing regulatory reporting information collections.

VI. Administrative Procedure Act

The Administrative Procedure Act (''APA'') generally requires federal agencies to publish a final rule at least 30 days before the effective date thereof. 5 U.S.C. 553. The APA also provides exceptions under which an agency may publish a final rule with an effective date that is less than 30 days from the date of publication of the final rule. Specifically, the APA provides a substantive rule may be published on a date that is less than 30 days before its effective date where the rule ''grants or recognizes an exemption or relieves a restriction,'' or where the agency finds good cause that is published in the final rule. 5 U.S.C. 553(d)(2)–(3).

The repeal of Regulation Q implements the repeal of Section 19(i) of the Federal Reserve Act, effective July 21, 2011, pursuant to Section 627 of the Dodd-Frank Act. The repeal relieves a restriction by repealing the prohibition against payment of interest on demand deposits by member banks. As such, the final rule is exempt under Section 553(d)(2) of the APA from the requirement of publication not less than 30 days before the effective date. The Board also finds good cause under Section 553(d)(3) of the APA for publication of the final rule on a date that is less than 30 days before the effective date. Publication of the final rule in this time frame will not impose a burden on anyone, since all persons subject to Regulation Q have been on notice since passage of the Dodd-Frank Act nearly a year ago that Regulation Q would be repealed effective July 21, 2011. In addition, the Board's request for comment published in the **Federal Register** on April 14 provided additional notice, over three months prior to the effective date, that the rule would be repealed. The Board does not have the legal authority to extend the effective date beyond July 21, 2011, because the law pursuant to which the Board promulgated the rule will cease to exist on that date. Accordingly, the Board finds good cause for not delaying the effective date of the final rule.

List of Subjects

12 CFR Part 204

Banks, Banking, Reporting and recordkeeping requirements.

12 CFR Part 217

Banks, Banking, Reporting and recordkeeping requirements.

12 CFR Part 230

Advertising, Banks, Banking, Consumer protection, Reporting and recordkeeping requirements, Truth in savings.

For the reasons set forth in the preamble, under the authority of section 627 of Public Law 111–203, 124 Stat. 1376 (July 21, 2010), the Board is amending 12 CFR parts 204, 217, and 230 to read as follows:

PART 204—RESERVE REQUIREMENTS OF DEPOSITORY INSTITUTIONS

■ 1. The authority citation for part 204 is amended to read as follows:

Authority: 12 U.S.C. 248(a), 248(c), 461, 601, 611, and 3105.

■ 2. In § 204.10, paragraph (c) is revised to read as follows:

§ 204.10 Payment of interest on balances.

* * * * *

(c) *Pass-through balances.* A pass-through correspondent that is an eligible institution may pass back to its respondent interest paid on balances held on behalf of that respondent. In the case of balances held by a pass-through correspondent that is not an eligible institution, a Reserve Bank shall pay interest only on the required reserve balances held on behalf of one or more

respondents, and the correspondent shall pass back to its respondents interest paid on balances in the correspondent's account.

* * * * *

PART 217—PROHIBITION AGAINST PAYMENT OF INTEREST ON DEMAND DEPOSITS (REGULATION Q)—[REMOVED AND RESERVED]

■ 3. Part 217 is removed and reserved.

PART 230—TRUTH IN SAVINGS (REGULATION DD)

■ 4. The authority citation for part 230 continues to read as follows:

Authority: 12 U.S.C. 4301 *et seq.*

Supplement I to Part 230—Official Staff Interpretations

■ 5. In Supplement I to Part 230:

■ A. Under *Section 230.2—Definitions,* paragraph *(n) Interest,* is revised.

■ B. Under *Section 230.7—Payment of interest,* subsection *(a)(1) Permissible methods,* the introductory text of paragraph (5) is revised.

The revisions read as follows:

Supplement I to Part 230—Official Staff Interpretations

* * * * *

Section 230.2 Definitions.

* * * * *

(n) Interest

1. *Relation to bonuses.* Bonuses are not interest for purposes of this regulation.

* * * * *

Section 230.7 Payment of interest.

(a)(1) Permissible methods

* * * * *

5. *Maturity of time accounts.* Institutions are not required to pay interest after time accounts mature. Examples include:

* * * * *

By order of the Board of Governors of the Federal Reserve System, July 12, 2011.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2011–17886 Filed 7–15–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 33

[Docket No. FAA–2010–0398; Amendment No. 33–31]

RIN 2120–AJ62

Airworthiness Standards; Rotor Overspeed Requirements

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule will amend the aircraft turbine engine rotor overspeed type certification standards. This action establishes uniform rotor overspeed design and test requirements for aircraft engines and turbochargers certificated by the FAA and the European Aviation Safety Agency (EASA). The rule also establishes uniform standards for the design and testing of engine rotor parts in the United States and in Europe, eliminating the need to comply with two differing sets of requirements.

DATES: This amendment becomes effective September 16, 2011.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this final rule, contact Tim Mouzakis, Engine and Propeller Directorate Standards Staff, ANE–111, Engine and Propeller Directorate, Federal Aviation Administration, 12 New England Executive Park, Burlington, Massachusetts 01803–5299; telephone (781) 238–7114; fax (781) 238–7199; e-mail *timoleon.mouzakis@.faa.gov.* For legal questions concerning this final rule contact Vincent Bennett, ANE–7, Office of Regional Counsel, Federal Aviation Administration, 12 New England Executive Park, Burlington, Massachusetts 01803–5299; telephone (781) 238–7044; fax (781) 238–7055; e-mail *vincent.bennett@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, the FAA is charged with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce, including minimum safety standards for aircraft engines. This final rule is within the scope of that authority because it updates existing regulations for rotor overspeed for aircraft turbine engines.

Background

Part 33 of Title 14, Code of Federal Regulations, prescribes airworthiness standards for original and amended type certificates for aircraft engines. The European Aviation Safety Agency (EASA) Certification Specification—Engines (CS–E) prescribes corresponding airworthiness standards to certify aircraft engines in Europe. While part 33 and the CS–E are similar, they differ in several respects. These differences may result in added costs, delays, and time required for certification. This rule will harmonize applicable U.S. and EASA standards and clarify existing overspeed requirements for aircraft turbine engine rotor parts.

Summary of the NPRM

The FAA published a notice of proposed rulemaking (NPRM) on April 26, 2010 (75 FR 21523). The proposed changes establish a uniform certification basis for aircraft turbine engine rotor parts between the FAA and EASA. The proposal discussed requiring that rotor parts be designed with a safety margin large enough that the parts have an overspeed capability that exceeds the engine's certified operating conditions, including overspeed conditions which can occur in the event of a failure of another engine component and/or system malfunction. For failures that may result in an overspeed, the proposal limited rotor growth to that which would not lead to a hazardous condition as defined in § 33.75. The comment period for the NPRM closed on July 26, 2010.

Summary of the Final Rule

There are minor differences between the proposal and this final rule. Sections 33.27(c) and (g) were changed in response to comments and our review of the proposal. This rule harmonizes rotor overspeed requirements found in part 33 with EASA CS–E 840, Rotor Integrity.

Summary of Comments

The FAA received comments from Rolls-Royce, General Electric Aviation, Turbomeca, Pratt and Whitney, and General Aviation Manufacturers Association (GAMA). The commenters

suggested minor improvements in the following areas:

- Differences in the definition of ''extremely remote'' in § 33.27(c);
- Exclusions of shaft sections from overspeed tests;
- Material properties of test rotors; and
- Validation of analytical tools.

Discussion of the Final Rule

The final rule requires that rotor parts be designed with a safety margin large enough that the parts have an overspeed capability exceeding the engine's certified operating conditions, including overspeed conditions, which can occur in the event of a failure of another engine component and/or system malfunction. For failures that may result in an overspeed, the final rule limits rotor growth to that which would not lead to a hazardous condition as defined by § 33.75.

To harmonize FAA and EASA standards, the FAA will:

- Change the current FAA overspeed design margin from 115 to 120 percent of maximum permissible speed for all engine ratings except one engine inoperative (OEI) ratings of less than 2½ minutes;
- Change the current FAA overspeed design margin from 100 to 105 percent for operating conditions associated with multiple failures;
- Introduce similar OEI overspeed design requirements;
- Require new similar rotor pass/fail design criteria;
- Require similar overspeed margin requirements;
- Allow the use of validated structural analysis tools to demonstrate compliance;
- Require that validated structural analysis tools be calibrated to actual overspeed tests of similar rotors; and
- Allow engine test durations of less than 5 minutes for failure conditions for which a 5-minute duration is not realistic.

Like EASA's CS–E, the final rule specifies that rotors may not burst for overspeed conditions that do not involve component or system failure. For component or engine failures that result in an overspeed, the final rule specifies that rotors may not burst and limits the amount of rotor growth.

Differences in Definition of Probability of Occurrence in § 33.27(c)

Section 33.27(c) proposed that overspeeds resulting from combinations of failures must also be considered unless the applicant can show that the probability of occurrence is not greater than 10^{-9} per flight. Rolls-Royce, General Electric, Turbomeca, Pratt and Whitney, and GAMA commented that the proposed criteria in § 33.27(c) is inconsistent with § 33.75, CS–E 510, and CS–E 840. The commenters also took issue with the FAA's criteria of probability of occurrence as not greater than 10^{-9} and FAA's use of the term ''per flight.'' They suggested that the probability of occurrence should follow the more flexible criteria of not greater that ''extremely remote,'' which has been defined in the previous rulemakings as between 10^{-7} to 10^{-9}. Finally, the commenters indicated that the term ''per engine flight hour'' should be substituted for ''per flight'' to be consistent with § 33.75 and CS–E 840.

We agree with the revised criteria proposed by the commenters. The final rule will reflect that overspeeds resulting from combinations of failures must also be considered, unless the applicant can show that the probability of occurrence is not greater than extremely remote (probability range of 10^{-7} to 10^{-9} per engine flight hour).

Exclusion of Shaft Sections From Overspeed Tests

Proposed § 33.27(f) allows exclusion of certain shaft sections, but not the whole shaft system, from the requirement when determining the terminal rotor speed due to shaft failure. Rolls-Royce commented that § 33.27(c) allows exclusion on a probability basis only of overspeeds ''resulting from combinations of failures,'' whereas CS–E 840(c) allows the probability exclusion for any cause if ''it can be shown to be Extremely Remote under the provisions of CS–E 850.''

Rolls-Royce requested that the lead sentence of § 33.27(c) be changed to, ''The highest overspeed which will result from a complete loss of load on a turbine rotor, unless it can be shown to be Extremely Remote or except as provided by paragraph (f) of this section.* * *''. The change proposed by Rolls-Royce would allow exclusion of the whole shaft system from consideration of failure, which is not the intent of the rule. Our changes to overspeed requirements due to shaft failures are consistent with those in CS–E–840 and CS–E–850(b). We did not change the rule due to this comment.

Material Properties of Test Rotors

Section 33.27(a)(1) proposed that test rotors used to demonstrate compliance with this section that do not have the most adverse combination of material properties and dimensional tolerances must be tested at conditions which have been adjusted to ensure the minimum specification rotor possesses the required overspeed capability.

Rolls-Royce claimed that determining the precise ''most adverse combination'' is not practical. Rolls-Royce noted that Advisory Circular (AC) 33.27–1, paragraph 7.g indicates that the applicant should consider ''the most adverse combination of dimensional tolerances and material properties,'' which allows the use of engineering judgment and best practices in lieu of an exhaustive assessment of all possible combinations and permutations. As a result, Rolls-Royce requested that the phrase ''that do not have the most adverse combination of material properties and dimensional tolerances'' be omitted from § 33.27(a)(1).

We disagree. We find that our proposed wording of § 33.27(a)(1) is consistent with EASA's regulation CS–E 840(a) and that the suggested change would not meet the intent of the proposed paragraph. Our intent in § 33.27(a)(1) is to ensure that the minimum specifications rotor is capable of meeting the test requirements of the proposed rule. Industry has been complying with this requirement, as stated in EASA regulations, for several years. The change proposed by Rolls-Royce would, therefore, diverge from EASA's rule and could increase cost to manufacturers. We did not change the final rule due to this comment.

Validation of Analytical Tools

We proposed in § 33.27(g) that if analysis is used to meet the overspeed requirements, then the analytical tool must be calibrated to prior overspeed test results of a similar rotor. The tool must be calibrated for the same material, rotor geometry, stress level, and temperature range as the rotor being certified. Calibration includes the ability to accurately predict rotor dimensional growth and burst speed. The predictions must also show that the rotor being certified does not have lower burst and growth margins than rotors used to calibrate the tool.

Rolls-Royce commented that the requirements for validation of analytical tools eligible for use in showing compliance in lieu of testing are overly restrictive. Rolls-Royce said the language of § 33.27(g) appears to invalidate any potential for the applicant to propose analysis methods to the Administrator for acceptance per AC 33.27–1, paragraphs 7.b and 7.c. Rolls-Royce noted that it seems unlikely that an applicant will have a tool calibrated for the same conditions and the same rotor as that being certified; such a certification appears redundant. Rolls-Royce requested that § 33.27(g) be

modified to read: ''If analysis is used to meet the overspeed requirements, then the analytical tool must be calibrated to prior overspeed test results of a similar rotor.''

We agree that the language of proposed 33.27(g) appears overly restrictive. We changed the language to read the analytical tool must be ''validated'' instead of ''calibrated'' for each material. The analytical model must be validated using rotors which ''surround'' the rotor being certified in terms of ''shape, stresses and temperature.'' The final rule now reads: ''If analysis is used to meet the overspeed requirements, then the analytical tool must be validated to prior overspeed test results of a similar rotor. The tool must be validated for each material. The rotor being certified must not exceed the boundaries of the rotors being used to validate the analytical tool in terms of geometric shape, operating stress, and temperature.'' This changed wording is also consistent with EASA advisory material AMC E 840.

Definition of Terms Used in the Final Rule

The following definitions of terms used in the final rule are provided for clarity:

Maximum permissible rotor speed. The maximum approved rotor speed, including transients, for the maximum approved rating, including One-Engine-Inoperative (OEI) ratings.

Overspeed Capability. The r.p.m. (revolutions per minute) at which the part fails or bursts.

Rotor Growth. The total increase in a rotor part's radial dimensions caused by an overspeed condition. Total growth includes both the recoverable (elastic) and the permanent (plastic) change in rotor dimensions.

Rulemaking Analyses and Notices

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. We have determined there is no new requirement for information collection associated with this final rule.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices, to the maximum extent practicable. We determined that no ICAO Standards or Recommended Practices corresponding to these proposed regulations exist.

Regulatory Evaluation, Regulatory Flexibility Determination, International Trade Impact Assessment, and Unfunded Mandates Assessment

Proposed changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble contains the FAA's analysis of the economic impacts of this final rule.

In conducting these analyses, the FAA has determined that this rule: (1) Has benefits that justify its costs; (2) is not an economically ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866; (3) is not ''significant'' as defined in DOT's Regulatory Policies and Procedures; (4) will not have a significant economic impact on a substantial number of small entities; (5) will not create unnecessary obstacles to the foreign commerce of the United States; and (6) will not impose an unfunded mandate on state, local, or tribal governments, or on the private sector by exceeding the threshold identified above.

Total Estimated Benefits and Costs of This Proposed Rule

Presently, turbine aircraft engine manufacturers must satisfy both FAA part 33 and EASA CS–E regulations to certify their products in the United States and Europe. Certification to one standard will improve certification efficiency by eliminating duplicate testing and documentation. We have not attempted to quantify the cost savings that may accrue due to this improved certification efficiency beyond noting that these are expected to be minor. We have drawn that conclusion based on the consensus among potentially affected aircraft engine manufacturers.

Industry must currently certificate to the two standards that are substantively similar, but have a few slightly different testing and documentation procedures and requirements. The rule harmonizes these procedures and requirements to the higher standard and, thereby, may increase safety. In addition, by reducing the amount of duplicative testing that would need to be either witnessed or analyzed by the FAA, the FAA is better able to prioritize its resources to other, more safety critical areas. Consequently, we determined that unquantifiable future minimal benefits from the rule may also accrue. We disagreed with a comment determining the precise ''most adverse combination'' of material properties and dimensional tolerances to establish the required overspeed capability. However, as noted in our response, the commenter's suggestion would result in a rule that is not consistent with the EASA regulations and the suggestion might increase costs to manufacturers. As a result, the FAA concludes that the combination of cost savings and potential increased safety benefits will make this rule cost beneficial. Further, we therefore determined that this rule is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, and is not ''significant'' as defined in DOT's Regulatory Policies and Procedures.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If

the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The net effect of this rule is to provide regulatory cost relief. Further, all but one U.S. aircraft turbine engine manufacturer exceeds the Small Business Administration small-entity criteria for aircraft engine manufacturers of 1,500 employees. U.S. transport category aircraft engine manufacturers include: General Electric (GE); CFM International (a joint company of GE and Snecma); Pratt & Whitney (P&W); Honeywell; Rolls-Royce Corporation (formerly Allison Engines); International Aero Engines (a privately-held consortium that includes P&W, Rolls-Royce, Japanese Aero Engines Corporation, and MTU Aero Engines); and Williams International. Williams International is the only one of these manufacturers that is categorized as a U.S. small business by the SBA criteria. As this final rule reduces costs and there is only one small entity manufacturing part 33 aircraft engines, therefore, as FAA Administrator, I certify this rule will not have a significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. We assessed the potential effect of this rule and determined that it uses European standards as the basis for regulation, and thus is consistent with the Trade Assessments Act.

Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $140.8 million in lieu of $100 million. This final rule does not contain such a mandate, therefore, the requirements of Title II of the Act do not apply.

Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore does not have federalism implications.

Environmental Analysis

FAA Order 1050.1E defines FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act (NEPA) in the absence of extraordinary circumstances. We determined this rulemaking action qualifies for the categorical exclusion identified in Chapter 3, paragraph 312d, and involves no extraordinary circumstances.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA has analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). We determined that it is not a ''significant energy action'' under the executive order and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by—

1. Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);

2. Visiting the FAA's Regulations and Policies web page at *http://www.faa.gov/regulations_policies/;* or

3. Accessing the Government Printing Office's web page at *http://www.gpoaccess.gov/fr/index.html.*

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue, SW, Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the notice, amendment, or docket number of this rulemaking.

Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://DocketsInfo.dot.gov.*

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. If you are a small entity and you have a question regarding this document, you may contact your local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. You can find out more about SBREFA on the Internet at *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 33

Air transportation, Aircraft, Aviation safety, Safety.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends Chapter I of Title 14, Code of Federal Regulations as follows:

PART 33—AIRWORTHINESS STANDARDS: AIRCRAFT ENGINES

■ 1. The authority citation for part 33 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44704.

■ 2. Revise § 33.27 to read as follows:

§ 33.27 Turbine, compressor, fan, and turbosupercharger rotor overspeed.

(a) For each fan, compressor, turbine, and turbosupercharger rotor, the

applicant must establish by test, analysis, or a combination of both, that each rotor will not burst when operated in the engine for 5 minutes at whichever of the conditions defined in paragraph (b) of this section is the most critical with respect to the integrity of such a rotor.

(1) Test rotors used to demonstrate compliance with this section that do not have the most adverse combination of material properties and dimensional tolerances must be tested at conditions which have been adjusted to ensure the minimum specification rotor possesses the required overspeed capability. This can be accomplished by increasing test speed, temperature, and/or loads.

(2) When an engine test is being used to demonstrate compliance with the overspeed conditions listed in paragraph (b)(3) or (b)(4) of this section and the failure of a component or system is sudden and transient, it may not be possible to operate the engine for 5 minutes after the failure. Under these circumstances, the actual overspeed duration is acceptable if the required maximum overspeed is achieved.

(b) When determining the maximum overspeed condition applicable to each rotor in order to comply with paragraphs (a) and (c) of this section, the applicant must evaluate the following rotor speeds taking into consideration the part's operating temperatures and temperature gradients throughout the engine's operating envelope:

(1) 120 percent of the maximum permissible rotor speed associated with any of the engine ratings except one-engine-inoperative (OEI) ratings of less than 2½ minutes.

(2) 115 percent of the maximum permissible rotor speed associated with any OEI ratings of less than 2½ minutes.

(3) 105 percent of the highest rotor speed that would result from either:

(i) The failure of the component or system which, in a representative installation of the engine, is the most critical with respect to overspeed when operating at any rating condition except OEI ratings of less than 2½ minutes, or

(ii) The failure of any component or system in a representative installation of the engine, in combination with any other failure of a component or system that would not normally be detected during a routine pre-flight check or during normal flight operation, that is the most critical with respect to overspeed, except as provided by paragraph (c) of this section, when operating at any rating condition except OEI ratings of less than 2½ minutes.

(4) 100 percent of the highest rotor speed that would result from the failure of the component or system which, in a representative installation of the engine, is the most critical with respect to overspeed when operating at any OEI rating of less than 2½ minutes.

(c) The highest overspeed that results from a complete loss of load on a turbine rotor, except as provided by paragraph (f) of this section, must be included in the overspeed conditions considered by paragraphs (b)(3)(i), (b)(3)(ii), and (b)(4) of this section, regardless of whether that overspeed results from a failure within the engine or external to the engine. The overspeed resulting from any other single failure must be considered when selecting the most limiting overspeed conditions applicable to each rotor. Overspeeds resulting from combinations of failures must also be considered unless the applicant can show that the probability of occurrence is not greater than extremely remote (probability range of 10^{-7} to 10^{-9} per engine flight hour).

(d) In addition, the applicant must demonstrate that each fan, compressor, turbine, and turbosupercharger rotor complies with paragraphs (d)(1) and (d)(2) of this section for the maximum overspeed achieved when subjected to the conditions specified in paragraphs (b)(3) and (b)(4) of this section. The applicant must use the approach in paragraph (a) of this section which specifies the required test conditions.

(1) Rotor Growth must not cause the engine to:

(i) Catch fire,

(ii) Release high-energy debris through the engine casing or result in a hazardous failure of the engine casing,

(iii) Generate loads greater than those ultimate loads specified in § 33.23(a), or

(iv) Lose the capability of being shut down.

(2) Following an overspeed event and after continued operation, the rotor may not exhibit conditions such as cracking or distortion which preclude continued safe operation.

(e) The design and functioning of engine control systems, instruments, and other methods not covered under § 33.28 must ensure that the engine operating limitations that affect turbine, compressor, fan, and turbosupercharger rotor structural integrity will not be exceeded in service.

(f) Failure of a shaft section may be excluded from consideration in determining the highest overspeed that would result from a complete loss of load on a turbine rotor if the applicant:

(1) Identifies the shaft as an engine life-limited-part and complies with § 33.70.

(2) Uses material and design features that are well understood and that can be analyzed by well-established and validated stress analysis techniques.

(3) Determines, based on an assessment of the environment surrounding the shaft section, that environmental influences are unlikely to cause a shaft failure. This assessment must include complexity of design, corrosion, wear, vibration, fire, contact with adjacent components or structure, overheating, and secondary effects from other failures or combination of failures.

(4) Identifies and declares, in accordance with § 33.5, any assumptions regarding the engine installation in making the assessment described above in paragraph (f)(3) of this section.

(5) Assesses, and considers as appropriate, experience with shaft sections of similar design.

(6) Does not exclude the entire shaft.

(g) If analysis is used to meet the overspeed requirements, then the analytical tool must be validated to prior overspeed test results of a similar rotor. The tool must be validated for each material. The rotor being certified must not exceed the boundaries of the rotors being used to validate the analytical tool in terms of geometric shape, operating stress, and temperature. Validation includes the ability to accurately predict rotor dimensional growth and the burst speed. The predictions must also show that the rotor being certified does not have lower burst and growth margins than rotors used to validate the tool.

Issued in Washington, DC, on June 30, 2011.

J. Randolph Babbitt,

Administrator.

[FR Doc. 2011–18002 Filed 7–15–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0257; Directorate Identifier 2010–NM–122–AD; Amendment 39–16741; AD 2011–14–06]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A318, A319, A320, and A321 Series Airplanes

AGENCY: Department of Transportation (DOT), Federal Aviation Administration (FAA).

ACTION: Final rule.

SUMMARY: We are superseding an existing airworthiness directive (AD)

that applies to the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

* * * * *

The issue 10 of Airbus A318/A319/A320/A321 ALI [Airworthiness Limitation Items] Document and issue 2 of Airbus A319 Corporate Jet ALI Document introduce more restrictive maintenance requirements/airworthiness limitations. Failure to comply with this issue 10 constitutes an unsafe condition.

* * * * *

The unsafe condition is fatigue cracking, accidental damage, or corrosion in principal structural elements and possible failure of certain life limited parts, which could result in reduced structural integrity of the airplane. We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective August 22, 2011.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 22, 2011.

The Director of the Federal Register previously approved the incorporation by reference of certain other publications, listed in this AD as of November 7, 2007 (72 FR 56262, October 3, 2007).

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2141; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on March 24, 2011 (76 FR 16582), and proposed to supersede AD 2007–20–05, Amendment 39–15215 (72 FR 56262, October 3, 2007).

Since we issued AD 2007–20–05, we have determined that more restrictive limitations are necessary. We have also added Model A318–121 and –122 airplanes to the applicability. The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2010–0071R1, dated May 28, 2010 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

The airworthiness limitations are currently included in Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS).

The airworthiness limitations applicable to the Damage Tolerant Airworthiness Limitation Items (DT ALI) are currently given in Airbus A318/A319/A320/A321 ALI Document reference AI/SE–M4/95A.0252/96 and Airbus A319 Corporate Jet ALI Document reference AI/SE–M2/95A.1038/99, which are approved by the European Aviation Safety Agency (EASA) and referenced in Airbus Airworthiness Limitations Section (ALS) Part 2.

The issue 10 of Airbus A318/A319/A320/A321 ALI Document and issue 2 of Airbus A319 Corporate Jet ALI Document introduce more restrictive maintenance requirements/airworthiness limitations. Failure to comply with this issue 10 constitutes an unsafe condition.

EASA AD 2010–0071 retains the requirements of EASA AD 2006–0165, which is superseded, and requires the implementation of more restrictive maintenance requirements/airworthiness limitations as specified in Airbus A318/A319/A320/A321 ALI Document reference AI/SE–M4/95A.0252/96 issue 10 and Airbus A319 Corporate Jet ALI Document reference AI/SE–M2/95A.1038/99.

This [EASA] AD has been revised to clarify the special compliance times defined in Table 1 of this [EASA] AD.

You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Revision to Airworthiness Limitation Items Document

Airbus has issued A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 11, dated September 2010. Issue 11 of Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96 does not add any additional burden on the operator. We have revised paragraphs (j) and (k), table 1, and Note 3, in this final rule to require compliance in accordance with Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Issue 11, dated September 2010.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD with the changes described previously. We determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a Note within the AD.

Costs of Compliance

We estimate that this AD will affect about 729 products of U.S. registry.

The actions that are required by AD 2007–20–05 and retained in this AD take about 1 work-hour per product, at an average labor rate of $85 per work hour. Based on these figures, the estimated cost of the currently required actions is $85 per product.

We estimate that it will take about 1 work-hour per product to comply with the new basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the AD on U.S. operators to be $61,965, or $85 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures

the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Amendment 39–15215 (72 FR 56262, October 3, 2007) and adding the following new AD:

2011–14–06 Airbus: Amendment 39–16741. Docket No. FAA–2011–0257; Directorate Identifier 2010–NM–122–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective August 22, 2011.

Affected ADs

(b) This AD supersedes AD 2007–20–05, Amendment 39–15215.

Applicability

(c) This AD applies to all Airbus Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–111, –211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes; certificated in any category.

Note 1: This AD requires revisions to certain operator maintenance documents to include new inspections. Compliance with these inspections is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by these inspections, the operator may not be able to accomplish the inspections described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (n) of this AD. The request should include a description of changes to the required inspections that will ensure the continued damage tolerance of the affected structure. The FAA has provided guidance for this determination in Advisory Circular (AC) 25.1529–1.

Subject

(d) Air Transport Association (ATA) of America Code 05: Wings.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

* * * * *

The issue 10 of Airbus A318/A319/A320/A321 ALI [Airworthiness Limitation Items] Document and issue 2 of Airbus A319 Corporate Jet ALI Document introduce more restrictive maintenance requirements/airworthiness limitations. Failure to comply with this issue 10 constitutes an unsafe condition.

* * * * *

The unsafe condition is fatigue cracking, accidental damage, or corrosion in principal structural elements and possible failure of certain life limited parts, which could result in reduced structural integrity of the airplane.

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Restatement of Requirements of AD 2007–20–05: Revise Airworthiness Limitations Section (ALS) To Incorporate Safe Life ALIs

(g) For Model A318–111 and –112 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–111, –211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes: Within 3 months after November 7, 2007 (the effective date of AD 2007–20–05), revise the ALS of the Instructions for Continued Airworthiness to incorporate Sub-part 1–2, ''Life Limits,'' and Sub-part 1–3, ''Demonstrated Fatigue Lives,'' of Airbus A318/A319/A320/A321 ALS Part 1—Safe Life Airworthiness Limitation Items, dated February 28, 2006. Accomplish the actions in Sub-part 1–2, ''Life Limits,'' and Sub-part 1–3, ''Demonstrated Fatigue Lives,'' of Airbus A318/A319/A320/A321 ALS Part 1—Safe Life Airworthiness Limitation Items, dated February 28, 2006, at the times specified in Sub-part 1–2, ''Life Limits,'' and Sub-part 1–3, ''Demonstrated Fatigue Lives,'' of Airbus A318/A319/A320/A321 ALS Part 1—Safe Life Airworthiness Limitation Items, dated February 28, 2006, except as provided by paragraph (i) of this AD.

Revise ALS To Incorporate Damage-Tolerant ALIs

(h) For Model A318–111 and –112 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–111, –211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes; except Model A319 airplanes on which Airbus Modifications 28238, 28162, and 28342 have been incorporated in production: Within 14 days after November 7, 2007, revise the ALS of the Instructions for Continued Airworthiness to incorporate Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005 (approved by the EASA on February 7, 2006); Issue 08, dated March 2006 (approved by the EASA on January 4, 2007); or Issue 09, dated November 2006 (approved by the EASA on May 21, 2007). Accomplish the actions in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005; Issue 08, dated March 2006; or Issue 09, dated November 2006; at the times specified in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005; Issue 08, dated March 2006; or Issue 09, dated November 2006; as applicable; except as provided by paragraph (i) of this AD. Doing the actions required by paragraph (j) of this AD terminates the requirements of this paragraph.

Grace Period for New or More Restrictive Actions

(i) For Model A318–111 and –112 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–111, –211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and

–232 airplanes: For any new or more restrictive life limit introduced with Sub-part 1–2, ''Life Limits,'' and Sub-part 1–3, ''Demonstrated Fatigue Lives,'' of Airbus A318/A319/A320/A321 ALS Part 1—Safe Life Airworthiness Limitation Items, dated February 28, 2006, replace the part at the time specified in Sub-part 1–2, ''Life Limits,'' and Sub-part 1–3, ''Demonstrated Fatigue Lives,'' of Airbus A318/A319/A320/A321 ALS Part 1—Safe Life Airworthiness Limitation Items, dated February 28, 2006, or within 6 months after November 7, 2007, whichever is later. For any new or more restrictive inspection introduced with Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005; Issue 08, dated March 2006; or Issue 09, dated November 2006; do the inspection at the time specified in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005; Issue 08, dated March 2006; or Issue 09, dated November 2006; as applicable; or within 6 months after November 7, 2007, whichever is later.

New Requirements of This AD: Revise ALS To Incorporate Damage-Tolerant ALIs With Revised Compliance Times

(j) Within 9 months after the effective date of this AD: Revise the maintenance program by incorporating all maintenance requirements and associated airworthiness limitations specified in the Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Issue 11, dated September 2010. Comply with all applicable maintenance requirements and associated airworthiness limitations included in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Issue 11, dated September 2010; except as provided by paragraph (k) of this AD. Doing the actions required by this paragraph terminates the requirements of paragraph (h) of this AD.

Special Compliance Times for Certain Tasks

(k) For new and more restrictive tasks introduced with Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Issue 11, dated September 2010; as specified in table 1 of this AD: The initial compliance time for doing the tasks is specified in table 1 of this AD.

TABLE 1—COMPLIANCE TIMES FOR NEW TASKS

Task	Applicability (as specified in the applicability column of the task).	Compliance time, whichever occurs later	
545102–01–6	Group 19–1A CFM, Group 19–1B CFM, and Model A320–200 airplanes with CFM Industrial (CFM)/International Aero Engine (IAE) engines.	The threshold as defined in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Issue 11, dated September 2010.	Within 2,000 flight cycles or 5,500 flight hours, after the effective date of this AD, whichever occurs first.
545102–01–7	Model A320–100	The threshold as defined in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Issue 11, dated September 2010.	Within 2,000 flight cycles or 2,000 flight hours, after the effective date of this AD, whichever occurs first.
572050–01–1 or alternative task 572050–02–1.	Group 19–1A and Group 19–1B	At the time of the next due accomplishment of any one of the tasks 572004, 572020, or 572053 as currently described in the Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005; Issue 08, dated March 2006; or Issue 09, dated November 2006.	Within 6 months after the effective date of this AD.
572050–01–4 or alternative task 572050–02–4.	Model A320–200	At the time of the next due accomplishment of any one of the tasks 572004, 572020, or 572053 as currently described in the Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005; Issue 08, dated March 2006; or Issue 09, dated November 2006.	Within 6 months after the effective date of this AD.
572050–01–5 or alternative task 572050–02–5.	Group 21–1A	At the time of the next due accomplishment of any one of the tasks 572004, 572020, or 572053 as currently described in the Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005; Issue 08, dated March 2006; or Issue 09, dated November 2006.	Within 6 months after the effective date of this AD.

TABLE 1—COMPLIANCE TIMES FOR NEW TASKS—Continued

572050–01–7 or alternative task 572050–02–7.	Model A320–100	At the time of the next due accomplishment of any one of the tasks 572004, 572020, or 572053 as currently described in the Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005; Issue 08, dated March 2006; or Issue 09, dated November 2006.	Within 6 months after the effective date of this AD.
534132–01–1	Model A320 PRE 30748	The threshold/interval as defined in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Issue 11, dated September 2010.	Within 100 days after the effective date of this AD, without exceeding the previous threshold/interval as defined in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005; Issue 08, dated March 2006; or Issue 09, dated November 2006.
531118–01–1	Model A318 (except (A318–121 and –122), Group 19–1A, Group 19–1B, Model A320, A321.	The threshold/interval as defined in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Issue 11, dated September 2010.	Within 100 days after the effective date of this AD, without exceeding the previous threshold/interval as defined in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005; Issue 08, dated March 2006; or Issue 09, dated November 2006.
531118–01–1	Model A318–121 and –122 airplanes	The threshold/interval as defined in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Issue 11, dated September 2010.	Within 100 days after the effective date of this AD.

Note 2: New ALI Task 572050 refers to the outer wing dry bay and is comprised of extracts from three ALI Tasks: 572004, 572020 and 572053. The threshold of ALI Task 572050 for the whole dry bay area is that of the lowest threshold of the source ALI tasks, *i.e.,* that of ALI Task 572053.

No Alternative Life Limits, Inspections, or Inspection Intervals

(l) After the actions specified in paragraphs (g) and (h) of this AD have been accomplished, no alternative life limits, inspections, or inspection intervals may be used, except as provided by paragraphs (i) and (m) of this AD, and except as required by paragraph (j) of this AD.

(m) After the actions specified in paragraph (j) of this AD have been accomplished, no alternative life limits, inspections, or inspection intervals may be used.

FAA AD Differences

Note 3: This AD differs from the MCAI and/or service information as follows: European Aviation Safety Agency (EASA) AD 2010–0071R1, dated May 28, 2010, requires operators to comply with the limitations specified in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Airbus A319 Corporate Jet Airworthiness Limitation Items, Document AI/SE–M2/95A.1038/99, Issue 02, dated March 2009; as applicable. This AD requires incorporating Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Issue 11, dated September 2010. Additionally, this AD does not require incorporating Airbus A319 Corporate Jet Airworthiness Limitation Items, Document AI/SE–M2/95A.1038/99, Issue 02, dated March 2009, because that ALI only specifies compliance with the limitations specified in Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; or Issue 11, dated September 2010.

Other FAA AD Provisions

(n) The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to *Attn:* Tim Dulin, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2141; fax (425) 227–1149. Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

Related Information

(o) Refer to MCAI EASA Airworthiness Directive 2010–0071R1, dated May 28, 2010; Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 7, dated December 2005; Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 08, dated March 2006; Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 09, dated November 2006; Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; and Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 11, dated September 2010; for related information.

Material Incorporated by Reference

(p) You must use the service information contained in Table 2 of this AD to do the

actions required by this AD, unless the AD specifies otherwise.

TABLE 2—ALL MATERIAL INCORPORATED BY REFERENCE

Document	Revision	Date
Airbus A318/A319/A320/A321 ALS Part 1—Safe Life Airworthiness Limitation Items	Revision 00	February 28, 2006.
Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96.	Issue 7	December 2005.
Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96.	Issue 08	March 2006.
Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96.	Issue 09	November 2006.
Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96.	Issue 10	October 2009.
Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96.	Issue 11	September 2010.

The issue level of Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; and Issue 11, dated September 2010; is indicated only on the title page and in the Record of Revisions of these documents.

(1) The Director of the Federal Register approved the incorporation by reference of Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 10, dated October 2009; and Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96, Issue 11, dated September 2010; under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The Director of the Federal Register previously approved the incorporation by reference of the service information contained in table 3 of this AD on November 7, 2007 (72 FR 56262, October 3, 2007).

TABLE 3—MATERIAL PREVIOUSLY INCORPORATED BY REFERENCE

Document	Revision	Date
Airbus A318/A319/A320/A321 ALS Part 1—Safe Life Airworthiness Limitation Items	Revision 00	February 28, 2006.
Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96.	Issue 7	December 2005.
Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96.	Issue 08	March 2006.
Airbus A318/A319/A320/A321 Airworthiness Limitation Items, Document AI/SE–M4/95A.0252/96.	Issue 09	November 2006.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office—EAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; e-mail *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.*

(4) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on June 24, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–16559 Filed 7–15–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0309; Directorate Identifier 2010–NM–255–AD; Amendment 39–16755; AD 2011–15–08]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300 B4–600, B4–600R, and F4–600R Series Airplanes, and Model A300 C4–605R Variant F Airplanes (Collectively Called A300–600 Series Airplanes); and Model A310 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

A specific failure case of the THSA [trimmable horizontal stabilizer actuator] upper primary attachment, which may result in a loading of the upper secondary attachment, has been identified by analysis.

Primary load path failure can be caused by bearing migration from the upper attachment gimbal by failure or loss of a retention bolt.

In case of failure of the THSA upper primary attachment, the THSA upper secondary attachment would engage. Because the upper attachment secondary load path can only withstand the loads for a limited period of time, the condition where it would be engaged could lead, if not detected, to the failure of the secondary load path, which would likely result in loss of control of the aeroplane.

* * * * *

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective August 22, 2011.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 22, 2011.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on April 8, 2011 (76 FR 19724). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> A specific failure case of the THSA [trimmable horizontal stabilizer actuator] upper primary attachment, which may result in a loading of the upper secondary attachment, has been identified by analysis.
>
> Primary load path failure can be caused by bearing migration from the upper attachment gimbal by failure or loss of a retention bolt.
>
> In case of failure of the THSA upper primary attachment, the THSA upper secondary attachment would engage. Because the upper attachment secondary load path can only withstand the loads for a limited period of time, the condition where it would be engaged could lead, if not detected, to the failure of the secondary load path, which would likely result in loss of control of the aeroplane.
>
> For the reasons explained above, this [EASA] AD requires installation of three secondary retention plates for the gimbal bearings on the THSA upper primary attachment.

You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a Note within the AD.

Costs of Compliance

We estimate that this AD will affect 215 products of U.S. registry. We also estimate that it will take about 4 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $3,021 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $722,615, or $3,361 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2011–15–08 Airbus: Amendment 39–16755. Docket No. FAA–2011–0309; Directorate Identifier 2010–NM–255–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective August 22, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Airbus Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes, Model A300 B4–605R and B4–622R airplanes, Model A300 F4–605R and F4–622R airplanes, and Model A300 C4–

605R Variant F airplanes; and Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes; certificated in any category.

Subject

(d) Air Transport Association (ATA) of America Code 27: Flight controls.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

A specific failure case of the THSA [trimmable horizontal stabilizer actuator] upper primary attachment, which may result in a loading of the upper secondary attachment, has been identified by analysis.

Primary load path failure can be caused by bearing migration from the upper attachment gimbal by failure or loss of a retention bolt.

In case of failure of the THSA upper primary attachment, the THSA upper secondary attachment would engage. Because the upper attachment secondary load path can only withstand the loads for a limited period of time, the condition where it would be engaged could lead, if not detected, to the failure of the secondary load path, which would likely result in loss of control of the aeroplane.

* * * * *

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Installation

(g) Within 30 months after the effective date of this AD, install three retention plates on the THSA upper primary attachment, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–27–6066 (for Model A300–600 series airplanes) or Airbus Mandatory Service Bulletin A310–27–2103 (for Model A310 series airplanes), both dated June 10, 2010.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(h) The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149. Information may be e-mailed to: *9–ANM–116–AMOC–REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

Related Information

(i) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2010–0224, dated November 4, 2010; and Airbus Mandatory Service Bulletins A300–27–6066 and A310–27–2103, both dated June 10, 2010.

Material Incorporated by Reference

(j) You must use Airbus Mandatory Service Bulletin A300–27–6066, dated June 10, 2010; or Airbus Mandatory Service Bulletin A310–27–2103, dated June 10, 2010; as applicable; to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Airbus SAS—EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; e-mail *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.*

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on July 6, 2011.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–17698 Filed 7–15–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0308; Directorate Identifier 2010–NM–233–AD; Amendment 39–16754; AD 2011–15–07]

RIN 2120–AA64

Airworthiness Directives; 328 Support Services GmbH (Type Certificate Previously Held by AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH) Model 328–100 and –300 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

During maintenance, it has been discovered that at the installation of the fixation brackets for rudder spring tabs and trim tabs an incorrect installation of the fixation brackets may have occurred. * * *

If the orientation of the fixation bracket is reversed or upside down the screws may not reach into the helicoil thread to a sufficient depth.

An incorrect installation, if not detected and corrected, could lead to an in-flight failure of the fixation brackets for rudder spring tabs and trim tabs resulting in and reduced control of the aeroplane.

* * * * *

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective August 22, 2011.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 22, 2011.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA,

1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on April 8, 2011 (76 FR 19721). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> During maintenance, it has been discovered that at the installation of the fixation brackets for rudder spring tabs and trim tabs an incorrect installation of the fixation brackets may have occurred. It is possible that the fixation bracket assembly may be incorrectly orientated and as a result the position of the helicoil inserts on the fixation bracket may be incorrect.
>
> If the orientation of the fixation bracket is reversed or upside down the screws may not reach into the helicoil thread to a sufficient depth.
>
> An incorrect installation, if not detected and corrected, could lead to an in-flight failure of the fixation brackets for rudder spring tabs and trim tabs resulting in and reduced control of the aeroplane.
>
> To address this potential unsafe condition, the TC [type certificate] holder has developed a one-time inspection to detect and correct any incorrect installations of the fixation brackets for rudder spring tabs and trim tabs.
>
> For the reasons described above, this [EASA] AD requires a one-time [detailed] inspection of all rudder trim- and spring tab fixation brackets, the correction of any parts that are incorrectly installed and the reporting of all findings to the TC holder. This [EASA] AD is considered to be an interim action and an improved design bracket attachment is expected to be developed.

The detailed inspection includes determining if the helicoil inserts of the rudder trim tab and spring tab fixation brackets are correctly oriented and are facing the fitting surface, and if not, inspecting the fittings and helicoil inserts for correct installation. The corrective actions include re-orienting the fittings and helicoil inserts, and replacing the fitting with a serviceable one. You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a Note within the AD.

Costs of Compliance

We estimate that this AD will affect about 55 products of U.S. registry. We also estimate that it will take about 2 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $9,350, or $170 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2011–15–07 328 Support Services GmbH (Type Certificate Previously Held by AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH): Amendment 39–16754. Docket No. FAA–2011–0308; Directorate Identifier 2010–NM–233–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective August 22, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to 328 Support Services GmbH (Type Certificate previously held by AvCraft Aerospace GmbH; Fairchild

Dornier GmbH; Dornier Luftfahrt GmbH) Model 328–100 and –300 airplanes, certificated in any category, all serial numbers.

Subject

(d) Air Transport Association (ATA) of America Code 55: Stabilizers.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

During maintenance, it has been discovered that at the installation of the fixation brackets for rudder spring tabs and trim tabs an incorrect installation of the fixation brackets may have occurred. * * *

If the orientation of the fixation bracket is reversed or upside down the screws may not reach into the helicoil thread to a sufficient depth.

An incorrect installation, if not detected and corrected, could lead to an in-flight failure of the fixation brackets for rudder spring tabs and trim tabs resulting in and reduced control of the aeroplane.

* * * * *

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection

(g) Within 400 flight hours after the effective date of this AD, do a detailed inspection to determine if the fixation brackets for the rudder spring tabs and trim tabs are installed correctly, in accordance with the Accomplishment Instructions of 328 Support Services Service Bulletin SB–328–55–493, dated April 21, 2010 (for Model 328–100 airplanes); or SB–328J–55–245, dated April 21, 2010 (for Model 328–300 airplanes).

Corrective Action

(h) If, during the inspection required by paragraph (g) of this AD, any incorrect installation of the fixation brackets for rudder spring tabs and trim tabs is detected, before further flight, correct the installation of the fixation brackets for rudder spring tabs and trim tabs, in accordance with the Accomplishment Instructions of 328 Support Services Service Bulletin SB–328–55–493, dated April 21, 2010 (for Model 328–100 airplanes); or SB–328J–55–245, dated April 21, 2010 (for Model 328–300 airplanes).

Reporting

(i) Within 30 days after the inspection required by paragraph (g) of this AD, or within 30 days after the effective date of this AD, whichever occurs later: Send the inspection report to 328 Support Services GmbH by using the Compliance Report attached to 328 Support Services Service Bulletin SB–328–55–493, dated April 21, 2010 (for Model 328–100 airplanes); or SB–328J–55–245, dated April 21, 2010 (for Model 328–300 airplanes). Send the report by mail or fax to: Attention: Dept. C, 328 Support Services GmbH, Customer Services, P.O. Box 1252, D–82231 Wessling, Federal Republic of Germany; fax +49 (0) 8153 88111–6565.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(j) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149. Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave., SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

Related Information

(k) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2010–0134, dated June 30, 2010; and 328 Support Services Service Bulletins SB–328–55–493 and SB–328J–55–245, both dated April 21, 2010; for related information.

Material Incorporated by Reference

(l) You must use 328 Support Services Service Bulletin SB–328–55–493, dated April 21, 2010, including Compliance Report; or 328 Support Services Service Bulletin SB–328J–55–245, dated April 21, 2010, including Compliance Report; as applicable; to do the actions required by this AD, unless the AD specifies otherwise. Only the even pages of these documents include the document date. The compliance reports attached to these documents do not contain document numbers, revision levels, or dates.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact 328 Support Services GmbH, Global Support Center, P.O. Box 1252, D–82231 Wessling, Federal Republic of Germany; telephone +49 8153 88111 6666; fax +49 8153 88111 6565; e-mail *gsc.op@328support.de;* Internet *http://www.328support.de*.

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on July 6, 2011.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–17703 Filed 7–15–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0718; Directorate Identifier 2011–NM–117–AD; Amendment 39–16756; AD 2011–15–09]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Model DHC–8–400 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above that would

supersede an existing AD. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

> Two cases of the main landing gear (MLG) alternate extension system (AES) cam mechanism failure were found during line checks. The cam mechanism operates the cable to open the MLG door and releases the MLG uplock in sequence. In the case where it is necessary to deploy the MLG using the AES, the failure of the MLG AES cam mechanism on one side will lead to an unsafe asymmetrical landing configuration.
> * * * * *

The unsafe condition is possible loss of control during landing. This AD requires actions that are intended to address the unsafe condition described in the MCAI.

DATES: This AD becomes effective August 2, 2011.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of August 2, 2011.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in the AD as of March 25, 2011 (76 FR 13080, March 10, 2011).

We must receive comments on this AD by September 1, 2011.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7318; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION:

Discussion

On February 22, 2011, we issued AD 2011–05–14, Amendment 39–16624 (76 FR 13080, March 10, 2011). That AD required actions intended to address an unsafe condition on the products listed above.

Since we issued AD 2011–05–14, we have received a report that the service information referenced in that AD as a source of accomplishment information was found to have inadequate inspection procedures. Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2011–01R1, dated May 20, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> Two cases of the main landing gear (MLG) alternate extension system (AES) cam mechanism failure were found during line checks. The cam mechanism operates the cable to open the MLG door and releases the MLG uplock in sequence. In the case where it is necessary to deploy the MLG using the AES, the failure of the MLG AES cam mechanism on one side will lead to an unsafe asymmetrical landing configuration.
>
> Preliminary investigation indicates that the cam mechanism failure may have occurred and remained dormant after a previous AES operation. The cam mechanism may not have fully returned to the normal rested position. With the cam mechanism out of normal rested position, normal powered landing gear door operation could introduce sufficient loads to fracture the cam mechanism or rupture the door release cable.
>
> This directive mandates the initial and subsequent [detailed] inspections for proper operation of the MLG AES cam mechanism, and rectify [repair or replace cam assembly with new or serviceable cam assembly] as necessary.
>
> Since the original issue of this [Canadian] directive, Bombardier Inc. has determined that the existing inspection procedure is insufficient for verification of proper MLG AES cam mechanism operation, and has superseded this inspection procedure. This revision of the [Canadian] directive mandates the use of the latest inspection [and rectification] procedure.

The unsafe condition is possible loss of control during landing. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Bombardier has issued Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between the AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a Note within the AD.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because since we issued AD 2011–05–14, Bombardier has determined that the existing inspection procedure referenced in AD 2011–05–14 is insufficient for verification of proper MLG AES cam mechanism operation, and has provided a revised inspection procedure. In the case where it is necessary to deploy the MLG using the AES, the failure of the MLG AES cam mechanism on one side will lead to an unsafe asymmetrical landing configuration. An asymmetrical landing configuration could result in possible loss of control during landing. This AD mandates the use of the revised inspection procedures. Therefore, we determined that notice and opportunity

for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–0718; Directorate Identifier 2011–NM–117–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Amendment 39–16624 (76 FR 13080, March 10, 2011) and adding the following new AD:

2011–15–09 Bombardier, Inc.: Amendment 39–16756. Docket No. FAA–2011–0718; Directorate Identifier 2011–NM–117–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective August 2, 2011.

Affected ADs

(b) This AD supersedes AD 2011–05–14, Amendment 39–16624.

Applicability

(c) This AD applies to Bombardier, Inc. Model DHC–8–400, –401, and –402 airplanes, certificated in any category, serial numbers 4001 and subsequent.

Subject

(d) Air Transport Association (ATA) of America Code 32: Landing Gear.

Reason

(e) The mandatory continued airworthiness information (MCAI) states:

Two cases of the main landing gear (MLG) alternate extension system (AES) cam mechanism failure were found during line checks. The cam mechanism operates the cable to open the MLG door and releases the MLG uplock in sequence. In the case where it is necessary to deploy the MLG using the AES, the failure of the MLG AES cam mechanism on one side will lead to an unsafe asymmetrical landing configuration. The unsafe condition is possible loss of control during landing.

* * * * *

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Restatement of Requirements of AD 2011–05–14, With New Service Information

(g) Within 50 flight hours or 10 days after March 25, 2011 (the effective date of AD 2011–05–14), whichever occurs first, do a detailed inspection for proper operation of the MLG AES cam mechanism, in accordance with paragraph A) of Bombardier Repair Drawing 8/4–32–0160, Issue 2, dated January 18, 2011; or Issue 3, dated February 15, 2011. Repeat the inspection thereafter at intervals not to exceed 50 flight hours or 10 days, whichever occurs first, until the inspection required by paragraph (i) of this AD is accomplished.

(1) If the cam mechanism is found to reset to the normal rested position without any sticking or binding, it is operating properly.

(2) If the cam mechanism has not reset to its normal rested position, or if any sticking or binding is observed, before further flight, remove the cam assembly, in accordance with paragraph A) of Bombardier Repair Drawing 8/4–32–0160, Issue 2, dated January 18, 2011; or Issue 3, dated February 15, 2011; and do the actions in paragraph (g)(2)(i) or (g)(2)(ii) of this AD.

(i) Repair the cam mechanism assembly, including doing detailed inspections for discrepancies (including an inspection to determine proper operation, an inspection for damage, an inspection for corrosion and cadmium coating degradation, and inspections to determine dimensions are within the limits specified in paragraph B) of Bombardier Repair Drawing 8/4–32–0160, Issue 2, dated January 18, 2011; or Issue 3, dated February 15, 2011), in accordance with paragraph B) of Bombardier Repair Drawing 8/4–32–0160, Issue 2, dated January 18, 2011; or Issue 3, dated February 15, 2011; and install the repaired cam assembly in accordance with paragraph C) of Bombardier Repair Drawing 8/4–32–0160, Issue 2, dated January 18, 2011; or Issue 3, dated February 15, 2011.

(ii) Install a new or serviceable cam assembly, in accordance with paragraph C) of Bombardier Repair Drawing 8/4–32–0160, Issue 2, dated January 18, 2011; or Issue 3, dated February 15, 2011.

(3) If the cam mechanism is found damaged or inoperative during the repair specified in paragraph (g)(2)(i) of this AD, or if any discrepancies are found and Bombardier Repair Drawing 8/4–32–0160, Issue 2, dated January 18, 2011; or Issue 3, dated February 15, 2011; does not specify repairs for those discrepancies, or repairs specified in paragraph (g)(2)(i) of this AD cannot be accomplished: Before further flight, repair and reinstall using a method approved by the Manager, ANE–170, New York Aircraft Certification Office (ACO), FAA, or Transport Canada Civil Aviation (TCCA) (or its delegated agent); or install a new or serviceable cam assembly, in

accordance with paragraph C) of Bombardier Repair Drawing 8/4–32–0160, Issue 2, dated January 18, 2011; or Issue 3, dated February 15, 2011.

Credit for Actions Accomplished in Accordance With Previous Service Information

(h) Actions done before March 25, 2011, in accordance with Bombardier 8/4–32–0160, Issue 1, dated January 14, 2011, are acceptable for compliance with the corresponding requirements of this AD.

New Requirements of This AD

(i) Within 50 flight hours or 10 days after the effective date of this AD, whichever occurs first, do a detailed inspection for proper operation of the MLG AES cam mechanism, in accordance with paragraph A) of Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011. Repeat the inspection thereafter at intervals not to exceed 50 flight hours or 10 days, whichever occurs first. Accomplishing this inspection terminates the requirements of paragraph (g) of this AD.

(1) If the cam mechanism is found to reset to the normal rested position without any sticking or binding, it is operating properly.

(2) If the cam mechanism has not reset to its normal rested position, or if any sticking or binding is observed, before further flight, remove the cam assembly, in accordance with paragraph A) of Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011, and do the actions in paragraph (i)(2)(i) or (i)(2)(ii) of this AD.

(i) Repair the cam mechanism assembly, including doing detailed inspections for discrepancies (including an inspection to determine proper operation, an inspection for damage, an inspection for corrosion and cadmium coating degradation, and inspections to determine dimensions are within the limits specified in paragraph B) of Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011), in accordance with paragraph B) of Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011; and install the repaired cam assembly in accordance with paragraph C) of Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011.

(ii) Install a new or serviceable cam assembly, in accordance with paragraph C) of Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011.

(3) If the cam mechanism is found damaged or inoperative during the repair specified in paragraph (i)(2)(i) of this AD, or if any discrepancies are found and Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011, does not specify repairs for those discrepancies, or repairs specified in paragraph (i)(2)(i) of this AD cannot be accomplished: Before further flight, repair and reinstall using a method approved by the Manager, ANE–170, New York Aircraft Certification Office (ACO), FAA, or Transport Canada Civil Aviation (TCCA) (or its delegated agent); or install a new or serviceable cam assembly, in accordance with paragraph C) of Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(j) The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, ANE–170, New York ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

Related Information

(k) Refer to MCAI Canadian Airworthiness Directive CF–2011–01R1, dated May 20, 2011; Bombardier Repair Drawing 8/4–32–0160, Issue 2, dated January 18, 2011; and Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011; for related information.

Material Incorporated by Reference

(l) You must use Bombardier Repair Drawing 8/4–32–0160, Issue 2, dated January 18, 2011; or Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011; as applicable; to do the actions required by this AD, unless the AD specifies otherwise. The issue dates for Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011, are identified on only the first page of that document.

(1) The Director of the Federal Register approved the incorporation by reference of Bombardier Repair Drawing 8/4–32–0160, Issue 3, dated February 15, 2011, under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The Director of the Federal Register previously approved the incorporation by reference of Bombardier Repair Drawing 8/4–32–0160, Issue 2, dated January 18, 2011, on March 25, 2011 (76 FR 13080, March 10, 2011).

(3) For service information identified in this AD, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416–375–4000; fax 416–375–4539; e-mail *thd.qseries@aero.bombardier.com*; Internet *http://www.bombardier.com*.

(4) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on July 6, 2011.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–17813 Filed 7–15–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9536]

RIN 1545–BK40

Determining the Amount of Taxes Paid for Purposes of the Foreign Tax Credit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations providing guidance relating to the determination of the amount of taxes paid for purposes of the foreign tax credit. These regulations address certain highly structured arrangements that produce inappropriate foreign tax credit results. The regulations affect individuals and corporations that claim direct and indirect foreign tax credits. The text of these temporary regulations also serves as the text of the proposed regulations (REG–126519–11) published in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on July 18, 2011.

Applicability Date: For dates of applicability, see § 1.901–2T(h)(3).

FOR FURTHER INFORMATION CONTACT: Jeffrey P. Cowan, at (202) 622–3850.

SUPPLEMENTARY INFORMATION:

Background

On March 30, 2007, the **Federal Register** published proposed regulations

(72 FR 15081) under section 901 of the Internal Revenue Code relating to the amount of taxes paid for purposes of the foreign tax credit. The IRS and the Treasury Department received written comments on the 2007 proposed regulations and a public hearing was held on July 30, 2007. On July 16, 2008, a notice of proposed rulemaking by cross-reference to temporary regulations and temporary regulations (TD 9416) (the ''2008 temporary regulations'') were published in the **Federal Register** at 73 FR 40792 and 73 FR 40727, respectively. Final regulations were published in the **Federal Register** in July 2011, and adopted the proposed regulations with the changes discussed in the preamble to the final regulations.

Explanation of Provision

Section 1.901–2(e)(5)(iv) of the final regulations provides that an amount paid to a foreign country is not a compulsory payment, and thus is not an amount of tax paid for purposes of the foreign tax credit, if such amount is attributable to a structured passive investment arrangement. An arrangement that satisfies the six conditions described in § 1.901–2(e)(5)(iv) is treated as a structured passive investment arrangement. One of the conditions is that the arrangement utilizes an entity that meets two requirements (the ''SPV condition''). See § 1.901–2(e)(5)(iv)(B)(*1*).

The first requirement of the SPV condition is that substantially all of the entity's gross income, as determined under U.S. tax principles, is attributable to passive investment income and substantially all of the entity's assets are held to produce such passive investment income. The second requirement is that there is a putative foreign tax payment (a ''foreign payment'') attributable to income of the entity, as determined under the laws of the foreign country to which such foreign payment is made. The foreign payment may be paid by the entity itself or by the owner(s) of the entity. Under the 2008 temporary regulations, a foreign payment attributable to income of the entity does not include a withholding tax imposed on a distribution or payment from the entity to a U.S. party. See § 1.901–2T(e)(5)(iv)(B)(*1*)(*ii*) of the 2008 temporary regulations.

The IRS and the Treasury Department have become aware that taxpayers can enter into arrangements that generate duplicative benefits involving foreign withholding taxes imposed on distributions made by an entity to a U.S. party. For example, if the parties undertake a transaction in which interests in an SPV are transferred by the U.S. party to a counterparty subject to a repurchase obligation, withholding taxes imposed on distributions from the SPV may be claimed as creditable in both jurisdictions. Accordingly, the exception for withholding taxes imposed on distributions or payments to U.S. parties was eliminated in the 2011 final regulations. These temporary regulations clarify the provisions of § 1.901–2(e)(5)(iv)(B)(*1*) by providing in a new paragraph § 1.901–2(e)(5)(iv)(B)(*1*)(*iii*) that a foreign payment attributable to income of an entity includes a withholding tax imposed on a dividend or other distribution (including distributions made by a pass-through entity or an entity that is disregarded as an entity separate from its owner for U.S. tax purposes) with respect to the equity of the entity.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that these regulations will primarily affect affiliated groups of corporations that have foreign operations which tend to be larger businesses. Moreover the number of taxpayers affected and the average burden are minimal. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Jeffrey P. Cowan, Office of Associate Chief Counsel (International). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.901–2 is amended by revising paragraphs (e)(5)(iii) and (iv) and adding paragraph (h)(3) to read as follows:

§ 1.901–2 Income, war profits, or excess profits tax paid or accrued.

* * * * *

(e) * * *

(5) * * *

(iii) through (iv)(B)(*1*)(*ii*) [Reserved] For further guidance, see § 1.901–2T(e)(5)(iii) through (e)(5)(iv)(B)(*1*)(*ii*).

(*iii*) [Reserved]. For further guidance, see § 1.901–2T(e)(5)(iv)(B)(*1*)(*iii*).

* * * * *

(h) * * *

(3) [Reserved]. For further guidance, see § 1.901–2T(h)(3).

■ **Par. 3.** Section 1.901–2T is revised to read as follows:

§ 1.901–2T Income, war profits, or excess profits tax paid or accrued.

(a) through (e)(5)(iv)(B)(*1*)(*ii*) [Reserved]. For further guidance, see § 1.901–2(a) through (e)(5)(iv)(B)(*1*)(*ii*).

(*iii*) A foreign payment attributable to income of the entity includes a withholding tax (within the meaning of section 901(k)(1)(B)) imposed on a dividend or other distribution (including distributions made by a pass-through entity or an entity that is disregarded as an entity separate from its owner for U.S. tax purposes) with respect to the equity of the entity.

(e)(5)(iv)(B)(*1*)(*2*) through (h)(2) [Reserved]. For further guidance, see § 1.901–2(e)(5)(iv)(B)(*2*) through (h)(2).

(h)(3) *Effective/applicability date.* This section applies to foreign payments that, if such payments were an amount of tax paid, would be considered paid or accrued under § 1.901–2(f) on or after July 14, 2014.

(h)(4) *Expiration date.* The applicability of this section expires on July 14, 2014.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

Approved: July 11, 2011.

Emily S. McMahon,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2011–17916 Filed 7–14–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9535]

RIN 1545–BK25

Determining the Amount of Taxes Paid for Purposes of the Foreign Tax Credit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations providing guidance relating to the determination of the amount of taxes paid for purposes of the foreign tax credit. These regulations address certain highly structured transactions that produce inappropriate foreign tax credit results. The regulations affect individuals and corporations that claim direct and indirect foreign tax credits.

DATES: *Effective Date:* These regulations are effective on July 18, 2011.

Applicability Date: For dates of applicability, see § 1.901–1(j) and § 1.901–2(h)(2).

FOR FURTHER INFORMATION CONTACT: Jeffrey P. Cowan, at (202) 622–3850.

SUPPLEMENTARY INFORMATION:

Background

On March 30, 2007, the **Federal Register** published proposed regulations (72 FR 15081) under section 901 of the Internal Revenue Code (''Code'') relating to the amount of taxes paid for purposes of the foreign tax credit (the ''2007 proposed regulations''). The IRS and the Treasury Department received written comments on the 2007 proposed regulations and a public hearing was held on July 30, 2007. In response to written comments, the IRS and the Treasury Department issued Notice 2007–95 (2007–2 CB 1091 (December 3, 2007)) (see § 601.601(d)(2)(ii)(*b*)) providing that the proposed rule for U.S.-owned foreign groups would be severed from the portion of the 2007 proposed regulations addressing the treatment of foreign payments attributable to certain structured passive investment arrangements. On July 16, 2008, a notice of proposed rulemaking by cross-reference to temporary regulations and temporary regulations (TD 9416) (the ''2008 temporary regulations'') were published in the **Federal Register** at 73 FR 40792 and 73 FR 40727, respectively. Corrections to those temporary regulations were published on November 14, 2008, in the **Federal Register** (73 FR 67387). The 2008 temporary regulations address the treatment of foreign payments attributable to structured passive investment arrangements and do not address the treatment of U.S.-owned foreign groups.

The IRS and the Treasury Department received written comments on the 2008 temporary regulations, which are discussed in this preamble. All comments are available at *http://www.regulations.gov* or upon request. A public hearing was not requested and none was held. This Treasury decision adopts the proposed regulation with the changes discussed in this preamble.

Summary of Comments and Explanation of Revisions

A. Treatment of Amounts Attributable to a Structured Passive Investment Arrangement

These final regulations retain the basic approach and structure of the 2008 temporary regulations. Thus, the final regulations provide that amounts paid to a foreign taxing authority that are attributable to a structured passive investment arrangement are not treated as an amount of tax paid for purposes of the foreign tax credit. An arrangement that satisfies six conditions, as described in this preamble, is treated as a structured passive investment arrangement.

A comment presented several proposals that collectively would have required further differentiation both among the various investors in structured passive investment arrangements based upon their business practices and relationships to other parties, as well as among the particular transactions undertaken by a special purpose vehicle involved in the arrangement. Because the IRS and the Treasury Department believe these proposals would introduce several subjective and factually-intensive elements into the regulations that would increase administrative burdens for taxpayers and the IRS, including a rule providing for only partial disallowance of foreign tax credits, the final regulations retain the approach of the 2008 temporary regulations, relying on objective, generally applicable standards to the extent possible. The IRS and the Treasury Department believe that this approach will appropriately disallow any foreign tax credits arising from artificial structures that are utilized to generate foreign tax credits and material duplicative foreign tax benefits.

B. Structured Passive Investment Arrangements

A comment recommended adding a requirement that the 2008 temporary regulations' six conditions be fulfilled as part of a plan or series of related transactions. The IRS and the Treasury Department did not adopt this comment. The standard in the regulations is designed to depend upon key objective aspects of an arrangement that indicate an abusive arrangement. The IRS and the Treasury Department believe that the introduction of a plan requirement or similar rule would introduce a subjective inquiry that is difficult to apply and unnecessary to achieve the purpose of the regulations.

C. Section 1.901–2(e)(5)(iv)(B)(1): Special Purpose Vehicle

The first condition provided in § 1.901–2T(e)(5)(iv)(B)(*1*) of the 2008 temporary regulations is that the arrangement utilizes an entity that meets two requirements (the ''SPV condition''). The first requirement is that substantially all of the entity's gross income, as determined under U.S. tax principles, is attributable to passive investment income and substantially all of the entity's assets are held to produce such passive investment income. The term entity, as defined in § 1.901–2T(e)(5)(iv)(C)(*3*) of the 2008 temporary regulations, includes a corporation, trust, partnership, or disregarded entity. For purposes of the first requirement, § 1.901–2T(e)(5)(iv)(C)(*5*) of the 2008 temporary regulations defines passive investment income as income defined in section 954(c) with certain modifications. Passive investment income generally includes the income of an upper-tier entity attributable to its equity interest in a lower-tier entity, but such income may be excluded from passive investment income where it is attributable to a qualified equity interest in certain lower-tier entities that are engaged in an active trade or business and other conditions apply (the ''holding company exception''). See § 1.901–2T(e)(5)(iv)(c)(*5*)(*ii*).

One comment recommended that the definition of passive investment income be modified to exclude personal service contract income as described in section 954(c)(1)(H) because such income is not derived from passive assets and would not ordinarily be used in a structured passive investment arrangement. The IRS and the Treasury Department agree with the comment, and accordingly these final regulations provide that passive investment income does not include personal service contract

income as described in section 954(c)(1)(H).

The IRS and the Treasury Department also received several comments regarding the holding company exception. One comment recommended that the definition of passive investment income exclude income attributable to equity interests in pass-through entities except to the extent that the income of the lower-tier entity satisfies the definition of passive investment income. The IRS and the Treasury Department did not adopt this proposal because the IRS and the Treasury Department believe that the rule in the 2008 temporary regulations is necessary to prevent taxpayers from using pass-through entities to avoid the limitations on the holding company exception, such as the holding of qualified equity interests and the sharing of investment risk. The interests in a pass-through entity can be substantially indistinguishable from interests in a corporate subsidiary, and, therefore, these final regulations treat such interests the same for purposes of the definition of passive investment income. The final regulations clarify that income attributable to equity interests in pass-through entities (including a partner's distributive share of partnership income and the income attributable to an entity disregarded for U.S. tax purposes) is treated as passive investment income unless the holding company exception applies.

The IRS and the Treasury Department have deleted the last two sentences in the 2008 temporary regulations in § 1.901–2T(e)(5)(iv)(B)(*1*)(*i*). These sentences described rules set out in more detail in the definition of passive investment income. The IRS and the Treasury Department believe that these sentences did not provide additional clarity to the definition of passive investment income.

One comment recommended expanding the holding company exception to treat income attributable to certain portfolio interests as active income if the income earned by the lower-tier entity was active income. As a condition to the application of the holding company exception, the potential holding company's equity interest in the lower-tier entity must be a qualified equity interest. The holding company exception focuses on whether a joint venture arrangement conducted through a holding company structure economically replicates the interests of the joint venturers in the active business of the lower-tier entity. It is not intended to insulate portfolio investments in lower-tier entities even if they operate active businesses. Therefore, the IRS and the Treasury Department do not believe that it is appropriate to broaden the holding company exception to apply to portfolio investments notwithstanding that in certain cases the lower-tier entity may have active operations.

Another comment recommended that the holding company exception be replaced with a rule that generally attributes all activities of lower-tier entities to their owners, subject to an anti-abuse exception. Under the suggested anti-abuse rule, the attribution rule would not apply if, with a view to avoiding the SPV condition, a holding company holds assets other than stock in subsidiaries, and, based on all the facts and circumstances, the ownership of those assets is expected to achieve substantially the same effect as holding those assets in a separate entity. A similar comment was considered and not adopted during the promulgation of the 2008 temporary regulations. The IRS and the Treasury Department believe that the commentator's recommendation would be difficult to administer because it would require factually intensive and subjective determinations. Therefore, this comment was not adopted.

Additionally, comments recommended clarifying the requirement in the holding company exception that substantially all of a potential holding company's opportunity for gain and risk of loss with respect to its qualified equity interest in a lower-tier entity be shared by the U.S. party or parties (or persons that are related to a U.S. party) and a counterparty or counterparties (or persons that are related to a counterparty). According to the comments, there are common situations where it is not clear that gain and risk of loss are shared, including preferred stock and stock-based compensation. The IRS and the Treasury Department believe that existing legal principles should apply to determine if an interest holder possesses the opportunity for gain and risk of loss and that additional guidance is generally unnecessary. The IRS and the Treasury Department further believe that the sharing of gain and risk of loss is dependent on facts and circumstances and therefore the final regulations provide that the assessment of opportunity for gain and risk of loss is based on all facts and circumstances.

Finally, comments requested clarification regarding the application of the holding company exception to fact patterns involving multiple counterparties or multiple U.S. parties. In response to the comments, these final regulations clarify that in cases involving more than one U.S. party or more than one counterparty or both, the requirement that the parties must share in substantially all of the upper-tier entity's opportunity for gain and risk of loss with respect to its interest in a lower-tier entity is applied by examining whether there is sufficient risk sharing by each of the groups comprising all U.S. parties (or person related to such U.S. parties) and all counterparties (or persons related to such counterparties). The IRS and the Treasury Department believe that the risk sharing requirement, as so modified, will continue to ensure that only bona fide joint ventures are eligible for the holding company exception. If there is more than one U.S. party or more than one counterparty, the final regulations do not require that each member of the U.S. party and counterparty groups share in the underlying investment risk. Finally, the holding company exception has been modified to provide that where a U.S. party owns an interest in an entity indirectly through a chain of entities, the exception is applied beginning with the lowest-tier entity in the chain before proceeding upward and the opportunity for gain and risk of loss borne by any upper-tier entity in the chain that is a counterparty is disregarded to the extent borne indirectly by a U.S. party.

The second of the two requirements of the SPV condition in the 2008 temporary regulations is that there is a foreign payment attributable to income of the entity. See § 1.901–2T(e)(5)(iv)(B)(*1*)(*ii*). The foreign payment may be paid by the entity itself or by the owner(s) of the entity. The 2007 proposed regulations and the 2008 temporary regulations both provide an exception that a foreign payment does not include a withholding tax imposed on distributions or payments made by an entity to a U.S. party. However, the IRS and the Treasury Department have become aware that taxpayers can enter into arrangements that generate duplicative benefits involving foreign withholding taxes imposed on distributions made by an entity to a U.S. party. For example, if the parties undertake a transaction in which interests in an SPV are transferred by the U.S. party to a counterparty subject to a repurchase obligation, withholding taxes imposed on distributions from the SPV may be claimed as creditable in both jurisdictions.

Accordingly, the exception for withholding taxes imposed on distributions or payments to U.S. parties is eliminated from § 1.901–2(e)(5)(iv)(B)(*1*)(*ii*) of the final regulations. The IRS and the Treasury

Department will promulgate additional guidance to clarify that a foreign payment attributable to income of an entity includes a withholding tax imposed on a dividend or other distribution (including distributions made by a pass-through entity or an entity that is disregarded as an entity separate from its owner for U.S. tax purposes) with respect to the equity of the entity.

The 2008 temporary regulations attribute to income of an entity foreign payments attributable to the entity's share of income of a lower-tier entity that is a branch or pass-through entity under either foreign or U.S. law. One comment recommended that the foreign payment rule be modified by eliminating the attribution of foreign payments made by a lower-tier entity that is a branch or pass-through entity under only U.S. law to the income of its owner because such attribution would not occur if the lower-tier entity were regarded as a corporation for U.S. tax purposes. The IRS and the Treasury Department agree with the comment that foreign payments by a lower-tier entity should not be attributed to the income of its owner. In cases where a lower-tier entity is liable for foreign payments under foreign law, the disallowance of foreign tax credits with respect to such taxes should turn on whether that entity, and not the owner of such entity, satisfies the SPV condition. Accordingly, the applicable sentence has been eliminated from § 1.901–2(e)(5)(iv)(B)(*1*)(*ii*) of the final regulations.

D. Section 1.901–2(e)(5)(iv)(B)(2): U.S. Party

Section 1.901–2(e)(5)(iv)(B)(*2*) of the final regulations adopts without change the second condition of the 2008 temporary regulations that a U.S. party is a person who is eligible to claim a credit under section 901(a), including a credit for taxes deemed paid under section 902 or 960, for all or a portion of the foreign payment if the foreign payment were an amount of tax paid (the ''U.S. party condition''). Comments recommended that the U.S. party condition be supplemented with a de minimis exception, including an exclusion for U.S. citizens and residents. The IRS and the Treasury Department do not believe that such a modification is consistent with the purposes of these regulations. Therefore, the IRS and the Treasury Department have not adopted this comment.

Another comment recommended that if a U.S. party is a member of an affiliated group of corporations that files a consolidated federal income tax return, then all members of the affiliated group should be treated as a single U.S. party for purposes of applying the final regulations. The IRS and the Treasury Department did not adopt this comment because the final regulations provide aggregation rules that address the comment.

E. Section 1.901–2(e)(5)(iv)(B)(3): Direct Investment

Section 1.901–2(e)(5)(iv)(B)(*3*) of the final regulations adopts without change the third condition of the 2008 temporary regulations (the ''direct investment condition''). The direct investment condition requires that the U.S. party's share of the foreign payment or payments is (or is expected to be) substantially greater than the amount of credits, if any, that the U.S. party reasonably would expect to be eligible to claim under section 901(a) for foreign taxes attributable to income generated by the U.S. party's proportionate share of the assets owned by the SPV if the U.S. party directly owned such assets.

Comments suggested that this condition in the 2008 temporary regulations will always be satisfied because it assumes the assets would not be held through a branch operation subject to net basis taxation and excludes assets that produce income subject to gross basis withholding tax. One comment recommended that the final regulations limit the condition to cases in which the arrangement increases the foreign payments attributable to the U.S. party relative to what would have been paid in the absence of a duplicative tax benefit. In contrast, the 2008 temporary regulations compare the amount of the U.S. party's foreign payment with the amount of taxes that would be expected to be paid if the U.S. party directly owned the assets in question.

The IRS and the Treasury Department disagree with this recommendation. The introduction of a standard that compares the foreign payments arising from a structured passive investment arrangement to alternative transactions that might have been undertaken under different incentives would add administrative complexity and uncertainty in the application of these regulations. Accordingly, the IRS and the Treasury Department have retained the condition unchanged from the 2008 temporary regulations both because it describes one of the abusive aspects of these arrangements and because it ensures that the regulations cannot be avoided through the use of foreign securities that produce income subject to withholding taxes.

F. Section 1.901–2(e)(5)(iv)(B)(4): Foreign Tax Benefit

Section 1.901–2(e)(5)(iv)(B)(*4*) of the final regulations adopts with minor changes the fourth condition of the 2008 temporary regulations (the ''foreign tax benefit condition''). The foreign tax benefit condition requires that the arrangement is reasonably expected to result in a tax benefit to a counterparty (or a related person) under the laws of a foreign country. If the foreign tax benefit available to the counterparty is a credit, then such credit must correspond to 10 percent or more of the U.S. party's share (for U.S. tax purposes) of the foreign payment. Other types of foreign tax benefits, such as exemptions, deductions, exclusions or losses, must correspond to 10 percent or more of the foreign base with respect to which the U.S. party's share (for U.S. tax purposes) of the foreign payment is imposed.

The IRS and the Treasury Department received several comments with respect to the foreign tax benefit condition. The comments asserted that the rule in the 2008 temporary regulations requiring at least 10 percent correspondence between the foreign tax benefit and the U.S. party's share of the foreign payment (''the 10 percent correspondence requirement'') is vague and more difficult to apply than a similar rule in the 2007 proposed regulations. Under the 2007 proposed regulations, any foreign tax benefit satisfied the condition, but the counterparty condition, described below, included minimum ownership requirements. One comment favored the clarity of the 2007 proposed rule. In addition, the comments questioned whether certain types of foreign tax benefits, such as exemptions or reduced tax rates on certain types of income, should be treated as foreign tax benefits for these purposes. Finally, comments sought clarification regarding how the percentage of correspondence is determined in cases involving more than two persons owning an interest in an SPV.

The 10 percent correspondence requirement is intended to limit any potential disallowance of foreign tax credits to cases in which there is a material duplication of the tax benefits. Accordingly, the final regulations retain this requirement. In addition, the final regulations do not exclude any particular tax benefit from the foreign tax benefit condition because duplication of tax benefits can assume a wide variety of forms. The IRS and the Treasury Department also believe that whether foreign tax benefits duplicate or correspond to the U.S. party's share of

the foreign tax benefits will generally be clear and no further elaboration of the rules is required.

Another comment noted that the foreign tax benefit condition may be difficult to apply in cases where the foreign tax benefit is claimed by a party related to the counterparty. The IRS and the Treasury Department concluded that it was necessary to include related parties because of the variety of duplication techniques otherwise available to taxpayers, including the use of benefits arising to members of a related group of entities, and accordingly the comment was not adopted.

Comments sought clarification that in arrangements involving two or more unrelated counterparties, the 10 percent correspondence requirement cannot be satisfied by aggregating the value of duplicative tax benefits received by the unrelated counterparties. The comments assert that the inclusion of benefits received by parties related to a counterparty in the foreign tax benefit condition in the 2008 temporary regulations suggested, by negative implication, that any benefits claimed by unrelated counterparties should not be aggregated. The IRS and the Treasury Department did not adopt this comment. The 10 percent correspondence requirement is intended to ensure that the disallowance of credits applies only where the duplication of tax benefits in the arrangement is material relative to the value of the otherwise creditable foreign payment, irrespective of whether the arrangement involves multiple U.S. parties, multiple counterparties, or both. Thus, in the final regulations the 10 percent correspondence requirement compares the aggregate amount of foreign tax benefits available to all counterparties and persons related to such counterparties to the aggregate amount of the U.S. parties' share of the foreign payment or the foreign base, as the case may be.

Comments also objected to the language in the foreign tax benefit condition providing that the arrangement is ''reasonably expected'' to result in a foreign tax benefit. According to the comments, a U.S. party may be unable to assess whether a counterparty is reasonably expected to receive a foreign tax benefit and it would be inappropriate to disallow a foreign tax credit where a U.S. party cannot make such an assessment. The IRS and the Treasury Department believe the reasonableness standard in the 2008 temporary regulations affords sufficient protection against unknowable or unexpected outcomes in the majority of cases. Further, the IRS and the Treasury Department are concerned that an actual knowledge requirement would be difficult to administer. Accordingly, the IRS and the Treasury Department have not adopted this comment.

G. Section 1.901–2(e)(5)(iv)(B)(5): Counterparty

The fifth condition provided in § 1.901–2T(e)(5)(iv)(B)(*5*) of the 2008 temporary regulations is that the arrangement include a person that, under the tax laws of a foreign country in which the person is subject to tax on the basis of place of management, place of incorporation or similar criterion or otherwise subject to a net basis tax, directly or indirectly owns or acquires equity interests in, or assets of, the SPV (the ''counterparty condition''). The 2008 temporary regulations provide that a counterparty does not include the SPV or a person with respect to which the same domestic corporation, U.S. citizen or resident alien individual directly or indirectly owns more than 80 percent of the total value of the stock (or equity interests) of each of the U.S. party and such person. Also, a counterparty does not include a person with respect to which the U.S. party directly or indirectly owns more than 80 percent of the total value of the stock (or equity interests), but only if the U.S. party is a domestic corporation, a U.S. citizen or a resident alien individual.

The IRS and the Treasury Department received several comments with respect to the counterparty condition. Comments noted that in certain tiered structures the rule could treat as a counterparty an upper-tier entity in which a U.S. investor and a foreign investor each hold interests, and that to the extent that the foreign tax benefits resulting from such structures are not duplicative, the counterparty condition is overly broad. For example, if a U.S. investor and foreign investor each own 50 percent of an upper-tier entity which in turn owns an SPV, the comments argue that the exempt treatment of distributions from the SPV to its upper-tier owner is not problematic so long as each of the investors in the upper-tier entity ultimately receives only those tax benefits associated with its 50 percent interest in the upper-tier entity. Comments suggested revising the counterparty condition to exclude such intermediary entities.

The IRS and the Treasury Department agree that foreign tax benefits claimed by a jointly-held upper-tier entity are not problematic so long as none of the indirect U.S. or foreign owners of the SPV claims duplicative tax benefits attributable to the arrangement. However, the IRS and the Treasury Department are concerned that revising the counterparty condition to exclude jointly-held entities could create opportunities for avoidance of the regulations. Accordingly, in lieu of revising the counterparty condition, the final regulations revise the foreign tax benefit condition to provide that certain tax benefits claimed by upper-tier entities do not correspond to the U.S. party's share of the foreign payment. Specifically, where a U.S. party indirectly owns a non-hybrid equity interest in an SPV, a foreign tax benefit available to a foreign entity in the chain of ownership which begins with the SPV and ends with the first-tier entity in such chain does not correspond to the U.S. party's share of the foreign payment attributable to the SPV to the extent that such benefit relates to earnings of the SPV that are distributed with respect to non-hybrid equity interests in the SPV that are owned indirectly by the U.S. party for purposes of both U.S. and foreign tax law. See § 1.901–2(e)(5)(iv)(B)(*4*). This revision is intended to ensure that the foreign tax benefit condition is not satisfied in cases where the U.S. and foreign investors claim only those tax benefits that are consistent with their respective investments in the arrangement and their interests are treated as equity and owned by the same persons in both jurisdictions.

One comment also recommended that dual citizens or U.S. residents, who are generally subject to U.S. tax on their worldwide income, should not be treated as counterparties because any reduction in foreign tax liability will result in a corresponding increase in U.S. tax. The IRS and the Treasury Department agree with this comment and have modified the final regulations to reflect this change.

One comment also recommended that individuals who are family members of a U.S. party not be treated as counterparties. The IRS and the Treasury Department disagree with the comment. The exception from the counterparty condition for certain U.S.-controlled foreign counterparties is based on the premise that the foreign tax benefit available to such a counterparty confers only a timing benefit that will reverse when the counterparty repatriates its earnings to the United States. Because such timing benefits are not the focus of these regulations, the 2007 proposed regulations and 2008 temporary regulations excluded certain foreign persons owned by the U.S. party or by certain United States persons who also own the U.S. party. In contrast, where an individual is related to a U.S.

party but is not a United States person for U.S. tax purposes, the reduction in foreign tax liability obtained by such individual does not result in a corresponding increase in U.S. tax. Accordingly, the final regulations do not include an exclusion for such individuals.

One comment recommended that individuals receiving stock in connection with the performance of services should not be treated as counterparties. The tax policy concerns of the IRS and the Treasury Department regarding structured transactions addressed by these regulations exist regardless of the means by which a person acquires its interest in an SPV. The presence of a duplicative tax benefit is no less problematic because its recipient acquired its interest in an SPV in return for services instead of capital. Accordingly, this recommendation was not adopted.

One comment recommended that in cases where one U.S. party owns more than 80 percent of a counterparty but another U.S. party does not, the regulations should treat a foreign payment as noncompulsory only to the extent of the unrelated U.S. party's share of the foreign payment. This comment was not adopted. These regulations are intended to disallow foreign tax credits claimed in connection with structured passive investment arrangements. The tax policy concerns of the IRS and the Treasury Department regarding such abusive transactions remain the same regardless of whether the arrangement satisfies the six conditions of the regulations with respect to one U.S. party or multiple U.S. parties.

One comment recommended that the final regulations adopt the de minimis rule set forth in the 2007 proposed regulations that requires a counterparty to own a certain percentage of the equity or assets of the SPV. In contrast, as explained in the preamble to the 2008 temporary regulations, the 2008 temporary regulations focus on whether there is a duplicative foreign tax benefit. The IRS and the Treasury Department continue to believe that focusing on a threshold amount of duplicative tax benefits is more consistent with the concerns underlying the regulations. Accordingly, this comment is not adopted.

Another comment recommended that the percentage of U.S. ownership required to exclude a person from being treated as a counterparty be reduced from the 2008 temporary regulations' threshold of more than 80 percent. The comment recommended that the threshold be reduced to either 80 percent or more, or 75 percent or more. The IRS and the Treasury Department do not believe that the proposal is consistent with the policy concerns addressed by these final regulations. Accordingly, this comment is not adopted.

H. Section 1.901–2(e)(5)(iv)(B)(6): Inconsistent Treatment

The IRS and the Treasury Department also received several comments with respect to the sixth condition of the 2008 temporary regulations (the ''inconsistent treatment condition''). The inconsistent treatment condition requires that the United States and an applicable foreign country treat the arrangement inconsistently under their respective tax systems and that the U.S. treatment results in either materially less income or a materially greater amount of foreign tax credits than would be available if the foreign law controlled the U.S. tax treatment. This condition is intended to limit the disallowance of credits to those arrangements that exploit inconsistencies in U.S. and foreign law to secure a foreign tax credit benefit.

A comment recommended that the final regulations adopt an additional requirement that the foreign tax benefit obtained by the counterparty be materially less if the U.S. tax treatment controlled for foreign tax purposes as well. The recommendation is intended to require that both the U.S. party's share of the foreign payments and the foreign tax benefit arise from the inconsistent treatment. The IRS and the Treasury Department believe that the foreign tax benefit condition of the 2008 temporary regulations is sufficient to ensure that the foreign tax benefit corresponds to or duplicates the U.S. party's share of the foreign payments or the foreign base and that such duplication is sufficiently indicative of inconsistency. Therefore, the IRS and the Treasury Department believe that any additional requirement under the inconsistent treatment condition is unnecessary, and the comment was not adopted.

These final regulations clarify the application of the inconsistent treatment condition in cases where multiple U.S. parties exist. Where an arrangement involves multiple U.S. parties, the inconsistent treatment condition is satisfied only if the amount of income attributable to the SPV that is recognized for U.S. tax purposes by the SPV and all the U.S. parties (and persons related to the U.S. party or parties) is materially less than the amount of income that would be recognized if the foreign tax treatment controlled for U.S. tax purposes or if the amount of foreign tax credits claimed by all U.S. parties is materially greater than it would be if the foreign tax treatment controlled for U.S. tax purposes.

I. Examples

These final regulations provide two new examples to illustrate changes that were adopted in the final regulations. Example 8 illustrates the application of the holding company exception when there is more than one U.S. party or more than one counterparty. Example 12 illustrates the application of the revised foreign tax benefit condition to a tiered holding company structure. Modifications to examples in the 2008 temporary regulations were also made to reflect comments received and other changes to the regulations.

J. Miscellaneous Amendments

These final regulations adopt with minor changes amendments made by the 2008 temporary regulations to § 1.901–1(a) and (b) to reflect statutory changes made by the Foreign Investors Tax Act of 1966 (Pub. L. 89–809 (80 Stat. 1539), section 106(b)), the Tax Reform Act of 1976 (Pub. L. 94–455 (90 Stat. 1520), section 1901(a)(114)), and the American Jobs Creation Act of 2004 (Pub. L. 108–357 (118 Stat. 1418–20), section 405(b)).

K. Effective Date

These final regulations generally apply to payments that, if such payments were an amount of tax paid, would be considered paid or accrued on or after July 17, 2011.

The IRS and the Treasury Department will continue to closely scrutinize other arrangements that are not covered by the regulations but produce inappropriate foreign tax credit results. Such arrangements may include arrangements that are similar to arrangements described in the final regulations, but that do not meet all of the conditions included in the final regulations. The IRS will continue to challenge the claimed U.S. tax results in appropriate cases, including under judicial doctrines. The IRS and the Treasury Department may also issue additional regulations in the future to address such other arrangements.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small

entities. This certification is based on the fact that these regulations will primarily affect affiliated groups of corporations that have foreign operations which tend to be larger businesses. Moreover the number of taxpayers affected and the average burden are minimal. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding this regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Jeffrey P. Cowan, Office of Associate Chief Counsel (International). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.901–1 is amended by revising paragraphs (a) and (b), and adding a second sentence in paragraph (j) to read as follows:

§ 1.901–1 Allowance of credit for taxes.

(a) *In general.* Citizens of the United States, domestic corporations, and certain aliens resident in the United States or Puerto Rico may choose to claim a credit, as provided in section 901, against the tax imposed by chapter 1 of the Internal Revenue Code (Code) for taxes paid or accrued to foreign countries and possessions of the United States, subject to the conditions prescribed in paragraphs (a)(1) through (a)(3) and paragraph (b) of this section.

(1) *Citizen of the United States.* A citizen of the United States, whether resident or nonresident, may claim a credit for—

(i) The amount of any income, war profits, and excess profits taxes paid or accrued during the taxable year to any foreign country or to any possession of the United States; and

(ii) His share of any such taxes of a partnership of which he is a member, or of an estate or trust of which he is a beneficiary.

(2) *Domestic corporation.* A domestic corporation may claim a credit for—

(i) The amount of any income, war profits, and excess profits taxes paid or accrued during the taxable year to any foreign country or to any possession of the United States;

(ii) Its share of any such taxes of a partnership of which it is a member, or of an estate or trust of which it is a beneficiary; and

(iii) The taxes deemed to have been paid under section 902 or 960.

(3) *Alien resident of the United States or Puerto Rico.* Except as provided in a Presidential proclamation described in section 901(c), an alien resident of the United States, or an alien individual who is a bona fide resident of Puerto Rico during the entire taxable year, may claim a credit for—

(i) The amount of any income, war profits, and excess profits taxes paid or accrued during the taxable year to any foreign country or to any possession of the United States; and

(ii) His distributive share of any such taxes of a partnership of which he is a member, or of an estate or trust of which he is a beneficiary.

(b) *Limitations.* Certain Code sections, including sections 814, 901(e) through (m), 904, 906, 907, 908, 909, 911, 999, and 6038, limit the credit against the tax imposed by chapter 1 of the Code for certain foreign taxes.

* * * * *

(j) *Effective/applicability date.* * * * Paragraphs (a) and (b) of this section apply to taxable years ending after July 13, 2011.

§ 1.901–1T [Removed]

■ **Par. 3.** Section 1.901–1T is removed.

■ **Par. 4.** Section 1.901–2 is amended by removing and reserving paragraph (e)(5)(iii), revising paragraph (e)(5)(iv), and revising paragraph (h)(2) to read as follows:

§ 1.901–2 Income, war profits, or excess profits tax paid or accrued.

* * * * *

(e) * * *

(5) * * *

(iii) [Reserved].

(iv) *Structured passive investment arrangements*—(A) *In general.* Notwithstanding paragraph (e)(5)(i) of this section, an amount paid to a foreign country (a ''foreign payment'') is not a compulsory payment, and thus is not an amount of tax paid, if the foreign payment is attributable (within the meaning of paragraph (e)(5)(iv)(B)(*1*)(*ii*) of this section) to a structured passive investment arrangement (as described in paragraph (e)(5)(iv)(B) of this section).

(B) *Conditions.* An arrangement is a structured passive investment arrangement if all of the following conditions are satisfied:

(*1*) *Special purpose vehicle (SPV).* An entity that is part of the arrangement meets the following requirements:

(*i*) Substantially all of the gross income (for U.S. tax purposes) of the entity, if any, is passive investment income, and substantially all of the assets of the entity are assets held to produce such passive investment income.

(*ii*) There is a foreign payment attributable to income of the entity (as determined under the laws of the foreign country to which such foreign payment is made), including the entity's share of income of a lower-tier entity that is a branch or pass-through entity under the laws of such foreign country, that, if the foreign payment were an amount of tax paid, would be paid or accrued in a U.S. taxable year in which the entity meets the requirements of paragraph (e)(5)(iv)(B)(*1*)(*i*) of this section. A foreign payment attributable to income of an entity includes a foreign payment attributable to income that is required to be taken into account by an owner of the entity, if the entity is a branch or pass-through entity under the laws of such foreign country.

(*2*) *U.S. party.* A person would be eligible to claim a credit under section 901(a) (including a credit for foreign taxes deemed paid under section 902 or 960) for all or a portion of the foreign payment described in paragraph (e)(5)(iv)(B)(*1*)(*ii*) of this section if the foreign payment were an amount of tax paid.

(*3*) *Direct investment.* The U.S. party's proportionate share of the foreign payment or payments described in paragraph (e)(5)(iv)(B)(*1*)(*ii*) of this section is (or is expected to be) substantially greater than the amount of credits, if any, that the U.S. party reasonably would expect to be eligible to claim under section 901(a) for foreign taxes attributable to income generated by the U.S. party's proportionate share of the assets owned by the SPV if the U.S. party directly owned such assets. For this purpose, direct ownership shall not include ownership through a branch, a permanent establishment or any other arrangement (such as an agency arrangement or dual resident status) that would result in the income generated by the U.S. party's proportionate share of the assets being subject to tax on a net basis in the foreign country to which the payment is made. A U.S. party's proportionate

share of the assets of the SPV shall be determined by reference to such U.S. party's proportionate share of the total value of all of the outstanding interests in the SPV that are held by its equity owners and creditors. A U.S. party's proportionate share of the assets of the SPV, however, shall not include any assets that produce income subject to gross basis withholding tax.

(*4*) *Foreign tax benefit.* The arrangement is reasonably expected to result in a credit, deduction, loss, exemption, exclusion or other tax benefit under the laws of a foreign country that is available to a counterparty or to a person that is related to the counterparty (determined under the principles of paragraph (e)(5)(iv)(C)(*7*) of this section by applying the tax laws of a foreign country in which the counterparty is subject to tax on a net basis). However, a foreign tax benefit in the form of a credit is described in this paragraph (e)(5)(iv)(B)(*4*) only if the amount of any such credit corresponds to 10 percent or more of the amount of the U.S. party's share (for U.S. tax purposes) of the foreign payment referred to in paragraph (e)(5)(iv)(B)(*1*)(*ii*) of this section. In addition, a foreign tax benefit in the form of a deduction, loss, exemption, exclusion or other tax benefit is described in this paragraph (e)(5)(iv)(B)(*4*) only if such amount corresponds to 10 percent or more of the foreign base with respect to which the U.S. party's share (for U.S. tax purposes) of the foreign payment is imposed. For purposes of the preceding two sentences, if an arrangement involves more than one U.S. party or more than one counterparty or both, the aggregate amount of foreign tax benefits available to all of the counterparties and persons related to such counterparties is compared to the aggregate amount of all of the U.S. parties' shares of the foreign payment or foreign base, as the case may be. Where a U.S. party indirectly owns interests in an SPV that are treated as equity interests for both U.S. and foreign tax purposes, a foreign tax benefit available to a foreign entity in the chain of ownership that begins with the SPV and ends with the first-tier entity in the chain does not correspond to the U.S. party's share of the foreign payment attributable to income of the SPV to the extent that such benefit relates to earnings of the SPV that are distributed with respect to equity interests in the SPV that are owned directly or indirectly by the U.S. party for purposes of both U.S. and foreign tax law.

(*5*) *Counterparty.* The arrangement involves a counterparty. A counterparty is a person that, under the tax laws of a foreign country in which the person is subject to tax on the basis of place of management, place of incorporation or similar criterion or otherwise subject to a net basis tax, directly or indirectly owns or acquires equity interests in, or assets of, the SPV. However, a counterparty does not include the SPV or a person with respect to which for U.S. tax purposes the same domestic corporation, U.S. citizen or resident alien individual directly or indirectly owns more than 80 percent of the total value of the stock (or equity interests) of each of the U.S. party and such person. A counterparty also does not include a person with respect to which for U.S. tax purposes the U.S. party directly or indirectly owns more than 80 percent of the total value of the stock (or equity interests), but only if the U.S. party is a domestic corporation, a U.S. citizen or a resident alien individual. In addition, a counterparty does not include an individual who is a U.S. citizen or resident alien.

(*6*) *Inconsistent treatment.* The United States and an applicable foreign country treat one or more of the aspects of the arrangement listed in paragraph (e)(5)(iv)(B)(*6*)(*i*) through (e)(5)(iv)(B)(*6*)(*iv*) of this section differently under their respective tax systems, and for one or more tax years when the arrangement is in effect one or both of the following two conditions applies; either the amount of income attributable to the SPV that is recognized for U.S. tax purposes by the SPV, the U.S. party or parties, and persons related to a U.S. party or parties is materially less than the amount of income that would be recognized if the foreign tax treatment controlled for U.S. tax purposes; or the amount of credits claimed by the U.S. party or parties (if the foreign payment described in paragraph (e)(5)(iv)(B)(*1*)(*ii*) of this section were an amount of tax paid) is materially greater than it would be if the foreign tax treatment controlled for U.S. tax purposes:

(*i*) The classification of the SPV (or an entity that has a direct or indirect ownership interest in the SPV) as a corporation or other entity subject to an entity-level tax, a partnership or other flow-through entity or an entity that is disregarded for tax purposes.

(*ii*) The characterization as debt, equity or an instrument that is disregarded for tax purposes of an instrument issued by the SPV (or an entity that has a direct or indirect ownership interest in the SPV) to a U.S. party, a counterparty or a person related to a U.S. party or a counterparty.

(*iii*) The proportion of the equity of the SPV (or an entity that directly or indirectly owns the SPV) that is considered to be owned directly or indirectly by a U.S. party and a counterparty.

(*iv*) The amount of taxable income that is attributable to the SPV for one or more tax years during which the arrangement is in effect.

(C) *Definitions.* The following definitions apply for purposes of paragraph (e)(5)(iv) of this section.

(*1*) *Applicable foreign country.* An *applicable foreign country* means each foreign country to which a foreign payment described in paragraph (e)(5)(iv)(B)(*1*)(*ii*) of this section is made or which confers a foreign tax benefit described in paragraph (e)(5)(iv)(B)(*4*) of this section.

(*2*) *Counterparty.* The term *counterparty* means a person described in paragraph (e)(5)(iv)(B)(*5*) of this section.

(*3*) *Entity.* The term *entity* includes a corporation, trust, partnership or disregarded entity described in § 301.7701–2(c)(2)(i).

(*4*) *Indirect ownership.* Indirect ownership of stock or another equity interest (such as an interest in a partnership) shall be determined in accordance with the principles of section 958(a)(2), regardless of whether the interest is owned by a U.S. or foreign entity.

(*5*) *Passive investment income*—(*i*) *In general.* The term *passive investment income* means income described in section 954(c), as modified by this paragraph (e)(5)(iv)(C)(*5*)(*i*) and paragraph (e)(5)(iv)(C)(*5*)(*ii*) of this section. In determining whether income is described in section 954(c), paragraphs (c)(1)(H), (c)(3), and (c)(6) of that section shall be disregarded. Sections 954(c), 954(h), and 954(i) shall be applied at the entity level as if the entity (as defined in paragraph (e)(5)(iv)(C)(*3*) of this section) were a controlled foreign corporation (as defined in section 957(a)). For purposes of determining if sections 954(h) and 954(i) apply for purposes of this paragraph (e)(5)(iv)(C)(*5*)(*i*) and paragraph (e)(5)(iv)(C)(*5*)(*ii*) of this section, any income of an entity attributable to transactions that, assuming the entity is an SPV, are with a person that is a counterparty, or with persons that are related to a counterparty within the meaning of paragraph (e)(5)(iv)(B)(*4*) of this section, shall not be treated as qualified banking or financing income or as qualified insurance income, and shall not be taken into account in applying sections 954(h) and 954(i) for purposes of determining whether other income of the entity is excluded from section

954(c)(1) under section 954(h) or 954(i), but only if any such person (or a person that is related to such person within the meaning of paragraph (e)(5)(iv)(B)(*4*) of this section) is eligible for a foreign tax benefit described in paragraph (e)(5)(iv)(B)(*4*) of this section. In addition, in applying section 954(h) for purposes of this paragraph (e)(5)(iv)(C)(*5*)(*i*) and paragraph (e)(5)(iv)(C)(*5*)(*ii*) of this section, section 954(h)(3)(E) shall not apply, section 954(h)(2)(A)(ii) shall be satisfied only if the entity conducts substantial activity with respect to its business through its own employees, and the term ''any foreign country'' shall be substituted for ''home country'' wherever it appears in section 954(h).

(*ii*) *Income attributable to lower-tier entities; holding company exception.* Income of an upper-tier entity that is attributable to an equity interest in a lower-tier entity, including dividends, an allocable share of partnership income, and income attributable to the ownership of an interest in an entity that is disregarded as an entity separate from its owner is passive investment income unless substantially all of the upper-tier entity's assets consist of qualified equity interests in one or more lower-tier entities, each of which is engaged in the active conduct of a trade or business and derives more than 50 percent of its gross income from such trade or business, and substantially all of the upper-tier entity's opportunity for gain and risk of loss with respect to each such interest in a lower-tier entity is shared by the U.S. party (or persons that are related to a U.S. party) and, assuming the entity is an SPV, a counterparty (or persons that are related to a counterparty) (''holding company exception''). If an arrangement involves more than one U.S. party or more than one counterparty or both, then substantially all of the upper-tier entity's opportunity for gain and risk of loss with respect to its interest in any lower-tier entity must be shared (directly or indirectly) by one or more U.S. parties (or persons related to such U.S. parties) and, assuming the upper-tier entity is an SPV, one or more counterparties (or persons related to such counterparties). Substantially all of the upper-tier entity's opportunity for gain and risk of loss with respect to its interest in any lower-tier entity is not shared if the opportunity for gain and risk of loss is borne (directly or indirectly) by one or more U.S. parties (or persons related to such U.S. party or parties) or, assuming the upper-tier entity is an SPV, by one or more counterparties (or persons related to such counterparty or counterparties). Whether and the extent to which a person is considered to share in an upper-tier entity's opportunity for gain and risk of loss is determined based on all the facts and circumstances, provided, however, that a person does not share in an upper-tier entity's opportunity for gain and risk of loss if its equity interest in the upper-tier entity was acquired in a sale-repurchase transaction or if its interest is treated as debt for U.S. tax purposes. If a U.S. party owns an interest in an entity indirectly through a chain of entities, the application of the holding company exception begins with the lowest-tier entity in the chain that may satisfy the holding company exception and proceeds upward; provided, however, that the opportunity for gain and risk of loss borne by any upper-tier entity in the chain that is a counterparty shall be disregarded to the extent borne indirectly by a U.S. party. An upper-tier entity that satisfies the holding company exception is itself considered to be engaged in the active conduct of a trade or business and to derive more than 50 percent of its gross income from such trade or business for purposes of applying the holding company exception to the owners of such entity. A lower-tier entity that is engaged in a banking, financing, or similar business shall not be considered to be engaged in the active conduct of a trade or business unless the income derived by such entity would be excluded from section 954(c)(1) under section 954(h) or 954(i) as modified by paragraph (e)(5)(iv)(C)(*5*)(*i*) of this section.

(*6*) *Qualified equity interest.* With respect to an interest in a corporation, the term *qualified equity interest* means stock representing 10 percent or more of the total combined voting power of all classes of stock entitled to vote and 10 percent or more of the total value of the stock of the corporation or disregarded entity, but does not include any preferred stock (as defined in section 351(g)(3)). Similar rules shall apply to determine whether an interest in an entity other than a corporation is a qualified equity interest.

(*7*) *Related person.* Two persons are related if—

(*i*) One person directly or indirectly owns stock (or an equity interest) possessing more than 50 percent of the total value of the other person; or

(*ii*) The same person directly or indirectly owns stock (or an equity interest) possessing more than 50 percent of the total value of both persons.

(*8*) *Special purpose vehicle (SPV).* The term *SPV* means the entity described in paragraph (e)(5)(iv)(B)(*1*) of this section.

(*9*) *U.S. party.* The term *U.S. party* means a person described in paragraph (e)(5)(iv)(B)(*2*) of this section.

(D) *Examples.* The following examples illustrate the rules of paragraph (e)(5)(iv) of this section. No inference is intended as to whether a taxpayer would be eligible to claim a credit under section 901(a) if a foreign payment were an amount of tax paid. The examples set forth below do not limit the application of other principles of existing law to determine the proper tax consequences of the structures or transactions addressed in the regulations.

Example 1. U.S. borrower transaction. (i) *Facts.* A domestic corporation (USP) forms a country M corporation (Newco), contributing $1.5 billion in exchange for 100% of the stock of Newco. Newco, in turn, loans the $1.5 billion to a second country M corporation (FSub) wholly owned by USP. USP then sells its entire interest in Newco to a country M corporation (FP) for the original purchase price of $1.5 billion, subject to an obligation to repurchase the interest in five years for $1.5 billion. The sale has the effect of transferring ownership of the Newco stock to FP for country M tax purposes. Assume the sale-repurchase transaction is structured in a way that qualifies as a collateralized loan for U.S. tax purposes. Therefore, USP remains the owner of the Newco stock for U.S. tax purposes. In year 1, FSub pays Newco $120 million of interest. Newco pays $36 million to country M with respect to such interest income and distributes the remaining $84 million to FP. Under country M law, the $84 million distribution is excluded from FP's income. None of FP's stock is owned, directly or indirectly, by USP or any shareholders of USP that are domestic corporations, U.S. citizens, or resident alien individuals. Under an income tax treaty between country M and the United States, country M does not impose country M tax on interest received by U.S. residents from sources in country M.

(ii) *Result.* The $36 million payment by Newco to country M is not a compulsory payment, and thus is not an amount of tax paid because the foreign payment is attributable to a structured passive investment arrangement. First, Newco is an SPV because all of Newco's income is passive investment income described in paragraph (e)(5)(iv)(C)(*5*) of this section; Newco's only asset, a note, is held to produce such income; the payment to country M is attributable to such income; and if the payment were an amount of tax paid it would be paid or accrued in a U.S. taxable year in which Newco meets the requirements of paragraph (e)(5)(iv)(B)(*1*)(*i*) of this section. Second, if the foreign payment were treated as an amount of tax paid, USP would be deemed to pay the foreign payment under section 902(a) and, therefore, would be eligible to claim a credit for such payment under section 901(a). Third, USP would not pay any

country M tax if it directly owned Newco's loan receivable. Fourth, the distribution from Newco to FP is exempt from tax under country M law, and the exempt amount corresponds to more than 10% of the foreign base with respect to which USP's share (which is 100% under U.S. tax law) of the foreign payment was imposed. Fifth, FP is a counterparty because FP owns stock of Newco under country M law and none of FP's stock is owned by USP or shareholders of USP that are domestic corporations, U.S. citizens, or resident alien individuals. Sixth, FP is the owner of 100% of Newco's stock for country M tax purposes, while USP is the owner of 100% of Newco's stock for U.S. tax purposes, and the amount of credits claimed by USP if the payment to country M were an amount of tax paid is materially greater than it would be if country M tax treatment controlled for U.S. tax purposes such that FP, rather than USP, owned 100% of Newco's stock. Because the payment to country M is not an amount of tax paid, USP is not deemed to pay any country M tax under section 902(a). USP has dividend income of $84 million and also has interest expense of $84 million. FSub's post-1986 undistributed earnings are reduced by $120 million of interest expense.

Example 2. U.S. borrower transaction. (i) *Facts.* The facts are the same as in *Example 1,* except that FSub is a wholly-owned subsidiary of Newco. In addition, assume FSub is engaged in the active conduct of manufacturing and selling widgets and derives more than 50% of its gross income from such business.

(ii) *Result.* The results are the same as in *Example 1.* Although Newco wholly owns FSub, which is engaged in the active conduct of manufacturing and selling widgets and derives more than 50% of its income from such business, Newco's income that is attributable to Newco's equity interest in FSub is passive investment income because the sale-repurchase transaction limits FP's interest in Newco and its assets to that of a creditor, so that substantially all of Newco's opportunity for gain and risk of loss with respect to its stock in FSub is borne by USP. See paragraph (e)(5)(iv)(C)(*5*)(*ii*) of this section. Accordingly, Newco's stock in FSub is held to produce passive investment income. Thus, Newco is an SPV because all of Newco's income is passive investment income described in paragraph (e)(5)(iv)(C)(*5*) of this section, Newco's assets are held to produce such income, the payment to country M is attributable to such income, and if the payment were an amount of tax paid it would be paid or accrued in a U.S. taxable year in which Newco meets the requirements of paragraph (e)(5)(iv)(B)(*1*)(*i*) of this section.

Example 3. U.S. borrower transaction. (i) *Facts.* (A) A domestic corporation (USP) loans $750 million to its wholly-owned domestic subsidiary (Sub). USP and Sub form a country M partnership (Partnership) to which each contributes $750 million. Partnership loans all of its $1.5 billion of capital to Issuer, a wholly-owned country M affiliate of USP, in exchange for a note and coupons providing for the payment of interest at a fixed rate over a five-year term. Partnership sells all of the coupons to Coupon Purchaser, a country N partnership owned by a country M corporation (Foreign Bank) and a wholly-owned country M subsidiary of Foreign Bank, for $300 million. At the time of the coupon sale, the fair market value of the coupons sold is $290 million and, pursuant to section 1286(b)(3), Partnership's basis allocated to the coupons sold is $290 million. Several months later and prior to any interest payments on the note, Foreign Bank and its subsidiary sell all of their interests in Coupon Purchaser to an unrelated country O corporation for $280 million. None of Foreign Bank's stock or its subsidiary's stock is owned, directly or indirectly, by USP or Sub or by any shareholders of USP or Sub that are domestic corporations, U.S. citizens, or resident alien individuals.

(B) Assume that both the United States and country M respect the sale of the coupons for tax law purposes. In the year of the coupon sale, for country M tax purposes USP's and Sub's shares of Partnership's profits total $300 million, a payment of $60 million to country M is made with respect to those profits, and Foreign Bank and its subsidiary, as partners of Coupon Purchaser, are entitled to deduct the $300 million purchase price of the coupons from their taxable income. For U.S. tax purposes, USP and Sub recognize their distributive shares of the $10 million premium income and claim a direct foreign tax credit for their shares of the $60 million payment to country M. Country M imposes no additional tax when Foreign Bank and its subsidiary sell their interests in Coupon Purchaser. Country M also does not impose country M tax on interest received by U.S. residents from sources in country M.

(ii) *Result.* The payment to country M is not a compulsory payment, and thus is not an amount of tax paid, because the foreign payment is attributable to a structured passive investment arrangement. First, Partnership is an SPV because all of Partnership's income is passive investment income described in paragraph (e)(5)(iv)(C)(*5*) of this section; Partnership's only asset, Issuer's note, is held to produce such income; the payment to country M is attributable to such income; and if the payment were an amount of tax paid, it would be paid or accrued in a U.S. taxable year in which Partnership meets the requirements of paragraph (e)(5)(iv)(B)(*1*)(*i*) of this section. Second, if the foreign payment were an amount of tax paid, USP and Sub would be eligible to claim a credit for such payment under section 901(a). Third, USP and Sub would not pay any country M tax if they directly owned Issuer's note. Fourth, for country M tax purposes, Foreign Bank and its subsidiary deduct the $300 million purchase price of the coupons and are exempt from country M tax on the $280 million received upon the sale of Coupon Purchaser, and the deduction and exemption correspond to more than 10% of the $300 million base with respect to which USP's and Sub's 100% share of the foreign payments was imposed. Fifth, Foreign Bank and its subsidiary are counterparties because they indirectly acquired assets of Partnership, the interest coupons on Issuer's note, and are not directly or indirectly owned by USP or Sub or shareholders of USP or Sub that are domestic corporations, U.S. citizens, or resident alien individuals. Sixth, the amount of taxable income of Partnership for one or more years is different for U.S. and country M tax purposes, and the amount of income attributable to USP and Sub for U.S. tax purposes is materially less than the amount of income they would recognize if the country M tax treatment of the coupon sale controlled for U.S. tax purposes. Because the payment to country M is not an amount of tax paid, USP and Sub are not considered to pay tax under section 901. USP and Sub have income of $10 million in the year of the coupon sale.

Example 4. Active business; no SPV. (i) *Facts.* A, a domestic corporation, wholly owns B, a country X corporation engaged in the manufacture and sale of widgets. On January 1, year 1, C, also a country X corporation, loans $400 million to B in exchange for an instrument that is debt for U.S. tax purposes and equity in B for country X tax purposes. As a result, C is considered to own stock of B for country X tax purposes. B loans $55 million to D, a country Y corporation wholly owned by A. In year 1, B has $166 million of net income attributable to its sales of widgets and $3.3 million of interest income attributable to the loan to D. Substantially all of B's assets are used in its widget business. Country Y does not impose tax on interest paid to nonresidents. B makes a payment of $50.8 million to country X with respect to B's net income. Country X does not impose tax on dividend payments between country X corporations. None of C's stock is owned, directly or indirectly, by A or by any shareholders of A that are domestic corporations, U.S. citizens, or resident alien individuals.

(ii) *Result.* B is not an SPV within the meaning of paragraph (e)(5)(iv)(B)(*1*) of this section because the amount of interest income received from D does not constitute substantially all of B's income and the $55 million note from D does not constitute substantially all of B's assets. Accordingly, the $50.8 million payment to country X is not attributable to a structured passive investment arrangement.

Example 5. U.S. lender transaction. (i) *Facts.* (A) A country X corporation (Foreign Bank) contributes $2 billion to a newly-formed country X company (Newco) in exchange for 90% of the common stock of Newco and securities that are treated as debt of Newco for U.S. tax purposes and preferred stock of Newco for country X tax purposes. A domestic corporation (USP) contributes $1 billion to Newco in exchange for 10% of Newco's common stock and securities that are treated as preferred stock of Newco for U.S. tax purposes and debt of Newco for country X tax purposes. Newco loans the $3 billion to a wholly-owned, country X subsidiary of Foreign Bank (FSub) in return for a $3 billion, seven-year note paying interest currently. The Newco securities held by USP entitle the holder to fixed distributions of $4 million per year, and the Newco securities held by Foreign Bank entitle the holder to receive $82 million per year, payable only on maturity of the $3 billion FSub note in year 7. At the end of

year 5, pursuant to a prearranged plan, Foreign Bank acquires USP's Newco stock and securities for a prearranged price of $1 billion. Country X does not impose tax on dividends received by one country X corporation from a second country X corporation. Under an income tax treaty between country X and the United States, country X does not impose country X tax on interest received by U.S. residents from sources in country X. None of Foreign Bank's stock is owned, directly or indirectly, by USP or any shareholders of USP that are domestic corporations, U.S. citizens, or resident alien individuals.

(B) In each of years 1 through 7, FSub pays Newco $124 million of interest on the $3 billion note. Newco distributes $4 million to USP in each of years 1 through 5. The distributions are deductible for country X tax purposes, and Newco pays country X $36 million with respect to $120 million of taxable income from the FSub note in each year. For U.S. tax purposes, in each year Newco's post-1986 undistributed earnings are increased by $124 million of interest income and reduced by accrued interest expense with respect to the Newco securities held by Foreign Bank.

(ii) *Result.* The $36 million payment to country X is not a compulsory payment, and thus is not an amount of tax paid, because the foreign payment is attributable to a structured passive investment arrangement. First, Newco is an SPV because all of Newco's income is passive investment income described in paragraph (e)(5)(iv)(C)(*5*) of this section; Newco's only asset, a note of FSub, is held to produce such income; the payment to country X is attributable to such income; and if the payment were an amount of tax paid it would be paid or accrued in a U.S. taxable year in which Newco meets the requirements of paragraph (e)(5)(iv)(B)(*1*)(*i*) of this section. Second, if the foreign payment were an amount of tax paid, USP would be deemed to pay its pro rata share of the foreign payment under section 902(a) in each of years 1 through 5 and, therefore, would be eligible to claim a credit under section 901(a). Third, USP would not pay any country X tax if it directly owned its proportionate share of Newco's assets, a note of FSub. Fourth, for country X tax purposes, Foreign Bank is eligible to receive a tax-free distribution of $82 million attributable to each of years 1 through 5, and that amount corresponds to more than 10% of the foreign base with respect to which USP's share of the foreign payment was imposed. Fifth, Foreign Bank is a counterparty because it owns stock of Newco for country X tax purposes and none of Foreign Bank's stock is owned, directly or indirectly, by USP or shareholders of USP that are domestic corporations, U.S. citizens, or resident alien individuals. Sixth, the United States and country X treat various aspects of the arrangement differently, including whether the Newco securities held by Foreign Bank and USP are debt or equity. The amount of credits claimed by USP if the payment to country X were an amount of tax paid is materially greater than it would be if the country X tax treatment controlled for U.S. tax purposes such that the securities held by USP were treated as debt or the securities held by Foreign Bank were treated as equity, and the amount of income recognized by Newco for U.S. tax purposes is materially less than the amount of income recognized for country X tax purposes. Because the payment to country X is not an amount of tax paid, USP is not deemed to pay any country X tax under section 902(a). USP has dividend income of $4 million in each of years 1 through 5.

Example 6. Holding company; no SPV. (i) *Facts.* A, a country X corporation, and B, a domestic corporation, each contribute $1 billion to a newly-formed country X entity (C) in exchange for 50% of the common stock of C. C is treated as a corporation for country X purposes and a partnership for U.S. tax purposes. C contributes $1.95 billion to a newly-formed country X corporation (D) in exchange for 100% of D's common stock. C loans its remaining $50 million to D. Accordingly, C's sole assets are stock and debt of D. D uses the entire $2 billion to engage in the business of manufacturing and selling widgets. In year 1, D derives $300 million of income from its widget business and derives $2 million of interest income. Also in year 1, C has dividend income of $200 million and interest income of $3.2 million with respect to its investment in D. Country X does not impose tax on dividends received by one country X corporation from a second country X corporation. C makes a payment of $960,000 to country X with respect to C's net income.

(ii) *Result.* C qualifies for the holding company exception described in paragraph (e)(5)(iv)(C)(*5*)(*ii*) of this section because C holds a qualified equity interest in D, D is engaged in an active trade or business and derives more than 50% of its gross income from such trade or business, C's interest in D constitutes substantially all of C's assets, and A and B share in substantially all of C's opportunity for gain and risk of loss with respect to D. As a result, C's dividend income from D is not passive investment income and C's stock in D is not held to produce such income. Accordingly, C is not an SPV within the meaning of paragraph (e)(5)(iv)(B)(*1*) of this section, and the $960,000 payment to country X is not attributable to a structured passive investment arrangement.

Example 7. Holding company; no SPV. (i) *Facts.* The facts are the same as in *Example 6,* except that instead of loaning $50 million to D, C contributes the $50 million to E in exchange for 10% of the stock of E. E is a country Y corporation that is not engaged in the active conduct of a trade or business. Also in year 1, D pays no dividends to C, E pays $3.2 million in dividends to C, and C makes a payment of $960,000 to country X with respect to C's net income.

(ii) *Result.* C qualifies for the holding company exception described in paragraph (e)(5)(iv)(C)(*5*)(*ii*) of this section because C holds a qualified equity interest in D, D is engaged in an active trade or business and derives more than 50% of its gross income from such trade or business, C's interest in D constitutes substantially all of C's assets, and A and B share in substantially all of C's opportunity for gain and risk of loss with respect to D. As a result, less than substantially all of C's assets are held to produce passive investment income. Accordingly, C is not an SPV because it does not meet the requirements of paragraph (e)(5)(iv)(B)(*1*) of this section, and the $960,000 payment to country X is not attributable to a structured passive investment arrangement.

Example 8. Holding company; no SPV. (i) *Facts.* The facts are the same as in *Example 6,* except that B's $1 billion investment in C consists of 30% of C's common stock and 100% of C's preferred stock. A's $1 billion investment in C consists of 70% of C's common stock. B sells its preferred stock to F, a country X corporation, subject to a repurchase obligation. Assume that under country X tax law, but not U.S. tax law, F is treated as the owner of the preferred shares and receives a distribution in year 1 of $50 million. The remaining earnings are distributed 70% to A and 30% to B.

(ii) *Result.* C qualifies for the holding company exception described in paragraph (e)(5)(iv)(C)(*5*)(*ii*) of this section because C holds a qualified equity interest in D, D is engaged in an active trade or business and derives more than 50% of its gross income from such trade or business, and C's interest in D constitutes substantially all of C's assets. Additionally, although F does not share in C's opportunity for gain and risk of loss with respect to C's interest in D because F acquired its interest in C in a sale-repurchase transaction, B (the U.S. party) and in the aggregate A and F (who would be counterparties assuming C were an SPV) share in substantially all of C's opportunity for gain and risk of loss with respect to D and such opportunity for gain and risk of loss is not borne exclusively either by B or by A and F in the aggregate. Accordingly, C's shares in D are not held to produce passive investment income and the $200 million dividend from D is not passive investment income. C is not an SPV within the meaning of paragraph (e)(5)(iv)(B)(*1*) of this section, and the $960,000 payment to country X is not attributable to a structured passive investment arrangement.

Example 9. Asset holding transaction. (i) *Facts.* (A) A domestic corporation (USP) contributes $6 billion of country Z debt obligations to a country Z entity (DE) in exchange for all of the class A and class B stock of DE. DE is a disregarded entity for U.S. tax purposes and a corporation for country Z tax purposes. A corporation unrelated to USP and organized in country Z (FC) contributes $1.5 billion to DE in exchange for all of the class C stock of DE. DE uses the $1.5 billion contributed by FC to redeem USP's class B stock. The terms of the class C stock entitle its holder to all income from DE, but FC is obligated immediately to contribute back to DE all distributions on the class C stock. USP and FC enter into—

(*1*) A contract under which USP agrees to buy after five years the class C stock for $1.5 billion; and

(*2*) An agreement under which USP agrees to pay FC periodic payments on $1.5 billion.

(B) The transaction is structured in such a way that, for U.S. tax purposes, there is a loan of $1.5 billion from FC to USP, and USP is the owner of the class C stock and the class A stock. In year 1, DE earns $400 million of

interest income on the country Z debt obligations. DE makes a payment to country Z of $100 million with respect to such income and distributes the remaining $300 million to FC. FC contributes the $300 million back to DE. None of FC's stock is owned, directly or indirectly, by USP or shareholders of USP that are domestic corporations, U.S. citizens, or resident alien individuals. Assume that country Z imposes a withholding tax on interest income derived by U.S. residents.

(C) Country Z treats FC as the owner of the class C stock. Pursuant to country Z tax law, FC is required to report the $400 million of income with respect to the $300 million distribution from DE, but is allowed to claim credits for DE's $100 million payment to country Z. For country Z tax purposes, FC is entitled to current deductions equal to the $300 million contributed back to DE.

(ii) *Result.* The payment to country Z is not a compulsory payment, and thus is not an amount of tax paid because the payment is attributable to a structured passive investment arrangement. First, DE is an SPV because all of DE's income is passive investment income described in paragraph (e)(5)(iv)(C)(*5*) of this section; all of DE's assets are held to produce such income; the payment to country Z is attributable to such income; and if the payment were an amount of tax paid it would be paid or accrued in a U.S. taxable year in which DE meets the requirements of paragraph (e)(5)(iv)(B)(*1*)(*i*) of this section. Second, if the payment were an amount of tax paid, USP would be eligible to claim a credit for such amount under section 901(a). Third, USP's proportionate share of DE's foreign payment of $100 million is substantially greater than the amount of credits USP would be eligible to claim if it directly held its proportionate share of DE's assets, excluding any assets that would produce income subject to gross basis withholding tax if directly held by USP. Fourth, FC is entitled to claim a credit under country Z tax law for the payment and recognizes a deduction for the $300 million contributed to DE under country Z law. The credit claimed by FC corresponds to more than 10% of USP's share (for U.S. tax purposes) of the foreign payment and the deductions claimed by FC correspond to more than 10% of the base with respect to which USP's share of the foreign payment was imposed. Fifth, FC is a counterparty because FC is considered to own equity of DE under country Z law and none of FC's stock is owned, directly or indirectly, by USP or shareholders of USP that are domestic corporations, U.S. citizens, or resident alien individuals. Sixth, the United States and country X treat certain aspects of the transaction differently, including the proportion of equity owned in DE by USP and FC, and the amount of credits claimed by USP if the country Z payment were an amount of tax paid is materially greater than it would be if the country X tax treatment controlled for U.S. tax purposes such that FC, rather than USP, owned the class C stock. Because the payment to country Z is not an amount of tax paid, USP is not considered to pay tax under section 901. USP has $400 million of interest income.

Example 10. Loss surrender. (i) *Facts.* The facts are the same as in *Example 9,* except that the deductions attributable to the arrangement contribute to a loss recognized by FC for country Z tax purposes, and pursuant to a group relief regime in country Z FC elects to surrender the loss to its country Z subsidiary.

(ii) *Result.* The results are the same as in *Example 9.* The surrender of the loss to a related party is a foreign tax benefit that corresponds to the base with respect to which USP's share of the foreign payment was imposed.

Example 11. Joint venture; no foreign tax benefit. (i) *Facts.* FC, a country X corporation, and USC, a domestic corporation, each contribute $1 billion to a newly-formed country X entity (C) in exchange for stock of C. FC and USC are entitled to equal 50% shares of all of C's income, gain, expense and loss. C is treated as a corporation for country X purposes and a partnership for U.S. tax purposes. In year 1, C earns $200 million of net passive investment income, makes a payment to country X of $60 million with respect to that income, and distributes $70 million to each of FC and USC. Country X does not impose tax on dividends received by one country X corporation from a second country X corporation.

(ii) *Result.* FC's tax-exempt receipt of $70 million, or its 50% share of C's profits, is not a foreign tax benefit within the meaning of paragraph (e)(5)(iv)(B)(*4*) of this section because it does not correspond to any part of the foreign base with respect to which USC's share of the foreign payment was imposed. Accordingly, the $60 million payment to country X is not attributable to a structured passive investment arrangement.

Example 12. Joint venture; no foreign tax benefit. (i) *Facts.* The facts are the same as in *Example 11,* except that C in turn contributes $2 billion to a wholly-owned and newly-formed country X entity (D) in exchange for stock of D. D is treated as a corporation for country X purposes and disregarded as an entity separate from its owner for U.S. tax purposes. C has no other assets and earns no other income. In year 1, D earns $200 million of passive investment income, makes a payment to country X of $60 million with respect to that income, and distributes $140 million to C.

(ii) *Result.* C's tax-exempt receipt of $140 million is not a foreign tax benefit within the meaning of paragraph (e)(5)(iv)(B)(*4*) of this section because it does not correspond to any part of the foreign base with respect to which USC's share of the foreign payment was imposed. Fifty percent of C's foreign tax exemption is not a foreign tax benefit within the meaning of paragraph (e)(5)(iv)(B)(*4*) because it relates to earnings of D that are distributed with respect to an equity interest in D that is owned indirectly by USC under both U.S. and foreign tax law. The remaining 50% of C's foreign tax exemption, as well as FC's tax-exempt receipt of $70 million from C, is also not a foreign tax benefit because it does not correspond to any part of the foreign base with respect to which USC's share of the foreign payment was imposed. Accordingly, the $60 million payment to country X is not attributable to a structured passive investment arrangement.

* * * * *

(h) * * *

(2) Paragraph (e)(5)(iv) of this section applies to foreign payments that, if such payments were an amount of tax paid, would be considered paid or accrued under § 1.901–2(f) on or after July 13, 2011. See 26 CFR 1.901–2T(e)(5)(iv) (revised as of April 1, 2011), for rules applicable to foreign payments that, if such payments were an amount of tax paid, would be considered paid or accrued before July 13, 2011.

§ 1.901–2T [Removed]

■ **Par. 5.** Section 1.901–2T is removed.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

Approved: July 11, 2011.

Emily S. McMahon,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2011–17920 Filed 7–13–11; 11:15 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0533]

RIN 1625–AA00

Safety Zones; Swimming Events in Captain of the Port Boston Zone

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing eight temporary safety zones for marine events within the Captain of the Port (COTP) Boston Zone for swimming events. This action is necessary to provide for the safety of life on navigable waters during the events. Entering into, transiting through, mooring or anchoring within these zones is prohibited unless authorized by the COTP Sector Boston.

DATES: This rule is effective in the CFR on July 18, 2011 through 11:59 p.m. on September 24, 2011. This rule is effective with actual notice for purposes of enforcement beginning at 8:30 a.m. on July 7, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0533 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0533 in the ''Keyword''

box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail MST1 David Labadie of the Waterways Management Division, U.S. Coast Guard Sector Boston; telephone 617–223–3010, e-mail *david.j.labadie@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because any delay encountered in this regulation's effective date by publishing a NPRM would be contrary to public interest since immediate action is needed to provide for the safety of life and property on navigable waters from the hazardous nature of swimming events such as large numbers of swimmers in congested waterways. We spoke with each event sponsor and each indicated they were unable and unwilling to move their event date to a later time. Sponsors stated they are unwilling to reschedule these events because they are held in conjunction with other activities and already scheduled on the most suitable dates where swim event's that are dependent on tide and current conditions predicted for the day will be conducive to the safety of the swim participants. Rescheduling would not be a viable option because most event locations, have fully booked marine event summer schedules making rescheduling unrealistic. These swimming events are all reoccurring annual marine events. The Coast Guard intends to make these safety zones permanent regulations and has submitted a NPRM for submission to the **Federal Register** requesting public comments. Additionally, the Coast Guard has ordered safety zones or special local regulations for all of these areas for past events and has not received public comments or concerns regarding the impact to waterway traffic from those events. Delaying the effective date by first publishing a NPRM would be contrary to the rule's objectives of ensuring safety of life on the navigable waters during these scheduled events as immediate action is needed to protect persons and vessels from the hazardous nature of swimming events.

Basis and Purpose

The legal basis for the temporary rule is 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; Pub. L. 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to define safety zones.

Marine events are frequently held on the navigable waters within the COTP Boston Zone. Based on the potential hazards of swimming events, the COTP Sector Boston has determined that swimming events proximate to watercrafts pose significant risk to public safety and property. The combination of increased numbers of recreation vessels, congested waterways, and large numbers of swimmers in the water has the potential to result in serious injuries or fatalities. In order to protect the safety of all waterway users including event participants and spectators, this temporary rule establishes temporary safety zones for the time and location of each event.

This rule prevents vessels from entering into, transiting through, mooring or anchoring within areas specifically designated as regulated areas during the periods of enforcement unless authorized by the COTP, or the designated representative.

Discussion of Rule

This temporary rule creates safety zones for eight swimming events in the COTP Boston Zone. These events are listed below in the text of the regulation.

Because large numbers of spectator vessels are expected to congregate around the location of these events, the regulated areas are needed to protect both spectators and participants from the safety hazards created by swimming events including marine casualties and the risk of boat collisions with swimmers in the water that may cause death or serious bodily harm. During the enforcement period of the regulated areas, persons and vessels are prohibited from entering into, transiting through, anchoring or mooring within the zone unless specifically authorized by the COTP or the designated representatives. The Coast Guard may be assisted by other federal, state and local agencies in the enforcement of these regulated areas.

The Coast Guard determined that these regulated areas will not have a significant impact on vessel traffic due to their temporary nature and limited size and the fact that vessels are allowed to transit the navigable waters outside of the regulated areas. Additionally, The Coast Guard has ordered safety zones or special local regulations for past events and has not received public comments or concerns regarding the impact to waterway traffic.

Advanced public notifications will also be made to the local maritime community by the Local Notice to Mariners as well as Broadcast Notice to Mariners.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Executive Order 12866 and Executive Order 13563

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

The Coast Guard determined that this rule is not a significant regulatory action for the following reasons: The regulated areas will be of limited duration, they cover only a small portion of the navigable waterways, and the events are designed to avoid, to the extent possible, deep draft, fishing, and recreational boating traffic routes. In addition, vessels requiring entry into the area of the regulated areas may be authorized to do so by the Captain of the Port.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently

owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in the designated regulated area during the enforcement periods stated for each event in the List of Subjects.

The temporary safety zones will not have a significant economic impact on a substantial number of small entities for the following reasons: The regulated areas will be of limited size and of short duration, and vessels that can safely do so may navigate in all other portions of the waterways except for the areas designated as regulated areas. Additionally, before the effective period, the Coast Guard will issue notice of the time and location of each regulated area through a Local Notice to Mariners and Broadcast Notice to Mariners.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves the establishment of temporary safety zones. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, and Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapters 701, 3306, 3703; 33 CFR 1.05–1 and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01–0533 to read as follows:

§ 165.T01–0533 Safety Zones; Swimming Events in Captain of the Port Boston Zone.

(a) *Regulations.* The general regulations contained in 33 CFR 165.23 as well as the following regulations apply to the swimming events listed in TABLE 1 of T01–0533. These regulations will be enforced for the duration of each event. Notifications of exact dates and times of the enforcement period will be made to the local maritime community through the Local Notice to Mariners and Broadcast Notice to Mariners. First Coast Guard District Local Notice to Mariners can be found at *http://www.navcen.uscg.gov/.*

(b) *Definitions.* The following definitions apply to this section:

(1) *Designated Representative.* Any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port (COTP), Sector Boston, to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) *Official Patrol Vessels.* Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP.

(3) S*pectators.* All persons and vessels not registered with the event sponsor as participants or official patrol vessels.

(c) Vessel operators desiring to enter or operate within the regulated areas should contact the COTP or the designated representative via VHF channel 16 to obtain permission to do so.

(d) Spectators or other vessels shall not anchor, block, loiter, or impede the transit of event participants or official patrol vessels in the regulated areas during the effective dates and times, or dates and times as modified through the Local Notice to Mariners, unless authorized by COTP or the designated representative.

(e) Upon being hailed by a U.S. Coast Guard vessel or the designated representative, by siren, radio, flashing light or other means, the operator of the vessel shall proceed as directed. Failure to comply with a lawful direction may result in expulsion from the area, citation for failure to comply, or both.

(f) The COTP or the designated representative may delay or terminate any marine event in this subpart at any time it is deemed necessary to ensure the safety of life or property.

(g) The regulated area for all swimming events listed in TABLE 1 of T01–0533 is that area of navigable waters within the area described in the table as LOCATION.

TABLE 1 OF T01–0533

6	June
6.1 Cohasset Triathlon	• Date: June 26, 2011. • Time: 8:30 a.m. to 10 a.m. • Location: All waters in the vicinity of Cohasset Harbor around Sandy Beach, within the following points (NAD 83): 42°15.6′ N, 070°48.1′ W. 42°15.5′ N, 070°48.1′ W. 42°15.4′ N, 070°47.9′ W. 42°15.4′ N, 070°47.8′ W.
7	July
7.1 Swim Across America Boston	• Date: July 15, 2011. • Time: 7 a.m. to 3 p.m. • Location: All waters of Boston Harbor between Rowes Warf and Little Brewster Island within the following points (NAD 83): 42°21.4′ N, 071°03.0′ W. 42°21.5′ N, 071°02.9′ W. 42°19.8′ N, 070°53.6′ W. 42°19.6′ N, 070°53.4′ W
7.2 Swim Across America Nantasket Beach	• Date: July 16, 2011. • Time: 9 a.m. to 11 a.m. • Location: All waters of Massachusetts Bay near Nantasket Beach within the following points (NAD 83): 42°16.7′ N, 070°51.9′ W. 42°16.9′ N, 070°51.3′ W. 42°16.3′ N, 070°50.5′ W. 42°16.1′ N, 070°51.0′ W.
8	August
8.1 Sharkfest Swim	• Date: August 8, 2011. • Time: 10 a.m. to 12 p.m. • Location: All waters of Old Harbor from near Columbia Point to Carson Beach within the following points (NAD 83): 42°19.1′ N, 071°02.2′ W. 42°19.2′ N, 071°01.9′ W. 42°19.7′ N, 071°02.8′ W.

TABLE 1 OF T01–0533—Continued

	42°19.4′ N, 071°02.9′ W.
8.2 Celebrate the Clean Harbor Swim	• Date: August 13, 2011. • Rain Date: following day. • Time: 9 a.m. to 12 p.m. • Location: All waters of Gloucester Harbor within the following points (NAD 83): 42°35.3′ N, 070°39.8′ W. 42°35.9′ N, 070°39.2′ W. 42°35.9′ N, 070°39.8′ W. 42°35.3′ N, 070°40.2′ W.
8.3 Boston Light Swim	• Date: August 13, 2011. • Time: 6 a.m. to 12 p.m. • Location: All waters of Boston Harbor between the L Street Bath House and Little Brewster Island within the following points (NAD 83): 42°19.7′ N, 071°02.2′ W. 42°19.9′ N, 071°10.7′ W 42°19.8′ N, 070°53.6′ W. 42°19.6′ N, 070°53.4′ W.
9	September
9.1 Mayflower Triathlon	• Date: September 3, 2011. • Time: 7:30 a.m. to 8:30 a.m. • Location: All waters of Plymouth Inner Harbor within the following points (NAD 83): 41°58.3′ N, 070°40.6′ W 41°58.7′ N, 070°39.1′ W. 41°56.8′ N, 070°37.8′ W. 41°57.1′ N, 070°39.2′ W.
9.2 Duxbury Beach Triathlon	• Date: September 24, 2011. • Time: 9 a.m. to 10 a.m. • Location: All waters of Duxbury Bay on the south side of the Powder Point Bridge within the following points (NAD 83): 42°02.8′ N, 070°39.1′ W. 42°03.0′ N, 070°38.7′ W. 42°02.8′ N, 070°38.6′ W. 42°02.7′ N, 070°39.0′ W.

Dated: July 7, 2011.

J.N. Healey,

Captain, U.S. Coast Guard, Captain of the Port Sector Boston.

[FR Doc. 2011–17983 Filed 7–15–11; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 63

[EPA–HQ–OAR–2003–0146; FRL–9439–2]

RIN 2060–AO55

National Emission Standards for Hazardous Air Pollutants From Petroleum Refineries

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; partial withdrawal.

SUMMARY: On October 28, 2009, the EPA proposed to withdraw the residual risk and technology review portions of the final rule amending the National Emission Standards for Hazardous Air Pollutants From Petroleum Refineries. EPA is now providing final notice of the partial withdrawal.

DATES: As of August 17, 2011, EPA withdraws portions of the final rule signed by then Administrator Stephen Johnson on January 16, 2009.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2003–0146. All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the EPA Docket Center, Environmental Protection Agency, EPA West Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Ms. Brenda Shine, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Refining and Chemicals Group (E143–01), Environmental Protection Agency, Research Triangle Park, NC 27711, telephone number: (919) 541–3608; fax number: (919) 541–0246; e-mail address: *shine.brenda@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information

Section 112 of the Clean Air Act (CAA) establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, after the EPA has identified categories of

sources emitting one or more of the HAP listed in section 112(b) of the CAA, section 112(d) calls for the Administrator to promulgate national emission standards for hazardous air pollutants for those sources. The EPA is then required to review these technology-based standards, and to revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, under CAA section 112(d)(6). The second stage in standard-setting focuses on reducing any remaining ''residual'' risk according to CAA section 112(f).

On January 16, 2009, then Administrator Stephen Johnson signed a final rule amending the National Emission Standards for Hazardous Air Pollutants From Petroleum Refineries, and the signed rule was made publicly available on the EPA's website. The signed rule included several different actions. First, it promulgated maximum achievable control technology (MACT) standards under CAA sections 112(d)(2) and (3) for heat exchange systems, which the EPA had not addressed in the original Refinery MACT 1 rule (40 CFR part 63, subpart CC). Second, pursuant to CAA section 112(f)(2), the rule addressed residual risk for all Refinery MACT 1 sources, including heat exchange systems. Third, it addressed the technology review pursuant to CAA section 112(d)(6) for all sources addressed in the original Refinery MACT 1 rule. Finally, the rule updated the table in the Refinery MACT 1 standards (Table 6) that cross-references the General Provisions in 40 CFR part 63, subpart A, and made a few additional clarifications to dates and cross-references in the Refinery MACT 1 standards.

The signed rule was submitted to the Office of the Federal Register for publication. Rahm Emanuel, Assistant to the President and Chief of Staff, issued a memorandum on January 20, 2009, directing Agencies to withdraw from the Office of the Federal Register ''all proposed or final regulations that have not been published in the **Federal Register** so that they can be reviewed and approved by a department or agency head.'' Although there was an exception for ''regulations subject to statutory or judicial deadlines,'' the Agency chose not to apply the exception in this case. One portion of the final rule, the CAA section 112(d)(6) review, was performed pursuant to the terms of a Consent Decree, which, as modified, required that by January 16, 2009, the EPA ''shall sign and promptly forward to the **Federal Register** for publication either final revisions to the standards for petroleum refineries in 40 CFR part 63, subpart CC pursuant to 42 U.S.C. 7412(d)(6) or a final determination that no revisions are necessary.'' Then Administrator Stephen Johnson signed the rule on January 16, 2009, and promptly forwarded it to the Office of the Federal Register, thus, fulfilling this obligation.[1]

Upon further review, the EPA determined that the residual risk and technology reviews may not accurately characterize the risk posed by this source category. Shortly after the rule was signed, the EPA responded to a *Request for Correction* under the EPA's *Information Quality Guidelines* from the city of Houston.[2] In that response, we recognized that we were currently taking action (and planned to take additional action) to gather better emissions information from the refining industry. Additionally, we noted that, during the comment period on the proposed rule, similar issues were raised concerning the representativeness of the emissions data and whether they provided an accurate basis for characterizing the risks posed.

After consideration of the public comments on the proposal to withdraw portions of the final rule, we are providing final notice of the Agency's decision to partially withdraw the final rule. As stated in the preamble to the proposed withdrawal, the EPA will provide the public with an opportunity to comment on any new proposed rule that may be issued addressing the residual risk and technology review requirements of the CAA for this source category.

II. Summary of Comments and Responses

The EPA received a total of six comment letters concerning the proposed partial withdrawal. Comment letters were received from industry trade associations, local environmental organizations, environmental groups, and members of the public. Summaries of the comments and our complete responses are included in the following section.

Comment: Four commenters supported the EPA's proposed partial withdrawal of the Refinery MACT 1 standards signed on January 16, 2009, and supported further analysis leading to a revised set of proposed standards. Several of these commenters asserted that the withdrawal is necessary because the EPA failed to adequately address their comments on the standards that were proposed on September 4, 2007 (72 FR 50716), and November 10, 2008 (73 FR 66694). Some of the comments submitted on those previous proposals and reiterated by the commenters included: (1) Objections to the EPA's interpretation of the CAA requirement that the standards provide an ''ample margin of safety''; (2) assertions that the maximum individual lifetime cancer risk allowed by the CAA is 1 in 1 million; (3) objections to the length of time allowed for compliance with standards for storage vessels with floating roofs; (4) identification of multiple deficiencies in the risk assessment methodology, including use of actual emissions rather than allowable emissions and the estimation of emissions at census block centroids rather than property lines; and (5) assertions that the emissions data used in the risk assessment were underestimated and unrepresentative. The commenters requested that the EPA collect more accurate emissions data and re-analyze the residual risk for Refinery MACT 1 using a methodology without the identified deficiencies.

Response: We appreciate the four commenters' support for the withdrawal of the residual risk and technology review portions of the revisions to the Refinery MACT 1 standards. In this notice, the EPA is not making any decisions regarding the scope of residual risk and technology review standards under the CAA or on the specific data that would form the basis for a particular decision. Substantive comments on those issues should be raised in the context of future proposed rules addressing the CAA residual risk and technology review for one or more specific source categories.

Comment: Two commenters objected to the proposed withdrawal of the residual risk and technology review portions of the Refinery MACT 1 standards that were signed on January 16, 2009. These commenters noted that the EPA spent several years collecting data and considering stakeholder comments, finally reaching the conclusion that the Refinery MACT 1 standards provide an ample margin of safety based on data that the EPA judged to be representative of the source category. The commenters asserted that

[1] We note that on January 30, 2009, the litigants notified EPA by letter that they believed the Agency had discharged its obligation under the Consent Decree, and that ''further review of the rule pursuant to the Emanuel memo will not violate the Consent Decree.'' (See Docket Item No. EPA–HQ–OAR–2003–0146–0209.)

[2] Letter to U.S. EPA Information Quality Guidelines staff from the Honorable Bill White, Mayor of Houston, July 9, 2008, Docket Item No. EPA–HQ–OAR–2003–0146–0166.3; EPA's response is Letter to Mayor Bill White, Houston, Texas, from Elizabeth Craig, Acting Assistant Administrator, Office of Air and Radiation, U.S. EPA, April 7, 2009. (See Docket Item No. EPA–HQ–OAR–2003–0146–0210.)

the docket for the Refinery MACT 1 rulemaking (Docket ID EPA–HQ–OAR–2003–0146) does not include any specific support for the EPA's decision to reject that previous conclusion. According to the commenters, the only support for withdrawing the rule and redoing the analyses is provided in public comments submitted for the proposed rules, and the EPA considered those comments prior to finalizing the rule signed on January 16, 2009. The commenters requested that the EPA present any additional data received or analyses performed since January 16, 2009, to support withdrawal of the standards, and clearly explain any differences in assumptions or methodologies used in the analyses.

One commenter asserted that residual risk and technology review for Refinery MACT 1 has been a time- and resource-consuming process, and due to the EPA's other obligations under the CAA, it is not in the best interest of the public for the EPA to repeat the entire process without good cause. The commenter detailed a number of analyses in the docket showing that the EPA believed its emissions estimates and risk assessment methodologies were appropriate for the rulemaking. The commenter also noted that, if the EPA always postponed regulatory action because data may become available in the future, no regulatory actions would ever be completed. According to the commenter, refiners continue to make improvements in emissions reductions, and the heat exchange system standards will reduce emissions from cooling towers, so further data collection would only serve to support the conclusion that the current standards provide an ample margin of safety.

Two commenters addressed the EPA's responsibilities under the Data Quality Act (DQA) related to the *Request for Correction* filed by Mayor White of Houston (RFC 02003). The commenters stated that the EPA fulfilled its DQA obligations through its response to Mayor White on April 7, 2009 (Docket Item No. EPA–HQ–OAR–2003–0146–0210), which describes the steps that the EPA plans to take to improve annual emissions estimates. Since the EPA has addressed the DQA concerns raised by Mayor White, the commenters asserted that it is not necessary for the Agency to take action on the proposed withdrawal of the Refinery MACT 1 standards to further address those concerns.

Response: As the commenters noted, we did reach the conclusions presented in the rule that was signed on January 16, 2009, through analysis of the data we had at the time. The commenters are correct that, as of the time of the proposed withdrawal, we had not yet received any specific, additional data to support changing the conclusions reached in the final rule. However, our proposal was not based on the receipt of such information. Our decision to withdraw the residual risk and technology review portions of the January 16, 2009, rule does not mean that we have made a decision to change our conclusions regarding what requirements are necessary and appropriate for the Refinery MACT 1 standards. Instead, as we noted when we proposed the withdrawal, we believe it is necessary to develop a more robust analysis based on the improved information we are in the process of gathering and developing.

With respect to duplicating the ''time- and resource-consuming process'' associated with the risk and technology review, we note that the EPA is now initiating the risk and technology review for the Refinery MACT 2 standards (40 CFR part 63, subpart UUU) and plans to conduct the Refinery MACT 1 and 2 reviews at the same time. Thus, our data collection efforts for purposes of the Refinery MACT 2 risk and technology review will also provide a significant portion of the information we will need for purposes of our new residual risk and technology review of the Refinery MACT 1 standards. Moreover, we believe that by more closely aligning our risk and technology review for Refinery MACT 1 and 2 sources, we will be able to develop a significantly improved analysis of the risks associated with petroleum refineries, and, therefore, can better determine the most effective way to address any residual risk posed by emissions from petroleum refineries. We see significant benefits in combining these efforts, both in terms of a more transparent risk evaluation of these co-located sources for the neighboring public and in terms of more consolidated standards for the regulated community. The EPA has already taken action to gather better emissions information from the refining industry, and to follow through on the commitments made in the response letter to Mayor White of Houston (Docket Item No. EPA–HQ–OAR–2003–0146–0210). For these reasons, we have concluded that the benefits of a consolidated risk and technology review outweigh the incremental analytical effort required to perform a new risk assessment for Refinery MACT 1 sources after collecting this more robust data.

One commenter suggested that the additional data may lead to the conclusion that the existing standards provide an ample margin of safety. We agree that is a possible outcome; however, any conclusions regarding the residual risk review for the Refinery MACT 1 standards will need to await our consideration of the more robust data we are now gathering. Those data will provide greater certainty for the final conclusions, and help to ensure the final standards are technically and legally defensible.

Finally, the EPA agrees that it has responded to the DQA request from Mayor White of Houston through the April 7, 2009, letter identified by the two commenters (Docket Item No. EPA–HQ–OAR–2003–0146–0210). In that letter, we outlined several initiatives that were either ongoing or planned for the near future in order to improve the quality of data we have concerning emissions from petroleum refineries, and we are continuing to move forward with all of those initiatives. We plan to use this improved information as we move forward to address emissions from petroleum refineries, including performing the residual risk and technology review for Refinery MACT 1 and 2 sources.

Comment: Two commenters noted that, if the EPA proceeds with the proposed partial withdrawal of Refinery MACT 1 standards, the Agency should make clear that the withdrawal completes the action related to the September 4, 2007, proposal. In other words, the commenters stated that the date for determining compliance with any new standards would be the proposal date of those new standards rather than September 4, 2007.

Response: We agree with the commenters. The appropriate dates for determining compliance with future standards would be the dates those standards are proposed and finalized.

Statutory and Executive Order Reviews

Under the CAA, the Administrator is withdrawing a final action that was signed by the Administrator and made publicly available on the the EPA website, but that never took effect through publication in the **Federal Register**. This action:

- Is a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities

under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA;

• Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994); and

• This notice does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: July 8, 2011.

Lisa P. Jackson,

Administrator.

[FR Doc. 2011–17901 Filed 7–15–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 97

[FRL–9435–6]

Data Availability Concerning Transport Rule Allowance Allocations to Existing Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of data availability (NODA).

SUMMARY: In the Transport Rule Federal Implementation Plans (FIPs), EPA finalized allowance allocations for 2012 and thereafter to existing units subject to the Transport Rule FIP trading programs in Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, West Virginia, and Wisconsin. As required in the Transport Rule, this NODA notifies the public of the availability of data on these allowance allocations for existing units. Through this NODA, EPA is also making available to the public the data upon which the allocations were based.

FOR FURTHER INFORMATION CONTACT: Questions concerning this action should be addressed to Brian Fisher, telephone (202) 343–9633, and e-mail *fisher.brian@epa.gov,* Michael Cohen, telephone (202) 343–9497 and e-mail *cohen.michael@epa.gov,* or Robert Miller, telephone (202) 343.9077, and e-mail *miller.robertl@epa.gov.* The mailing address for the aforementioned contacts is U.S. Environmental Protection Agency, CAMD (6204J), 1200 Pennsylvania Ave., NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: The detailed unit-by-unit data, calculations, and allowance allocation determinations are set forth in a technical support document in an Excel spreadsheet format titled ''Unit Level Allocations Under the Transport Rule FIP'' and available on EPA's Web site at *http://www.epa.gov/airtransport/actions.html.*

EPA is not requesting responses to the data made available through this NODA, which makes available data on allowance allocations finalized in the Transport Rule. Providing an allocation to an existing unit does not constitute a determination that the unit is a covered unit, and not providing an existing-unit allocation to a unit does not constitute a determination that the unit is not a covered unit. *See* §§ 97.411(a)(1), 97.511(a)(1), 97.611(a)(1), and 97.711(a)(1) of the Transport Rule.

Under the Transport Rule FIPs, EPA must record allowance allocations by certain deadlines. In particular, allowance allocations addressed by this NODA for existing units for 2012 must be recorded, within 90 days of the publication of the Transport Rule in the **Federal Register**, in the compliance accounts of existing units. *See* §§ 97.421(a), 97.521(a), 97.621(a), and 97.721(a) of the Transport Rule.

For 2013 and beyond, the Administrator must record, by certain specified deadlines, allowance allocations for existing units. *See* §§ 97.421(b) through (f), 97.521(b) through (f), 97.621(b) through (f), and 97.721(b) through (f) of the Transport Rule.

Under certain circumstances, the allowance allocations addressed in this NODA to existing units are subject to termination or correction, and the provisions establishing these allocations may be replaced by a SIP revision. *See* §§ 97.411(a)(2), 97.511(a)(2), 97.611(a)(2), and 97.711(a)(2) (concerning termination of allocations of non-operating units) and 97.411(c), 97.511(c), 97.611(c), and 97.711(c) (concerning incorrect allocations) of the Transport Rule and §§ 52.38(a)(3) through (5) and (b)(3) through (5) and 52.39(d) through (i) of the Transport Rule (concerning SIP revisions).

Dated: July 6, 2011.

Jackie Krieger,

Chief of Staff, Office of Atmospheric Programs.

[FR Doc. 2011–17903 Filed 7–15–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1983–0002; FRL–9440–4]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Withdrawal of direct final rule.

SUMMARY: On May 24, 2011, EPA published a Notice of Intent for Partial Deletion (76 FR 30081) and a direct final rule of Partial Deletion (76 FR 30027) for the remaining portions of Operable Unit 9 (OU9), the Residential Populated Areas, of the California Gulch Superfund Site (Site), located in Lake County, Colorado, from the National Priorities List. The EPA is withdrawing the Final Rule of Partial Deletion due to adverse comments that were received during the public comment period. After consideration of the comments received, if appropriate, EPA will publish a Notice of Partial Deletion in the **Federal Register** based on the parallel Notice of Intent for Partial Deletion and place a copy of the final partial deletion package, including a

Responsiveness Summary, if prepared, in the Site repositories.

DATES: *Effective Date:* This withdrawal of the direct final action is effective as of July 18, 2011.

ADDRESSES: *Information Repositories:* Comprehensive information on the Site, as well as the comments that we received during the comment period, are available in docket EPA–HQ–SFUND–1983–0002, accessed through the *http://www.regulations.gov* Web site. Although listed in the docket index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statue. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in h*ttp://www.regulations.gov* or in hard copy at:

U.S. EPA Region 8, Superfund Records Center, 1595 Wynkoop Street, Denver, CO 80202. (303) 312–6473 or toll free (800) 227–8917; Viewing hours: 8 a.m. to 4:30 p.m., Monday through Friday, excluding holidays;

and

Lake County Public Library, 1115 Harrison Avenue, Leadville, CO 80461. (719) 486–0569: Viewing hours: Monday and Wednesday 10 a.m. to 8 p.m.; Tuesday and Thursday 10 a.m. to 5 p.m.; Friday and Saturday 1 p.m. to 5 p.m.;

and

Timberline Campus Library of Colorado Mountain College, 901 U.S. Highway 24 South, Leadville, CO 80461. (719) 486–4250; Viewing hours: Monday to Thursday 8 a.m. to 9 p.m.; Friday 8 a.m. to 5 p.m.; Saturday 12 p.m. to 5 p.m.; and Sunday 12 p.m. to 8 p.m.

FOR FURTHER INFORMATION CONTACT: Linda Kiefer, Remedial Project Manager, U.S. Environmental Protection Agency, Region 8, Mailcode EPR–SR, 1595 Wynkoop Street, Denver, CO 80202–1129, (303) 312–6689, e-mail: *kiefer.linda@epa.gov.*

SUPPLEMENTARY INFORMATION:

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous Waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water Supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

Dated: July 12, 2011.

James B. Martin,

Regional Administrator, Region 8.

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

Accordingly, the amendment to Table 1of Appendix B to CFR Part 300 to revise the entry ''California Gulch'', ''Leadville, CO'' is withdrawn as of July 18, 2011.

[FR Doc. 2011–18004 Filed 7–15–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE TREASURY

48 CFR Chapter 10

RIN 1505–AC04

Department of the Treasury Acquisition Regulation

AGENCY: Office of the Procurement Executive, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury is issuing this final rule amending the Department of the Treasury Acquisition Regulation (DTAR) to: update, revise, or remove, as applicable, outdated text and references; add new text to maintain consistency with the Federal Acquisition Regulation (FAR); incorporate Treasury-specific policy associated with current FAR requirements; reflect the Treasury's organization and delegation of authorities; and make minor editorial changes. This final rule adopts the provisions in the December 17, 2010, proposed rule with a minor change, thus renumbering one paragraph in the DTAR.

DATES: *Effective date:* August 17, 2011.

FOR FURTHER INFORMATION CONTACT: Mr. Fernando T. Tonolete, Procurement Analyst, at (202) 622–6416 for clarification of content or information pertaining to status or publication schedules.

SUPPLEMENTARY INFORMATION: On December 17, 2010, the Department of the Treasury published a proposed rule (75 FR 78953) to update the Department of the Treasury Acquisition Regulation (DTAR) 2002 Edition, first published on June 14, 2002, and available at: *http://www.access.gpo.gov/nara/cfr/.* The DTAR will be maintained separately and combined with Department of the Treasury Acquisition Procedures (DTAP) for expediency of use by Treasury staff. The DTAR and combined DTAR/DTAP will be posted at: *http://www.treasury.gov/about/organizational-structure/offices/Mgt/Pages/ProcurementPolicy-Regulations.aspx.*

The December 17, 2010 proposed rule invited public comments on several changes to the DTAR. Among other changes, the proposed changes included revised definitions and scope of the DTAR. In addition, the proposal included new sections that address Treasury's Mentor-Protégé program, new provisions concerning contractor publicity, and new provisions on types of contracts (specifying that Bureaus must appoint a Task and Delivery Ombudsman). Finally, several editorial and grammatical changes were made in order to make the DTAR easier to read. See the December 17, 2010, proposed rule for further information.

The comment period closed on February 15, 2011. No comments were received and the Department adopts the proposed rule without change.

Procedural Matters

Executive Order 12866

This rule is not a significant regulatory action under Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993.

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* applies to this rule. It is hereby certified that the changes included in this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

The revisions are not considered substantive; revisions only update and reorganize existing coverage. Further, the revisions to the Mentor-Protégé program, although having some economic impact on participating small entities, are not expected to affect a substantial number of small entities. The program is designed for mentoring firms to provide developmental assistance to protégés in the areas of management, personnel, organization, technical capability, financial strength, and training/certifications. As a result, the approximately 44 participating small entities may experience short-term gains including an increase in the areas of revenue, number of contract awards, personnel, technical capabilities, and business relationships. Long-term, program participation should provide increased access to prime or subcontractor opportunities at the Treasury. Subsequently, this program serves to improve the Department of the Treasury's small business goal attainment.

Paperwork Reduction Act

The information collections contained in this proposed rule have been previously approved by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*) and assigned OMB control numbers 1505–0081; 1505–0080; and 1505–0107. Under the Paperwork Reduction Act, an agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a valid OMB control number.

List of Subjects in 48 CFR Parts 1001, 1002, 1009, 1016, 1019, 1028, 1032, 1033, 1034, 1036, 1048, and 1052

Government procurement.

Dated: June 6, 2011.

Thomas A. Sharpe, Jr.,

Senior Procurement Executive, Office of the Procurement Executive.

Accordingly, the Department of the Treasury revises 48 CFR Chapter 10 to read as follows:

CHAPTER 10—DEPARTMENT OF THE TREASURY

Part

SUBCHAPTER A—GENERAL

PART 1001—DEPARTMENT OF THE TREASURY ACQUISITION REGULATION (DTAR) SYSTEM

Authority: 41 U.S.C. 418b.

Subpart 1001.1—Purpose, Authority, Issuance

1001.101 Purpose.

This subpart establishes Chapter 10, the Department of the Treasury Acquisition Regulation (DTAR), within Title 48 of the Federal Acquisition Regulation (FAR) System. The DTAR contains policies and procedures that supplement FAR coverage and directly affect the contractual relationship between the Department of the Treasury and its business partners (e.g., prospective offerors/bidders and contractors). When FAR coverage is adequate, there will be no corresponding DTAR coverage.

1001.104 Applicability.

The DTAR applies to all acquisitions of supplies and services, which obligate appropriated funds. For acquisitions made from non-appropriated funds, the Senior Procurement Executive will determine the rules and procedures that will apply. The DTAR does not apply to the acquisitions of the U.S. Mint.

1001.105 Issuance.

1001.105–1 Publication and code arrangement.

The DTAR and its subsequent changes will be published in the Federal Register and codified in the Code of Federal Regulations (CFR). The DTAR will be issued as 48 CFR Chapter 10.

1001.105–2 Arrangement of regulations.

(a) *References and citations.* The DTAR is divided into the same parts, subparts, sections, subsections, and paragraphs as the FAR except that 10 or 100 will precede the DTAR citation so that there are four numbers to the left of the first decimal. Reference to DTAR material must be made in a manner similar to that prescribed by FAR 1.105–2(c).

1001.105–3 Copies.

Copies of the DTAR in Federal Register or CFR form may be purchased from the Superintendent of Documents, Government Printing Office (GPO), Washington, DC 20402.

1001.106 OMB Approval under the Paperwork Reduction Act.

OMB has assigned the following control numbers that must appear on the upper right corner of the face page of each solicitation, contract, modification, and order: OMB Control No. 1505–0081 (Offeror submissions), OMB Control No. 1505–0080 (Contractor submissions), OMB Control No. 1505–0107 (Protests). OMB regulations and OMB's approval and assignment of control numbers are conditioned upon Treasury bureaus not requiring more than three copies (including the original) of any document of information. OMB has granted a waiver to permit the Department to require up to eight copies of proposal packages, including proprietary data, for solicitations, provided that contractors who submit only an original and two copies will not be placed at a disadvantage.

Subpart 1001.3—Agency Acquisition Regulations

1001.301 Policy.

(a)(1) The DTAR (48 CFR Chapter 10) is issued for Treasury implementation in accordance with the authority cited in FAR 1.301(b). The DTAR supplements the Federal Acquisition Regulation by establishing uniform policies for all acquisition activities throughout the Department of the Treasury, except for the United States Mint.

1001.304 Agency control and compliance procedures.

(a) The DTAR is under the direct oversight and control of Treasury's Office of the Procurement Executive (OPE), which is responsible for the evaluation, review, and issuance of all Department-wide acquisition regulations and guidance.

Subpart 1001.4—Deviations from the FAR

1001.403 Individual deviations.

The SPE is authorized to approve individual contract FAR and DTAR deviations.

1001.404 Class deviations.

(a) The SPE is authorized to approve class FAR and DTAR deviations.

Subpart 1001.6—Career Development, Contracting Authority and Responsibilities

1001.670 Contract clause.

Contracting Officers must insert a clause substantially similar to the clause in section 1052.201–70, Contracting Officer's Technical Representative (COTR) Appointment and Authority, in all solicitations and contracts. Exceptions to the requirement for inclusion of the COTR clause and the appointment of a COTR may be made at the discretion of the BCPO.

PART 1002—DEFINITIONS OF WORDS AND TERMS

Sec.

Subpart 1002.1—Definitions

Authority: 41 U.S.C. 418b.

Subpart 1002.1—Definitions

1002.101 Definitions.

Bureau means any one of the following Treasury organizations:

(1) Alcohol and Tobacco Tax and Trade Bureau (TTB);

(2) Bureau of Engraving & Printing (BEP);

(3) Bureau of Public Debt (BPD);

(4) Departmental Offices (DO);

(5) Financial Crimes Enforcement Network (FinCEN);

(6) Financial Management Service (FMS);

(7) Inspector General (OIG);

(8) Internal Revenue Service (IRS);

(9) Office of the Comptroller of the Currency (OCC);

(10) Office of Thrift Supervision (OTS);

(11) Special Inspector General for the Troubled Asset Relief Program (SIGTARP);

(12) Treasury Inspector General for Tax Administration (TIGTA); or

(13) U.S. Mint.

Bureau Chief Procurement Officer (BCPO) means the senior acquisition person at each headquarters office or bureau. Within the Internal Revenue Service, this may be the Director, Procurement or the Deputy Director, Procurement.

Contracting Activity means an organization within a bureau or the Departmental Offices, having delegated acquisition authority.

Head of Contracting Activity (HCA) means the Senior Procurement Executive for Departmental Offices, the Deputy Commissioner for Operations Support for the Internal Revenue Service, and the heads of each bureau, as listed in section 1.b.(1) of Department of the Treasury Directive 12–11.

Head of the Agency means the Assistant Secretary for Management and Chief Financial Officer as designated by Treasury Order 101–30.

Legal Counsel means the Treasury or bureau office providing legal services to the contracting activity.

Senior Procurement Executive (SPE) for the Department of the Treasury is the Director, Office of the Procurement Executive.

1002.70 Abbreviations.

BCPO Bureau Chief Procurement Officer
COTR Contracting Officer's Technical Representative
HCA Head of the Contracting Activity
OPE Office of the Procurement Executive
OSDBU Office of Small and Disadvantaged Business Utilization
SPE Senior Procurement Executive

SUBCHAPTER B—ACQUISITION PLANNING

PART 1009—CONTRACTOR QUALIFICATIONS

Sec.

Subpart 1009.2—Qualifications Requirements

Authority: 41 U.S.C. 418b.

Subpart 1009.2—Qualifications Requirements

1009.204–70 Contractor publicity.

31 U.S.C. 333(a) prohibits the use of Treasury names, abbreviations, or symbols, in connection with, or as a part of, any advertisement, solicitation, business activity, or product, in a manner that may imply endorsement by Treasury. Bureaus shall insert a clause substantially the same as 1052.210–70 Contractor Publicity in all solicitations and contracts.

SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES

PART 1016—TYPES OF CONTRACTS

Sec.

Subpart 1016.5—Indefinite-Delivery Contracts

Authority: Authority: 41 U.S.C. 418b.

Subpart 1016.5—Indefinite-Delivery Contracts

1016.505 Ordering.

(b)(6) Bureaus shall designate a Task and Delivery Ombudsman in accordance with bureau procedures. In the absence of a designation, the Bureau Competition Advocate will serve in that capacity.

SUBCHAPTER D—SOCIOECONOMIC PROGRAMS

PART 1019—SMALL BUSINESS PROGRAMS

Sec.

Subpart 1019.2—Policies

Subpart 1019.7—The Small Business Subcontracting Program

Subpart 1019.8—Contracting With the Small Business Administration (The 8(a) Program)

Authority: 41 U.S.C. 418b.

Subpart 1019.2—Policies

1019.202 Specific policies.

1019.202–70 The Treasury Mentor Protégé Program.

(a) [Reserved]

(b) [Reserved]

(c) *Non-affiliation.* For purposes of the Small Business Act, a protégé firm may not be considered an affiliate of a mentor firm solely on the basis that the protégé firm is receiving developmental assistance referred to in paragraph (m) of this section, from such mentor firm under the Mentor-Protégé Program.

(d) *General policy.* (1) Eligible contractors, not included on the ''List of Parties Excluded from Federal Procurement and Nonprocurement Programs,'' that are approved as mentors will enter into agreements with eligible protégés. Mentors provide appropriate developmental assistance to enhance the capabilities of protégés to perform as contractors or subcontractors.

(2) A firm's status as a protégé under a Treasury contract shall not have an effect on the firm's eligibility to seek other contracts or subcontracts.

(e) *Incentives for contractor participation.* (1) Under the Small Business Act, 15 U.S.C. 637(d)(4)(E), Treasury is authorized to provide appropriate incentives in negotiated contractual actions to encourage subcontracting opportunities consistent with the efficient and economical performance of the contract. Proposed mentor-protégé efforts will be considered during the evaluation of such negotiated, competitive offers. Contracting Officers may provide, as an incentive, a bonus score, not to exceed 5% of the relative importance assigned to the non-price factors. If this incentive is used, the Contracting Officer shall include language in the solicitation indicating that this adjustment may occur.

(2) Before awarding a contract that requires a subcontracting plan, the existence of a mentor-protégé arrangement, and performance (if any) under such an existing arrangement, will be considered by the Contracting Officer in:

(i) Evaluating the quality of a proposed subcontracting plan under FAR 19.705–4; and,

(ii) Evaluating the contractor compliance with the subcontracting plans submitted in previous contracts as a factor in determining contractor responsibility under FAR 19.705–5(a)(1).

(3) The Office of Small and Disadvantaged Business Utilization (OSDBU) Mentoring Award is a non-monetary award that will be presented (annually on a fiscal year basis or as often as is appropriate) to the mentoring firm providing the most effective developmental support of a protégé. The Mentor-Protégé Program Manager will recommend an award winner to the Director, OSDBU.

(f) [Reserved]

(g) *Mentor firms.* A mentor firm may be either a large or small business, eligible for award of a Government contract that can provide developmental assistance to enhance the capabilities of protégés to perform as subcontractors. Mentors will be encouraged to enter into arrangements with protégés in addition to firms with whom they have established business relationships.

(h) *Protégé firms.* (1) For selection as a protégé, a firm must be:

(i) A small business, women-owned small business, small disadvantaged business, small business owned and controlled by veteran or service disabled veteran, or qualified HUBZone small business, or a qualified 8(a) concern;

(ii) Qualified as a small business under the NAICS code for the services or supplies to be provided by the protégé under its subcontract to the mentor; and

(iii) Eligible for award of Government contracts.

(2) Except small disadvantaged businesses and qualified HUBZone small business firms, a protégé firm may self-certify to a mentor firm that it meets the requirements set forth in paragraph (h)(1) of this section. Mentors may rely in good faith on written representations by potential protégés that they meet the specified eligibility requirements. The h(1)(i), small disadvantaged business, or qualified HUBZone small business status eligibility and documentation requirements are determined according to FAR 19.304 and 19.1303, respectively.

(3) Protégés may not have multiple mentors unless approved, in writing, by the Director, OSDBU. Protégés participating in other agency mentor protégé programs in addition to the Treasury Mentor-Protégé Program should maintain a system for preparing separate reports of mentoring activity for each agency's program.

(i) *Selection of protégé firms.* (1) Mentor firms will be solely responsible for selecting protégé firms. The mentor is encouraged to identify and select the types of protégé firms listed in 1019.202–70(h). Mentor firms may have multiple protégés.

(2) The selection of protégé firms by mentor firms may not be protested. Any question regarding the size or eligibility status of an entity selected by a mentor to be a protégé must be referred solely to Treasury's OSDBU for resolution. Treasury, at its discretion, may seek an advisory opinion from the Small Business Administration (SBA).

(j) *Application process for mentor firms to participate in the program.* (1) Firms interested in becoming a mentor firm may apply in writing to Treasury's OSDBU. The application will be evaluated based upon the description of the nature and extent of technical and managerial support proposed as well as the extent of other developmental assistance in the form of equity investment, loans, joint-venture support and traditional subcontracting support.

(k) *OSDBU review and approval process of agreement.* (1) OSDBU will review the information specified in 1019.202–70(l). The OSDBU review will be completed no later than 30 calendar days after receipt.

(2) Upon completion of the review, the mentor may implement the developmental assistance program.

(3) An approved agreement will be incorporated into the mentor firm's contract(s) with Treasury.

(4) If OSDBU disapproves the agreement, the mentor may provide additional information for reconsideration. Upon finding deficiencies that OSDBU considers correctable, OSDBU will notify the mentor and provide a list of defects. Any additional information or corrections requested will be provided within 30 calendar days. The review of any supplemental material will be completed within 30 calendar days after receipt by OSDBU. When submission of additional data is required during a proposal evaluation for a new contract award, shorter timeframes for submission, review and re-evaluation for approval may be authorized by OSDBU.

(5) The agreement defines the relationship between the mentor and protégé firms only. The agreement itself does not create any privity of contract between the mentor or protégé and Treasury.

(l) *Agreement contents.* The contents of the agreement will contain:

(1) Names and addresses of mentor and protégé firms and a point of contact within both firms who will oversee the agreement;

(2) Procedures for the mentor firm to notify the protégé firm, OSDBU and the Contracting Officer, in writing, at least 30 days in advance of the mentor firm's intent to voluntarily withdraw from the Mentor-Protégé Program;

(3) Procedures for a protégé firm to notify the mentor firm in writing at least 30 days in advance of the protégé firm's intent to voluntarily terminate the mentor-protégé agreement. The mentor must notify OSDBU and the Contracting Officer immediately upon receipt of such notice from the protégé;

(4) Each proposed mentor-protégé relationship must include information on the mentor's ability to provide developmental assistance to the protégé and how that assistance will potentially increase contracting and subcontracting opportunities for the protégé firm;

(5) A description of the type of developmental program that will be provided by the mentor firm to the protégé firm, to include a description of the potential subcontract work, and a schedule for providing assistance and criteria for evaluation of the protégés developmental success;

(6) A listing of the types and dollar amounts of subcontracts that may be awarded to the protégé firm;

(7) Program participation term;

(8) Termination procedures;

(9) Plan for accomplishing work should the agreement be terminated; and

(10) Other terms and conditions, as appropriate.

(m) *Developmental assistance.* The forms of developmental assistance a mentor can provide to a protégé include:

(1) Management guidance relating to financial management, organizational management, overall business management/planning, business development, and technical assistance.

(2) Loans;

(3) Rent-free use of facilities and/or equipment;

(4) Property;

(5) Temporary assignment of personnel to protégé for purpose of training; and

(6) Any other types of mutually beneficial assistance.

(n) *Obligation.* (1) Mentor or protégé firms may voluntarily withdraw from the Mentor-Protégé Program. However, such withdrawal shall not excuse the contractor from compliance with contract requirements.

(2) At the conclusion of each year in the Mentor-Protégé Program, the contractor and protégé must formally brief the Department of the Treasury team regarding program accomplishments as they pertain to the approved agreement. Individual briefings may be conducted, at the request of either party. Treasury will consider the following:

(i) Specific actions taken by the mentor, during the evaluation period, to increase the participation of protégés as suppliers to the Federal government and to commercial entities;

(ii) Specific actions taken by the mentor, during the evaluation period, to develop the technical and corporate administrative expertise of a protégé as defined in the agreement;

(iii) To what extent the protégé has met the developmental objectives in the agreement; and

(iv) To what extent the mentor firm's participation in the Mentor-Protégé Program resulted in the protégé receiving contract(s) and subcontract(s) from private firms and agencies other than the Department of the Treasury.

(v) Mentor and protégé firms must submit an evaluation to OSDBU at the conclusion of the mutually agreed upon program period, the conclusion of the contract, or the voluntary withdrawal by either party from the Mentor-Protégé Program, whichever comes first.

(o) [Reserved]

(p) *Solicitation provisions and contract clauses* (1) Insert the provision at 1052.219–73, Department of the Treasury Mentor-Protégé Program, in all unrestricted solicitations exceeding $500,000 ($1,000,000 for construction) that offer subcontracting possibilities.

(2) Insert the clause at 1052.219–75, Mentor Requirements and Evaluation, in contracts where the contractor is a participant in the Treasury Mentor-Protégé Program.

Subpart 1019.8—Contracting With the Small Business Administration (The 8(A) Program)

1019.81 Preparing the contracts.

1019.811–3 Contract clauses.

(d)(3) Insert the clause at 1052.219–18, Notification of Competition Limited to Eligible 8(a) Concerns—Alternate III (Deviation), for paragraph (c) of FAR 52.219–18, Notification of Competition Limited to Eligible 8(a) Concerns, in all solicitations and contracts that exceed $100,000 and are processed under 1019.8.

(f) Insert the clause at 1052.219–72, Section 8(a) Direct Awards, in solicitations and contracts that exceed $100,000 and are processed under 1019.8 for paragraph (c) of FAR 52.219–11, Special 8(a) Contract Conditions; FAR 52.219–12, Special 8(a) Subcontract Conditions; and FAR 52.219–17, Section 8(a) Award.

SUBCHAPTER E—GENERAL CONTRACTING REQUIREMENTS

PART 1028—BONDS AND INSURANCE

Sec.

Authority: 41 U.S.C. 418b.

Subpart 1028.3—Insurance

1028.307 Insurance under cost-reimbursement contracts.

1028.307–1 Group insurance plans.

(a) Plans shall be submitted to the CO.

(b) [Reserved]

1028.310 Contract clause for work on a Government installation.

1028.310–70 Contract clause.

(a) Insert a clause substantially similar to 1052.228–70, ''Insurance Requirements,'' in all solicitations and contracts that contain the clause at FAR 52.228–5.

1028.311 Solicitation provision and contract clause on liability insurance under cost reimbursement contracts.

1028.311–2 Agency solicitation provisions and contract clauses.

Insert a clause substantially similar to 1052.228–70, ''Insurance Requirements,'' in all solicitations and contracts that contain the clause at FAR 52.228–7.

PART 1032—CONTRACT FINANCING

Sec.

Authority: 41 U.S.C. 418b.

Subpart 1032.1—Non-Commercial Item Purchase Financing

1032.113 Customary contract financing.

The specified arrangements are considered customary within Treasury.

Subpart 1032.2—Commercial Item Purchase Financing

1032.202 General.

1032.202–1 Policy.

(b)(2) Commercial interim payments and commercial advance payments may also be made when the contract price is at or below the simplified acquisition threshold.

PART 1033—PROTESTS, DISPUTES, AND APPEALS

Sec.

Authority: 41 U.S.C. 418b.

Subpart 1033.2—Disputes and Appeals

1033.201 Definitions.

Agency Board of Contract Appeals means the Civilian Board of Contract Appeals (CBCA). The CBCA is the authorized representative of the Secretary of the Treasury in hearing, considering, and determining all appeals of decisions of Contracting Officers filed by contractors pursuant to FAR Subpart 33.2. Appeals are governed by the Rules of Procedure of the CBCA.

SUBCHAPTER F—SPECIAL CATEGORIES OF CONTRACTING

PART 1034—MAJOR SYSTEM ACQUISITION

Sec.

Subpart 34.0—General

Subpart 34.2—Earned Value Management System

Authority: 41 U.S.C. 418b.

Subpart 34.0—General

1034.001 Definitions.

Core Earned Value Management is a process for ensuring that the contractor's self validated earned value management system is capable of producing earned value management data and meets, at a minimum, the following core ANSI/EIA Standard-748 criteria:

(1) (ANSI #1) Define the authorized work elements for the program. A work breakdown structure (WBS), tailored for effective internal management control, is commonly used in this process.

(2) (ANSI #2) Identify the program organizational structure including the major subcontractors responsible for accomplishing the authorized work, and define the organizational elements in which work will be planned and controlled.

(3) (ANSI #3) Provide for the integration of the company's planning, scheduling, budgeting, work authorization, and cost accumulation processes with each other, and as appropriate, the program WBS and the program organizational structure.

(4) (ANSI #6) Schedule the authorized work in a manner that describes the sequence of work and identifies significant task interdependencies required to meet the needs of the program.

(5) (ANSI #7) Identify physical products, milestones, technical performance goals, or other indicators that will be used to measure progress.

(6) (ANSI #8) Establish and maintain a time-phased budget baseline, at the control account level, against which program performance can be measured. Initial budgets established for performance measurement will be based on either internal management goals or the external customer negotiated target cost including estimates for authorized but vaguely defined work. Budget for far-term efforts may be held in higher-level accounts until an appropriate time for allocation at the control account level. On government contracts, if an over-target baseline is used for performance measurement reporting purposes, prior notification must be provided to the customer.

(7) (ANSI #16) Record direct costs in a manner consistent with the budgets in a formal system controlled by the general books of account.

(8) (ANSI #22) At least on a monthly basis, generate the following information at the control account and other levels as necessary for management control using actual cost data from, or reconcilable with, the accounting system:

(i) Comparison of the amount of planned budget and the amount of budget earned for work accomplished. This comparison provides the schedule variance.

(ii) Comparison of the amount of the budget earned and the actual (applied where appropriate) direct costs for the same work. This comparison provides the cost variance.

(9) (ANSI #27) Develop revised estimates of cost at completion based on performance to date, commitment values for material, and estimates of future conditions. Compare this information with the performance measurement baseline to identify variances at completion important to management and any applicable customer reporting requirements, including statements of funding requirements.

(10) (ANSI #28) Incorporate authorized changes in a timely manner, recording the effects of such changes in budgets and schedules. In the directed effort prior to negotiation of a change, base such revisions on the amount estimated and budgeted to the program organizations.

Development, Modernization, Enhancement (DME) is the portion of an IT investment/project which deals with developing and implementing new or enhanced technology in support of an agency's mission.

Major acquisitions for development are defined as contracts, awarded in support of one or more Major IT investments with DME activities, which meet the contract threshold for fully applying FAR 34.2 procedures.

Performance-based acquisition management means a documented, systematic process for program management, which includes integration of program scope, schedule and cost objectives, establishment of a baseline plan for accomplishment of program objectives, and use of earned value techniques for performance measurement during execution of the program. A performance-based acquisition (as defined in FAR 37.101) or an acquisition with a defined quality assurance plan that includes performance standards/measures should be the basis for monitoring the contractor.

1034.004 Acquisition strategy.

(a) A program manager's acquisition strategy written at the system or investment level in accordance with FAR 7.103(e) shall include at a minimum:

(1) The relationship of each individual acquisition (Contract, Delivery Order, Task Order, or Interagency Agreement) to the overall investment requirements and management structure;

(2) What work is being performed in-house (by government personnel) versus contracted out for the investment;

(3) A description of the effort, by acquisition, and the plans to include required clauses in the acquisitions;

(4) A timetable of major acquisition award and administration activities, including plans for contract transitions;

(5) An investment/system surveillance plan;

(6) Financial and human resource requirements to manage the acquisition processes through the investment lifecycle;

(7) Consideration of optimal contract types, including considerations of performance based approaches, small business utilization, Section 508, etc.; and

(8) Assurances that the acquisition strategy section and supporting acquisition plans will maximize competition, including enabling downstream competition through avoidance of vendor ''lock in''.

(b) The acquisition strategy shall be approved by a chartered interdisciplinary acquisition team that includes a representative of the procurement organization designated in accordance with bureau procedures.

Subpart 34.2—Earned Value Management System

1034.201 Policy.

(a) (1) An Earned Value Management System (EVMS) is required for major acquisitions for development/modernization/enhancement (DME) in accordance with OMB Circular A–11. This includes prototypes and tests to select the most cost effective alternative during the Planning Phase, the work during the Acquisition Phase, and any developmental, modification or upgrade work done during the Operational/

Steady State Phase. EVMS is to be applied to contractor efforts regardless of contract type. The Contracting Officer shall procure the Contractor-developed component(s) of major project(s) that have been vetted through the Treasury governance process and the acquisition has been identified by the program manager as requiring the Contractor's use of an EVMS. In addition to major acquisitions for development, the Department of the Treasury may also require the Contractor's use of an EVMS for other acquisitions. The following thresholds apply to DME costs at the Contract Line Item Number (CLIN) level for performance-based acquisitions and to DME costs at the acquisition level (Contract, Task Order, or IAG) for non-performance-based contracts:

Contract, task order, IAG, or CLIN value	Reporting requirements for IT investments	Applicable ANSI/EIA criteria	Level of EVMS validation/ acceptance	IBR required	Level of EVMS surveillance (contractor)
>$50 M	Full	32	CFA [1] Acceptance	Yes	CFA Surveillance unless another interested party alternative is requested by the Bureau and approved by the Treasury CIO.
Between $20M and $50M	Full	32	Contractor Self-Validation.	Yes.	
<$20M	Core	10	Contractor Self-Validation.	Independent Baseline Validation IBR (Core).	Treasury/Bureau Surveillance.*

* In accordance with Bureau Annual Surveillance Strategy.
[1] CFA—Cognizant Federal Agency (See FAR 42.003).

(2) For the purpose of this subpart, CLIN may be interpreted as a single Contract Line Item Number, Contract Line Item Number with Sub-CLINs, or Multiple Contract Line Item Numbers included in a single DME effort. Do not break down any DME effort below the aggregation of the requirement to avoid use of the actual threshold prescriptions.

(b) *Acquisition Planning.* All written acquisition plans shall include the following:

(1) A determination from the requirements official as to whether the program is a major acquisition as defined under OMB Circular A–11 and FAR Part 34;

(2) If so, whether the program is required to include EVM and if the Contractor is required to use an EVMS;

(3) If so, whether the program official is EVM trained and qualified or has support from someone who is EVM trained and certified; and

(4) Whether a Full Integrated Baseline Review (IBR) will be completed within 90 days when the acquisition DME value is $20 Million or more, or a Core Integrated Baseline Review when the acquisition DME value is less than $20 Million).

(c) *Solicitations and Awards.* Unless a waiver has been granted (See paragraph (e) of this section), all solicitations and awards for major investments with DME valued at $20 Million or more require EVMS from the Contractor and its Subcontractor as follows:

(1) FAR Clause 52.234–4, Earned Value Management System; and, as appropriate, 1052.234–4, Earned Value Management System Alternate I) (See 1034.203 below), must contain a requirement that the Contractor and its subcontractors have:

(i) AN EVMS that has been determined as meeting the Full criteria of ANSI/EIA Standard-748 compliance (valued at $20 Million or more);

(ii) An EVMS that has been determined as meeting the Core criteria of ANSI/EIA Standard-748 compliance (valued at below $20 Million, See 5. DTAR Special Solicitation Provisions and Contract Clauses, 1052.234–2 and 1052.234–3); or

(iii) That the Contractor deliver a plan to provide EVM data that meets the standard.

(2) Provide for the completion of an IBR, or, as appropriate, for subcontracts with DME less than $20 million, an IBR (Core) that meets the Government standard, and provide periodic reporting of the EVM data.

(3) All EVM determinations as set forth in paragraphs 3(c)(i)(A) and (B) of this section, shall be documented in the pre-award and contract files, as appropriate.

(d) *Program Management.* For those acquisitions to which EVM applies, the program manager (PM)/(COTR) shall:

(1) Ensure that EVM requirements are included in the acquisition Statement of Objectives (SOO), Performance Work Statement (PWS), or Statement of Work (SOW);

(2) Determine whether the Contractor's EVMS (and that of its subcontractors) is ANSI/EIA Standard 748 compliant, or determine whether the Contractor's plan to provide EVM data meets the required standard; and

(3) Validate and approve the IBR/IBR (Core) and the subsequently issued EVM reports. These program management requirements shall be included in the Contracting Officer's written appointment letter to the COTR.

(e) *Waivers.* In accordance with Bureau policy, a waiver(s) to the guidance described within the Department of the Treasury Earned Value Management Guide (Treasury EVM Guide) may be granted by the Departmental Treasury CIO based on Bureau documented and Bureau CIO approved requests. Examples of waiver justifications may include, but are not limited to:

(1) Urgency of work to be performed;

(2) Limited duration of work to be performed;

(3) Cost of adding EVMS requirement to a contract versus benefit achieved;

(4) Percentage of DME costs vis-à-vis the life cycle investment costs; and

(5) Level of risk.

1034.202 Integrated Baseline Reviews.

(a) When an EVMS is required, and depending on the DME CLIN value threshold, the Government will conduct a Full IBR or a Core IBR.

(b) The purpose of the Full IBR and the Core IBR is to verify the technical content and the realism of the related performance budgets, resources, and schedules. It should provide a mutual understanding of the inherent risks in offerors'/contractors' performance plans and the underlying management control systems, and it should formulate a plan to handle these risks.

(c) Both the IBR and the IBR (Core) are joint assessments by the offeror or Contractor, and the Government, of the—

(1) Ability of the project's technical plan to achieve the objectives of the scope of work;

(2) Adequacy of the time allocated for performing the defined tasks to successfully achieve the project schedule objectives;

(3) Ability of the Performance Measurement Baseline (PMB) to successfully execute the project and attain cost objectives, recognizing the relationship between budget resources, funding, schedule, and scope of work;

(4) Availability of personnel, facilities, and equipment when required, to perform the defined tasks needed to execute the program successfully; and

(5) The degree to which the management process provides effective and integrated technical/schedule/cost planning and baseline control.

(d) An IBR/IBR (Core) may be held either pre- or post-award; however, the post-award IBR/IBR (Core) must be completed within 90 days after award, or the Contracting Officer shall obtain a copy of the Program Manager's written review of the requirement and assessment of the IBR/IBR (Core) timing based on the risk associated with the acquisition. While a post-award IBR is preferred, a pre-award IBR will be acceptable. **Note:** The IBR (Core) may be included within the Quality Assurance Surveillance Plan (QASP).

(e) The solicitation and award shall include the process and schedule for EVMS validation as meeting the ANSI/EIA 748 through EVMS Compliance Recognition documents or a Compliance Evaluation Review where a compliance document does not exist, and periodic systems surveillance.

1034.203 Solicitation provisions and contract clauses.

(a) For major investment acquisitions that included a DME effort value of greater than $50 Million, the Contracting Officer shall follow the requirements provided at FAR Subpart 34.203.

(b) For major investment acquisitions that include a DME effort with a value between $20–$50 Million:

(1) The Contracting Officer shall insert the FAR provision at FAR 52.234–2, Notice of Earned Value Management System—Pre-Award IBR, with the clause at 1052.234–2, Notice of Earned Value System—Pre-Award Alternate I in solicitations and awards that require the contractor to use an EVMS and for which the Government requires an IBR *prior to award.*

(2) The Contracting Officer shall insert the FAR provision at FAR 52.234–3, Notice of Earned Value Management System—Post-Award IBR, with 1052.234–3, Notice of Earned Value System—Post-Award Alternate I in solicitations and awards that require the contractor to use an Earned Value Management System (EVMS) and for which the Government requires an IBR *after award.*

(3) The contracting officer shall insert the FAR clause at FAR 52.234–4, Earned Value Management System, with 1052.234–4, Earned Value Management System Alternate I), in solicitations and awards that require a contractor to use an EVMS.

(c) For major acquisitions that include a DME effort with a value of less than $20 Million:

(1) The Contracting Officer shall insert the provision 1052.234–70, Notice of Earned Value Management System—Pre-Award IBR (Core), in solicitations for awards that require the contractor to use an Earned Value Management System (EVMS) and for which the Government requires an IBR prior to award.

(2) The Contracting Officer shall insert the provision 1052.234–71, Notice of Earned Value Management System—Post-Award IBR (Core), in solicitations for contracts that require the contractor to use an Earned Value Management System (EVMS) and for which the Government requires an IBR after award.

(3) The Contracting Officer shall insert the clause 1052.234–72, Core Earned Value Management System, in solicitations and awards that require a contractor to use an EVMS.

PART 1036—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

Sec.

Authority: 41 U.S.C. 418b.

Subpart 1036.6—Architect-Engineer Services

1036.602–5 Short selection process for contracts not to exceed the simplified acquisition threshold.

Bureaus are authorized to use either process.

SUBCHAPTER G—CONTRACT MANAGEMENT

PART 1042—CONTRACT ADMINISTRATION AND AUDIT SERVICES

Sec.

Authority: 41 U.S.C. 418b.

1042.1500 Procedures.

Contracting Officers are responsible for preparing interim and final past performance evaluations.

SUBCHAPTER H—CLAUSES AND FORMS

PART 1052—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Sec.

Authority: 41 U.S.C. 418b.

Subpart 1052.2—Texts of Provisions and Clauses

1052.201–70 Contracting Officer's Technical Representative (COTR) appointment and authority.

As prescribed in 1001.670–6, insert the following clause:

CONTRACTING OFFICER'S TECHNICAL REPRESENTATIVE (COTR) APPOINTMENT AND AUTHORITY AUG 2011

(a) The COTR is _____[insert name, address and telephone number].

(b) Performance of work under this contract is subject to the technical direction of the COTR identified above, or a representative designated in writing. The term ''technical direction'' includes, without limitation, direction to the contractor that directs or redirects the labor effort, shifts the work between work areas or locations, and/or fills in details and otherwise serves to

ensure that tasks outlined in the work statement are accomplished satisfactorily.

(c) Technical direction must be within the scope of the contract specification(s)/work statement. The COTR does not have authority to issue technical direction that:

(1) Constitutes a change of assignment or additional work outside the contract specification(s)/work statement;

(2) Constitutes a change as defined in the clause entitled ''Changes'';

(3) In any manner causes an increase or decrease in the contract price, or the time required for contract performance;

(4) Changes any of the terms, conditions, or specification(s)/work statement of the contract;

(5) Interferes with the contractor's right to perform under the terms and conditions of the contract; or

(6) Directs, supervises or otherwise controls the actions of the contractor's employees.

(d) Technical direction may be oral or in writing. The COTR must confirm oral direction in writing within five workdays, with a copy to the Contracting Officer.

(e) The Contractor shall proceed promptly with performance resulting from the technical direction issued by the COTR. If, in the opinion of the contractor, any direction of the COTR or the designated representative falls within the limitations of (c) above, the contractor shall immediately notify the Contracting Officer no later than the beginning of the next Government work day.

(f) Failure of the Contractor and the Contracting Officer to agree that technical direction is within the scope of the contract shall be subject to the terms of the clause entitled ''Disputes.''

(End of clause)

1052.210–70 Contractor publicity.

As prescribed in 1009.204–70, insert the following clause:

CONTRACTOR PUBLICITY AUG 2011

The Contractor, or any entity or representative acting on behalf of the Contractor, shall not refer to the equipment or services furnished pursuant to the provisions of this contract in any news release or commercial advertising, or in connection with any news release or commercial advertising, without first obtaining explicit written consent to do so from the Contracting Officer. Should any reference to such equipment or services appear in any news release or commercial advertising issued by or on behalf of the Contractor without the required consent, the Government shall consider institution of all remedies available under applicable law, including 31 U.S.C. 333, and this contract. Further, any violation of this provision may be considered during the evaluation of past performance in future competitively negotiated acquisitions.

(End of clause)

1052.219–18 Notification of competition limited to eligible 8(a) concerns—Alternate III (Deviation) (May 1998).

In accordance with 1019.811–3(d)(3), substitute the following for the paragraph (c) in FAR 52.219–18:

(c) Any award resulting from this solicitation will be made directly by the contracting officer to the successful 8(a) offeror selected through the evaluation criteria set forth in this solicitation.

1052.219–72 Section 8(a) direct awards.

As prescribed in 1019.811–3(f), insert the following clause:

8(A) BUSINESS DEVELOPMENT PROGRAM AWARDS (JUNE 2003)

(a) This purchase/delivery/task order or contract is issued by the contracting activity directly to the 8(a) program participant/contractor pursuant to the Partnership Agreement between the Small Business Administration (SBA) and the Department of the Treasury. However, the Small Business Administration is the prime contractor and retains responsibility for 8(a) certification, 8(a) eligibility determinations and related issues, and provides counseling and assistance to the 8(a) contractor under the 8(a) Business Development program. The cognizant SBA district office is:

[To be completed by the contracting officer at the time of award]

(b) The contracting officer is responsible for administering the purchase/delivery/task order or contract and taking any action on behalf of the Government under the terms and conditions of the purchase/delivery/task order or contract, to include providing the cognizant SBA district office with a signed copy of the purchase/delivery/task order or contract award within 15 days of the award. However, the contracting officer shall give advance notice to the SBA before it issues a final notice terminating performance, either in whole or in part, under the purchase order or contract. The contracting officer shall also coordinate with SBA prior to processing any novation agreement. The contracting officer may assign contract administration functions to a contract administration office.

(c) The contractor agrees:

(1) to notify the contracting officer, simultaneously with its notification to SBA (as required by SBA's 8(a) regulations), when the owner or owners upon whom 8(a) eligibility is based, plan to relinquish ownership or control of the concern. Consistent with 15 U.S.C. 637(a)(21), transfer of ownership or control shall result in termination of the contract for convenience, unless SBA waives the requirement for termination prior to the actual relinquishing of control; and,

(2) to adhere to the requirements of FAR 52.219–14, Limitations on Subcontracting.

(End of clause)

1052.219–73 Department of the Treasury Mentor-Protégé Program.

As prescribed in 1019.202–70.(p), insert the following clause:

DEPARTMENT OF THE TREASURY MENTOR-PROTÉGÉ PROGRAM (JUNE 2003)

(a) Large and small businesses are encouraged to participate in the Department of the Treasury Mentor-Protégé Program. Mentor firms provide small business protégés with developmental assistance to enhance their capabilities and ability to obtain Federal contracts.

(b) Mentor firms are large prime contractors or eligible small businesses capable of providing developmental assistance. Protégé firms are small businesses as defined in 13 CFR parts 121, 124, and 126.

Developmental assistance includes technical, managerial, financial, and other mutually beneficial assistance to aid protégé. Contractors interested in participating in the Program are encouraged to contact the Department of the Treasury Office of Small and Disadvantaged Business Utilization for further information.

(End of provision)

1052.219–75 Mentor Requirements and Evaluation.

As prescribed in 1019.202–70(p), insert the following clause:

MENTOR REQUIREMENTS AND EVALUATION AUG 2011

(a) Mentor and protégé firms shall submit an evaluation to the Department of the Treasury's Office of Small and Disadvantaged Business Utilization (OSDBU) at the conclusion of the mutually agreed upon Program period, or the voluntary withdrawal by either party from the Program, whichever occurs first. At the conclusion of each year in the Mentor-Protégé Program, the prime contractor and protégé will formally brief the Department of the Treasury Mentor-Protégé Program Manager regarding program accomplishments under their mentor-protégé agreements.

(b) A mentor or protégé must notify the OSDBU and the contracting officer, in writing, at least 30 calendar days in advance of the effective date of the firm's withdrawal from the Program. A mentor firm must notify the OSDBU and the contracting officer upon receipt of a protégé's notice of withdrawal from the Program.

(c) Contracting officers may provide, as an incentive, a bonus score, not to exceed 5% of the relative importance assigned to the non-price factors. If this incentive is used, the contracting officer shall include language in the solicitation indicating that this adjustment may occur.

(End of clause)

1052.228–70 Insurance requirements.

As prescribed in 1028.310–70 and 1028.311–2, insert a clause substantially as follows: The contracting officer may specify additional kinds (e.g., aircraft public and passenger liability, vessel liability) or increased amounts of insurance.

INSURANCE AUG 2011

In accordance with the clause entitled ''Insurance—Work on a Government Installation'' [or ''*Insurance—Liability to Third Persons''*] in Section I, insurance of the following kinds and minimum amounts shall be provided and maintained during the period of performance of this contract:

(a) Worker's compensation and employer's liability. The contractor shall, as a minimum, meet the requirements specified at FAR 28.307–2(a).

(b) General liability. The contractor shall, at a minimum, meet the requirements specified at FAR 28.307–2(b).

(c) Automobile liability. The contractor shall, at a minimum, meet the requirements specified at FAR 28.307–2(c).

(End of clause)

1052.234–2 Notice of Earned Value Management System—Pre-Award IBR—Alternate I AUG 2011

As prescribed in DTAR 1034.203, substitute the following paragraph (a) for paragraph (a) of the basic FAR clause:

(a) The offeror shall provide either documentation that the Cognizant Federal Agency has determined that the proposed earned value management system (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (ANSI Standard) or documentation that supports the offeror's self-validation that the EVMS complies with the ANSI Standard, as applicable.

(End of Provision)

1052.234–3 Notice of Earned Value Management System—Post-Award IBR—Alternate I AUG 2011

As prescribed in DTAR 1034.203, substitute the following paragraph (a) for paragraph (a) of the basic FAR clause:

(a) The offeror shall provide either documentation that the Cognizant Federal Agency has determined that the proposed earned value management system (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (ANSI Standard) or documentation that supports the offeror's self-validation that the EVMS complies with the ANSI Standard, as applicable.

(End of Provision)

1052.234–4 Earned Value Management System Alternate I AUG 2011

As prescribed in DTAR 1034.203, substitute the following paragraph (a) for paragraph (a) of the basic FAR clause:

(a) The Contractor shall use an earned value management system (EVMS) that has been determined by the Cognizant Federal Agency (CFA) or has been determined through Contractor's self-validation to be compliant with the guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been determined compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit reports in accordance with the requirements of this contract.

(End of Clause)

1052.234–70 Notice of Earned Value Management System—Pre-Award IBR (Core) AUG 2011

As prescribed in DTAR 1034.203, insert this provision in solicitations and awards that require the Contractor to use an earned value management system (EVMS) and for which the Government requires an IBR *prior to award.*

(a) The offeror shall provide either documentation that the Cognizant Federal Agency has determined that the proposed earned value management system (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (ANSI Standard) or documentation that supports its self-validation that the EVMS used for this award complies with Core EVM criteria.

(b) If the offeror proposes to use a system that has not been determined to be in compliance with the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the EVMS guidelines.

(1) The plan shall—

(i) Describe the EVMS the offeror intends to use in performance of the contracts;

(ii) Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;

(iii) Describe the management system and its application in terms of the EVMS guidelines;

(iv) Describe the proposed procedures for administration of the guidelines, as applied to subcontracts; and

(v) Provide documentation describing the process and results of any third-party or self-evaluation of the system's compliance with the EVMS guidelines.

(2) The offeror shall provide information and assistance as required by the contracting officer to support review of the plan.

(3) The Government will review and approve the offeror's plan for an EVMS before contract award.

(4) The offeror's EVMS plan must provide milestones that indicate when the offeror anticipates that the EVM system will be compliant with the requirements in paragraph (a) of this provision.

(c) Offerors shall identify the major subcontractors, or major subcontracted effort if major subcontracts have not been selected subject to the guidelines. The prime Contractor and the Government shall agree to subcontractors selected for application of the EVMS requirements.

(d) The Government will conduct an Integrated Baseline Review (IBR), as designed by the agency, prior to contract award. The objective of the IBR is for the Government and the Contractor to jointly assess technical areas, such as the Contractor's planning, to ensure complete coverage of the contract requirements, logical scheduling of the work activities, adequate resources, methodologies for earned value (budgeted cost for work performed (BCWP)), and identification of inherent risks.

(End of Provision)

1052.234–71 Notice of Earned Value Management System—Post-Award IBR (Core) AUG 2011

As prescribed in DTAR 1034.203, insert this provision in solicitations and awards that require the contractor to use an earned value management system (EVMS) and for which the Government requires an IBR *after award.*

(a) The offeror shall provide either documentation that the Cognizant Federal Agency has determined that the proposed EVMS complies with the EVMS guidelines in ANSI/EIA Standard-748 (ANSI Standard) or documentation that supports its self-validation that the EVMS used for this award complies with Core EVM criteria.

(b) If the offeror proposes to use a system that has not been determined to be in compliance with the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the EVMS guidelines.

(1) The plan shall—

(i) Describe the EVMS the offeror intends to use in performance of the contracts;

(ii) Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;

(iii) Describe the management system and its application in terms of the EVMS guidelines;

(iv) Describe the proposed procedures for administration of the guidelines, as applied to subcontracts; and

(v) Provide documentation describing the process and results of any third-party or self-evaluation of the system's compliance with the EVMS guidelines.

(2) The offeror shall provide information and assistance as required by the contracting officer to support review of the plan.

(3) The Government will review and approve the offeror's plan for an EVMS before contract award.

(4) The offeror's EVMS plan must provide milestones that indicate when the offeror anticipates that the EVMS will be compliant with the requirements in paragraph (a) of this provision.

(c) Offerors shall identify the major subcontractors, or major subcontracted effort if major subcontracts have not been selected subject to the guidelines. The prime Contractor and the Government shall agree to subcontractors selected for application of the EVMS requirements.

(d) The Government will conduct an Integrated Baseline Review (IBR), as designed by the agency, prior to contract award. The objective of the IBR is for the Government and the Contractor to jointly assess technical areas, such as the Contractor's planning, to ensure complete coverage of the contract requirements, logical scheduling of the work activities, adequate resources, methodologies for earned value (budgeted cost for work performed (BCWP)), and identification of inherent risks.

(End of Provision)

1052.234–72 Core Earned Value Management System AUG 2011

As prescribed in DTAR 1034.203, insert this clause in major investment solicitations and awards with DME that require a contractor to use an earned value management system (EVMS).

(a) The Contractor shall use an earned value management system (EVMS) that has either been determined by the Cognizant Federal Agency (CFA) to be compliant with the guidelines in ANSI/EIA Standard-748 (current version at the time of award) or documentation that supports its validation that the EVMS used to manage this contract meets the following ANSI/EIA–748 criteria:

(1) (ANSI #1) Define the authorized work elements for the program. A work breakdown structure (WBS), tailored for effective internal management control, is commonly used in this process.

(2) (ANSI #2) Identify the program organizational structure including the major subcontractors responsible for accomplishing the authorized work, and define the organizational elements in which work will be planned and controlled.

(3) (ANSI #3) Provide for the integration of the company's planning, scheduling, budgeting, work authorization, and cost accumulation processes with each other, and as appropriate, the program WBS and the program organizational structure.

(4) (ANSI #6) Schedule the authorized work in a manner that describes the sequence of work and identifies significant task interdependencies required to meet the needs of the program.

(5) (ANSI #7) Identify physical products, milestones, technical performance goals, or other indicators that will be used to measure progress.

(6) (ANSI #8) Establish and maintain a time-phased budget baseline, at the control account level, against which program performance can be measured. Initial budgets established for performance measurement will be based on either internal management goals or the external customer negotiated target cost including estimates for authorized but vaguely defined work. Budget for far-term efforts may be held in higher-level accounts until an appropriate time for allocation at the control account level. On government contracts, if an over-target baseline is used for performance measurement reporting purposes, prior notification must be provided to the customer.

(7) (ANSI #16) Record direct costs in a manner consistent with the budgets in a formal system controlled by the general books of account.

(8) (ANSI #22) At least on a monthly basis, generate the following information at the control account and other levels as necessary for management control using actual cost data from, or reconcilable with, the accounting system:

(i) Comparison of the amount of planned budget and the amount of budget earned for work accomplished. This comparison provides the schedule variance.

(ii) Comparison of the amount of the budget earned and the actual (applied where appropriate) direct costs for the same work. This comparison provides the cost variance.

(9) (ANSI #27) Develop revised estimates of cost at completion based on performance to date, commitment values for material, and estimates of future conditions. Compare this information with the performance measurement baseline to identify variances at completion important to management and any applicable customer reporting requirements, including statements of funding requirements.

(10) (ANSI #28) Incorporate authorized changes in a timely manner, recording the effects of such changes in budgets and schedules. In the directed effort prior to negotiation of a change, base such revisions on the amount estimated and budgeted to the program organizations. If the Contractor's current EVMS has not been determined compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor's EVMS has not been determined by the CFA as complying with EVMS guidelines or the Contractor does not have an existing cost/schedule control system that is compliant with the guidelines in paragraph (a), the Contractor shall—

(1) Apply the current system to the contract; and

(2) Take necessary actions to meet the milestones in the Contractor's EVMS plan approved by the contracting officer.

(c) The Government will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post award IBR shall be conducted as early as practicable after contract award.

(d) The contracting officer may require an IBR upon the—

(1) Exercise of significant options; or

(2) Incorporation of major modifications.

(e) Unless a waiver is granted by the CFA, Contractor-proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

(f) The Contractor shall provide access to all pertinent records and data requested by the contracting officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the performance criteria referenced in paragraph (a) of this clause.

(g) The Contractor shall require the subcontractors specified below to comply with the requirements of this clause: [Insert list of applicable subcontractors].

(End of Clause)

[FR Doc. 2011–17623 Filed 7–15–11; 8:45 am]

BILLING CODE 4810–25–P

Proposed Rules

Federal Register
Vol. 76, No. 137
Monday, July 18, 2011

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

7 CFR Part 800

RIN 0580–AB15

Inspection and Weighing of Grain in Combined and Single Lots

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Department of Agriculture's (USDA), Grain Inspection, Packers and Stockyards Administration (GIPSA) is proposing to revise the regulations that cover the official grain inspection and weighing service procedures that GIPSA's Federal Grain Inspection Service (FGIS) performs under the authority of the United States Grain Standards Act (USGSA), as amended. Specifically, GIPSA proposes to update the regulations issued under the USGSA pertaining to grain exported in large reusable containers typically loaded onto export ships. GIPSA proposes to add new definitions of composite and average grades, limit the number of such containers that could be averaged or combined to form a single lot, restrict the inspection and weighing of such container lots to the official service provider's area of responsibility, specify a 60-day retention period for file samples representing such container lots, and make consistent the weighing certification procedures for container lots with those for inspection certification procedures. GIPSA believes that these proposed revisions would enhance the integrity of the Federal grain export certification process and the uniformity of USDA-certified export grain shipped in large reusable containers as to grade, thus facilitating the marketing of all U.S. grain shipped for export.

DATES: Comments must be received on or before September 16, 2011.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Tess Butler, GIPSA, USDA, 1400 Independence Avenue, SW., room 2542–S, Washington, DC 20250–3642.
- *E-mail:* Comments to comments.gipsa@usda.gov.
- *Fax:* (202) 690–2173.

All comments will become a matter of public record and should be identified as ''Containerized Grain Proposed Rule Comments,'' making reference to the date and page number of this issue of the **Federal Register**. Comments will be available for public inspection on *http://www.regulations.gov* and in the above office during regular business hours (7 CFR 1.27(b)). Please call GIPSA at (202) 720–7486 to make an appointment to read the comments.

FOR FURTHER INFORMATION CONTACT: Robert Lijewski, Director, USDA, GIPSA, Field Management Division, 1400 Independence Avenue, SW., Room 2409–S, Washington, DC 20250–3630, phone (202) 720–0224.

SUPPLEMENTARY INFORMATION:

Background

The United States Grain Standards Act (USGSA) (7 U.S.C. 71–87k), as amended, provides an official inspection system that facilitates the marketing of grain in domestic and international markets. The Secretary of Agriculture (Secretary) is authorized by the USGSA to establish standards of kind, class, quality, and condition for various grains and to establish standards or procedures for accurate weighing and weight certification and controls, including safeguards over equipment calibration and maintenance, for grain shipped in interstate or foreign commerce. Additionally, the Secretary can amend or revoke these standards or procedures as needed in order to adjust to current industry needs and practices. Under authority delegated by the Secretary, GIPSA is authorized to establish and maintain regulations that cover the inspection and weighing of grain under the USGSA.

Grain exported in large reusable containers has grown exponentially in the past 5 years to levels that GIPSA believes have far exceeded grain industry expectations. Increased exports of containerized grain have, in turn, increased the demand for USDA grain inspection services provided by FGIS and its official grain export service providers. While the overall market share for U.S. export grain shipped in large reusable containers has grown rapidly, USGSA regulations (7 CFR 800) for export grain shipments have focused primarily on the inspection and grading of grain exported in shiplots, unit trains, and lash barges—not on grain exported in multiple large reusable containers that are considered collectively as a single lot.

The last amendments to the USGSA regulations occurred in 1980 (45 FR 15810) when grain was not typically exported in large reusable containers but was exported after being loaded in bulk onto ships, unit trains, and lash barges. In recent years, however, demand has increased for grain that is exported in large reusable containers, which enables buyers and sellers to negotiate contract terms that specify the exact quantity and quality of grain to be delivered. Typically, the industry uses large reusable containers that may be 20 feet or 40 feet in length, 8′0″ or 8′6″ in width, and 8′6″ or 9′6″ in height to transport bulk or sacked grain. Large reusable containers are usually a metal truck/trailer body that can be detached from the chassis for loading into a vessel, a railcar, or stacked in a container depot. Sales contracts usually cover multiple container parcels known as ''bookings'' (*i.e.,* grain in multiple large reusable containers that may be from different sources but are sold under a single sales contract and a single certificate) that are shipped to multiple end users, but collectively are considered a single lot. Unless exempted from official inspection and weighing requirements, a sales contract must stipulate that the overall quality in a booking meets an official USDA grade standard. Accordingly, export grain sellers often request that GIPSA combine inspection results from the individual containers and issue one official inspection certificate for the booking.

Description of Proposed Revisions

GIPSA and grain buyers expect grain in one booking to be of overall uniform quality. To guarantee that quality is maintained for grain exported in large reusable containers, GIPSA believes that

the USGSA regulations pertaining to grain exported in such containers must be revised to ensure that sellers ship the exact quantity and quality of grain specified in the sales contracts (unless otherwise stated, or ''if applicable'') that are currently required for grain loaded onto ships, unit trains, and lash barges. Therefore, GIPSA proposes to revise the USGSA regulations by adding new definitions of composite and average grades, establishing procedures for grain shipped in multiple large reusable containers that would be certified on one certificate; limit the number of such containers that could be averaged or combined into a single lot; restrict the inspection and weighing of such container lots to the official service provider's area of responsibility, whether a designated state, delegated state, or private agency; and specify a 60-day retention period for file samples representing large reusable container lots so that such containers would be in line with the current retention schedule of short voyage export ships and barges.

In § 800.0 of the regulations, GIPSA proposes adding definitions for the terms ''average grade'' and ''composite grade'' to address methods of combining multiple samples to achieve a single grade. This is necessary to issue the USDA inspection certificate for the single lot.

Sections 800.84 and 800.85 would be amended to require the applicant to provide written instructions, otherwise known as a load order, to official personnel that reflect contract requirements, if applicable, for quality and quantity for carriers graded on a composite or average grade basis and to limit the number of large reusable containers that may be averaged or combined to comprise a single lot. Under existing procedures, a single inspection certificate can be issued for hundreds of individual large reusable containers of grain. When large numbers of large reusable containers loaded with grain are combined into a single lot, however, GIPSA has found that the bookings may not be uniform with respect to overall quality. GIPSA has observed over time, however, that limiting the maximum number of individual units to 20 large reusable containers, 5 railcars, or 15 trucks that may be combined to form an average grade analysis for a single lot increases the likelihood that a shipment of grain is more uniform in quality and meets buyers' expectations. Our proposal would also require that grain in any single lot be loaded in a reasonably continuous operation (§ 800.0(b)(85)) to ensure that the quality of the grain in large reusable containers does not diminish over time. This proposed change would align the regulations regarding export grain loaded in large reusable containers with those regulations for grain loaded onto ships, unit trains, and lash barges. GIPSA believes that creating a reasonably continuous loading requirement for large reusable containers that is the same for ships, unit trains, and lash barges would promote the marketing of export grain by establishing a more equitable playing field among grain buyers and sellers.

In addition to ensuring that bookings (groupings of large reusable containers in a contract) are uniform in overall quality, the proposed revisions to the regulations would also require that all lots are loaded in a reasonably continuous operation (§ 800.0(b)(85)), that the loaded grain is maintained in good condition, that weighing in combined lots is performed in accordance with USGSA regulations, and that all large reusable containers of USDA-certified grain for export are uniform in quality, adhere to contract specifications, if applicable, as reflected in the load order, and meet customers' expectations. GIPSA believes that establishing regulations for grain exported in large reusable containers that parallel the continuous loading operation of inspection and loading procedures for grain exported in shiplots, unit trains, and lash barges would enhance the enforcement of the USGSA and ensure that U.S. grain shipped in all carriers adheres to contract specifications, if applicable. USGSA regulations currently define the term ''carrier'' as a truck, trailer, truck/trailer(s) combination, railroad car, barge, ship, or other container used to transport bulk or sacked grain, which includes large reusable containers.

Section 800.97(c)(1) would be revised to add the term ''container'' in order to make clear that the basic requirement would be that one official certificate must be issued for the weighing of each large reusable container, truck, trailer, truck/trailer combination, railroad car, barge, or similarly sized carrier. Additional regulatory text would limit the number of carriers on a weight certificate at a single location and would specify that weighing take place in a reasonably continuous operation. This would align the weight certification procedures with the inspection certification procedures as there would be a reasonably continuous operation procedure for both the inspection and weighing of all carriers.

Section 800.98(b) would be revised to remove the requirement that grain in each single lot be weighed at the same location, and include a new provision that would allow grain weighed at multiple locations to be certified as a combined lot in a single booking. Weighing performed at each individual location is still required to be completed in a reasonably continuous operation that parallels the current inspection procedures. This new provision would enable foreign buyers to purchase grain shipped in multiple large reusable containers under one sales contract by allowing U.S. grain exporters to weigh grain for a combined lot at different locations within an official agency's designated/delegated area. Official agencies are State or local government agencies, or persons, designated/delegated by GIPSA to perform official inspection and/or weighing services under the USGSA. The limitation of weighing and certifying grain in combined lots at one location would be eliminated to promote the marketability of grain by allowing large reusable containers from several loading facilities to be included on one weight certificate. As a result, more than one elevator or loading location may exist on a combined lot weight certificate since weighing would be permitted at multiple locations.

New requirements would be added in § 800.152 related to the retention of file samples from containers, short voyage ships, and barges. The table currently in this section would be amended to include a column for ''Other'' to clarify that the file retention requirements apply to situations involving bins, tanks, and submitted samples since bins, tanks, and submitted samples do not fall under the ''in,'' ''out,'' or ''export'' categories.

Alternatives Considered

We considered continuing using the current inspection procedures for all grain exported in large reusable containers. GIPSA believes, however, that a limitless amount of large reusable containers combined into a single lot would increase sampling variability due to the infinite sample size.

GIPSA also considered mandating that each individual large reusable container be inspected and certified. Doing so, however, would unnecessarily burden U.S. grain exporters and USDA's official inspection system with increased labor and equipment costs, and would affect the timeliness of certificate issuance.

GIPSA believes that the proposed revisions to the USGSA regulations would continue to promote the orderly marketing of U.S. grain. The proposed revisions were carefully designed to ensure the integrity of the USDA

certificate and foster consumer confidence in U.S. grain.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), GIPSA has considered the economic impact of this action on small entities. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened.

Under the provisions of the USGSA, grain exported from the U.S., unless exempted, must be officially inspected and weighed. Mandatory inspection and weighing services are provided by GIPSA at 47 export facilities and by delegated States at 17 facilities, and seven facilities for U.S. grain transshipped through Canadian ports. All of these facilities are owned by multi-national corporations, large cooperatives, or public entities that do not meet the requirements for small entities established by the Small Business Administration (SBA). Furthermore, these regulations are applied equally to all entities. The USGSA (7 U.S.C. 87f–1) requires the registration of all persons engaged in the business of buying grain for sale in foreign commerce. In addition, those persons who handle, weigh, or transport grain for sale in foreign commerce must also register. Section 800.30 of the USGSA regulations (7 CFR 800.30) define a foreign commerce grain business as any person who regularly engages in buying for sale, handling, weighing, or transporting grain totaling 15,000 metric tons or more during the preceding or current calendar year. At present, there are 113 registrants registered to export grain. While most of the 113 registrants are large businesses, we believe that some are small.

The SBA defines small businesses by their North American Industry Classification System Codes (NAICS).[1] The SBA defines small grain exporters in its regulations (13 CFR 121.201) as entities having less than $7,000,000 in average annual receipts (NAICS code 115114). Small grain exporters that export less than 15,000 metric tons per year are exempt from the mandatory inspection and weighing requirements under § 800.18 of the USGSA regulations (7 CFR 800.18). This ''waiver'' was established to provide economic relief to small grain exporter businesses from inspection and weighing requirements without impairing the objectives of the USGSA.

This proposed rule would revise the regulations regarding procedures for official export grain inspection and weighing services performed under the authority of the USGSA. The proposed rule would also amend the USGSA regulations for grain shipped in large reusable containers for export, add new definitions for composite and average grades for grain in multiple large reusable containers certified on one certificate, limit the number of large reusable containers that would be averaged or combined in a single lot, restrict the inspection and weighing of large reusable container lots to the official service provider's area of responsibility to align large reusable containers with other shipments of grain; specify a 60-day retention period for file samples representing large reusable container lots; and align weighing certification procedures for large reusable container lots with those for inspection certification procedures.

There would be no additional reporting or record keeping requirements imposed upon small entities as a result of this proposed rule. GIPSA has not identified any other Federal rules which may duplicate, overlap or conflict with this proposed rule. Given the forgoing discussion, GIPSA has therefore determined that this proposed rule would not have a significant economic impact on a substantial number of small entities as defined in the RFA.

We welcome comments on the cost of compliance with this proposed rule, and particularly on the impact of this proposed rule on small businesses. We also welcome comments on any alternatives to the proposed rule that may achieve the same purpose with less cost or burden.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This action is not intended to have retroactive effect. The USGSA provides in section 87g (7 U.S.C. 87g) that no subdivision may require or impose any requirements or restrictions concerning the inspection, weighing, or description of grain under the USGSA. Otherwise, this rule would not preempt any State or local laws, or regulations, or policies unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

Executive Order 13175

This proposed rule has been reviewed with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. This rule would not have substantial and direct effects on Tribal governments and would not have significant Tribal implications.

Paperwork Reduction Act

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the information collection and recordkeeping requirements in Part 800 have been approved by Office of Management and Budget under Control No. 0580–0013.

E-Government Compliance

GIPSA is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 7 CFR Part 800

Administrative practice and procedure, exports, grains, reporting and recordkeeping requirements.

For the reasons set out in the preamble, GIPSA proposes to amend 7 CFR Part 800 as follows:

PART 800—GENERAL REGULATIONS

1. The authority citation for part 800 continues to read as follows:

Authority: 7 U.S.C. 71–87k.

2. Amend § 800.0(b) by removing the numerical paragraph designations (1) through (107) and adding definitions for ''average grade'' and ''composite grade'' in alphabetical order to read as follows:

§ 800.0 Meaning of terms.

* * * * *

(b) * * *

Average grade. Multiple carrier units or sublots that are graded individually then averaged to form a single lot inspection.

* * * * *

Composite grade. Multiple samples obtained from the same type of carriers (*e.g.,* trucklots, containers) that are combined into one sample for grade to form a single lot inspection.

* * * * *

3. Amend § 800.84 by revising paragraphs (a), (b)(1), (b)(2) and the introductory text of paragraph (c) to read as follows:

[1] See: *http://www.sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf.*

§ 800.84 Inspection of grain in land carriers, containers, and barges in single lots.

(a) *General.* The inspection of bulk or sacked grain loaded or unloaded from any carrier or container, except shiplot grain, must be conducted in accordance with the provision in this section and procedures prescribed in the instructions. Applicant must provide written instructions to official personnel, reflecting contract requirements for quality and quantity for the inspection of multiple carriers graded on a composite grade or average grade basis.

(b) * * *

(1) *Single grade.* When grain in a carrier(s) is/are offered for inspection as one lot and the grain is found to be uniform in condition, the grain must be sampled, inspected, graded, and certified as one lot. For the purpose of this paragraph, condition only includes the factors heating and odor.

(i) *Composite grade.* Grain loaded in multiple carriers offered for inspection may be combined into a single sample for grade analysis and certified as a single lot, *provided that* the grain in each individual carrier is inspected and found uniform in respect to odor, condition, and insect infestation, and sampling is performed at the individual loading location in a reasonably continuous operation. The maximum number of individual units that may be combined to form a composite grade analysis is 20 containers, 5 railcars, or 15 trucks. Composite analysis must be restricted to carriers inspected within the official service provider's area of responsibility.

(ii) *Average grade.* Grain loaded in multiple carriers offered for inspection may be graded individually, then averaged for certification as a single lot, *provided that:* the grain in each individual carrier is inspected and graded as an individual unit; the grain is found to be uniform in respect to odor, condition, and insect infestation; and sampling is performed at the individual loading location in a reasonably continuous operation. The maximum number of individual units that may be combined to form an average grade analysis is 20 containers, 5 railcars, or 15 trucks. Average grade analysis is restricted to carriers inspected within the official service provider's area of responsibility.

(2) *Multiple grade.* When grain in a carrier is offered for inspection as one lot and the grain is found to be not uniform in condition because portions of the grain are heating or have an odor, the grain in each portion will be sampled, inspected, and graded separately; but the results must be shown on one certificate. The certificate must show the approximate quantity or weight of each portion, the location of each portion in the carrier or container, and the grade of the grain in each portion. The requirements of this section are not applicable when an applicant requests that the grade of the entire carrier be based on a determination of heating or odor when only a portion of the carrier is found to be heating or have an odor.

* * * * *

(c) *One certificate per carrier: exceptions.* Except as provided in this paragraph, one official certificate must be issued for the inspection of the grain in each truck, trailer, truck/trailer(s) combination, container, railcar, barge, or similarly-sized carrier, or composite/average grade analysis on multiple carrier units. The requirements of this paragraph are not applicable:

* * * * *

4. Amend § 800.85 by revising paragraphs (b)(1), (c)(1), (c)(2), (h)(4), and (h)(5) to read as follows:

§ 800.85 Inspection of grain in combined lots.

* * * * *

(b) * * *

(1) *For inspection during loading, unloading, or at rest.* Applications for official inspection of grain as a combined lot must:

(i) Be filed in accordance with § 800.116;

(ii) Show the estimated quantity of grain that is to be certified as one lot;

(iii) Show the contract grade, and if applicable; other inspection criteria required by the contract; and

(iv) Identify each carrier into which grain is being loaded or from which grain is being unloaded.

* * * * *

(c) * * *

(1) *Inspection during loading, or unloading, or at rest.* Grain in two or more land carriers or barges that are to be officially inspected as a combined lot, must be sampled in a reasonably continuous operation. Representative samples must be obtained from the grain in each individual carrier and inspected in accordance with procedures as prescribed in the instructions.

(2) *Recertification.* Grain that has been officially inspected and certified as two or more single, composite, or average quality lots may be recertified as a combined lot provided that:

(i) The grain in each lot was sampled in a reasonably continuous operation;

(ii) The original inspection certificates issued for the single, composite, or average quality lots have been surrendered to official personnel;

(iii) Representative file samples of the single, composite, or average quality lots are available;

(iv) The grain in the single, composite, or average quality lots is of the same grade or better grade and quality than as specified in the written instructions provided by the shipper;

(v) Official personnel who performed the inspection service for the single, composite, or average quality lots and the official personnel who are to recertify the grain as a combined lot must determine that the samples used as a basis for the inspection of the grain in the single, composite, or average quality lots were representative at the time of sampling and have not changed in quality or condition; and

(vi) The quality or condition of the grain meets uniformity requirements established by the Service for official inspection of grain in combined lots.

* * * * *

(h) * * *

(4) *Combined-lot certification; general.* Each official certificate for a combined-lot inspection service must show the identification for the ''combined lot'' or, at the request of the applicant, the identification of each carrier in the combined lot. If the identification of each carrier is not shown, the statement ''Carrier identification available on the official work record'' must be shown on the inspection certificate in the space provided for remarks. The identification and any seal information for the carriers may be shown in the Remarks section on the reverse side of the inspection certificate, provided that the statement ''See reverse side'' is shown on the face of the certificate in the space provided for remarks, or on an additional page.

(5) *Recertification.* If a request for a combined-lot inspection service is filed after the grain has been officially inspected and certified as single, composite, or average quality lots, the combined-lot inspection certificate must show, in addition to the requirements of paragraph (h)(4) of this section the following:

(i) The date of inspection of the grain in the combined lot (if the single, composite, or average quality lots were inspected on different dates, the latest of the dates must be shown);

(ii) A serial number other than the serial numbers of the official inspection certificates that are to be superseded;

(iii) The location of the grain, if at rest, or the name(s) of the elevator(s) from which or into which the grain in the combined lot was loaded or unloaded;

(iv) A statement showing the approximate quantity of grain in the combined lot;

(v) A completed statement showing the identification of any superseded certificates; and

(vi) If at the time of issuing the combined-lot inspection certificate the superseded certificates are not in the custody of the official personnel, a statement indicating that the superseded certificates have not been surrendered must be clearly shown in the space provided for remarks. If the superseded certificates are in the custody of official personnel, the superseded certificates must be clearly marked ''Void.''

* * * * *

5. Amend § 800.97 by revising paragraphs (b)(1) and (c)(1) to read as follows:

§ 800.97 Weighing grain in containers, land carriers, barges, and shiplots.

* * * * *

(b) * * *

(1) *General.* If grain in a carrier is offered for inspection or weighing service as one lot, the grain must be weighed at the individual weighing location in a reasonably continuous operation and certified as one lot. The identification of the carrier(s) must be recorded on the scale tape or ticket and the weight certificate.

* * * * *

(c) *Certification of trucklots, containerlots, carlots, and bargelots.* (1) *Basic requirement.* One official certificate must be issued for the weighing of the grain in each container, truck, trailer, truck/trailer(s) combination, railroad car, barge, or similarly sized carrier. This requirement is not applicable to multiple grain carriers weighed as a single lot or combined lot under § 800.98.

* * * * *

6. Amend § 800.98 by revising paragraphs (b)(1), (b)(2), and (c)(2) to read as follows:

§ 800.98 Weighing grain in combined lots.

* * * * *

(b) * * *

(1) *Single lot weighing.* Single lots of grain that are to be weighed as a combined lot may be weighed at multiple locations, provided that the lots are contained in the same type of carrier and weighing is performed at each individual location in a reasonably continuous operation. The grain loaded into or unloaded from each carrier must be weighed in accordance with procedures prescribed in the instructions. In the case of sacked grain, a representative weight sample must be obtained from the grain in each carrier unless otherwise specified in the instructions.

(2) *Recertification.* Grain that has been weighed and certified as two or more single lots may be recertified as a combined lot, provided that the original weight certificates issued for the single lots have been or will be surrendered to the appropriate agency or field office, and the official personnel who performed the weighing service for the single lots and the official personnel who are to recertify the grain as a combined lot determine that the weight of the grain in the lots has not since changed, and in the case of sacked grain, that the weight samples used as a basis for weighing the single lots were representative at the time of the weighing.

* * * * *

(c) * * *

(2) *Recertification.* If a request for a combined-lot Class X or Class Y weighing service is filed after the grain in the single lots has been weighed and certified, the combined-lot weighing certificate must show the following:

(i) The date of weighing the grain in the combined lot (if the single lots were weighed on different dates, the latest dates must be shown);

(ii) A serial number, other than the serial numbers of the weight certificates that are to be superseded;

(iii) The name of the elevator(s) from which or into which the grain in the combined lot was loaded or unloaded;

(iv) A statement showing the weight of the grain in the combined lot;

(v) A completed statement showing the identification of any superseded certificate as follows: ''This combined-lot certificate supersedes certificate Nos. _____, dated _____; and

(vi) If at any time of issuing the combined-lot weight certificate, the superseded certificates are not in the custody of the agency or field office, the statement ''The superseded certificates identified herein have not been surrendered'' must be shown clearly in the space provided for remarks beneath the statement identifying the superseded certificates. If the superseded certificates are in the custody of the agency or field office, the superseded certificates must be clearly marked ''Void.''

* * * * *

7. Amend § 800.152 by revising paragraph (b) to read as follows:

§ 800.152 Maintenance and retention of file samples.

* * * * *

(b) *Minimum retention period.* Upon request by an agency and with the approval of the Service, specified file samples or classes of file samples may be retained for shorter periods of time.

Carrier	In	Out	Export	Other
(1) Trucks	3	5	30	.....
(2) Railcars	5	10	30	.....
(3) Ships & Barges	5	25	90	.....
(4) Ships and Barges (short voyage—5 days or less)	5	25	60	.....
(5) Containers	5	60	60	.....
(6) Bins & Tanks	.....	.....	.....	3
(7) Submitted Samples	.....	.....	.....	3

* * * * *

J. Dudley Butler,

Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 2011–17994 Filed 7–15–11; 8:45 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 930

[Doc. No. AMS–FV–11–0047; FV11–930–1 PR]

Tart Cherries Grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin; Suspension of Order Regulations Regarding Random Row Diversion

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule invites comments on changes to the grower diversion regulations prescribed under the marketing order for tart cherries (order). The order regulates the handling of tart cherries grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin and is administered locally by the Cherry Industry Administrative Board (Board). This rule would suspend indefinitely the regulations establishing random row as a method of grower diversion. With growers consistently choosing other diversion methods which offer more flexibility and fewer potential problems, the Board recommended this suspension to bring grower diversion requirements in line with current industry practices.

DATES: Comments must be received by July 28, 2011.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; *Fax:* (202) 720–8938; or *Internet: http://www.regulations.gov.* All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the Internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Jennie M. Varela, Marketing Specialist, or Christian D. Nissen, Regional Manager, Southeast Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; *Telephone:* (863) 324–3375, *Fax:* (863) 325–8793, or *E-mail: Jennie.Varela@ams.usda.gov* or *Christian.Nissen@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Laurel May, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; *Telephone:* (202) 720–2491, *Fax:* (202) 720–8938, or *E-mail: Laurel.May@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This proposal is issued under Marketing Agreement and Order No. 930, both as amended (7 CFR part 930), regulating the handling of tart cherries grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposed rule invites comments on changes to the grower diversion regulations prescribed under the order. This rule would suspend indefinitely the regulations establishing random row as a method of grower diversion. With growers consistently choosing other diversion methods which offer more flexibility and fewer potential problems, the Board recommended this suspension to bring grower diversion requirements in line with current industry practices. The Board unanimously recommended this action at a meeting on March 24, 2011.

Section 930.58 of the order provides authority for voluntary grower diversion. Under volume regulation, growers can divert all or a portion of their cherries which otherwise, upon delivery to a handler, would be subject to regulation. Section 930.158 prescribes the rules and regulations for grower diversion, including the procedures and deadline dates for applying for diversion and the types of diversion available to growers. Currently, there are four types of grower diversion: Random row, whole block, partial block, and in-orchard tank. This rule would suspend portions of § 930.158 that provide random row as an option under grower diversion.

The order contains volume control provisions that allow the industry to address fluctuations in production from season to season, helping to stabilize supplies and prices. When volume control is in effect, free and restricted percentages are established. Handlers can meet their restricted percentage obligation by placing cherries in inventory reserve, diverting cherries themselves, or redeeming grower diversion certificates.

Under voluntary grower diversion, growers can divert cherries from production in exchange for Board issued grower diversion certificates stating the quantity diverted. Growers can then present these certificates to handlers who may redeem them as a method of complying with their restricted percentage obligation under volume regulation. By diverting cherries from production, growers can avoid the costs of harvesting and transporting fruit, reduce the supply, and mitigate the downward pressure on prices that result from oversupply.

Following the promulgation of the order in 1996, the Board recommended regulations outlining two grower diversion options for the 1997 crop year, whole block and random row (63 FR 20019). Under whole block diversion, growers select entire orchard blocks to be left unharvested. With random row diversion, the Board randomly selects

rows of trees the grower is to leave unharvested, providing growers with a way to divert a portion of an orchard rather than a whole orchard block.

For the 1998 crop year and subsequent seasons, the grower diversion program was expanded to include two additional options, partial block and in-orchard tank diversions (63 FR 33523). Partial block diversion allows the grower to select a contiguous portion of an orchard block that will be left unharvested. With in-orchard tank diversion, cherries are harvested into tanks, the volume is calculated, and then diverted in the orchard.

The addition of these options provided growers with greater flexibility when considering diversion, and marked a substantial decline in the use of random row. For the last ten years, random row has been the least utilized grower diversion option, and accounted for less than three percent of total grower diversion during the last three seasons.

During the discussion of this issue, the Board noted several issues that have contributed to the nominal use of random row as a grower diversion option. Random row diversion is the least flexible of grower diversion options in terms of quality control. When a grower selects a whole block or partial block to divert, the grower controls which fruit will be harvested and which trees will be left unharvested. Similarly, under in-orchard tank diversion, the grower determines what fruit is picked and stored in the tanks for diversion. Consequently, these three methods allow the grower to incorporate quality into the decision of which cherries to divert. Delivering higher quality fruit not only brings the grower a greater return, but higher quality benefits the industry overall.

Under the random row method of diversion, the diverted rows are selected randomly by the Board. This could result in the best quality fruit being left in the orchard, with lower quality fruit delivered to handlers, leading to lower grower returns.

In addition to quality concerns, the logistics of random row also present particular challenges to the grower. With the exception of in-orchard tank diversion, all grower diversion methods require the grower to submit an orchard map to the Board. The burden of having to keep orchard maps precisely up-to-date is borne by growers. The random selection of rows by the Board places additional importance on the accuracy and precision of submitted maps. Inaccurate maps can lead to harvesting errors, with rows selected for diversion being inadvertently harvested.

Even if maps are kept current, diverting random rows during harvest can be challenging. While whole and partial block diversions allow growers to leave contiguous areas unharvested, random row diversions require that specified rows be left unharvested, increasing the likelihood of error. Further, given the prevalence of contract harvesting, workers are often unfamiliar with the groves they are harvesting, and mistakes are made in identifying the specific rows to be left unharvested.

The greater potential for error during harvesting is of major concern to growers because penalties for errors in random row diversion are costly. If a grower discovers an error during harvest, two trees must be left unharvested for every one of the trees improperly harvested in order to remain in compliance, with the grower only receiving the original diversion amount. If the grower reports an error at the end of harvesting, a reduced diversion amount is calculated. If an unreported error is discovered by the Board after harvesting is complete, no diversion certificate would be issued.

In addition to the issues affecting grower interest in this option, the Board also has concerns regarding the use of random row diversion. Specifically, the Board is concerned about the potential for miscalculations or misuse that could lead to overstated diversion amounts. Random row diversion differs from the other options in that the diverted tonnage receiving certificates is calculated based on volume delivered from the orchard. In contrast, whole and partial block diversions involve sampling trees in the selected area to determine the volume being diverted before harvest takes place, and in-orchard tank diversion is determined by the actual volume measured in the tanks.

Calculating the diverted volume after delivery creates opportunity for error. It can be difficult to determine if the volume delivered to the handler all came from appropriately mapped groves, included in the grower's diversion application. With diversion calculations based on delivered volume, it is important that the volume only include cherries from those orchards in which random rows were diverted. Some growers care for and deliver fruit from orchards other than their own. There is concern that the handler accepting delivery could easily mistake how much volume came from the grower's own mapped orchards, resulting in the overstatement of the amount diverted.

With the availability of other diversion options that offer the grower more flexibility and less potential problems, random row represents a very small percentage of total grower diversion. Further, with the higher potential for harvesting errors and for miscalculations of diversion amounts, the Board believes random row is the most problematic of the diversion options. Consequently, the Board unanimously recommended this action which would suspend the regulations providing random row as a grower diversion option. The Board voted to suspend the regulations rather than eliminating them altogether in the event the industry would want to reinstate random row diversion in the future.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 40 handlers of tart cherries who are subject to regulation under the marketing order and approximately 600 producers of tart cherries in the regulated area. Small agricultural service firms have been defined by the Small Business Administration (SBA) as those having annual receipts of less than $7,000,000, and small agricultural producers are defined as those having annual receipts of less than $750,000 (13 CFR 121.201).

According to the National Agricultural Statistics Service, and Board data, the average annual grower price for tart cherries during the 2009–2010 season was $0.197 per pound, and total shipments were around 227 million pounds. Therefore, average receipts for tart cherry producers were around $75,000, well below the SBA threshold for small producers. The Food Institute estimates an f.o.b. price of $0.84 per pound for frozen tart cherries, which make up the majority of processed tart cherries. Using this data, average annual handler receipts were about $4.8 million, also below the SBA threshold for small agricultural service

firms. Assuming a normal distribution, the majority of producers and handlers of tart cherries may be classified as small entities.

This action would change the grower diversion regulations prescribed under the order. This rule would suspend indefinitely the regulations in § 930.158 establishing random row as a method of grower diversion. With growers consistently choosing other diversion methods which offer more flexibility and fewer potential problems, the Board recommended this suspension to bring grower diversion requirements in line with current industry practices. The authority for this action is provided for in § 930.58 of the order. The Board unanimously recommended this action at a meeting on March 24, 2011.

This proposed rule would not impose any additional costs on growers. The grower diversion program under the order is completely voluntary. In an effort to stabilize supplies and prices, the tart cherry industry uses mechanisms under the order to attempt to bring supply and demand into balance. Under voluntary grower diversion, growers can divert cherries from production in exchange for Board issued grower diversion certificates stating the quantity diverted. Growers can then present these certificates to handlers who may redeem them as a method of complying with their restricted percentage obligation under volume regulation. By diverting cherries from production, growers can avoid the costs of harvesting and transporting fruit, reduce the supply, and mitigate the downward pressure on prices that result from oversupply.

This action would only suspend the regulations that provide random row as a method of grower diversion. The other three options, whole lot, partial block, and in-orchard tank, would remain unchanged by this action. Random row is the least utilized of the grower diversion options, with the other three options accounting for 97 percent of diversion volume. Consequently, this change would bring the regulations in line with current industry preferences and practices. Further, the remaining grower diversion options offer the grower some flexibility to control quality, which in turn could increase grower returns. The effects of this rule are not expected to be disproportionately greater or less for small entities than for larger entities.

One alternative action considered by the Board was to remove the regulations pertaining to random row diversion. However, the Board agreed that suspension would be the most appropriate action should the industry determine it would like to reinstate random row as a diversion option in the future. Thus, termination was rejected as an alternative.

This rule would not impose any additional reporting or recordkeeping requirements on either small or large tart cherry handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this proposed rule.

In addition, the Board's meeting was widely publicized throughout the tart cherry industry and all interested persons were invited to attend the meeting and participate in Board deliberations on all issues. Like all Board meetings, the March 24, 2011, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/MarketingOrdersSmallBusinessGuide.* Any questions about the compliance guide should be sent to Laurel May at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A ten-day comment period is provided to allow interested persons to respond to this proposal. Ten days is deemed appropriate because the 2011–12 tart cherry crop harvest will begin in mid to late July 2011. Also, growers need to make their determinations as to grower diversion prior to harvest. Further, growers and handlers are aware of this action, which was unanimously recommended by the Board at a public meeting on March 24, 2011. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 930

Marketing agreements, Reporting and recordkeeping requirements, Tart cherries.

For the reasons set forth in the preamble, 7 CFR part 930 is proposed to be amended as follows:

PART 930—TART CHERRIES GROWN IN MICHIGAN, NEW YORK, PENNSYLVANIA, OREGON, UTAH, WASHINGTON, AND WISCONSIN

1. The authority citation for 7 CFR part 930 continues to read as follows:

Authority: 7 U.S.C. 601–674.

§ 930.158 [Amended]

2. In § 930.158:

A. Suspend paragraph (b)(1) indefinitely.

B. In paragraph (c)(3), redesignate the first two sentences as paragraph (c)(3)(i) and the remaining sentences as paragraph (c)(3)(ii).

C. Newly redesignated paragraph (c)(3)(ii) is suspended indefinitely.

Dated: July 12, 2011.

Rayne Pegg,

Administrator, Agricultural Marketing Service.

[FR Doc. 2011–17883 Filed 7–15–11; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

[NRC–2011–0162]

Consideration of Rulemaking To Address Prompt Remediation of Residual Radioactivity During Operations

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of public Webinar and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (Commission or NRC) is seeking input from the public, licensees, Agreement States, non-Agreement States, and other stakeholders on a potential rulemaking to address prompt remediation of residual radioactivity during the operational phase of licensed material sites and nuclear reactors. The NRC has not initiated a rulemaking, but is in the process of gathering information and seeking stakeholder input on this subject for developing a technical basis document. To aid in this process, the NRC is requesting comments on the issues discussed in Section III, ''Specific Questions,'' in the Supplementary Information Section of this document. Additionally, the NRC will hold a public Webinar to facilitate the public's and other stakeholders'

understanding of these issues and the submission of comments.

DATES: The public Webinar will be held in Rockville, Maryland on July 25, 2011, from 1 p.m. to 5 p.m. (EDT). Submit comments on the issues discussed in this document by September 16, 2011. Comments received after this date will be considered if it is practical to do so.

ADDRESSES: Please include Docket ID NRC–2011–0162 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed. You may submit comments by any one of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2011–0162. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668, e-mail: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

You can access publicly available documents related to this notice using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.* The Draft Proposed Technical Basis is available electronically under ADAMS Accession Number ML111580353.
- *Federal Rulemaking Web site:* Public comments and supporting materials related to this notice can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0162.

FOR FURTHER INFORMATION CONTACT: Mr. Chad Glenn, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6722; email: *chad.glenn@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRC recently published the Decommissioning Planning Rule (DPR) (76 FR 33512; June 17, 2011). The DPR applies to the operational phase of a licensed facility, and requires licensees to operate in a way to minimize spills, leaks, and other unplanned releases of radioactive contaminants into the environment. It also requires licensees to check periodically for radiological contamination throughout the site, including subsurface soil and groundwater. The DPR does not have a mandatory requirement for licensees to conduct radiological remediation during operations. Within the Staff Requirements Memorandum (SRM), SRM–SECY–07–0177 (ADAMS Accession No. ML073440549), that approved the proposed DPR, the Commission directed the staff to ''make further improvements to the decommissioning planning process by addressing remediation of residual radioactivity during the operational phase with the objective of avoiding complex decommissioning challenges that can lead to legacy sites.'' Therefore, the NRC staff is considering a potential rulemaking requiring prompt remediation during operations, and has begun gathering information pertinent to its considerations.

II. Discussion

Currently, there are no NRC regulations that require licensees to promptly remediate radiological contamination. To enhance stakeholder engagement in developing a technical basis as a precursor to a proposed rule, the NRC staff developed a Draft Proposed Technical Basis to facilitate discussion with, and to solicit input from, interested stakeholders. The Draft Proposed Technical Basis describes the NRC's preferred approach as a rulemaking to require licensees to promptly remediate radioactive spills and leaks when certain threshold limits are met. NRC's preferred approach contemplates using the NRC screening values for soil and the U.S. Environmental Protection Agency (EPA) maximum contamination levels for groundwater as the threshold limits. The preferred approach would also include a provision allowing licensees to delay remediation when certain conditions are met. To justify a delayed remediation, licensees would be required to perform analyses such as dose assessment, risk-assessments and/or cost-benefit analyses for the NRC's review.

In addition to the preferred approach, the NRC staff considered the following as alternative frameworks for requiring prompt remediation during operations:

(1) Issuing a regulation that would require licensees to conduct prompt remediation of a spill or leak when certain contaminant thresholds, such as the restricted release limits in Title 10 of the *Code of Federal Regulations* (10 CFR), § 20.1403, are exceeded. Unlike the preferred approach, this alternative would not provide the licensee with the opportunity to conduct an analysis to justify delayed remediation.

(2) Issuing site-specific license conditions requiring timely remediation following identification of contamination above some specified volume or concentration.

(3) Issuing new guidance in the form of a NUREG.

(4) No action (i.e., the NRC staff would rely on existing regulations and guidance documents to encourage licensees to consider prompt remediation after spills or leaks).

For more information on the preferred approach and alternatives, please refer to the Draft Proposed Technical Basis (ML111580353).

III. Specific Questions

To assist the NRC in developing a comprehensive technical basis document for a potential rulemaking requiring prompt remediation, the NRC is seeking stakeholder input on the following questions:

1. Should the NRC conduct rulemaking to address remediation of residual radioactivity during the operational phase? Why or why not?

2. If the NRC implements a rule that requires prompt remediation of radioactive spills and leaks, what

concentration, dose limits, or other threshold limits should trigger prompt remediation? Should the thresholds differ for soil versus groundwater contamination? For example, should the NRC screening criteria be used to establish threshold levels for soil contamination? Should the EPA's maximum contaminant levels be used for drinking water?

3. Should the NRC allow licensees to justify delaying remediation under certain conditions when the contaminant level exceeds the threshold limit? If yes, then what conditions should be used to justify a delayed remediation?

4. Should factors such as safety, operational impact, and cost be a basis for delaying remediation?

5. If the NRC implements a rule that allows licensees to analyze residual radioactivity to justify delaying remediation, then what should the licensee's analysis cover? For example, what kind of dose assessment, risk-assessments and/or cost-benefit analyses should be performed to justify delayed remediation? What other types of analyses are relevant?

6. If the NRC implements a rule that allows licensees to analyze residual radioactivity to justify delaying remediation, what role should the cost of prompt remediation versus remediation at the time of decommissioning play in the analysis?

7. If the NRC implements a rule that allows licensees to analyze residual radioactivity to justify delaying remediation, what standards or criteria should a licensee use to demonstrate to the NRC that a sufficient justification to delay remediation has been met?

8. Are there any other alternatives beyond those discussed in the Draft Proposed Technical Basis document that the NRC should have considered to address prompt remediation?

9. What other issues should the NRC staff consider in developing a technical basis for a rulemaking to address prompt remediation of residual radioactivity during site operations?

IV. Public Webinar

To facilitate the understanding of the public and other stakeholders of these issues and the submission of comments, the NRC staff has scheduled a public Webinar, from 1 p.m. to 5 p.m. (EDT). Webinar participants will be able to view the presentation slides prepared by the NRC and electronically submit comments over the Internet. Participants must register to participate in the Webinar. Registration information may be found in the meeting notice (ML111780802). The meeting notice can also be accessed through the NRC's public Web site under the headings Public Meetings & Involvement > Public Meeting Schedule; see Web page *http://www.nrc.gov/public-involve/public-meetings/index.cfm.* Additionally, the final agenda for the public Webinar and the Draft Proposed Technical Basis document will be posted no fewer than 10 days prior to the Webinar at this Web site. Those who are unable to participate via Webinar may also participate via teleconference. For details on how to participate via teleconference, please contact Sarah Achten; telephone: 301–415–6009; email: *sarah.achten@nrc.gov* or T.R. Rowe; telephone: 301–415–8008; email: *t.rowe@nrc.gov.*

Dated at Rockville, Maryland, this 8th day of July 2011.

For the Nuclear Regulatory Commission.

Keith I. McConnell,

Deputy Director, Decommissioning and Uranium Recovery, Licensing Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2011–17913 Filed 7–15–11; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–126519–11]

RIN 1545–BK41

Determining the Amount of Taxes Paid for Purposes of the Foreign Tax Credit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section in this issue of the **Federal Register**, the IRS is issuing temporary regulations that provide guidance relating to the determination of the amount of taxes paid for purposes of the foreign tax credit. These regulations address certain highly structured arrangements that produce inappropriate foreign tax credit results. The text of those temporary regulations published in this issue of the **Federal Register** also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by October 17, 2011.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG–126519–11), room 5205, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–126519–11), Courier's desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20044, or sent electronically, via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–126519–11).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Jeffrey P. Cowan, (202) 622–3850; concerning submissions of comments or a request for a public hearing, Oluwafunmilayo Taylor at (202) 622–7180.

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** contain amendments to the Income Tax Regulations (26 CFR part 1) which provide rules relating to the determination of the amount of taxes paid for purposes of the foreign tax credit. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations. The regulations affect individuals and corporations that claim direct and indirect foreign tax credits.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f), these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any electronic or written comments (a

signed original and eight (8) copies) that are submitted timely to the IRS. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person who timely submitted written comments. If a public hearing is scheduled, notice of the date, time, and place of the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Jeffrey P. Cowan of the Office of Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.901–2 is amended by revising paragraphs (e)(5)(iii) and (iv) and adding paragraph (h)(3) to read as follows:

§ 1.901–2 Income, war profits, or excess profits tax paid or accrued.

* * * * *

(e) * * *

(5) * * *

(iii) through (iv)(B)(*1*)(*ii*) [The text of proposed § 1.901–2(e)(5)(iv)(B)(*1*)(*iii*) through (iv)(B)(*1*)(*ii*) is the same as the text of § 1.901–2T(e)(5)(iv)(B)(*1*)(*iii*) through (iv)(B)(*1*)(*ii*) published elsewhere in this issue of the **Federal Register.**]

(*iii*) [The text of proposed § 1.901–2(e)(5)(iv)(B)(*1*)(*iii*) is the same as the text of § 1.901–2T(e)(5)(iv)(B)(*1*)(*iii*) published elsewhere in this issue of the **Federal Register.**]

* * * * *

(h) * * *

(3) [The text of proposed § 1.901–2(h)(3) is the same as the text of § 1.901–2T(h)(3) published elsewhere in this issue of the **Federal Register**.]

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2011–17919 Filed 7–14–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AN33

Claim-Related Documents or Supporting Evidence Not of Record

AGENCY: Department of Veterans Affairs.

ACTION: Withdrawal of proposed rule.

SUMMARY: In a document published in the **Federal Register** on November 12, 2009, the Department of Veterans Affairs (VA) proposed to add a new section to its adjudication regulations to establish temporary VA procedures for when claimants allege the submission of claim-related documents or evidence in support of a claim during the time period of April 14, 2007, through October 14, 2008, when such documents or evidence are not of record in the official VA file.

DATES: The proposed rule published at 74 FR 58232 on November 12, 2009, is withdrawn as of July 18, 2011.

FOR FURTHER INFORMATION CONTACT: Thomas J. Kniffen, Chief, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–9725. You may also request further information regarding this rulemaking at *CPRULEANDCOSTQUESTIONS.vbaco@va.gov*

SUPPLEMENTARY INFORMATION: In response to Department of Veterans Affairs (VA) Office of Inspector General (OIG) audit findings of improper document handling and control, dated August 20, 2008, the Secretary of Veterans Affairs suspended all document-shredding activities effective October 14, 2008, and provided temporary claims-handling and document control procedures to all regional office (RO) personnel regarding veterans who allege that they submitted claim-related documents or evidence in support of a claim between April 14, 2007, through October 14, 2008, that are not of record in official VA files. The proposed rulemaking was initiated to codify the temporary claims-handling and document control procedures established by the Secretary.

Since October 14, 2008, VA has consistently conformed to scrupulous nationwide document control procedures established by the Secretary. Additionally, new claims-handling procedures were implemented to handle submissions that may have occurred within the time period August 14, 2007, through October 14, 2008. These special procedures relaxed certain administrative claim submission requirements for claimants who asserted that they had submitted a claim or evidence during that period.

Specifically, procedures called for VA regional office personnel to recognize a claimant's or representative's assertion that a claim and/or supporting evidence had been previously submitted to VA during the 18-month window from April 14, 2007, to October 14, 2008. The procedures stated that VA would consider such a claim and/or evidence as though the claim and/or evidence was received on the date asserted by the claimant. The procedures provided specific instructions to VA regional office personnel on how to handle assertions of previously filed claims and/or evidence in favor of claimants where: (1) There was no record that the claim was received by VA, (2) VA adjudicated the claim based on a resubmission at a later date (i.e., a duplicate claim) because the first submittal was not retained, or (3) the claim was considered by VA based on an incomplete record because the supporting evidence or information was not added to the record. VA accordingly established effective dates or readjudicated claims based on claimants' assertions of previously filed claims and/or evidence during the 18-month period. The relaxed procedures were developed to ameliorate any loss of claims, information, or evidence that may have occurred as a result of inappropriate document disposal in VA regional offices during that period.

VA believes that it has addressed all allegations of document or evidence submissions from claimants who may have been affected by improper document handling and control during the period April 14, 2007, through October 14, 2008, and that VA is unlikely to receive any additional allegations of submissions during that time period. As we explained in the preamble to the notice of proposed rulemaking, if a submitted claim-related document or evidence is not of record in official VA files, a ''veteran reasonably would have inquired about the document submission or would have been informed of its misplacement or destruction within 18 months from the asserted date of submission.'' 74 FR 58232 (Nov. 12, 2009). Because it has been over 30 months since October 2008, we do not anticipate any new allegations of submissions during the time period April 2007 to October 2008. Additionally, the notice of proposed rulemaking, published in November 2009, informed the public, including

claimants and veterans service organizations, that VA had established temporary claims-handling procedures for claimants who allege that they submitted a claim-related document or evidence during the aforementioned time period that was not of record in official VA files. Furthermore, it is VA's general policy that any claimant can assert at any time that VA misplaced or inadvertently destroyed documents and that VA will take appropriate action under existing procedures. Therefore, upon further study we have determined that this rulemaking is unnecessary. VA is withdrawing the proposed rule as it is no longer required.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on June 9, 2011, for publication.

Dated: July 13, 2011.

Robert C. McFetridge,

Director, Office of Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

[FR Doc. 2011–17959 Filed 7–15–11; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2005–TX–0025; FRL–9439–7]

Approval and Promulgation of Implementation Plans; Texas; Revisions to the New Source Review (NSR) State Implementation Plan (SIP); General Definitions; Definition of Modification of Existing Facility

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; Proposed withdrawal of prior proposed disapproval.

SUMMARY: EPA is proposing to approve revisions to the applicable State Implementation Plan (SIP) for the State of Texas that relate to severable portions of the definition of ''modification of existing facility'' in the general definitions for the Texas NSR Program. EPA proposes to find that these changes to the Texas SIP comply with the Federal Clean Air Act (the Act or CAA) and EPA regulations, and are consistent with EPA policies. EPA is also proposing to withdraw an action proposed on September 23, 2009, regarding two provisions that have been superseded by later submitted revisions. EPA is taking this action under section 110 of the Act.

DATES: Comments must be received on or before August 17, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R06–OAR–2005–TX–0025 by one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

(2) *E-mail:* Mr. Stanley M. Spruiell at *spruiell.stanley@epa.gov.*

(3) U.S. EPA Region 6 ''Contact Us'' Web site: *http://epa.gov/region6/r6coment.htm.* Please click on ''6PD'' (Multimedia) and select ''Air'' before submitting comments.

(4) *Fax:* Mr. Stanley M. Spruiell, Air Permits Section (6PD–R), at fax number 214–665–6762.

(5) *Mail:* Mr. Stanley M. Spruiell, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

(6) *Hand or Courier Delivery:* Mr. Stanley M. Spruiell, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Such deliveries are accepted only between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R06–OAR–2005–TX–0025. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means that EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. The file will be made available by appointment for public inspection in the Region 6 Freedom of Information Act Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below or Mr. Bill Deese at (214) 665–7253 to make an appointment. If possible, please make the appointment at least two working days in advance of your visit. There will be a 15 cent per page fee for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area at 1445 Ross Avenue, Suite 700, Dallas, Texas.

The State submittals, which are part of the EPA docket, are also available for public inspection at the State Air Agency during official business hours by appointment: Texas Commission on Environmental Quality (TCEQ), Office of Air Quality, 12124 Park 35 Circle, Austin, Texas 78753.

FOR FURTHER INFORMATION CONTACT: Mr. Stanley M. Spruiell, Air Permits Section (6PD–R), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone (214) 665–7212; fax number (214) 665–6762; e-mail address *spruiell.stanley@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever

any reference to ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Table of Contents

I. The State's Submittals

On March 13, 1996; July 22, 1998; and September 4, 2002; the State of Texas submitted revisions to the Texas State Implementation Plan (SIP) concerning the definition of ''modification of existing facility'' for minor source permitting under Title 30 of the Texas Administrative Code (30 TAC), Chapter 116—Control of Air Pollution by Permits for New Construction or Modification, Subchapter A—Definitions. The definition of ''modification of existing facility'' is located at 30 TAC 116.10(11) in the September 4, 2002 submittal. The March 13, 1996, revisions to this definition were repealed and readopted, and new versions were submitted to EPA on July 22, 1998. This definition was later recodified from 30 TAC 116.10(9) to 116.10(11) in a SIP submittal dated September 4, 2002.

Section 30 TAC 116.10—General Definitions—is currently approved as adopted by Texas on August 21, 2002, and as approved April 14, 2010 (75 FR 19468). As approved, the current SIP does not include all the definitions under Section 116.10, including the definition of ''modification of existing facility'' found in Section 116.10(11). Today, we propose to approve the portions of this definition first adopted by Texas on February 14, 1996 (submitted March 13, 1996). The next submittal reflects the Texas repeal and readoption of this definition as Section 116.10(9) on June 17, 1998 (submitted July 22, 1998). The regulatory history of the March 13, 1996 submittal was used to evaluate the later submittals. We propose to approve the definition ''modification of existing facility'' as submitted on July 22, 1998, and the redesignation of this definition to Section 116.10(11) adopted August 21, 2002 (submitted September 4, 2002). We also propose to approve Subparagraphs (C) and (D) of this definition as submitted July 22, 1998, and September 4, 2002.

Finally, please note that Texas submitted further revisions to 30 TAC 116.10 on October 5, 2010. This includes the removal of two definitions, the renumbering of other definitions, and revisions to certain definitions. In this October 2010 submittal, TCEQ renumbered the definition of ''modification of existing facility'' to Section 116.10(9) and relettered Subparagraphs (C) and (D) to Subparagraphs (B) and (C), respectively, with no other changes. We are not proposing action on the October 5, 2010, SIP submittal here. We will address the October 2010 SIP revisions in a separate action.

Additional information related to these SIP submittals is contained in the Technical Support Document (TSD), which is in the docket for this action.

The table below summarizes the changes that were submitted and are affected by this action. A summary of EPA's evaluation of each section and the basis for this proposal is discussed in section III of this preamble. The TSD includes a detailed evaluation of the referenced SIP submittals.

Section	Title	Date submitted	Date adopted by the State	Comments
30 TAC 116.10(11)	Definition of modification of existing facility—Introductory paragraph.	3/13/1996	2/14/1996	Initial adoption.
		7/22/1998	6/17/1998	Repeal and readoption as Section 116.10(9).
		9/4/2002	8/21/2002	Recodification to Section 116.10(11).
30 TAC 116.10(11)(C)	Exclusion of maintenance or replacement of equipment.	3/13/1996	2/14/1996	Initial adoption.
		7/22/1998	6/17/1998	Repeal and readoption as Section 116.10(9)(C).
		9/4/2002	8/21/2002	Recodification to Section 116.10(11)(C).
30 TAC 116.10(11)(D)	Exclusion of increase in annual hours of operation.	12/15/1995	11/16/1995	Initial adoption.
		7/22/1998	6/17/1998	Repeal and readoption as Section 116.10(9)(D).
		9/4/2002	8/21/2002	Recodification to Section 116.10(11)(D).

On September 23, 2009 (74 FR 48450), EPA proposed to disapprove 30 TAC 116.10(11)(A) and (B). In a separate SIP revision submitted October 5, 2010, Texas revised 30 TAC 116.10(11)(A) and repealed 30 TAC 116.10(11)(B).

As noted in the original proposed action on Subparagraphs (A) and (B), the two Subparagraphs are not severable from each other. 74 FR 48450, at 48452. The two provisions were considered in conjunction with each other as our basis of evaluation in the original proposal. Because (B) is now repealed and the wording of (A) has been changed in a later submitted revision, the basis of evaluation in the original proposed action has changed. EPA therefore proposes to withdraw its previously proposed action so that the submitted revised Subparagraph (A) and the impact of the repeal of Subparagraph (B) upon the revised Subparagraph (A) may be addressed in a future separate action.

This course of action will promote efficiency, mitigate confusion, and facilitate new comments on the future proposed action on the October 5, 2010 submittal with a proper basis of evaluation. Given the need for comments and evaluation of the newly submitted regulatory wording changes to Subparagraph (A), EPA considers any established deadline under the *Business Coalition for Clean Air Appeal Group (BCCA)* Settlement Agreement to be inapplicable with respect to this provision.[1]

The repeal of Subparagraph (B) in the October 2010 SIP submittal also renders moot and inapplicable any obligation to act on that provision under the BCCA Settlement Agreement. Because Subparagraph (B) was repealed and is no longer before EPA for action, no further action is needed on this provision. Consequently, EPA now proposes to withdraw its previously proposed action on Subparagraph (B).

II. What action is EPA proposing to take?

We have evaluated severable portions of the SIP submissions of 30 TAC 116.10(11), which include the introductory paragraph of the definition of ''modification of existing facility,'' and Subparagraphs (C) and (D) of that definition for consistency with the CAA, NSR regulations for new and modified sources in 40 CFR Part 51, and the approved Texas SIP. We have also reviewed the rules for enforceability and legal sufficiency.

This action addresses severable portions of the definition of modification of existing facility under 30 TAC 116.10(11), including the introductory paragraph and Subparagraphs (C) and (D) of the definition submitted March 13, 1996; July 22, 1998; and September 4, 2002. A technical analysis of the submittals for this definition has found that these changes meet the CAA and 40 CFR Part 51 and are consistent with EPA policies. Therefore, EPA proposes to approve the severable portions of the definition of ''modification of existing facility'' under 30 TAC 116.10(11), including the introductory paragraph of Section 116.10(11) and Subparagraphs (C) and (D) of this definition, submitted on March 13, 1996; July 22, 1998; and September 4, 2002. As discussed earlier, in a separate SIP submittal dated October 5, 2010, 30 TAC 116.10(11) and Subparagraphs, (C), and (D) were renamed as 30 TAC 116.10(9) and Subparagraphs (B) and (C), respectively. EPA is not proposing action on the changes submitted October 2010, and will address these revisions in a separate action.

In a separate action on September 23, 2009, 74 FR 48450, EPA proposed to disapprove severable provisions in Subparagraphs (A), (B), and (G) of the definition ''modification of existing facility.'' EPA is currently reviewing the proposal on Subparagraph (G) and will take action on this proposal in the future. In light of revisions that were submitted on October 5, 2010, revising the language of Subparagraph (A) and eliminating Subparagraph (B), EPA is proposing to withdraw its proposed actions on Subparagraphs (A) and (B). Subparagraph (A) as it appears in the October 5, 2010 submittal will be evaluated and will be addressed in a separate future action.

III. EPA's Evaluation of Severable Portions of the Definition of ''Modification of Existing Facility''

A. Section 30 TAC 116.10(11)—Introductory Paragraph of the Definition of ''Modification of Existing Facility''

1. What is the background of the introductory paragraph of 30 TAC 116.10(11)?

The TCEQ initially submitted the introductory paragraph of the general definition of ''modification of existing facility'' on March 13, 1996. On July 22, 1998, TCEQ repealed and resubmitted this definition as readopted at 30 TAC 116.10(9). On September 4, 2002, TCEQ submitted revisions that redesignated this definition to 30 TAC 116.10(11). The submitted regulatory definition of the introductory paragraph that we are addressing here provides:

> (11) Modification of existing facility—Any physical change in, or change in the method of operation of, a facility in a manner that increases the amount of air contaminants emitted by the facility into the atmosphere or which results in the emission of any air contaminant not previously emitted. * * *

2. What Is EPA's evaluation of the submitted revisions to the introductory paragraph of 30 TAC 116.10(11)?

EPA approved the definition of ''facility'' in Subchapter A: Definitions on September 6, 2006 (71 FR 52698) as part of the Texas SIP. ''Facility'' is defined as ''A discrete or identifiable structure, device, item, equipment, or enclosure that constitutes or contains a stationary source, including appurtenances other than emission control equipment. A mine, quarry, well test, or road is not a facility.'' See approved SIP at 30 TAC 116.10(6). The submitted regulatory definition for ''modification of existing facility'' also is in Subchapter A, Section 116.10. Therefore, ''existing facility'' is limited by the terms of the SIP definition of ''facility.'' In our evaluation of this introductory paragraph in the submitted regulatory definition of modification of existing facility, we compared it to how ''modification'' is defined in the CAA and in our regulations.

The CAA defines modification in Section 111(a)(4) as:

> (4) The term ''modification'' means any physical change in, or change in the method of operation of, a stationary source which increases the amount of any air pollutant emitted by such source or which results in the emission of any pollutant not previously emitted.

In 40 CFR 52.01(d), the phrases ''modification'' and ''modified source'' are defined as any physical change in, or change in the method of operation of, a stationary source which increases the emission rate of any air pollutant for which a national standard has been promulgated under part 50 of this chapter or which results in the emission of any such pollutant not previously emitted.

The introductory paragraph of 30 TAC 116.10(11) is substantially the same as the definitions in section 111(a)(4) of the Act and 40 CFR 52.01(d).

The existence of a similar definition for ''major modification,'' in Section 116.12—Nonattainment and Prevention of Significant Review Definitions—that is applicable for Major NSR[2] serves to distinguish the provisions in the introductory paragraph from the Major NSR Program and limit its application to Minor NSR.

We are proposing to approve the introductory paragraph of 30 TAC 116.10(11), as submitted March 13, 1996; July 22, 1998; and September 4, 2002.

[1] Under a Settlement Agreement for a lawsuit *Business Coalition for Clean Air Appeal Group* v. *EPA,* Case No. 3–08CV1791–G, EPA must take final action on the NSR Rules Revisions submitted March 13, 1996; July 22, 1998; and September 4, 2002 by October 31, 2011. If today's proposed action is finalized by October 31, 2011, it will satisfy this deadline. Under § 110(k)(2) of the Clean Air Act, EPA must take final action on the revisions submitted October 5, 2010, no later than April 5, 2012.

[2] Section 116.12 as currently approved in the Texas SIP applies only to the Major NSR Program for Nonattainment Review. SIP revisions submitted February 1, 2006, and March 11, 2011, revised the definition to apply to both Nonattainment Review and Prevention of Significant Deterioration. EPA is currently reviewing these revisions and plans to act upon them shortly. The definitions in Section 116.12 are effective as State rules and the TCEQ implements them as part of its Major NSR Program.

B. Section 30 TAC 116.10(11)(C)—Exclusion for Maintenance and Replacement of Equipment

1. What is the background for 30 TAC 116.10(11)(C)?

On March 13, 1996, this provision was submitted as Subparagraph (C) under the definition of ''modification of existing facility.'' In the July 22, 1998, submittal, the provision was repealed and resubmitted as 30 TAC 116.10(9)(C). On September 4, 2002, TCEQ submitted revisions that redesignated this definition to 30 TAC 116.10(11)(C). As submitted, Subparagraph (C) provides that the following is not a modification to an existing facility:

(C) Maintenance or replacement of equipment components that do not increase or tend to increase the amount or change the characteristics of the air contaminants emitted into the atmosphere;

2. What is EPA's evaluation of the submitted revisions to 30 TAC 116.10(11)(C)?

The submitted Subparagraph (C) mirrors the definition in the Texas Clean Air Act (TCAA). EPA approved this statutory provision into the Texas SIP on May 31, 1972 (37 FR 10896). Under Subparagraph (C), any maintenance and repair of equipment components that increases emissions, or tends to increase emissions, will be considered a modification consistent with the introductory paragraph of 30 TAC 116.10(11). Accordingly, the limitation in Subparagraph (C) protects against increases in emissions and thereby does not interfere with attainment or reasonable further progress. The definition of ''major modification'' in Section 116.12 has a similarly protective, but different, exclusion for routine maintenance, repair, and replacement. The existence of a similar exclusion in the Section 116.12 that is applicable for Major NSR serves to distinguish the provisions in paragraph (C) from the Major NSR Program and limit its application to Minor NSR.

Accordingly, we are proposing to approve 30 TAC 116.10(11)(C), as submitted March 13, 1996; July 22, 1998; and September 4, 2002.

C. Section 30 TAC 116.10(11)(D)—Exclusion for an Increase in Annual Hours of Operation

1. What is the background of 30 TAC 116.10(11)(D)?

On March 13, 1996, this provision was submitted as Subparagraph (D) under the definition of ''modification of existing facility.'' In the July 22, 1998, submittal, the provision was repealed and resubmitted as 30 TAC 116.10(9)(D). On September 4, 2002, TCEQ submitted revisions that redesignated this definition to 30 TAC 116.10(11)(D). As submitted, Subparagraph (D) provides that the following is not a modification to an existing facility:

(D) An increase in the annual hours of operation unless the existing facility has received a preconstruction permit or has been exempted, under TCAA, § 382.057, from preconstruction permit requirements;

2. What is EPA's evaluation of the submitted revisions to 30 TAC 116.10(11)(D)?

The submitted Subparagraph (D) mirrors the definition in the Texas Clean Air Act (TCAA). EPA approved this statutory provision into the Texas SIP on May 31, 1972 (37 FR 10896). Subparagraph (D) is similar to 40 CFR 52.01(d)(2)(ii), which provides that an increase in the hours of operation shall not be considered a change in the method of operation.

The submitted Subparagraph (D) is substantially the same as 40 CFR 52.01(d)(2)(ii). Furthermore, Subparagraph (D) includes additional language that clarifies that an increase in hours of operation may be a modification for existing minor facilities having preconstruction permits or exemptions, under TCAA § 382.057 [3] for preconstruction permit requirements. This language limits the reach of the exclusion in scenarios where an existing facility is subject to limitations on hours of operation under the terms of a preconstruction permit or an exemption. This is consistent with federal requirements in 40 CFR 52.01(d)(2)(ii). Subparagraph (D) meets and improves upon the federal requirements as described above. Again, the definition of ''major modification'' in Section 116.12 has a similar, but different, exclusion for an increase in the annual hours of operation. The existence of a similar exclusion in the Section 116.12 that is applicable for Major NSR serves to distinguish the provisions in paragraph (D) from the Major NSR Program and limit its application to Minor NSR.

Accordingly, we are proposing to approve 30 TAC 116.10(11)(D), as submitted March 13, 1996; July 22, 1998; and September 4, 2002.

IV. Proposed Action

Today, EPA proposes to approve the following revisions to the Texas SIP to include severable provisions of the definition of '' modification of existing facility'' under 30 TAC 116.10(11), submitted March 13, 1996; July 22, 1998; and September 4, 2002. This includes the following:

- 30 TAC 116.10(11)—the introductory paragraph of the definition of ''modification of existing facility'';
- 30 TAC 116.10(11)(C)—Exclusion for maintenance and replacement of equipment; and
- 30 TAC 116.10(11)(D)—Exclusion for an increase in annual hours of operation.

Final action on these revisions on or before October 31, 2011, will meet EPA's obligation on the NSR Rules Revisions; 112(g) Revisions component of the May 21, 2009, Settlement Agreement between EPA and the Business Coalition for Clean Air Appeal Group, Texas Association of Business, and Texas Oil and Gas Association.

EPA is proposing to withdraw its prior proposed disapprovals regarding the following provisions:

- 30 TAC 116.10(11)(A). EPA proposed to disapprove Subparagraph (A) in a separate action on September 23, 2009, 74 FR 48450. EPA is currently reviewing October 5, 2010 submitted revisions to Subparagraph (A) that have been subsequently submitted, and therefore proposes to withdraw its former proposal and act on Subparagraph (A) under the later submitted revisions in a separate action.
- 30 TAC 116.10(11)(B). EPA proposed to disapprove Subparagraph (B) in a separate action on September 23, 2009, 74 FR 48450. EPA takes notice of the repeal of Subparagraph (B) in the October 5, 2010 submittal and therefore proposes to withdraw its former proposal as moot. The provision no longer is before EPA for action.

EPA is not taking any action on the following severable provisions of 30 TAC 116.10(11):

- 30 TAC 116.10(11)(E). EPA disapproved Subparagraph (E) in a separate action on April 14, 2010, 75 FR 19468. EPA will address any subsequent revisions to Subparagraph (E) in a separate action.
- 30 TAC 116.10(11)(F). EPA disapproved Subparagraph (F) in a separate action on July 15, 2010, 75 FR 41312. EPA will address any subsequent revisions to Subparagraph (F) in a separate action.

EPA is not reopening the public comment period for the following severable provision of 30 TAC 116.10(11):

- 30 TAC 116.10(11)(G). EPA proposed to disapprove this provision on September 23, 2009. EPA is currently

[3] The term ''exemptions'' is a misnomer. Exemptions in Texas now are called Permits by Rule. An ''exemption'' since 1972 in Texas and in the Texas SIP, is an authorization to construct and/or modify if certain conditions are met.

reviewing the proposal and will act on Subparagraph (G) at a future time.

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. See 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this notice merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: July 4, 2011.

Al Armendariz,

Regional Administrator, Region 6.

[FR Doc. 2011–17873 Filed 7–15–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 229 and 665

[Docket No. 110131070–1084–01]

RIN 0648–BA30

Taking of Marine Mammals Incidental to Commercial Fishing Operations; False Killer Whale Take Reduction Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; notice of availability of draft take reduction plan; request for comments.

SUMMARY: NMFS announces the availability of a Draft False Killer Whale Take Reduction Plan developed by the False Killer Whale Take Reduction Team. This proposed rule would implement the proposed False Killer Whale Take Reduction Plan (FKWTRP), which is based on consensus recommendations included in the Draft False Killer Whale Take Reduction Plan. The proposed FKWTRP includes some changes and modifications proposed by NMFS. This action is necessary because current mortality and serious injury of the Hawaii Pelagic stock of false killer whales incidental to the Hawaii-based pelagic longline fisheries are above the stock's potential biological removal (PBR), and are therefore inconsistent with the short and long-term goals of the Marine Mammal Protection Act (MMPA). The FKWTRP is intended to meet the requirements of the MMPA through both regulatory and non-regulatory measures. Proposed regulatory measures include gear requirements, longline prohibited areas, training and certification in marine mammal handling and release, captains' supervision of marine mammal handling and release, and posting of NMFS-approved placards on longline vessels. NMFS is also proposing non-regulatory measures, including research and data collection recommendations.

DATES: Written comments on the proposed rule must be received no later October 17, 2011.

ADDRESSES: Comments on the proposed rule, identified by 0648–BA30, may be sent to either of the following addresses:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal: *http://www.regulations.gov; or.*
- *Mail:* Mail written comments to Regulatory Branch Chief, Protected Resources Division, National Marine Fisheries Service, Pacific Islands Regional Office (PIR), 1601 Kapiolani Blvd., Suite 1110, Honolulu, HI 96814, Attn: Proposed False Killer Whale Take Reduction Plan.

Instructions: Comments must be submitted to one of these two addresses to ensure that the comments are received, documented, and considered by NMFS. Comments sent to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted to *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

This proposed rule (the proposed False Killer Whale Take Reduction Plan), the recommendations submitted by the False Killer Whale Take Reduction Team (FKWTRT) (the Draft False Killer Whale Take Reduction Plan), references, and other background documents are available at *www.regulations.gov,* or the Take Reduction Team Web site: *www.nmfs.noaa.gov/pr/interactions/trt/falsekillerwhale.htm,* or by submitting a request to the Regulatory Branch Chief [see **ADDRESSES**].

FOR FURTHER INFORMATION CONTACT: Nancy Young, NMFS PIR, *Nancy.Young@noaa.gov,* 808–944–2282; Lance Smith, NMFS PIR,

Lance.Smith@noaa.gov, 808–944–2258; or Kristy Long, NMFS Office of Protected Resources, *Kristy.Long@noaa.gov,* 301–713–2322.

SUPPLEMENTARY INFORMATION:

Summary

The proposed False Killer Whale Take Reduction Plan (FKWTRP) is intended to meet the statutory mandates and requirements of the Marine Mammal Protection Act (MMPA, 16 U.S.C. 1362 *et seq.*) through both regulatory measures and non-regulatory components, including research and data collection priorities. The proposed regulatory measures include: Hook and branchline requirements for the deep-set longline fishery; modification of an existing longline prohibited area around the Main Hawaiian Islands; a new longline prohibited area that would be closed to deep-set longline fishing only when triggered by a specified level of false killer whale mortalities or serious injuries; expanded content of the existing, mandatory Protected Species Workshop for Hawaii-based longline fisheries to include new information on marine mammal interaction mitigation techniques certification; a requirement for longline vessel captains to supervise the handling and release of hooked or entangled marine mammals; and required posting of NMFS-approved placards on longline vessels. Proposed non-regulatory measures, the implementation of which would be NMFS' responsibility, include: Increasing the precision of bycatch estimates in the deep-set longline fishery; notifying the False Killer Whale Take Reduction Team (FWKTRT) when there is an observed interaction of a known or possible false killer whale; expediting the process for confirming the species identification of animals involved in such interactions and for making serious injury determinations; specifying changes to the observer training and data collection protocols; expedited processing of data from NMFS' 2010 survey of the Hawaiian Islands to obtain updated marine mammal abundance estimates; and reconvening the FWKTRT at regular intervals. The proposed FKWTRP also includes prioritized research recommendations to better inform long-term solutions for reducing false killer whale mortalities and serious injuries. More details on the proposed measures may be found in the sections ''Proposed Regulatory Measures,'' ''Proposed Non-Regulatory Measures,'' and ''Additional Research and Data Collection'' below.

Bycatch Reduction Requirements in the MMPA

Section 118(c)(1) of the MMPA requires NMFS to classify all U.S. commercial fisheries according to the level of serious injury and mortality (death) of marine mammals that occurs incidental to each fishery. NMFS reviews and revises these classifications each year, and publishes the annual MMPA List of Fisheries in the **Federal Register**. The MMPA and implementing regulations (50 CFR 229.2) define three categories of fisheries: Category I, II, and III fisheries as those that, respectively, have frequent, occasional, or a remote likelihood of or no known incidental mortality or serious injury (M&SI) of marine mammals. NMFS has also established numerical definitions of these three categories that quantify each fishery's effects on individual marine mammal stocks.

Section 118(f)(1) of the Marine Mammal Protection Act (MMPA) requires NMFS to develop and implement take reduction plans to assist in the recovery or prevent the depletion of each strategic marine mammal stock that interacts with Category I and II fisheries. Category I and II fisheries are fisheries that have frequent or occasional incidental M&SI of marine mammals, respectively. Section 118(f)(1) also provides NMFS discretion to develop and implement a take reduction plan for any other marine mammal stocks that interact with a Category I fishery, which the agency determines, after notice and opportunity for public comment, has a high level of M&SI across a number of such marine mammal stocks.

The MMPA defines a strategic stock as a marine mammal stock: (1) For which the level of direct human-caused mortality exceeds a sustainability threshold called the ''potential biological removal'' (PBR) level; (2) which is declining and likely to be listed under the Endangered Species Act (ESA) in the foreseeable future; or (3) which is listed as threatened or endangered under the ESA or as a depleted species under the MMPA. 16 U.S.C. 1362(2). PBR is the maximum number of animals, not including natural deaths, that can be removed annually from a stock, while allowing that stock to reach or maintain its optimum sustainable population level.

The immediate goal of a take reduction plan for a strategic stock is to reduce, within six months of its implementation, the incidental M&SI of marine mammals from commercial fishing to levels less than the PBR level established for that stock. The long-term goal is to reduce, within five years of its implementation, the incidental M&SI of marine mammals from commercial fishing operations to insignificant levels approaching a zero M&SI rate (which NMFS has defined in regulations as 10 percent of the PBR for a stock of marine mammals, 50 CFR 229.2), taking into account the economics of the fishery, the availability of existing technology, and existing state or regional fishery management plans.

Scope of the Plan

Commercial Fisheries

The proposed FKWTRP addresses incidental M&SI of false killer whales (*Pseudorca crassidens*) in the Category I Hawaii-based deep-set longline fishery (defined on the List of Fisheries as the ''HI deep-set (tuna target) longline/set line'' and ''Western Pacific Pelagic (Deep-set component)'' fisheries), and the Category II Hawaii-based shallow-set longline fishery (defined on the List of Fisheries as the ''HI shallow-set (swordfish target) longline/set line'' and ''Western Pacific Pelagic Shallow-set component'' fisheries). These fisheries operate in both U.S. waters and on the high seas. In the List of Fisheries, the high seas components of the fisheries are not considered separate fisheries, but as extensions of the fisheries operating within U.S. waters. The proposed FKWTRP also considers potential impacts to marine mammal stocks from the Hawaii shortline and kaka line fisheries; however, because information concerning actual impacts is currently undeveloped, NMFS is not proposing regulations for these fisheries in this proposed rule.

Marine Mammal Species and Stocks

The proposed FKWTRP is primarily focused on fishery impacts on the Hawaii Pelagic stock of false killer whales. Two additional stocks of false killer whales in the Pacific Islands Region, the Hawaii Insular and Palmyra Atoll stocks, are also addressed. The Hawaii Pelagic stock of false killer whales is the only strategic stock, as of the final 2010 Stock Assessment Report (SAR) (Carretta *et al.,* 2011), but all three are known or have potential to interact with the Category I Hawaii-based deep-set longline fishery.

One additional stock of false killer whales in the Pacific Islands Region, the American Samoa stock, was newly defined in the 2010 SAR, but no abundance estimate or PBR level is currently available for this stock (Carretta *et al.,* 2011). NMFS has some information from the NMFS Pacific Islands Regional Office (PIRO) Observer

Program (PIROP) on the level of M&SI occurring incidental to the American Samoa longline fishery, but without a PBR, NMFS has insufficient information to determine whether the level of incidental M&SI is sustainable. This proposed FKWTRP does not address bycatch of false killer whales in American Samoa; instead, it focuses on the incidental M&SI of false killer whale stocks that interact with fisheries known to have unsustainable levels of bycatch of this species. However, NMFS will continue to evaluate incidental interaction rates in the American Samoa longline fishery as observer coverage in this fishery increases, and will consider additional conservation and management measures if warranted by the information developed.

The 2011 MMPA List of Fisheries (75 FR 68468, November 8, 2010) identifies several other species or stocks of marine mammals that have been observed as injured or killed incidental to the Hawaii-based deep-set and shallow-set fisheries, including: Blainville's beaked whale, Hawaii stock (*Mesoplodon densirostris*); bottlenose dolphin, Hawaii Pelagic stock (*Tursiops truncatus*); humpback whale, Central North Pacific (CNP) stock (*Megaptera novaeangliae*); pantropical spotted dolphin, Hawaii stock (*Stenella attenuata*); Risso's dolphin, Hawaii stock (*Grampus griseus*); short-finned pilot whale, Hawaii stock (*Globicephala macrorhynchus*); striped dolphin, Hawaii stock (*Stenella coeruleoalba*); Bryde's whale, Hawaii stock (*Balaenoptera edeni*); Kogia *spp.* whale (Pgymy sperm whale (*Kogia breviceps*) or dwarf sperm whale (*Kogia sima*); Hawaii stock). With the exception of humpback whales, the incidental M&SI of all of these stocks is at or below the insignificance threshold (i.e., 10 percent of PBR), and are not addressed in this proposed rule. The CNP stock of humpback whales, although a strategic stock because of its endangered status, is not designated as ''strategic'' because of fishery interactions, and NMFS has determined that incidental taking from commercial fishing will have a negligible impact on CNP humpback whales (75 FR 29984, May 28, 2010). For these reasons, the proposed FKWTRP also does not address incidental M&SI of humpback whales.

Goals of the FKWTRP

The Hawaii Pelagic stock is the only stock of false killer whales in the Pacific Islands Region for which M&SI incidental to the Hawaii-based longline fisheries is known to exceed the stock's PBR level, as of the final 2010 SAR (Carretta *et al.,* 2011). The short-term goal of the proposed FKWTRP is to reduce, within six months of its implementation, M&SI of the Hawaii Pelagic stock of false killer whales incidental to the Hawaii-based longline fisheries occurring within the U.S. Exclusive Economic Zone (EEZ) around the Hawaiian Islands to less than the stock's PBR level of 2.5 false killer whales per year (Carretta *et al.,* 2011).

The Hawaii Pelagic stock is a transboundary stock that inhabits waters both within and outside of the EEZ around Hawaii; however, the extent of the stock's range into the high seas is unknown. The Hawaii-based longline fisheries operate both within the EEZ and on the high seas, and incidental M&SI of the Hawaii Pelagic stock of false killer whales have been documented both within the EEZ and on the high seas. Better information on the full geographic range of this stock and bycatch estimates in international fisheries are needed to reduce the uncertainties regarding impacts of false killer whale incidental takes on the high seas, but these uncertainties do not affect the Hawaii Pelagic false killer whale stock's designation as strategic. To ensure that conservation measures of the FKWTRP would not simply displace fishing effort and its corresponding impacts on the Hawaii Pelagic false killer whale from the EEZ to the high seas, NMFS is requiring that incidental M&SI of the high seas component of the Hawaii Pelagic stock not increase above current levels (i.e., 5.3 false killer whales per year, as of the 2010 SAR, Carretta *et al.,* 2011).

The long-term goal of the proposed FKWTRP is to reduce, within five years of its implementation, the incidental M&SI of the Hawaii Pelagic, Hawaii Insular, and Palmyra Atoll stocks of false killer whales to insignificant levels (i.e., less than 10 percent of their respective PBR levels).

History of the FKWTRT

NMFS established the FKWTRT on January 19, 2010 (75 FR 2853), and selected team members according to guidance provided in MMPA section 118(f)(6)(C). NMFS strove to select an experienced and committed team with a balanced representation of stakeholders. Members of the FKWTRT included representatives of the Hawaii-based deep-set and shallow-set longline fisheries, conservation organizations, scientific and research organizations, the State of Hawaii, the Marine Mammal Commission, the Western Pacific Fishery Management Council, and NMFS.

Four professionally-facilitated meetings were held between February 2010 and July 2010. During these meetings, NMFS presented false killer whale abundance and incidental M&SI estimates, characterization and regulatory structure of the Hawaii-based longline fisheries, and analysis of observer, logbook, and other fisheries data. In addition, NMFS, in consultation with the FKWTRT, performed and presented analyses of observer data to identify variables that may be predictors of depredation by cetaceans or bycatch of false killer whales. NMFS also developed a model to perform predictive simulations to evaluate potential mitigation strategies. Each meeting included facilitated discussions to examine the findings of the analyses, and to develop and draft various components of a Draft FKWTRP, with an emphasis on management and research recommendations.

The FKWTRT reached consensus at the July 2010 meeting, and on July 19, 2010, submitted to NMFS a Draft FKWTRP including recommendations for regulatory bycatch reduction measures, as well as research needs and other non-regulatory measures (FKWTRT, 2010). The team's consensus recommendations formed the basis of this proposed FKWTRP.

Distribution and Stock Structure of False Killer Whales in the Pacific Islands Region

False killer whales are found worldwide mainly in tropical and warm-temperate waters (Stacey *et al.,* 1994). In the North Pacific, this species is well known from southern Japan, Hawaii, and the eastern tropical Pacific. There are a total of six stranding records from Hawaiian waters (Nitta, 1991; Maldini, 2005). One on-effort sighting of false killer whales was made during a NMFS 2002 shipboard survey of waters within the EEZ around Hawaii (Barlow, 2006). Smaller-scale surveys conducted around the Main Hawaiian Islands (MHI) show that false killer whales are also encountered in nearshore waters (Baird *et al.,* 2008; Mobley *et al.,* 2000). This species also occurs in the EEZ around Palmyra Atoll, Johnston Atoll, and American Samoa (Barlow and Rankin, 2007; Carretta *et al.,* 2011).

Genetic analyses of tissue samples collected within the Indo-Pacific indicate restricted gene flow between false killer whales sampled near the MHI and false killer whales sampled in all other regions (Chivers *et al.,* 2007; 2010). The recent update from Chivers *et al.* (2010) included additional samples and analysis of eight nuclear DNA (nDNA) microsatellites, revealing strong phylogenetic patterns that are consistent with local evolution of

haplotypes that are nearly unique to the separate insular population around the MHI. Further, the recent analysis also revealed significant differentiation, both in mitochondrial and nDNA, between pelagic false killer whales in the Eastern North Pacific (ENP) and Central North Pacific (CNP) strata defined in Chivers *et al.* (2010), though the sample distribution to the east and west of Hawaii is insufficient to determine whether the sampled strata represent one or more stocks, and where stock boundaries would be. Since 2003, NMFS observers have been collecting tissue samples of bycaught cetaceans in the Hawaii-based longline fisheries for genetic analysis whenever possible. Between 2003 and 2010, eight false killer whale samples (four collected outside the EEZ around Hawaii and four collected within the EEZ but more than 100 nautical miles (nm) (185 km) from the MHI) were determined to have Pacific pelagic haplotypes (Chivers *et al.,* 2010).

Recent satellite telemetry studies, boat-based surveys, and photo-identification analyses of false killer whales around Hawaii have demonstrated that the insular and pelagic stocks have overlapping ranges, rather than a clear separation in distribution. Hawaii Insular false killer whales have been documented as far as 112 km (60 nm) from the MHI, and Hawaii Pelagic stock animals have been documented as close as 42 km (23 nm) to the islands (Baird *et al.,* 2008; Baird, 2009; Baird *et al.,* 2010; Forney *et al.,* 2010). Based on a review of new information (Forney *et al.,* 2010), the 2010 SAR recognizes a new, overlapping distribution for Hawaii Insular and Hawaii Pelagic stocks of false killer whales around Hawaii: Unless stock identity can be confirmed through other evidence (e.g., genetic data), animals within 40 km (22 nm) of the MHI are considered part of the Hawaii Insular stock; animals beyond 140 km (76 nm) of the MHI are considered part of the Hawaii Pelagic stock, and the two stocks overlap between 40 km (22 nm) and 140 km (76 nm) from shore (Carretta *et al.,* 2011).

The 2010 SAR also clarifies that the Hawaii Pelagic stock includes animals found both within the EEZ around Hawaii and in adjacent high seas; however, because data on false killer whale abundance, distribution, and human-caused impacts are largely lacking for the high seas, the status of this stock is evaluated based on data from the EEZ around Hawaii (Carretta *et al.,* 2011; NMFS, 2005a). The Palmyra Atoll stock of false killer whales remains a separate stock, because comparisons amongst false killer whales sampled at Palmyra Atoll and those sampled from the Hawaii Insular stock and the pelagic ENP revealed restricted gene flow, although the sample size remains low for robust comparisons (Chivers *et al.,* 2007; 2010). NMFS will continue to obtain and analyze additional tissue samples for genetic studies of stock structure, and will evaluate new information on stock ranges as it becomes available.

In the 2010 SAR, there are four Pacific Islands Region management stocks of false killer whales: (1) The Hawaii Insular stock, which includes false killer whales inhabiting waters within 140 km (approximately 75 nm) of the MHI; (2) the Hawaii Pelagic stock, which includes false killer whales inhabiting waters greater than 40 km (22 nm) from the MHI; (3) the Palmyra Atoll stock, which includes false killer whales found within the EEZ around Palmyra Atoll; and (4) the American Samoa stock, which includes false killer whales found within the EEZ around American Samoa (Carretta *et al.,* 2011). The American Samoa stock was not included in the scope of the FKWTRT's discussions, and is not described further in this proposed FKWTRP.

Abundance Estimates and Potential Biological Removal Levels

Hawaii Insular Stock of False Killer Whales

A mark-recapture study of photo-identification data obtained during 2000–2004 around the MHI produced an estimate of 123 Hawaii Insular false killer whales (coefficient of variation, or CV = 0.72; the CV is a measurement of the variation in the data, and is calculated as the ratio of the standard deviation to the mean) (Carretta *et al.,* 2011; Baird *et al.,* 2005). The minimum population estimate for the Hawaii Insular stock of false killer whales is the number of distinct individuals identified in this population during the 2002–2004 photo-identification studies, that is, 76 individual whales (Baird *et al.,* 2005). This is similar to the log-normal 20th percentile of the mark-recapture abundance estimate, 71 false killer whales. A recent study (Baird, 2009) summarized information on false killer whale sightings near Hawaii between 1989 and 2007, based on various survey methods, and provided evidence that the Hawaii Insular stock of false killer whales may have declined during the last two decades. Evidence of a decline is also supported by a recent genetic study that indicates there has been a decline in the effective population size (Chivers *et al.,* 2010). No data are available on current or maximum net productivity rate for this stock.

PBR is defined as the product of minimum population size, one-half the maximum productivity rate, and a recovery factor (MMPA Sec. 3(20), 16 U.S.C. 1362). The PBR level for the Hawaii Insular false killer whale stock is calculated as the minimum population size (76) times one half the default maximum net growth rate for cetaceans (one half of 4 percent) times a recovery factor of 0.40 (for a stock of unknown status with a human-caused M&SI rate CV > 0.80; see Wade and Angliss, 1997), resulting in a PBR of 0.61 false killer whales per year, as of the 2010 SAR (Carretta *et al.,* 2011).

NMFS proposed to list the Hawaiian Insular population of false killer whales (defined to be the same as the Hawaii Insular stock) as an endangered distinct population segment (DPS) under the ESA (75 FR 70169, November 17, 2010). A final listing decision is expected by November 2011.

HI Pelagic Stock of False Killer Whales

Analyses of a NMFS 2002 shipboard line-transect survey of the EEZ around Hawaii (Hawaiian Islands Cetacean and Ecosystem Assessment Survey, or HICEAS) resulted in an abundance estimate of 236 (CV = 1.13) false killer whales (Barlow 2006) outside of 75 nm (139 km) of the MHI. A recent re-analysis of the HICEAS data using improved methods and incorporating additional sighting information obtained on line-transect surveys south of the EEZ around Hawaii during 2005, resulted in a revised estimate of 484 (CV = 0.93) false killer whales within the EEZ around Hawaii outside of about 75 nm (139 km) of the MHI (Barlow and Rankin, 2007). This is the best available abundance estimate for the Hawaii Pelagic stock of false killer whales. The 2005 survey (Barlow and Rankin, 2007) also resulted in a separate abundance estimate of 906 (CV = 0.68) false killer whales in international waters south of the EEZ around Hawaii and within the EEZ around Johnston Atoll, but it is unknown how many of these animals might belong to the Hawaii Pelagic stock. The log-normal 20th percentile (''Nmin'') of the 2002 abundance estimate for the EEZ around Hawaii outside of 75 nm (139 km) from the MHI (Barlow and Rankin, 2007) is 249 false killer whales. No data are available on current population trend or on current or maximum net productivity rate for this stock.

Following the NMFS Guidelines for Assessing Marine Mammal Stocks (GAMMS) (NMFS, 2005a), the PBR is

calculated only within the EEZ around Hawaii because abundance estimates and estimates of human-caused M&SI from all U.S. and non-U.S. sources are not available in the high seas where this stock may also occur. The PBR level for the Hawaii Pelagic stock of false killer whale is thus calculated as the minimum population size within the EEZ around Hawaii (249) times one half the default maximum net growth rate for cetaceans (one half of 4 percent) times a recovery factor of 0.50 (for a stock of unknown status with a M&SI rate in the EEZ around Hawaii CV ≤ 0.30; Wade and Angliss, 1997), resulting in a PBR of 2.5 false killer whales per year, as of the 2010 SAR (Carretta *et al.,* 2011).

Palmyra Atoll Stock of False Killer Whales

Recent line transect surveys in the EEZ around Palmyra Atoll produced an estimate of 1,329 (CV = 0.65) false killer whales (Barlow and Rankin, 2007). This is the best available abundance estimate for false killer whales within the EEZ around Palmyra Atoll. The log-normal 20th percentile of the 2002 abundance estimate for the EEZ around Palmyra Atoll (Barlow and Rankin, 2007) is 806 false killer whales. No data are available on current population trend or on current or maximum net productivity rate for this stock.

The PBR level for the Palmyra Atoll false killer whale stock is calculated as the minimum population size (806) times one half the default maximum net growth rate for cetaceans (one half of 4 percent) times a recovery factor of 0.40 (for a stock of unknown status with a M&SI rate CV > 0.80; Wade and Angliss, 1997), resulting in a PBR of 6.4 false killer whales per year, as of the 2010 SAR (Carretta *et al.,* 2011).

Mortality and Serious Injury Estimates

The total incidental M&SI of cetaceans in the shallow-set longline fishery (with 100 percent observer coverage) and the estimated annual and 5-year average incidental M&SI of cetaceans in the deep-set longline fishery are reported by McCracken and Forney (2010). Their methodology includes prorating all estimated incidental takes of false killer whales based on the proportions of observed interactions that resulted in death or serious injury (89 percent), or non-serious injury (11 percent). Further, incidental takes of false killer whales of unknown stock origin within the Hawaii Insular/Pelagic stock overlap zone are prorated based on the density of each stock in that area, as recommended in the NMFS GAMMS (NMFS, 2005a) and by the Pacific Scientific Review Group. No genetic samples are available to establish stock identity for these incidental takes, but both stocks are considered by NMFS to be at risk of interacting with longline gear within this region. Until methods of determining stock identity for animals observed incidentally taken within the overlap zone are available (e.g., photos, tissue samples), this proration approach produces the best available method for accounting for potential impacts to both stocks.

Based on these bycatch analyses, estimates of annual and 5-year average annual incidental M&SI of false killer whales, by stock and EEZ area, are presented in the 2010 SAR (Carretta *et al.,* 2011). Using data from 2004–2008, the mean estimated annual incidental M&SI of false killer whales in the Hawaii Pelagic stock occurring outside of the EEZ was 5.3 (CV = 0.5) and inside the EEZ around Hawaii was 7.3 (CV = 0.3). The mean estimated annual incidental M&SI of false killer whales in the Hawaii Insular stock was 0.60 (CV = 1.3) and 0.3 (CV = 1.3) for the Palmyra Atoll stock (Carretta *et al.,* 2011). These estimates of incidental M&SI do not include any unidentified animals (8 observed animals) that may have been false killer whales, and, therefore, are minimum estimates. Efforts are currently underway to develop methods of prorating the unidentified animals by species and stock, taking into account geographic differences in their ranges and observed rates of documented interactions with each species; these estimates will likely be included in the draft 2011 SAR.

Components of the Proposed FKWTRP

The proposed FKWTRP includes both regulatory and non-regulatory measures, as well as a suite of research recommendations. While the primary focus of the proposed FKWTRP involves the Hawaii-based deep-set longline fishery, there are measures that apply to other fisheries known or suspected to interact with false killer whales.

NMFS believes the suite of proposed measures described below are currently appropriate for meeting the goals of the FKWTRP, but anticipates that new information on the biology, distribution, abundance, and stock structure of false killer whales, as well as on the extent and nature of interactions between commercial fisheries and false killer whales, will become available in the future. Similarly, future innovations in fishing gear and/or fishing methods may change the extent and nature of interactions between commercial fisheries and false killer whales. As such, NMFS and the FKWTRT agreed to evaluate the success of the final FKWTRP at periodic intervals over the next several years, and to consider amending the FKWTRP, if warranted, based on the results of ongoing monitoring, research, and evaluation.

NMFS proposes to incorporate nearly all of the FKWTRT's consensus recommendations included in the Draft FKWTRP into the proposed FKWTRP, with some modifications. Changes from the FKWTRT's consensus recommendations are noted, along with the rationale for any proposed changes. The FKWTRT also discussed other mitigation and conservation measures that they did not include in their consensus recommendations because they were either economically or technologically infeasible, or did not meet the goals of the MMPA. Information on these can be reviewed in the Draft FKWTRP (FKWTRT, 2010).

One of the FKWTRT's consensus recommendations will not be implemented through this proposed rule. Specifically, the FKWTRT recommended that NMFS require longline vessel crew to notify the captain in the event of a marine mammal interaction. NMFS agrees that crewmembers should immediately notify the captain in the event of a marine mammal hooking or entanglement, and accordingly NMFS is proposing to require that a standard placard be posted on longline vessels instructing this response (see ''*(6) Requirement for Captains' Supervision of Marine Mammal Interactions''* and ''*(7) Captain Notification Placard Posting Requirement''* below). However, since the captain is ultimately responsible for the crew's response, handling, and release of the marine mammal, NMFS believes that the captain should be directly responsible for ensuring that an effective marine mammal notification procedure is implemented onboard the vessel.

Proposed Regulatory Measures

NMFS proposes the following regulatory measures:

(1) Require the use of ''weak'' circle hooks sized 16/0 or smaller with a maximum wire diameter of 4.0 mm (0.157 in) and other specific characteristics in the Hawaii-based deep-set longline fishery;

(2) Establish a minimum 2.0 mm (0.079 in) diameter for monofilament leaders and branchlines in the Hawaii-based deep-set longline fishery, and a minimum breaking strength of 400 pounds (181 kg) for leaders and branchlines if any other material is used;

(3) Modify the existing Main Hawaiian Islands Longline Prohibited Area as described in 50 CFR 665.806 to eliminate the seasonal contraction of the boundary; the 71,384 km² (20,812 nmi²) area north of the MHI that is currently open to longline fishing between October–January would be closed to longline fishing year-round;

(4) Expand the content of the existing, mandatory Protected Species Workshop for the Hawaii-based longline fishery to include new information on marine mammal interaction mitigation techniques;

(5) Require a NMFS-approved marine mammal handling and release informational placard to be posted onboard all Hawaii-based longline vessels;

(6) Require the captain of the longline vessel to supervise the handling and release of any hooked or entangled marine mammal;

(7) Require a NMFS-approved placard that instructs the vessel crew to notify the captain in the event of a marine mammal interaction be posted onboard all Hawaii-based longline vessels; and

(8) Establish a Southern Exclusion Zone that would be closed to the commercial Hawaii-based deep-set longline fishery for varying periods of time whenever specific levels of serious injuries or mortalities of false killer whales are observed within the EEZ around Hawaii.

These proposed measures are more fully described below.

(1) ''Weak'' Circle Hook Requirement

Analysis of observer data and predictive simulations indicate that the use of small circle hooks (size 16/0 or smaller) in the deep-set longline fishery would likely reduce the number of false killer whale incidental takes (i.e., prevent some hookings) by approximately 6 percent, and may reduce the severity of injuries (e.g., mouth hookings rather than ingestion) following interactions (FKWTRT, 2010). Small circle hooks are also generally weaker (i.e., straighten with less force) than the Japanese-style tuna hooks used by a portion of the longline fleet, so some false killer whales that are hooked in the lip, jaw, body, or flukes may be able to pull free (i.e., straighten the hook) if tension is placed on the line. Thus, the required use of small circle hooks may further reduce the number of incidental M&SI of false killer whales in the deep-set longline fishery.

The standard wire diameter for small circle hooks in the deep-set longline fishery is 4.5 mm [0.177 in]. The FKWTRT believes that small circle hooks with a smaller wire diameter (e.g., 4.0 mm [0.157 in] or 4.2 mm [0.165 in]) would provide even greater conservation benefits to false killer whales. Such ''weak'' hooks exploit the size and weight disparity between the fishery's target species and other species, and promote the release of larger, non-target or bycatch species (Bigelow *et al.,* 2011). In this case, it would be expected that the hook would be strong enough to retain target catch, but would bend and straighten under the pull strain of a hooked marine mammal, allowing the animal to release itself and thereby reduce the severity of the animal's injury. However, these weaker hooks are not currently used in the fishery, and their effects on rates of target catch, and therefore their commercial viability, have not been tested. Consequently, the FKWTRT recommended that weak hooks be required in the deep-set longline fishery if it could be demonstrated through additional research that weak hooks do not have a substantial negative impact on bigeye tuna catch rates (i.e., the aggregate weight of bigeye tuna caught on 4.0 mm [0.157 in] or 4.2 mm [0.165 in] circle hooks is not more than 10 percent less than the weight of bigeye tuna caught on 4.5 mm [0.177 in] circle hooks). The rate of false killer whale bycatch is so low that a very large sample size (number of hooks) would be required to detect a difference in bycatch between hooks. However, the FKWTRT recommended the required use of weak circle hooks based on the effects to target species alone, given the expected, though unverified, reduction in the severity of injuries to hooked false killer whales.

NMFS, in partnership and collaboration with the Hawaii-based deep-set longline fishery and independent researchers, conducted a study to quantify the effects of strong (4.5 mm [0.177 in] wire diameter) and weak (4.0 mm [0.157 in] wire diameter) 15/0 circle hooks on bigeye tuna catch. The study examined catch rates of target, incidental (retained non-target), and bycatch (discarded) species; size selectivity; and frequency of straightened hooks. Analysis of data from 127 longline sets conducted between October-December 2010 showed no significant differences in catch per set between hook types for 20 species, including bigeye tuna. There were also no significant differences in bigeye tuna catch per set in either the number of individuals or weight estimated from fork lengths (Bigelow *et al.,* 2011). Weak hooks had a statistically significant higher rate of straightening, though the rate of straightening was relatively low (0.462 per 1,000 weak hooks, and 0.291 with no catch), and lower than studies of weak hooks in other fisheries (Bigelow *et al.,* 2011).

The researchers note that the study was conducted during a time of year when landed bigeye tuna have a lower mean weight, and it is unknown whether similar results would have been obtained if the research were conducted when bigeye tuna of a larger average size were available to the fishery. However, the study shows that weak hooks can retain even very large bigeye tuna (~122 kg [269 lb], Bigelow *et al.,* 2011). Based on the results of this study showing no statistically significant reduction in target species catch rates, and given the expected positive reduction in the severity of injuries to marine mammals, as recommended by the FKWTRT, NMFS is proposing the required use of weak circle hooks.

The FKWTRT recommended, and NMFS proposes, the required use of circle hooks sized 16/0 or less in the deep-set longline fishery, with the following characteristics: wire diameter not to exceed 4.0 mm (0.157 in); the shank composed of round, non-flattened wire; and 10 degree offset or less. Any hook not meeting the requirement would not be allowed to be used on deep-set trips, though other hooks may be on board the fishing vessel if stowed and unavailable for use.

This proposed new regulation would be added to 50 CFR 665.813, under a revised section heading of ''Western Pacific longline fishing requirements.'' NMFS also proposes to specifically cross-reference this gear requirement in the take reduction plan regulations under 50 CFR part 229.

(2) Minimum Monofilament Diameter Requirement for Leaders/Branchlines

An examination of observer data from false killer whale and ''blackfish'' (animals identified as either false killer whales or pilot whales) interactions indicated that approximately 10 percent (3 of 29) of animals that were entangled or hooked externally or in the mouth were released because the mainline or branchline broke (FKWTRT, 2010). Animals that are released with substantial trailing gear (with the potential to wrap around pectoral fins/flippers, peduncle, or head; be ingested; or accumulate drag) are usually considered seriously injured (Andersen *et al.,* 2008). The FKWTRT believed that, had the line not broken in these cases, the animals might have been able to pull free (i.e., straighten the hook), or attempts could have been made by the

captain, crew, or observer to disentangle or dehook the animals. As such, the FKWTRT recommended a minimum breaking strength for branchlines, via a minimum diameter requirement.

For the deep-set longline fishery, the FKWTRT recommended, and NMFS proposes, that any monofilament line used in branchlines or leaders must be 2.0 mm (0.079 in) or larger in diameter. This diameter monofilament line has a breaking strength of approximately 400 pounds (181 kg). Any other materials used in branchlines or leaders must have a breaking strength of 400 pounds (181 kg) or greater. The intent is that the gear be assembled and maintained such that the hook is the weakest component of the terminal tackle.

This proposed new regulation would be added to 50 CFR 665.813, under a revised section heading of ''Western Pacific longline fishing requirements.'' NMFS also proposes to specifically cross-reference this gear requirement in the take reduction plan regulations under 50 CFR part 229.

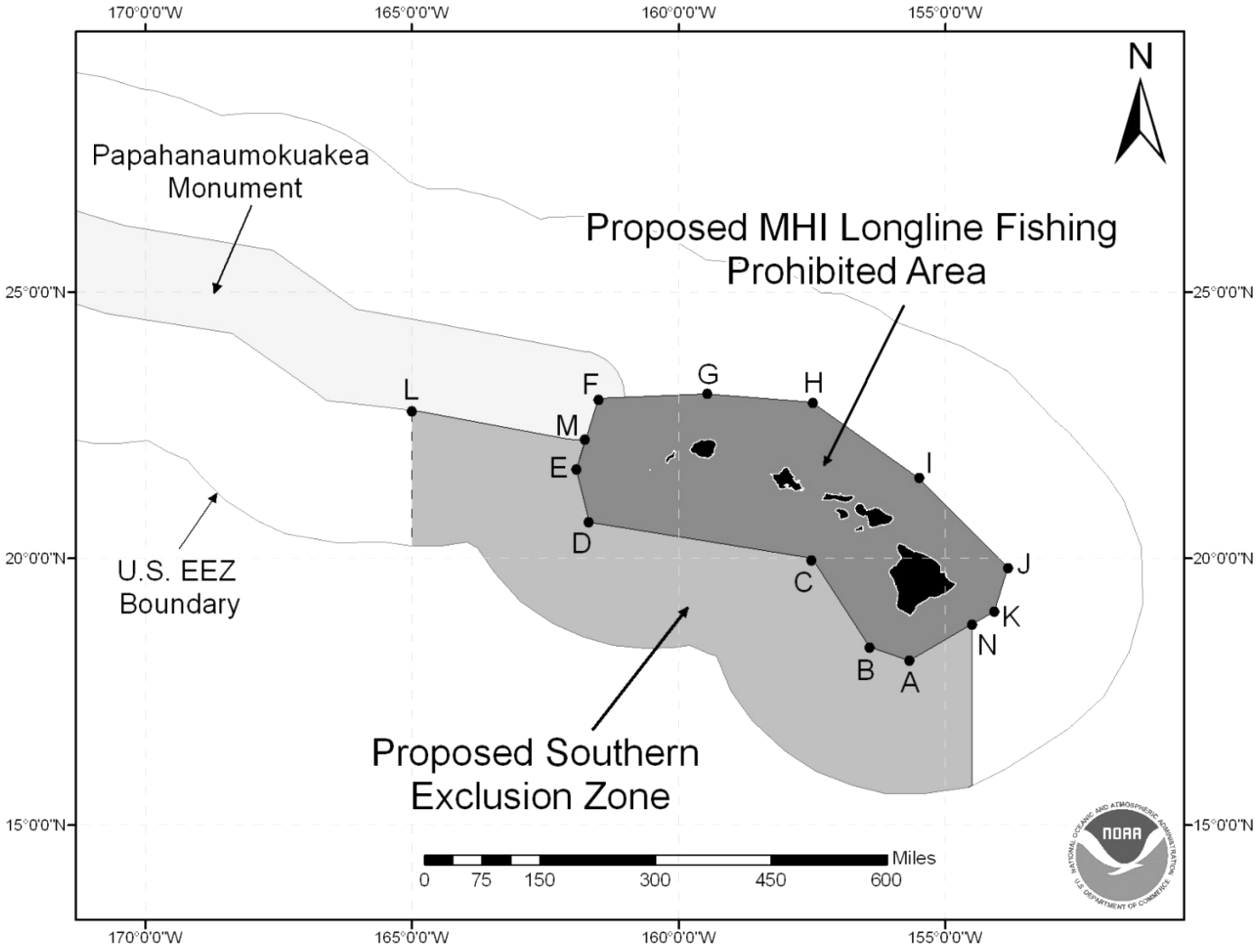
(3) Main Hawaiian Islands Longline Fishing Prohibited Area

An existing longline exclusion zone prohibits longline fishing year-round around the MHI (50 CFR 665.806(c)). The outer extent of the boundary contracts seasonally to allow longline fishing to occur closer to the windward shores of the MHI between October and January (WPRFMC, 2009); this seasonally open area covers 71,384 km^2 (20,812 nmi^2). Incidental M&SI of false killer whales and blackfish have been documented in the area where longline fishing is only allowed between October and January. This area falls within the area of overlap between the Hawaii Insular and Hawaii Pelagic stocks of false killer whales as defined in the 2010 SAR (Carretta *et al.,* 2011). Given that longline fishing in this area may impact both false killer whale stocks, the FKWTRT recommended that this area be closed to commercial longline fishing year-round. Such an exclusion would, in effect, maintain the current boundary of the February-September longline exclusion zone prohibitions throughout the entire year. It is anticipated that this closure would substantially reduce the risk the deep- and shallow-set longline fisheries pose to the Hawaii Insular stock of false killer whales, because longline fishing would thereby be prohibited from nearly the entire range of the Hawaii Insular stock. It would also likely reduce incidental M&SI of the Hawaii Pelagic stock of false killer whales in that area.

NMFS is proposing to implement this recommendation by revising the boundaries of the existing MHI longline fishing prohibited area at 50 CFR 665.806(c) to eliminate the seasonal contraction (Figure 1). NMFS also proposes to prohibit commercial longline fishing in this Main Hawaiian Islands Longline Fishing Prohibited Area in the take reduction plan regulations under 50 CFR part 229.

BILLING CODE 3510–22–P

Figure 1. Proposed Main Hawaiian Islands Longline Fishing Prohibited Area and Southern Exclusion Zone. Inflection points are lettered as per the proposed regulations.



BILLING CODE 3510–22–C

(4) Required Annual Certification in Marine Mammal Interaction Mitigation

The FKWTRT recommended that NMFS develop and implement a mandatory, annual certification program to educate owners and operators of Hawaii-based longline vessels about ways to reduce incidental M&SI of marine mammals. The FKWTRT believes specific training would significantly increase the potential for captains and crew to free hooked or entangled false killer whales from gear in a manner that would reduce the severity of the injury (FKWTRT 2010). The FKWTRT recommended NMFS expand the existing Protected Species Workshops, required under 50 CFR 665.814, to incorporate additional information regarding marine mammal interactions, including an MMPA regulatory overview; species identification; marine mammal handling and release techniques; and best practices for reducing marine mammal bycatch. The FKWTRT also recommended that NMFS develop a voluntary component of the training on marine mammal photo-identification techniques for owners and operators interested in participating in the research.

NMFS is proposing to implement the FKWTRT's recommendation. Under existing regulations for Western Pacific pelagic fisheries (50 CFR 665.814, Protected Species Workshop), owners and operators of all western Pacific Pelagic longline vessels must successfully complete a workshop each year, and a valid workshop certificate is needed for owners to maintain or renew permits and for operators at sea. Sea turtle and seabird handling is specified in these regulations; there is no regulatory requirement for training in marine mammal handling. However, since 2004, NMFS has incorporated training on marine mammal identification, careful handling and release techniques, and an overview of, as well as an explanation of the purpose and justification for marine mammal bycatch reporting requirements that apply to the longline fisheries into these workshops. NMFS proposes to expand the content of the workshops in consultation with the FKWTRT, as appropriate, to meet the needs of the FKWTRP. To ensure the marine mammal component is maintained by regulation as part of the workshops, NMFS is also proposing to add the requirement for certification to the take reduction plan regulations at 50 CFR part 229, under MMPA authority.

(5) Marine Mammal Handling and Release Guidelines Posting Requirement

The FKWTRT recommended, and NMFS proposes, to require posting a NMFS-approved marine mammal handling and release informational placard onboard all longline vessels in the Hawaii-based fleet in a location where it would be visible to the captain and crew. NMFS believes this proposed action would facilitate the careful handling and release of false killer whales and other small cetaceans caught incidentally during longline fishing. The posting requirement would ensure NMFS' guidelines are readily available for reference during a hooking or entanglement event. This proposed requirement would be part of the take reduction plan regulations at 50 CFR part 229.

(6) Requirement for Captains' Supervision of Marine Mammal Interactions

As noted above (see *''(4) Required Annual Certification in Marine Mammal Interaction Mitigation''*), longline vessel captains are required to attend and be certified annually in protected species interaction mitigation techniques (50 CFR 665.814). NMFS proposes to expand the content of these workshops to include more specific training in marine mammal handling and release. Vessel crew members are not required to receive certification. Therefore, the captain may be the only person on the vessel trained in marine mammal handling and release protocols, particularly on trips without an observer. However, the FKWTRT noted that captains may not always be on deck while the gear is being hauled and thus may not observe or be aware of marine mammal bycatch events. The FKWTRT recommended, and NMFS proposes, to require the captain of each longline vessel to supervise the handling and release of any hooked or entangled marine mammal. The captain would not necessarily need to be on deck, but could, for example, oversee and direct specific actions from the wheelhouse, if he or she were in visual and/or verbal contact with the crew. This proposed requirement would be part of the take reduction plan regulations at 50 CFR part 229.

(7) Captain Notification Placard Posting Requirement

The FKWTRT recommended, and NMFS proposes, to require a NMFS-approved placard, that instructs the vessel crew to notify the captain immediately if a marine mammal is hooked or entangled, be posted onboard all active longline vessels in a location where it would be visible to the crew. It is expected that this measure would facilitate crew notification of the captain, thereby ensuring the captain is aware of any marine mammal interactions and supervises the handling and release, as required above in *''(6) Requirement for Captains' Supervision of Marine Mammal Interactions.''* This proposed requirement would be part of the take reduction plan regulations at 50 CFR part 229.

(8) Southern Exclusion Zone Closure

The FKWTRT recommended and NMFS proposes to establish a ''Southern Exclusion Zone'' (SEZ) that would be closed to deep-set longline fishing upon reaching a specified threshold level (or ''trigger'') of observed false killer whale mortalities or serious injuries inside the EEZ around Hawaii. Using observed incidental M&SI would allow for real-time management of the SEZ to prevent incidental M&SI from exceeding PBR, rather than waiting until the end of the year for extrapolated M&SI estimates, by which time PBR might be exceeded. The SEZ would be bounded on the east at 154.5° W. longitude, on the west at 165° W. longitude, on the north by the existing February-September MHI Longline Exclusion Zone and the Papahanaumokuakea Marine National Monument; and on the south by the EEZ boundary (Figure 1). The SEZ closure would cover 386,122 km^2 (112,575 nmi^2), that if implemented, would reduce the area available to longline fishing within the EEZ around Hawaii by approximately 17 percent.

The FKWTRT recommended these boundaries because they encompass an area with a high historical concentration of observed false killer whale and blackfish incidental takes in the deep-set longline fishery. As such, the FKWTRT and NMFS determined that this is an area where protective measures (i.e., a closure) would be likely to have the greatest conservation benefit. A closure would prevent further false killer whale M&SI in the deep-set longline fishery in that area. The FKWTRT and NMFS also believe that, to be effective, the proposed closure must be sufficiently large to prevent false killer whales from simply following boats and gear to areas outside of the closure. NMFS believes the closure of the SEZ, when triggered by specific levels of observed false killer whale M&SI, would be necessary and appropriate to eliminate future interactions in the area and to reduce the overall level of false killer whale interactions in the deep-set longline fishery.

The FKWTRT recommended that the SEZ be managed on the basis of ''Plan Years,'' rather than calendar years. A ''Plan Year'' would be the 365-day period starting the first day of the month immediately following 30-days after publication of the final FKWTRP in the **Federal Register**. The FKWTRT believed this would allow for the more immediate implementation of the management measures, instead of delaying implementation until the beginning of the calendar year following publication of the final FKWTRP in the **Federal Register**. Instead, NMFS proposes to base the cycle on the fishing year, which is currently defined to be the same as the calendar year (50 CFR 665.12). Management of the SEZ using fishing years would mean there was a single definition of the annual cycle, rather than the multiple, non-synchronous cycles if ''Plan Years'' were used. The single annual cycle would facilitate understanding within the regulated community and provide for efficient administration of the measures. Additionally, managing on the basis of fishing years would not result in a delay in implementation of take reduction measures: NMFS proposes that observed incidental M&SI would be counted toward the trigger immediately upon the effective date of the final FKWTRP. If that date does not coincide with the beginning of the fishing year, observed incidental M&SI would be counted against the trigger from that point forward for the remaining portion of the first fishing year. Any incidental M&SI in the first year that was observed before the effective date of the final FKWTRP would not be counted retroactively against the trigger.

For example, if the final rule becomes effective on May 15, 2012, all false killer whale incidental M&SI that are observed from that point forward until December 31, 2012 would count toward the trigger. However, in that example, any false killer whale mortalities or serious injuries that occurred in that calendar year before May 15 (i.e., from January 1–May 14, 2012) would not be counted toward the trigger for 2012. The tally of M&SI would be ''re-set'' on January 1, 2013, and any observed takes from January 1–December 31, 2013 would count toward the trigger in 2013.

The proposed SEZ measures would apply only to the deep-set longline fishery, and not the shallow-set longline fishery, because of the deep-set longline fishery's much higher rate of false killer whale mortalities and serious injuries. Additionally, the shallow-set longline fishery operates largely outside of the EEZ around Hawaii, and thus has an even lower likelihood of interacting with a false killer whale within the EEZ. Therefore, mortalities and serious injuries of false killer whales in the shallow-set longline fishery would not count toward the SEZ trigger, and the fishery would not be affected by any closure of the SEZ. However, mortalities and serious injuries of false killer whales in the shallow-set longline fishery would still be included in NMFS estimates and would be presented in the SAR.

The following paragraphs describe five proposed steps NMFS would take when determining whether to prohibit deep-set longline fishing in the SEZ. Although the proposed SEZ management measures are largely consistent with the Draft FKWTRP, there are several instances where diversions from the FKWTRT's recommendations were necessary. Those instances are specifically noted and explained.

(a) *Defining the trigger.* The SEZ would be managed in real-time based on observed incidental M&SI of false killer whales, so that false killer whale incidental M&SI in the deep-set longline fishery inside the EEZ around Hawaii does not exceed the Hawaii Pelagic stock's PBR level. Therefore, the FWKTRT recommended that the real-time, estimated incidental M&SI be calculated using a simple extrapolation from the observed number of false killer whale incidental M&SI, using the level of observer coverage for that year. Because of inter-annual variability in incidental M&SI, NMFS typically calculates 5-year average annual incidental M&SI levels for comparing against PBR, rather than relying on single-year estimates. Therefore, NMFS proposes to convert this extrapolated estimate of incidental M&SI to a 5-year average for comparison against PBR. This is consistent with the FKWTRT's deliberations. For example, at the current level of 20 percent observer coverage, two observed mortalities or serious injuries of false killer whales inside the EEZ around Hawaii would result in an estimate of 10 false killer whales for that year, which exceeds the stock's current PBR level of 2.5. But, if no other false killer whales were taken in the following 4 years, a 5-year average incidental M&SI would be approximately 2 animals per year, which is below the stock's PBR level. Any additional observed mortalities or serious injuries would cause the estimated incidental M&SI level to exceed the stock's PBR level, thus indicating the existing management measures in the FKWTRP were not sufficiently reducing incidental M&SI and additional management measures (i.e., a closure of the SEZ) would be necessary. Thus, under this scenario where PBR was 2.5 and observer coverage was 20 percent, the trigger would be set at 2 observed false killer whale mortalities or serious injuries.

The two factors on which the trigger is based—observer coverage and the PBR for the Hawaii Pelagic stock of false killer whales—may change from one year to the next. NMFS proposes to specify the equation used to calculate the trigger in the FKWTRP regulations and to publish a notice in the **Federal Register** upon initial FKWTRP implementation and whenever the trigger was changed, specifying the levels of PBR and observer coverage used to calculate the trigger.

NMFS proposes to calculate the trigger for implementing additional required management measures using the following equation:

trigger ≤ 5 * (observer coverage) * (PBR)

The following process described how this equation would be used for calculating the trigger for closing the SEZ:

(i) Divide the (unknown) trigger (i.e., the number of observed animals that are determined to have been killed or seriously injured) by the level of observer coverage to obtain the extrapolated annual estimate of incidental M&SI: (trigger)/(observer coverage) = annual incidental M&SI estimate;

(ii) Assuming there would be no additional incidental M&SI in the following four years, divide the estimate from step (i) by 5 to obtain the 5-year average annual incidental M&SI level: [(trigger)/(observer coverage)]/5 = 5-year average incidental M&SI estimate;

(iii) Set the 5-year average annual incidental M&SI estimate from step (ii) to less than or equal to PBR: [(trigger)/(observer coverage)]/5 ≤ PBR;

(iv) Solve for the trigger: Trigger ≤ 5 * (observer coverage) * (PBR); and

(v) Round the trigger down to the nearest whole number, because the trigger is based on numbers of observed (whole) animals that are determined to have been killed or seriously injured.

For example, if PBR were 2.5 and observer coverage were 25 percent, the trigger would be set at 3, that is (5 * (0.25) * (2.5) = 3.125, rounded down to nearest whole number). If the trigger were zero, NMFS would close the SEZ at the beginning of the fishing year without waiting for a single observed false killer whale mortality or serious injury.

These figures would not represent the official bycatch estimates for false killer

whales in the fishery; the official bycatch estimates are calculated by separate methods and are presented in the annual SARs. For example, the official bycatch estimates include prorated incidental takes of false killer whales of unknown stock origin within the Hawaii insular/pelagic stock overlap zone, and prorated incidental takes based on the proportions of observed interactions that resulted in death, serious injury, or non-serious injury. Additionally, the estimates used in calculating the trigger would be necessarily less accurate and precise than the official estimates because they would calculated in real-time as false killer whales were observed incidentally taken by the fishery throughout the year, without the benefit of the entire year's data.

The proposed trigger would apply only to the Hawaii Pelagic stock of false killer whales given the stock's strategic status, the stated short-term goal of the proposed FKWTRP, and the location of the proposed closure. For the purposes of identifying the SEZ trigger and implementing contingency measures, any false killer whale incidentally taken inside the EEZ around Hawaii would be assumed to be part of the Hawaii Pelagic stock, unless the animal could be positively identified as belonging to the Insular stock through photo-identification or genetic analysis of a tissue sample. Additionally, only observed serious injuries or mortalities would be counted when determining whether the trigger was met; injuries determined to be non-serious would not count toward the trigger. Therefore, a determination would need to be made before incidental M&SI could be calculated. Under current protocol, on-board observers collect data on marine mammal interactions. NMFS PIROP staff debrief the observers and ensure the data are, in fact, accurate. NMFS scientists then evaluate each interaction by comparing the data against objective criteria to determine whether the injury is serious. Finally, NMFS Pacific Islands and Southwest Fisheries Science Centers and the Pacific Scientific Review Group review the scientists' determination before NMFS makes a final injury determination (i.e., non-serious or serious). The FKWTRT recommended that NMFS expedite the process of making serious injury determinations for these animals, to allow for the timely implementation of specified contingency measures (see ''*(3) Expedite False Killer Whale Serious Injury Determinations''* under ''Proposed Non-Regulatory Measures'' below).

(b) *Observed incidental M&SI below the trigger.* For each mortality or serious injury in the deep-set longline fishery inside the EEZ around Hawaii that is below the established trigger in a given fishing year, NMFS would notify the FKWTRT, and for the last mortality or serious injury before the trigger is met, NMFS would convene the FKWTRT by teleconference to discuss the circumstances of the event. For example, if the trigger is set at 4 observed false killer whales, NMFS would notify the FKWTRT of the first and second mortalities or serious injuries, and would convene the FKWTRT by teleconference after the third observed mortality or serious injury. This process is a slight modification from the FKWTRT's recommendations; the FKWTRT only explicitly considered the case of a trigger of 2, and thus did not make specific recommendations regarding NMFS' actions for observed incidental M&SI other than the single mortality or serious injury just before the trigger would be met. However, NMFS believes this proposed process meets the FKWTRT's intent regarding notification and discussion of observed false killer whale incidental M&SI.

(c) *Observed mortality or serious injury that meets the trigger.* The FKWTRT recommended, and NMFS proposes, that if there is an observed false killer whale mortality or serious injury in the deep-set longline fishery inside the EEZ around Hawaii that meets the established trigger for a given year, NMFS would close the SEZ until the end of that year, and then convene the FKWTRT for an in-person meeting. As described above, NMFS would first need to confirm that the animal was a false killer whale and determine that the animal was seriously injured or killed, before NMFS closed the SEZ. For example, if the trigger is set at 4 observed false killer whales, following the fourth observed false killer whale mortality or serious injury, NMFS would close the SEZ to deep-set longline fishing until the end of the year and would convene the FKWTRT for an in-person meeting. NMFS would reopen the SEZ at the beginning of the next year. The availability of funding may limit NMFS' ability to convene the FKWTRT for an in-person meeting. Regardless of whether NMFS has convened an in-person FKWTRT meeting, NMFS would reopen the SEZ at the beginning of the next year.

If a closure of the proposed SEZ is triggered, NMFS would notify the fishery and close the area for the specified time period (the rest of the year) through a **Federal Register** notice. The notice would include the specifics of the closure, as well as when and how the SEZ would be reopened.

Additional mortalities or serious injuries of false killer whales in the deep-set longline fishery in the EEZ after the SEZ is closed may warrant review of FKWTRP implementation or effectiveness. Therefore, if during the same calendar year following closure of the SEZ, there is an observed false killer whale mortality or serious injury on a deep-set longline trip anywhere in the EEZ around Hawaii, then NMFS would again convene the FKWTRT to discuss the circumstances of the event and consider the effectiveness of the SEZ closure. The FKWTRT may be convened by teleconference or other efficient means.

(d) *Observed incidental mortality or serious injury in consecutive year(s).* If the SEZ is closed in a given year, and there is one observed false killer whale mortality or serious injury in the deep-set longline fishery inside the EEZ around Hawaii in any of the next four consecutive years, NMFS proposes to convene the FKWTRT for an in-person meeting, and close the SEZ to deep-set longline fishing until reopened by NMFS after consultation with the FKWTRT.

This proposed measure differs from the FKWTRT's recommendation. The FKWTRT recommended that if NMFS closed the SEZ in a given year upon meeting the established trigger (and reopened the SEZ at the beginning of the next year), NMFS would again close the SEZ in the next consecutive year only if the same trigger was met. NMFS believes the FKWTRT's recommendation for this step is incompatible with the statutory requirement to bring incidental M&SI below PBR within six months of plan implementation, and to insignificant levels within 5 years. For example, at the current level of 20 percent observer coverage and PBR level of 2.5, the trigger would be set at 2. If there were two observed mortalities or serious injuries of false killer whales inside the EEZ around Hawaii, this would result in an estimated 10 false killer whale mortalities or serious injuries for that year. If, as per the FKWTRT's recommendation, the same trigger (2) was met in the next year, this would also result in an estimate of 10 false killer whales for that year, for a total of 20 false killer whale mortalities or serious injuries in two years. Even if no other false killer whales were taken in the following 3 years, a 5-year average incidental M&SI would be approximately 4 animals per year, which exceeds the stock's PBR level of

2.5 animals per year. The amount by which PBR would be exceeded under the FKWTRT's recommended trigger/closure regime would be even larger as PBR (and the trigger) increases. Therefore, NMFS is proposing a lower threshold for closing the SEZ, to increase assurance that false killer whale mortalities and serious injuries do not exceed PBR.

As stated in ''(a) *Defining the trigger''* above, the calculation for the trigger assumes there would be no additional incidental M&SI in the four years following the initial, temporary SEZ closure. In almost all cases (except for the unlikely scenarios where there are very high levels of observer coverage and a high PBR), a single additional mortality or serious injury in any of those four years would cause the 5-year average incidental M&SI level to exceed PBR, thus necessitating re-closure of the SEZ. The FKWTRT's recommendation to use the same trigger in consecutive years is not compatible with the assumptions of the trigger calculation. Additionally, the FKWTRT developed the SEZ and its associated closures as a ''backstop'' to reduce false killer whale incidental M&SI should the other measures in the plan fail to achieve the required reductions. The fact that false killer whales may continue to be hooked or entangled in the shallow-set longline fishery anywhere it operates, and in the deep-set longline fishery in open areas of the EEZ around Hawaii and on the high seas provides support for a more protective set of restrictions in the SEZ.

For example, if PBR were 4 and observer coverage were 20 percent, the trigger would be set at 4. If 4 false killer whale incidental M&SI were observed in the current year (''year 1''), the annual incidental M&SI estimate would be 20, and assuming zero incidental M&SI in the next four years, the 5-year average annual incidental M&SI level would be 4, which is equal to PBR. Under this scenario, NMFS would close the SEZ after the fourth observed false killer whale mortality or serious injury, and reopen the SEZ at the beginning of the next year. If there was 1 false killer whale mortality or serious injury observed in the following year (''year 2''), the annual incidental M&SI estimate for year 2 would be 5, and the 5-year average annual incidental M&SI level (including the estimated 20 M&SI from year 1, and the estimated 5 M&SI from year 2, and assuming zero M&SI for the following 3 years) would be 5, which exceeds PBR. Therefore, NMFS would close the SEZ following the first observed mortality or serious injury in year 2.

If a closure of the proposed SEZ is triggered, NMFS proposes to notify the fishery and close the area through a **Federal Register** notice. The notice would include the specifics of the closure, as well as conditions NMFS would consider in determining when and how to reopen the SEZ.

(e) *Reopening the SEZ.* The FKWTRT recommended that NMFS reopen the SEZ if one or more of the follow criteria were met: (i) NMFS determines, upon consideration of the FKWTRT's recommendations and evaluation of all relevant circumstances (e.g., the mortality or serious injury was a result of non-compliance with gear requirements, rather than an indication that the FKWTRP measures were ineffective), that reopening of the SEZ is warranted; (ii) in the 2-year period immediately following the date of the SEZ closure, the deep-set longline fishery has zero observed false killer whale incidental M&SI within the remaining open areas of the EEZ around Hawaii; (iii) in the 2-year period immediately following the date of the closure, the deep-set longline fishery has reduced its combined rate of false killer whale incidental M&SI within the remaining open areas of the EEZ around Hawaii and on the high seas (which includes the EEZ around Johnston Atoll, but not Palmyra Atoll) by an amount proportionate to the rate that would be required to reduce false killer whale incidental M&SI within the EEZ around Hawaii to below the stock's PBR (e.g., if the PBR for the Hawaii Pelagic stock inside the EEZ around Hawaii was 2.5 and false killer whale incidental M&SI inside the EEZ was 7.3, an approximately 66 percent reduction in estimated incidental M&SI for the entire deep-set fishery would be necessary to meet the threshold); or (iv) the average estimated level of false killer whale incidental M&SI in the deep-set longline fishery within the remaining open areas of the EEZ around Hawaii for up to the 5 most recent years following implementation of the final FKWTRP is below the PBR for the Hawaii Pelagic stock of false killer whales at that time.

NMFS may consider these and other criteria when determining when to reopen the SEZ, but is not proposing to include the criteria in regulations. NMFS needs to maintain flexibility and consider scenarios not addressed by the criteria developed by the FKWTRT. For example, if the FKWTRT recommended and NMFS adopted additional measures intended to reduce false killer whale incidental M&SI, NMFS could reopen the SEZ before the criteria outlined above were met. Alternatively, NMFS could consider keeping the SEZ closed for a period longer than specified in the criteria above, if the total number of false killer whale incidental M&SI, including those incidentally taken in open areas of the EEZ, exceeded PBR to such a degree that the 5-year average incidental M&SI level could not drop below PBR.

The proposed requirements for the SEZ trigger and procedures would be specified at 50 CFR part 229.

Proposed Non-Regulatory Measures

NMFS proposes the following 6 non-regulatory measures, the implementation for which would be NMFS' responsibility:

(1) Increase the precision of bycatch estimates in the deep-set longline fishery;

(2) Notify the FWKTRT when there is an observed interaction of a known or possible false killer whale, and provide the FKWTRT with any non-confidential information regarding the interaction;

(3) Expedite the process for confirming the species identification of animals involved in such interactions and for making serious injury determinations;

(4) Make specific changes to the observer training and data collection protocols;

(5) Expedite processing the 2010 HICEAS II survey data and provide preliminary results to the FKWTRT; and

(6) Reconvene the FWKTRT at regular intervals.

Though these measures are part of the proposed FKWTRP, they are not proposed as regulations, and would not be included in the take reduction plan regulations at 50 CFR part 229. These proposed non-regulatory measures are more fully described below.

(1) Increase Precision of Bycatch Estimates

NMFS currently requires that observer coverage in the deep-set longline fishery be maintained at an annual level of at least 20 percent, as per the Terms and Conditions of the October 4, 2005 ESA Biological Opinion on the deep-set longline fishery (NMFS, 2005b). Coverage levels vary throughout the year because of fluctuation in the longline fleet's activity level, the demands of 100 percent coverage in the shallow-set longline fishery, and an influx of observers after completing the PIROP observer training course (McCracken, 2009). Observed trips in the deep-set longline fishery are selected using two sampling schemes to accommodate this fluctuating coverage and to utilize observers efficiently. The primary scheme is a systematic sample of ''call numbers,'' which are assigned

when longline vessels call the PIROP contractor before departing on a fishing trip (McCracken, 2009). Currently, the quarterly sample selected under this systematic design is targeted at 15 percent, but it may be closer to 10 percent, particularly in the first quarter of the year. Additional trips needed to reach the full targeted level (i.e., 20 percent) are selected using a secondary sampling scheme, when all trips selected by the systematic sample are already covered and an observer is available for deployment. The additional trips are randomly selected with equal probability from the calls received that day that had not already been selected. This secondary sampling, or ''day sampling,'' is flexible and dependent on the need to deploy observers (McCracken, 2009).

The FKWTRT recommended NMFS increase observer coverage in the deep-set longline fishery to at least a 25 percent average quarterly coverage rate, to increase the precision (i.e., decrease the error) of the bycatch estimate in the fishery. Following submission of the FKWTRT's recommendations, NMFS conducted an analysis to determine how the error in estimated bycatch of cetaceans could be reduced by increasing observer coverage (McCracken and Boggs, 2010). This analysis indicates that ensuring the systematic coverage is at a minimum of 15 percent year-round provides a greater benefit in relation to error reduction than a systematic sample increase from 15 percent to 20 percent, or an overall sample increase from 20 percent to 25 percent.

NMFS proposes to implement an increase in systematic observer coverage in the deep-set longline fishery, though there would be no increase in overall coverage. Day sampling would continue to be used to meet the additional minimum of 5 percent to attain the targeted 20 percent coverage for the deep-set longline fishery. NMFS would work with the observer contractor to reallocate observers and schedule observer trainings appropriately to ensure enough observers are available to meet the new sampling targets for the deep-set longline fishery. NMFS has already begun to implement these changes.

(2) Notify the FKWTRT of Observed Interactions

The FKWTRT requested that NMFS notify the Team when there is an observed interaction of a known or possible false killer whale, and provide the Team with any non-confidential information regarding the interaction. This information is currently available through PIROP's quarterly and annual reports. Because this information may be useful for the FKWTRT as it considers the success of the management measures and considers amendments, NMFS proposes to expedite the internal processing and approval of observer data on the trips where false killer whales or possible false killer whales were injured or killed, and provide any non-confidential information to the FKWTRT members for their consideration as soon as practical after the event. NMFS has already begun to implement these changes.

(3) Expedite False Killer Whale Serious Injury Determinations

The FKWTRT recommended that when there is an observed interaction of a known or possible false killer whale, NMFS should confirm species identification and make the serious injury determination as soon as possible after the observer debriefing and data approval for the interaction, and provide the non-confidential information to the FKWTRT with the rationale for the determination. Currently, preliminary serious injury determinations for the Hawaii-based longline fisheries are made once a year by NMFS scientists, and are reviewed by the Pacific Scientific Review Group (PSRG) at their annual meeting before being finalized. NMFS understands that an expedited process to provide final serious injury determinations closer to real-time would assist the FWKTRT in monitoring the success of the FKWTRP, and would be necessary to determine whether the trigger for closing the Southern Exclusion Zone has been met. Therefore, NMFS proposes to make the serious injury determinations as soon as possible by coordinating with PIROP, NMFS Pacific Islands and Southwest Fisheries Science Centers, and the Pacific Scientific Review Group.

(4) Changes to Observer Data Collection Protocol and Training

In its deliberations, the FKWTRT relied heavily on analyses of observer program data. The FKWTRT noted that specific information that is not currently collected would be useful to support future FKWTRT deliberations and to further understand and identify patterns of marine mammal bycatch. The FKWTRT recommended that NMFS modify the observer data forms to collect the following types of information: (a) Differentiation among marine mammal mouth hooking types (lip, jaw, internal, ingested, other); (b) more detail on how bycaught marine mammals are handled and any efforts made to release them without gear; (c) hook type and terminal tackle configuration of the gear involved in the interaction; (d) whether sets are split, and the configuration of split sets; (e) details of vessel light configuration and how the lights are utilized; (f) presence/absence of false killer whales during setting and haul-back of gear; (g) false killer whale sighting data (e.g., location, group size, behavior) during transits, as well as visual sighting effort data; and (h) injuries to vessel crew that are incurred due to gear changes and release of protected species.

The FKWTRT also made recommendations regarding observer protocol during and after marine mammal interactions. The FKWTRT recommended that observers should: (a) Encourage the vessel crew to inform the captain immediately if/when a marine mammal is hooked or entangled; (b) encourage the vessel crew not to cut the line unless instructed by the vessel captain or the observer; (c) encourage captains to comment on the observer's Marine Mammal Biological Data Form after an interaction when a captain can offer additional information; and (d) retain gear from interactions, including branchlines and leaders even in the absence of a hook, and collect any marine mammal tissues that may be present on the gear.

The FKWTRT made the following recommendations regarding observer training: (a) Include videos from prior marine mammal hookings and entanglements and subsequent releases; (b) provide better photographic equipment to experienced observers and train them in photo-identification of individual false killer whales through dorsal fin and other markings, to support false killer whale research; and (c) train a highly-qualified sub-set of observers to obtain biopsy samples of bow-riding false killer whales, after authorization through a research permit.

NMFS proposes to implement the recommended changes, as possible, through appropriate changes to the data collection forms, observer protocol, and/or observer training, but notes that some of the recommendations are already being implemented through existing data forms, protocol, and training. For example, the Marine Mammal Biological Data form prompts the observer to differentiate between mouth hookings and ingested hooks, if known, and would only require the addition of check boxes for lip or jaw hookings. The form also contains check boxes for each gear type that remained on the animal (e.g., branchline, weight), boxes to note the hook type and size involved in the interaction, and a comment section

specifically for describing the gear remaining on the animal. The form also has space for other comments and drawings of the interaction, and observers are instructed to provide as much detail as possible on all aspects of the interaction, including any efforts to remove gear from the animal. NMFS may develop a list of specific questions to ask the observer during debriefing to prompt for further detail. For these specific items, the forms may need only minor changes to address the FKWTRT's recommendations.

Regarding observer protocol during and after marine mammal interactions, observers are already instructed (via training and the Observer Manual) to share with the vessel operator all data items recorded, when requested, and if he or she is in disagreement with the observer, allow operators to record their own views on the original data forms. Observers are also trained to retain gear from marine mammal interactions and to collect any marine mammal tissue on the gear. Finally, regarding observer training, NMFS includes 4 to 5 videos from prior marine mammal hookings and entanglements in a lecture about marine mammal interactions. These presentations are regularly updated with new videos when available.

(5) 2010 HICEAS II Survey Data

NMFS conducted a cetacean assessment survey in the EEZ around Hawaii (Hawaiian Islands Cetacean and Ecosystem Assessment Survey, or HICEAS II) in August–December 2010. The survey was a collaborative effort between the NMFS Pacific Islands and Southwest Fisheries Science Centers, and involved 175 days at sea on two NOAA research vessels. It is anticipated that the HICEAS II survey will result in updated abundance estimates for all Hawaiian cetaceans, including false killer whales; preliminary estimates will likely be available by the end of 2011 or early 2012. The FKWTRT recommend that NMFS expedite the processing of the survey data and provide preliminary results to the FKWTRT once the PSRG has completed its review. The FKWTRT also recommended the PSRG complete its review as expeditiously as possible.

To the extent possible, NMFS proposes to expedite processing and review of the 2010 HICEAS II survey data and provide preliminary results to the FKWTRT.

(6) Reconvene FWKTRT at Regular Intervals

The FKWTRT recommended that NMFS should reconvene the FKWTRT every 6 months for at least 2 years following implementation of the FKWTRP, and at appropriate intervals thereafter to continue to monitor the progress of the FKWTRP in reaching its short- and long-term goals, and discuss amending to the FKWTRP if necessary. The availability of funding may limit the frequency with which NMFS can reconvene the FKWTRT for in-person meetings. Therefore, NMFS proposes to reconvene the FKWTRT at regular intervals for in-person meetings and/or teleconferences, depending on available funding.

Additional Research and Data Collection

The FKWTRT developed a list of 35 research recommendations, which were prioritized within and across four categories: False killer whale biology; longline gear and fishing; shortline and kaka line fishing; and false killer whale assessment. The top nine ranked research activities include: (1) Evaluate the impact of weak and/or circle hooks on false killer whale bycatch; (2) understand the impact of weak hooks on target species catch rates; (3) develop methods for the longline fleet to use acoustic recorders to determine false killer whale presence prior to setting gear; (4) assess shortline and kaka line fishing, including the number of vessels, location, timing, and method of fishing; (5) distinguish false killer whale calls from other odontocete species; (6) telemetry studies to examine the range and movement of false killer whales; (7) regular surveys of the EEZ around Hawaii, at least every 5 years, to estimate cetacean abundance; (8) continue research into false killer whale abundance using towed and stationary acoustics; and (9) collect additional false killer whale genetic samples to assess population structure. The FKWTRT also listed five additional research topics that were not included in the ranked list. Details of all of the recommended research topics can be found in Chapter 9 of the Draft FKWTRP (FKWTRT 2010). The FKWTRT noted the iterative process inherent in research and the need to maintain the list of research priorities as a ''living document,'' with changes and additions anticipated over the course of the take reduction process.

NMFS proposes to pursue the additional research and data collection goals outlined by the FKWTRT, within the constraints of available funding. Further, NMFS proposes to consider the FKWTRT's recommendations for additional research and data collection when establishing NMFS' funding priorities. NMFS would follow the recommendations to the extent that good scientific practice and resources allow. As feasible and appropriate, NMFS would consult and coordinate with the FKWTRT during this process. As noted above for non-regulatory measures, these research recommendations are part of the proposed FKWTRP, but they are not proposed as regulations and would not be included in the take reduction plan regulations at 50 CFR part 229.

Evaluating the Effectiveness of the FKWTRP

The MMPA specifies that take reduction teams shall meet every six months, or at such other intervals as necessary, to monitor the implementation of the final take reduction plan until the objectives of the plan have been met. Under the proposed FKWTRP, the FKWTRT would periodically: (1) Analyze the status of scientific information on false killer whales; (2) evaluate the effectiveness of the FWKTRP, both in terms of meeting MMPA and stated goals; and (3) adjust the FKWTRP's management measures and research program, as appropriate, to ensure that the short- and long-term goals of the FKWTRP will be met. NMFS would provide to the FKWTRT updates on the following types of information to inform these periodic assessments: (1) Status of FWKTRP implementation; (2) SARs; (3) observed false killer whale interactions in the longline fishery and associated serious injury determinations; (4) preliminary results of the HICEAS II survey; (5) other data collection and research findings, including the results of the weak circle hook experiment; and (6) the status of observer coverage. The timing of these assessments would be tied to both the availability of data and the time needed to adequately evaluate the effectiveness of management measures or the results of the research program.

Measures of Success

The short-term and long-term goals of the FKWTRP are described above (''Goals of the FKWTRP''), and are defined to meet the MMPA requirements for reducing incidental false killer whale incidental M&SI. The FKWTRT recognized that there may be other measures of success of the FKWTRP, and identified 12 measures of progress or success for various components of the Draft FKWTRP. These include: (1) Fully implement circle hooks in the deep-set longline fishery; (2) complete weak circle hook research and associated implementation of weak circle hooks, as indicated by research; (3) achieve zero false killer whale incidental M&SI in two years

within the EEZ around Hawaii; (4) achieve a reduction of false killer whale incidental M&SI consistent with the percentage needed to move below PBR within the EEZ around Hawaii; (5) reduce the false killer whale incidental M&SI rate; (6) measurably reduce the false killer whale incidental take rate; (7) convene the FKWTRT twice each year for the two years following FKWTRP implementation; (8) achieve observer deployment levels of 25 percent or more in the deep-set longline fishery; (9) make progress in each of the four identified research categories; (10) complete the 2010 HICEAS II survey and provide the results to the FKWTRT in the manner recommended in the Draft FKWTRP; (11) complete cetacean assessment surveys on the recommended schedule (every five years); and (12) achieve rapid processing of and notification of the FKWTRT of false killer whale incidental M&SI information.

NMFS would monitor and consult with the FKWTRT regarding progress toward meeting the goals of the FKWTRP and the other identified measures of success. The measures of success listed above may change based on the management measures contained in the final FKWTRP (e.g., an increase in precision of bycatch estimates rather than an overall increase in observer coverage in the deep-set longline fishery).

Public Comments Solicited

NMFS is soliciting comments on any aspect of this proposed rule, including the development and implementation of the FKWTRP pursuant to MMPA section 118(f)(1) and the regulatory and non-regulatory measures proposed. NMFS is particularly interested in comments on the proposed SEZ, including the methods for calculating and determining the trigger, changing the trigger, and implementing the closure based on the trigger. NMFS is also specifically soliciting comments on the timing for implementing the proposed measures, and whether certain proposed measures, such as the hook and branchline requirements, would benefit from delayed implementation to allow time for suppliers to obtain an adequate quantity of the required gear, and for fishermen to purchase and switch over their gear.

Classification

NMFS determined that this action is consistent to the maximum extent practicable with the enforceable policies of the approved coastal management program of the State of Hawaii. This determination has been submitted for review by the responsible state agency under section 307 of the Coastal Zone Management Act.

Executive Order (E.O.) 13132 requires agencies to take into account any federalism impacts of regulations under development. It includes specific consultation directives for situations where a regulation will preempt state law, or impose substantial direct compliance costs on state and local governments (unless required by statute). This proposed rule does not contain policies with federalism implications under E.O. 13132. All of the proposed actions would occur in the Exclusive Economic Zone beyond state jurisdiction. Pursuant to E.O. 13132, the Assistant Secretary for Legislative and Intergovernmental Affairs will provide notice of the proposed action and request comments from the governor of the State of Hawaii.

NMFS prepared a draft environmental assessment for this action that discusses the impact on the environment as a result of this proposed rule. The Preferred Alternative (the proposed action) would be expected to have beneficial effects on false killer whales and other protected species due to potential reductions in interactions and/or injury severity from use of weak circle hooks, minimum line diameter, and closed areas; increased precision of bycatch estimates to better inform management and facilitate adaptive management; and the potential for increased post-interaction survival of entangled or hooked marine mammals due to better training in handling/release, captains' supervision of interactions, crew notification of captains when a marine mammal is hooked or entangled, and posting of handling/release guidelines on the vessel. No effects to the physical environment, including designated Essential Fish Habitat, Habitat Areas of Particular Concern, Critical Habitat, or physical features, or to target and non-target species would be expected. Potential effects to the socioeconomic environment include costs to the regulated community for replacement of fishing gear, increased travel time and fuel costs, increased certification requirements, and potential reduced revenue due to reduced catch and fishing effort; potential reductions in revenue and income of fishing gear suppliers due to some gear inventory being unsellable to the Hawaii-based longline fisheries; direct and indirect beneficial quality of life effects on groups that value the false killer whale, including recreationists and tourists, wildlife viewers, scientists and educators, and members of present and future generations of the general public; and some positive effect on non-longline commercial fisheries or recreational/subsistence fisheries if target fish population abundance rises. A copy of the draft environmental assessment is available on *www.regulations.gov* and the FKWTRT website (*http://www.nmfs.noaa.gov/pr/interactions/trt/falsekillerwhale.htm),* and is available upon request from the Regulatory Branch Chief [see **ADDRESSES**].

This proposed rule has been determined to be not significant for the purposes of E.O. 12866.

NMFS prepared an initial regulatory flexibility analysis (IRFA), pursuant to section 603 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), that describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and its legal basis are included in the preamble of this proposed rule. A summary of the analysis follows. The full analysis is available on *www.regulations.gov* or by request from the Regulatory Branch Chief [see **ADDRESSES**].

The number of longline vessel operations was identified from the list of Hawaii longline limited access permit holders. The maximum number of active vessels in Hawaii's longline fleet in the last 5 years is 129. Given that these vessels are owned by 88 individuals, it is assumed based on available data that the fleet is made up of 88 independently-owned businesses. There is only one business with 14 vessels that may not meet the criteria of a small business. Therefore, the analysis identifies 87 small businesses that are anticipated to be directly regulated by the alternatives considered. Of these small businesses identified, 68 businesses own 1 vessel each, 15 businesses own 2 vessels each, 2 businesses own 3 vessels each, 1 business owns 5 vessels, and 1 business owns 6 vessels. For the purpose of this analysis, it is assumed that all these small business are associated with the deep-set longline fishery.

The alternatives considered and analyzed include three options. Alternative 1 (the No Action alternative) would maintain the status quo management for the Hawaii-based longline fisheries under the Fishery Ecosystem Plan for Pacific Pelagic Fisheries of the Western Pacific Region. Alternative 2 (the Preferred Alternative and proposed action) would implement the regulatory and non-regulatory measures recommended by the FKWTRT, with some modifications. These measures are described in the

preamble of this proposed rule. Alternative 3 would close the EEZ around Hawaii to all commercial longline fishing. Alternatives 2 and 3 are herein referred to as the ''Action Alternatives.''

The Action Alternatives are not expected to generate benefits to the small businesses in the longline fishery, as both alternatives would further restrict the location of longline fishing, and in the case of the Preferred Alternative, require the use of specific gear, additional training, and response to marine mammal interactions.

Costs associated with the Preferred Alternative stem from labor and material costs of replacing hooks and monofilament branchlines; potential lost revenue due to potential effects of weak circle hooks on the total weight of tuna caught and revenue generated; additional travel costs (fuel and time) of fishing outside the MHI longline exclusion zone during the time it is currently open to longline fishing, as well as the cost of fishing outside the SEZ (if triggered); and annual cost of Protected Species Workshop certification of operators and owners. Initial, one-time costs would be expected to range from $2,000 to $5,000 per business for the 68 businesses owning 1 vessel each, to $14,000–$33,000 for the single business owning 6 vessels. Annual ongoing costs would be expected to range from $23,000 to $62,000 per business for the 68 businesses owning 1 vessel each, to $140,000–$370,000 for the single business owning 6 vessels. Cost per business for the small number of vessels owning between 2 and 5 vessels would be expected to fall within the ranges identified above.

The complete closure of the EEZ around Hawaii to longline fishing under Alternative 3 would be expected to incur more significant overall annual costs to small businesses, although no one-time capital costs are anticipated. These costs are associated with the opportunity cost of increased travel time to fishing grounds outside of the EEZ. Annual ongoing costs associated with implementing Alternative 3 range from $67,000 to $79,000 per business for the 68 businesses owning 1 vessel each, to $401,000–$474,000 for the single business owning 6 vessels. Cost per business for the small number of vessels owning between 2 and 5 vessels would be expected to fall within the ranges identified above.

No additional reporting, record-keeping, and other compliance requirements are anticipated for small businesses. NMFS has identified no Federal rules that may duplicate, overlap, or conflict with the action alternatives. After careful examination of the best available scientific data on false killer whales, NMFS believes that only the two Action Alternatives have the potential to accomplish the stated objectives and legal mandates associated with the conservation of this species. Retention of the ''No Action'' alternative is not a viable choice for several reasons. Retaining the No Action alternative would be contrary to the agency's obligations under the MMPA to reduce fishery impacts on false killer whales to acceptable levels. Additionally, adopting the status quo would not be consistent with the objectives identified by the agency for this action. Both Alternatives 2 and 3 would meet the objectives of the proposed rule. Alternative 3 was not selected because it would likely result in substantially greater economic impacts to small entities than the Preferred Alternative, without a greater likelihood of achieving the objectives of the proposed rule.

References Cited

A list of all references cited in this proposed rule may be found on *www.regulations.gov* and the FKWTRT website (*http://www.nmfs.noaa.gov/pr/interactions/trt/falsekillerwhale.htm),* and is available upon request from the Regulatory Branch Chief (see **ADDRESSES**).

List of Subjects

50 CFR Part 229

Administrative practice and procedure, Fisheries, Marine mammals.

50 CFR Part 665

Administrative practice and procedure, Fisheries, Hawaii, Longline, Marine mammals.

Dated: July 11, 2011.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR chapters II and VI are proposed to be amended as follows:

CHAPTER II

PART 229—AUTHORIZATION FOR COMMERCIAL FISHERIES UNDER THE MARINE MAMMAL PROTECTION ACT OF 1972

1. The authority citation for 50 CFR part 229 reads as follows:

Authority: 16 U.S.C. 1361 *et seq.*

2. In § 229.3, add paragraphs (v) through (y) to read as follows:

§ 229.3 Prohibitions.

* * * * *

(v) It is prohibited to deep-set from a vessel registered for use under a Hawaii longline limited access permit unless the vessel complies with the gear requirements specified in § 665.813(k) and (l) of this title.

(w) It is prohibited to fish with longline gear in the Main Hawaiian Islands Longline Fishing Prohibited Area, as defined in § 665.806(c) of this title.

(x) It is prohibited to deep-set in the Southern Exclusion Zone, as defined in § 229.37(d)(2) of this part, during the time the area is closed to deep-set longline fishing pursuant to paragraph § 229.37(e) of this part.

(y) It is prohibited to fish with longline gear from a vessel registered for use under a Hawaii longline limited access permit in violation of the marine mammal handling and release requirements at paragraph § 229.37(f) of this part.

3. In subpart C, add § 229.37 to read as follows:

§ 229.37 False Killer Whale Take Reduction Plan.

(a) *Purpose and scope.* The purpose of this section is to implement the False Killer Whale Take Reduction Plan to reduce mortality and serious injury of the Hawaii pelagic, Hawaii insular, and Palmyra Atoll stocks of false killer whales in the Hawaii-based deep-set and shallow-set pelagic longline fisheries. The requirements in this section apply to vessel owners and operators, and vessels registered for use with Hawaii longline limited access permits issued under § 665.801(b) of this title.

(b) *Definitions.* In addition to the definitions contained in § 229.2 of this part, terms in this section have the following meanings:

(1) *Deep-set or Deep-setting* has the same meaning as the definition at § 665.800 of this title.

(2) *Longline gear* has the same meaning as the definition at § 665.800 of this title.

(c) *Gear requirements.* While deep-setting, the owner and operator of a vessel registered for use under a Hawaii longline limited access permit must comply with the hook, branch line, and leader requirements described in § 665.813(k) and (l) of this title.

(d) *Prohibited area management.* (1) MHI Longline Fishing Prohibited Area. Longline fishing is prohibited in the MHI Longline Fishing Prohibited Area as defined in § 665.806(c) of this title.

(2) Southern Exclusion Zone. Deep-set longline fishing is prohibited in the Southern Exclusion Zone when the zone is closed to protect false killer whales pursuant to the procedures outlined in paragraph (e) of this section. The Southern Exclusion Zone consists of the portion of the EEZ around the Hawaiian Archipelago enclosed by straight lines connecting the following coordinates in the order listed:

Point	N. lat.	W. lon.
L	22°46.16′	165° 00.00′
M	22° 14.45′	161° 44.38′
E	21°40.00′	161° 55.00′
D	20°40.00′	161° 40.00′
C	20°00.00′	157° 30.00′
B	18°20.00′	156° 25.00′
A	18°05.00′	155° 40.00′
N	18°45.02′	154° 30.00′

and from Point A south along longitude 165°00′ W. until intersecting the EEZ boundary around the Hawaiian Archipelago, and from Point H south along longitude 154°30′ W. until intersecting the EEZ boundary around the Hawaiian Archipelago.

(e) *Southern Exclusion Zone trigger and procedures.* (1) Prior to the start of each fishing year, the Assistant Administrator will publish in the **Federal Register** the expected observer coverage for the fishing year, the potential biological removal level for the Hawaii Pelagic stock of false killer whales, and the associated trigger calculated using the formula in paragraph (e)(2) of this section.

(2) As used in this section, *trigger* means the number of observed false killer whale mortalities or serious injuries in the deep-set longline fishery that occur in the EEZ around the Hawaiian Archipelago, and that serves as the bycatch threshold for closing the Southern Exclusion Zone to deep-set longline fishing. The trigger is calculated using the formula

Trigger = 5 * (percent observer coverage) * (potential biological removal)

and is rounded down to the nearest whole number.

(3) Unless otherwise subject to subparagraph (e)(4), if there is an observed false killer whale mortality or serious injury in the EEZ around the Hawaiian Archipelago on a declared deep-set longline trip that meets the established trigger for a given fishing year, the Southern Exclusion Zone will be closed to deep-setting until the end of that fishing year.

(4) If during any of the four calendar years following closure of the Southern Exclusion Zone in accordance with paragraph (e)(3) of this section, there is one observed false killer whale mortality or serious injury on a declared deep-set longline trip anywhere in the U.S. EEZ around the Hawaiian Archipelago, the Southern Exclusion Zone will be closed to deep-set longline fishing until the area is reopened by the Assistant Administrator.

(5) If during the same calendar year following closure of the Southern Exclusion Zone in accordance with paragraph (e)(3) of this section, there is one observed false killer whale mortality or serious injury on a declared deep-set longline trip anywhere in the U.S. EEZ around the Hawaiian Archipelago, then NMFS shall immediately convene the False Killer Whale Take Reduction Team.

(6) Upon determining that closing the Southern Exclusion Zone is warranted pursuant to the procedures in paragraphs (e)(1) through (4) of this section, the Assistant Administrator will provide notice to Hawaii longline permit holders and the False Killer Whale Take Reduction Team, publish a notice in the **Federal Register**, and post information on the NMFS Pacific Islands Regional Office Web site. The notice will announce that the fishery will be closed beginning at a specified date, which is not earlier than 7 days after the date of filing the closure notice for public inspection at the Office of the Federal Register.

(f) *Marine mammal handling and release.* (1) Each year, both the owner and the operator of a vessel registered for use with a longline permit issued under § 665.801 of this title must attend and be certified for completion of a workshop conducted by NMFS on interaction mitigation techniques for sea turtles, seabirds, and marine mammals, as required under § 665.814 of this title.

(2) Longline vessel operators (captains) must supervise and be in visual and/or verbal contact with the crew during any handling or release of marine mammals.

(3) A NMFS-approved placard setting forth marine mammal handling and/or release procedures must be posted on the longline vessel in a conspicuous place that is regularly accessible and visible to the crew.

(4) A NMFS-approved placard instructing vessel crew to notify the captain in the event of a marine mammal interaction must be posted on the longline vessel in a conspicuous place that is regularly accessible and visible to the crew.

CHAPTER VI

PART 665—FISHERIES IN THE WESTERN PACIFIC

4. The authority citation for 50 CFR part 665 reads as follows:

Authority: 16 U.S.C. 1801 *et seq.,* or 16 U.S.C. 1361 *et seq.*

5. In 665.802, add paragraph (n) to read as follows:

§ 665.802 Prohibitions.

* * * * *

(n) Fail to comply with hook, leader and branchline requirements while engaged in deep-setting from a vessel registered for use under a Hawaii longline limited access permit issued under § 665.801(b) in violation of § 665.813(k) and (l).

* * * * *

6. In § 665.806, revise paragraph (c) to read as follows:

§ 665.806 Longline fishing prohibited area management.

* * * * *

(c) Main Hawaiian Islands. The longline fishing prohibited area around the main Hawaiian Islands is the portion of the EEZ seaward of the Hawaiian Archipelago bounded by straight lines connecting the following coordinated in the order listed:

Point	N. lat.	W. long.
A	18°05′	155°40′
B	18°20′	156°25′
C	20°00′	157°30′
D	20°40′	161°40′
E	21°40′	161°55′
F	23°00′	161°30′
G	23°05′	159°30′
H	22°55′	157°30′
I	21°30′	155°30′
J	19°50′	153°50′
K	19°00′	154°05′
A	18°05′	155°40′

* * * * *

7. In § 665.813, revise the section heading and add paragraphs (k) and (l) to read as follows:

§ 665.813 Western Pacific longline fishing requirements.

* * * * *

(k) While deep-setting, owners and operators of vessels registered for use under a Hawaii longline limited access permit must use only hooks meeting the following specifications:

(1) Circle hooks of size 16/0 or smaller, or equivalent;

(2) Hook shank composed of round, non-flattened wire, with a wire diameter not to exceed 4.0 mm; and

(3) Offset not to exceed 10 degrees.

(l) While deep-setting, owners and operators of vessels registered for use

under a valid Hawaii longline limited access permit must use leaders and branch lines that all have a diameter of 2.0 mm or larger if the leaders and branch lines are made of monofilament nylon. If any other material is used for a leader or branch line, that material must have a breaking strength of at least 400 lb (181 kg).

[FR Doc. 2011–17965 Filed 7–15–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 110207103–1113–01]

RIN 0648–BA80

Fisheries of the Exclusive Economic Zone Off Alaska; Chinook Salmon Bycatch Management in the Bering Sea Pollock Fishery; Economic Data Collection

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement the Chinook Salmon Economic Data Report Program to evaluate the effectiveness of Chinook salmon bycatch management measures for the Bering Sea pollock fishery that were implemented under Amendment 91 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP). The data collected for this program would be submitted by members of the American Fisheries Act inshore, catcher/processor, and mothership sectors, as well as representatives for the six western Alaska Community Development Quota organizations that presently receive allocations of Bering Sea pollock. The proposed rule is intended to promote the goals and objectives of the FMP, the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable law.

DATES: Written comments must be received no later than August 17, 2011.

ADDRESSES: Send comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian. You may submit comments, identified by RIN 0648–BA80, by any one of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov*.
- *Mail:* P.O. Box 21668, Juneau, AK 99802.
- *Fax:* (907) 586–7557.
- *Hand delivery to the Federal Building:* 709 West 9th Street, Room 420A, Juneau, AK.

All comments received are a part of the public record. Comments will generally be posted without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Electronic copies of the Regulatory Impact Review/Initial Regulatory Flexibility Analysis (RIR/IRFA), Categorical Exclusion, and the four Paperwork Reduction Act Analyses (including Chinook salmon Economic Data Report forms) prepared for this action may be obtained from *http://www.regulations.gov* or from the NMFS Alaska Region Web site at *http://alaskafisheries.noaa.gov*.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to NMFS at the above address, and by e-mail to *mailto:OIRA_Submission@omb.eop.gov,* or by fax to 202–395–7285.

FOR FURTHER INFORMATION CONTACT: Jeff Hartman or Patsy A. Bearden at 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the U.S. groundfish fisheries of the Bering Sea and Aleutian Islands Management Area (BSAI) in the exclusive economic zone under the FMP. The North Pacific Fishery Management Council (Council) prepared the FMP pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) 16 U.S.C. 1801, *et seq*. Regulations implementing the FMP appear at 50 CFR part 679. General regulations that pertain to U.S. fisheries appear at subpart H of 50 CFR part 600.

This proposed rule would implement the Chinook Salmon Economic Data Report (EDR) program for the Chinook salmon bycatch management measures implemented under Amendment 91 to the FMP. The Chinook Salmon EDR program applies to owners and operators of catcher vessels, catcher/processors, motherships, and the six Western Alaska Community Development Quota (CDQ) Program groups qualified to participate in the pollock (*Theragra chalcogramma*) fishery in the Bering Sea subarea of the BSAI. The proposed rule also applies to the representatives of participants in the Bering Sea pollock fishery.

Background

AFA Sectors, Cooperatives, and CDQ Groups

NMFS manages the Bering Sea pollock fishery under the American Fisheries Act (AFA) (16 U.S.C. 1851 note). The AFA ''rationalized'' the Bering Sea pollock fishery in part by authorizing the formation and management of fishery cooperatives in the three pollock sectors (catcher/processor, mothership, and inshore). A portion of the Bering Sea pollock fishery is managed by a separate CDQ program. The inshore sector's pollock is subdivided among seven inshore cooperatives. The purpose of these AFA cooperatives is to further subdivide each sector's or inshore cooperative's pollock allocation among participants in the sector or cooperative through private contractual agreements. The cooperatives manage these allocations to ensure that individual vessels and companies do not harvest more than their agreed upon share of pollock. The cooperatives also facilitate transfers of pollock among the cooperative members, enforce contract provisions, and are allowed to participate in an intercooperative agreement to reduce salmon bycatch. A more detailed description of AFA cooperatives and intercooperative agreements may be found in the RIR/IRFA for this proposed action (see **ADDRESSES**).

The total allowable catch (TAC) for Bering Sea pollock and allocations to each of the AFA sectors and CDQ groups participating in the Bering Sea pollock fishery are specified annually (see 75 FR 11749, March 12, 2010 for 2010/2011 specifications). After the CDQ Program allocation and allowance for incidental catch of pollock in other fisheries is subtracted, NMFS allocates the remaining TAC to vessels harvesting pollock for processing by inshore processors, vessels harvesting pollock for processing by catcher/processors, and vessels harvesting pollock for processing by motherships. Some

catcher vessels do not join an inshore cooperative. These CVs participate in the inshore open-access fishery and so do not receive an allocation of pollock. Each year, catcher vessels eligible to deliver pollock to the seven AFA inshore processors may form inshore cooperatives associated with a particular inshore processor. The AFA catcher/processor sector consists of AFA-eligible vessels in the Pollock Conservation Cooperative (PCC) and High Seas Catcher's Cooperative (HSCC). The HSCC consists of owners of the catcher vessels eligible to deliver pollock to the catcher/processors. NMFS issues an annual allocation of pollock to the entire catcher/processor sector, based on the aggregate of each vessel's pollock catch history.

The AFA mothership sector consists of three motherships and the AFA-eligible catcher vessels that deliver pollock to these motherships. The catcher vessels have formed a cooperative called the Mothership Fleet Cooperative (MFC). The MFC sub-allocates the mothership sector pollock allocation among the catcher vessels authorized to harvest this pollock. NMFS does not manage the sub-allocations of pollock among members of the PCC, HSCC, or MFC. The cooperatives control the harvest by their member vessels so that the pollock allocation to the sector is not exceeded. However, NMFS monitors pollock harvest by all members of the catcher/processor sector and mothership sector. NMFS retains the authority to close directed fishing by sector if vessels in that sector continue to fish once the sector's seasonal allocation of pollock has been harvested.

Chinook Salmon Bycatch in the Bering Sea Pollock Fishery

The Magnuson-Stevens Act defines bycatch as fish that are harvested in a commercial fishery but neither sold nor kept for personal use. Chinook salmon is categorized as bycatch under the Magnuson-Stevens Act, the BSAI FMP, and NMFS regulations at 50 CFR part 679. Bycatch of any species, including discard or other mortality caused by fishing, is a concern of the Council and NMFS. National Standard 9 of the Magnuson-Stevens Act specifically requires the Council to select conservation and management measures and that NMFS implement those measures to minimize bycatch and bycatch mortality to the extent practicable. Due to the deployment methods used in large-scale trawl operations, Chinook salmon bycatch in the Bering Sea pollock fishery is assumed to have 100 percent mortality.

Fishing vessels harvest pollock using pelagic (mid-water) trawl gear, which consists of large nets towed through the water by the vessel. At times, Chinook salmon and pollock occur in the same locations in the Bering Sea. Consequently, Chinook salmon are accidently caught in the nets as fishermen catch pollock; this incidental catch is called bycatch.

The Bering Sea pollock fishery catches up to 95 percent of the Chinook salmon taken incidentally as bycatch in the BSAI groundfish fisheries. From 1992 through 2001, the average Chinook salmon bycatch in the Bering Sea pollock fishery was 32,482 fish. Bycatch increased substantially from 2002 through 2007, with an average of 74,067 Chinook salmon per year caught during this period. A historic high of approximately 122,000 Chinook salmon were taken in the Bering Sea pollock fishery in 2007. However, Chinook salmon bycatch has declined in recent years to 21,500 fish in 2008, 12,424 fish in 2009, and 12,195 fish in 2010.

Chinook salmon bycatch varies seasonally and by sector. In most years, the majority of Chinook salmon bycatch occurs during the A season of the Bering Sea pollock fishery. The variation in bycatch rates among sectors and seasons (A and B season) is due, in part, to the different fishing practices, location of Chinook salmon, and location of fishing effort for each sector to fully harvest their pollock allocations in the A and B seasons.

As documented in the RIR/IRFA for this action (See **ADDRESSES**), AFA pollock vessel operators and members of AFA sectors and cooperatives are often unable to detect the location of Chinook salmon prior to intercepting them while fishing for pollock. Some of the challenges to minimizing Chinook salmon bycatch include:

- Individual Chinook salmon are difficult to detect in the water column with current sonar technology, prior to or during a haul and retrieval of pollock trawl gear;
- Chinook salmon migrate throughout many areas frequented by pollock trawlers;
- On the pollock fishing grounds, Chinook salmon bycatch rates change for multiple reasons, including variation in the Chinook salmon population strength and spatial and temporal migration through the Bering Sea; and
- Most actions taken to avoid Chinook salmon bycatch are likely to be costly to participants in this fishery and difficult for individual vessel operators to assess if voluntary efforts to avoid Chinook salmon bycatch will result in a future benefit to themselves or others.

Amendment 91 to the BSAI FMP

In January 2011, NMFS implemented Amendment 91 to the BSAI FMP to manage Chinook salmon bycatch in the Bering Sea pollock fishery. Amendment 91 combines limits on the amount of Chinook salmon that may be caught incidentally with an Incentive Plan Agreement (IPA) and a performance standard. This combination of measures is designed to minimize bycatch to the extent practicable in all years and prevent bycatch from reaching the limit in most years.

Under Amendment 91, NMFS allocates transferable Chinook salmon prohibited species catch (PSC) to an entity representing the catcher/processor sector, mothership sector, inshore cooperatives, and CDQ groups participating in the Bering Sea pollock fishery. The entity representative administers any transfer of Chinook salmon PSC with the representative of any other group that received transferable Chinook salmon PSC. These transfers could occur between any qualifying sector, inshore cooperative, or CDQ group, and must be approved by NMFS. Chinook salmon PSC allocations may be further sub-allocated to members of the sector or cooperative and may be exchanged among the members of that sector or cooperative. NMFS does not monitor or account for these sub-allocations and transfers of Chinook salmon PSC within a qualifying sector or cooperative.

The requirements for receiving transferable Chinook salmon PSC, as well as the amount of Chinook salmon PSC vary among sectors, inshore cooperatives, or CDQ groups. If all members of the catcher/processor or mothership sector form a single ''sector-level entity'' and join an IPA that is approved by NMFS and meet other qualifications in Amendment 91, that sector will receive an allocation of Chinook salmon PSC that is based on that sector's proportional amount of 60,000 Chinook salmon. The proposed rule for Amendment 91 provides a detailed explanation of these requirements (75 FR 14016, March 23, 2010).

NMFS authorizes inshore cooperatives and the CDQ groups as entities eligible to receive annual allocations on behalf of others. The representative that receives Chinook salmon PSC for the inshore cooperatives would be the same person named on the cooperative's annual application for pollock allocations. An inshore cooperative or a CDQ group must notify NMFS in writing if its representative for purposes of Chinook salmon PSC

allocations is a different person. The CDQ groups are authorized under section 305(i)(1) of the Magnuson-Stevens Act to receive fishery allocations from NMFS. The representative for a CDQ group would be its chief executive officer.

PSC allocations are based on either a 60,000 Chinook salmon PSC limit if some or all of the pollock industry participates in an industry-developed IPA, or a lower limit of 47,591 Chinook salmon PSC if industry does not form any IPAs.

Amendment 91 requires that each sector meet the terms of a ''performance standard,'' including a requirement to not exceed that sector's portion of a lower limit for Chinook salmon PSC of 47,591 Chinook salmon in all but two of any seven consecutive years. The Chinook salmon performance standard in Amendment 91 is intended to encourage pollock vessels to avoid Chinook salmon bycatch, even in years when Chinook salmon bycatch is low.

A key component of Amendment 91 is the ability for fishery participants to form IPAs and work together to avoid Chinook salmon bycatch. An IPA is a private contract among vessel owners or CDQ groups that establishes incentives for participants to avoid bycatch at all levels of Chinook salmon abundance. The parties to an IPA must be owners of AFA-eligible catcher vessels, catcher/processors, or motherships, or the representatives of CDQ groups, and meet other participation requirements.

Each IPA must have an IPA representative that is responsible for submitting the IPA to NMFS for approval and submitting the IPA Annual Report to the Council. The IPA representative must manage the bycatch of participating vessels to keep total bycatch below the performance standard for the sector in which the vessel participates.

Participation in an IPA is voluntary. Any vessel or CDQ group that chooses not to participate in an IPA would be subject to a restrictive opt-out cap or backstop that provides a maximum of 28,496 Chinook salmon PSC. Any vessel or CDQ group that fishes under the backstop cap would not be evaluated in an IPA Annual Report or included in annual calculations of a sector's performance standard. These caps are described in greater detail in the RIR/IRFA for this proposed action (see **ADDRESSES**).

For the 2011 pollock fishery, three IPAs have been formed to represent catcher/processors, catcher vessels delivering to inshore processors, and catcher vessels delivering to motherships. A variety of incentives is applied in each IPA and summarized in the RIR/IRFA for this proposed action (see **ADDRESSES**). An IPA plan is required for each IPA to describe the structure of the incentives or penalties for reducing Chinook salmon PSC at the level of a sector, cooperative, or individual vessel. Participants are required to demonstrate through an IPA Annual Report that the vessel owners that are signatories to the IPA are accomplishing the Council's intent that each vessel does its best to avoid Chinook salmon at all times while fishing for pollock and that collectively, bycatch is minimized in each year.

After implementing Amendment 91 and its performance standard, allocation of transferable Chinook salmon PSC allocations, and the formation of incentives developed in each IPA, the Council anticipates the likelihood of the following responses from participants in the pollock fishery:

- Substantial changes in sector or cooperative plans and agreements for distribution and use of Chinook salmon PSC;
- Creation of a market for trading Chinook salmon PSC between sectors and cooperatives and among their members and the joint trading of sub-allocations of Chinook salmon PSC and pollock by vessels;
- Changes in the location and timing of fishing effort for pollock and the bycatch of Chinook salmon;
- Increase in cost of harvesting pollock; and
- Reduction of the annual bycatch of Chinook salmon.

Current Data for Evaluating Amendment 91

IPA and IPA Annual Report

The IPA and IPA Annual Report were described and implemented in the final rule for Amendment 91 (75 FR 53026, August 30, 2010). These two required documents, along with other existing data (e.g., catch accounting and observer data) provide useful information for evaluating some aspects of the effectiveness of Amendment 91.

The representative of each approved IPA is required to submit a written IPA Annual Report to the Council for each year following the year in which the IPA is first effective. Each IPA Annual Report is intended to provide a qualitative evaluation and some quantitative information on the effectiveness of the IPAs. Each IPA Annual Report must describe—

- The incentive measures in effect in the previous year;
- How the incentive measures affected individual vessels;
- Whether incentive measures were effective in achieving Chinook salmon savings beyond levels that would have been achieved in the absence of the incentive measures;
- Any amendments to the terms of the IPA that were approved by NMFS since the last annual report; and
- The reasons that any amendments to the IPA plan were made.

The RIR for this action anticipates that the IPA and IPA Annual Reports implemented may provide limited qualitative and quantitative industry data on the effects of the Amendment 91 management measures including—

- Summaries of temporal and spatial shifts in effort undertaken by the fleets;
- Comparisons of Chinook salmon bycatch rates achieved by vessels participating in an IPA versus any vessels not participating in an IPA;
- An overview of the use of new gear technologies;
- Assessment of the effect of area closures for directed pollock fishing or other restrictions required by an IPA; and
- Descriptions of research undertaken to reduce Chinook salmon bycatch.

AFA Annual Cooperative Report

At the beginning of each year, all AFA cooperatives must submit an AFA Cooperative Report to the Council by April 1 of the following year, detailing the activities of the cooperative for the previous year (50 CFR 679.61(f)). Each AFA Cooperative Report must include the cooperative's allocated catch of pollock and sideboard species, actions taken by the cooperative for vessels that exceeded their allowed catch and bycatch in pollock and all sideboard fisheries, any sub-allocations of pollock and sideboard species made by the cooperative to individual vessels, total weight of pollock landed outside the State of Alaska on a vessel-by-vessel basis, and the number of salmon taken by species and season, including Chinook salmon.

AFA Cooperative Reports may contain some information for evaluating Amendment 91. Specifically, the Council's purpose and need statement identifies the need to evaluate how Amendment 91 affects ''where, when, and how pollock fishing and salmon bycatch occur.'' The AFA Cooperative Reports could provide helpful data for that element of the assessment. For example, AFA Cooperative Reports could provide some explanation for why fishing effort at the beginning of a pollock season or at some other point in a season may have been lower, higher, or similar to a previous season (and if

Amendment 91 caused any of the changes).

Limitations to IPA, IPA Annual Report, and AFA Cooperative Annual Report for Evaluating Amendment 91

While IPAs, IPA Annual Reports, and AFA Cooperative Annual Reports may contain information on the response of AFA sectors to Amendment 91, the data are limited for evaluating the effectiveness of the incentives and performance standards in Amendment 91. Some of the limitations are as follows.

- IPAs, IPA Annual Report, or AFA Cooperative Annual Report data are not required to be reported in a specific or systematic format, so the format may vary by each group submitting a report. As a result, it is likely that data will not be sufficiently uniform and consistent to provide reliable comparisons between two or more AFA sectors, AFA cooperatives, or IPAs.
- Except for the sector-level entity allocation and transfer data provided by Amendment 91, the IPA Annual Report and AFA Cooperative Annual Reports are not required to include tracking of sub-allocations or transfers of Chinook salmon PSC that may occur among participants in each sector. Additional information on transfers of Chinook salmon PSC and pollock between members of a sector or cooperative would assist in the evaluation of Amendment 91.
- Prices of pollock and Chinook salmon PSC allocations and transactions could be helpful in evaluating Amendment 91. The market value of PSC allocations reflects its expected value to the pollock fishery. However, neither IPA Annual Reports nor AFA Cooperative Annual Reports presently require that each transaction between a person buying and selling Chinook salmon PSC be recorded with a corresponding price.
- Amendment 91 does not require reporting information in the IPA Annual Report or AFA Cooperative Annual Reports to track how costs may vary by vessel under the new program. It would be helpful to have data on certain operating costs, such as how the amount of fuel and cost of fuel used by AFA vessels operating in the Bering Sea pollock fishery would change under the various IPAs.

Catch Accounting and Observer Data

The two primary sources of information used to account for pollock harvests and salmon bycatch in the Bering Sea pollock fishery are onboard and shoreside observer information and industry-reported data on catch and processed product amounts. Both sources are electronically recorded and submitted to NMFS.

Catch accounting and observer data provide analysts with information on the amount, date and location of pollock catch and Chinook salmon bycatch. This information would assist with verification of qualitative information, submitted by industry in the IPA Annual Reports on how Amendment 91 has altered pollock catch and Chinook salmon bycatch.

In 2005, NMFS implemented an interagency electronic reporting system with its data entry component, eLandings, for the catch accounting system to reduce reporting redundancy and consolidate fishery landings reported to three different agencies. All vessels in the Bering Sea pollock fishery are required to report all groundfish landings, discard, and production through a web-based interface known as eLandings. There is also a stand-alone application (SeaLandings) available for the vessels fishing and processing catch at sea (the at-sea fleet). The at-sea fleet submits eLandings files via e-mail. The eLandings software provides managers with real-time access to individual vessel information, including individual pollock vessel catch and bycatch and unused amounts of allocated pollock and Chinook salmon PSC. Each industry report submitted via eLandings undergoes error checking by NMFS. Data are then stored in a database and are made available to management staff at NMFS and the Alaska Department of Fish and Game. There are two basic eLandings report types used for catch estimation: Production reports and landing reports.

In addition to electronic catch reporting for the AFA pollock fishery, the trawl gear catcher vessel daily fishing log (DFL) is a required paper log used to record trawl groundfish discard and disposition data by haul and location. A trawl catcher vessel delivering groundfish to a shoreside processor, stationary floating processor, or mothership, is required to submit a DFL to the shoreside processor, stationary floating processor, or mothership. Any discard and disposition information submitted by a trawl catcher vessel in the DFL to a shoreside processor, stationary floating processor or mothership, must also be reported by the shoreside processor, stationary floating processor or mothership in eLandings.

Observer data are also used in the catch accounting system; and a multi-stage sampling design is used to sample the species composition of the catch, length distribution of select species, and other catch components. Observer data collected on vessels in the Bering Sea pollock fishery are transmitted electronically to a NMFS database. This database contains all data collected by observers at processing plants and onboard vessels, including fishing locations, groundfish and non-target catch, catch composition, length frequencies, age structures, and salmon PSC (including Chinook salmon PSC). Observer data are merged with industry reports nightly and are available to fishery managers the following day.

For catcher/processors and catcher vessels delivering pollock to motherships, observer data combined with each vessel's eLandings landing report may be used to analyze a variety of effects, including—

- Comparisons of Chinook salmon bycatch rates of vessels fishing in different areas during the same period of time or similar areas at different periods of time;
- Comparisons of percentages of the TAC harvested at times of relatively high or low Chinook salmon encounter rates; and
- Trends in rates and variation of Chinook salmon bycatch by vessel type and location week or season, and across cooperatives, sectors, or the entire AFA fleet.

Limitations to the Use of Catch Accounting and Observer Data for Evaluating Amendment 91

While tracking periodic trends in Chinook salmon bycatch may offer insights to the effectiveness of Amendment 91, catch and observer data would need to be augmented by other supporting data to evaluate whether Amendment 91 incentives have caused a given change in Chinook salmon bycatch. For example, a decrease in bycatch rates may be the result of either a decrease in Chinook salmon abundance on the fishing grounds or may be caused by a change in fishing behavior where the fleet is intentionally avoiding Chinook salmon bycatch because of a regulatory or industry incentive to avoid bycatch. Catch accounting and observer data do not provide quantitative or qualitative information to identify effects of Amendment 91 incentives.

For catcher vessels delivering shoreside to a stationary floating processor or mothership, all groundfish catch and Chinook salmon PSC is accounted for at the time of landing. Because catcher vessels delivering shoreside or to a stationary floating processor may trawl in several locations before delivering to a processor, it is not possible to verify the amount of

Chinook salmon bycatch in each haul. Attempts to apportion Chinook salmon bycatch to a specific trawl catcher vessel haul using vessel monitoring system (VMS) or other data are subject to error. This data limitation may complicate efforts to attribute a change in Chinook salmon bycatch by a trawl catcher vessel to a specific incentive designed to reduce Chinook salmon bycatch. For example, the effect of an IPA penalty for a catcher vessel that exceeded a predetermined Chinook salmon bycatch rate in a specific statistical area may be difficult to assess if the catcher vessel is deploying trawl gear on consecutive hauls inside and outside that statistical area and during the same fishing trip. Because catcher vessels delivering to motherships are required to deliver catch from a single unsorted haul to a mothership, some accounting of Chinook salmon bycatch by haul and location of catch may be possible, thus improving the prospects for tracking the effects of some Chinook salmon bycatch incentives.

Determining the amount of Chinook salmon bycatch in each catcher/processor haul is more straightforward than is to determine for each catcher vessel haul. Each catcher/processor is currently required to provide a continuous census accounting of Chinook salmon bycatch at sea. For example, each haul must be observed, and all salmon are removed and counted at the flow scale. The haul start and end times and location of each haul are recorded by the observer and the validated with VMS. The combination of this location data and haul-by-haul catch accounting allows for Chinook salmon bycatch to be accurately recorded. Even for catcher/processors, however, catch accounting and observer data alone will not explain which bycatch incentives for each sector or cooperative may have affected the amount of bycatch by time and location. For example, catch accounting data, by itself, would not verify if an operator of a catcher/processor or catcher vessel transited to new fishing grounds to avoid Chinook salmon bycatch. Various factors such as weather, time, area encounters with Chinook salmon, or market prices for pollock could easily have influenced the movements and fishing effort by a vessel, and its rate of Chinook salmon bycatch.

New Data Collection for Evaluating Amendment 91

Introduction

In December 2009, the Council recommended revisions of two existing recordkeeping and reporting collections and requirements for three new data surveys/reports to improve the quality and quantity of data to assess the effectiveness of Amendment 91. NMFS proposes to collect information on vessel movements on the fishing grounds and information on pollock allocations, sub-allocations, and transfers between members in an AFA cooperative through revisions to the existing IPA Annual Report and AFA Cooperative Annual Report requirements. These new data requirements are described below in the section entitled: Revisions to Existing Collections for Chinook Salmon EDR Program. The three new EDR surveys/reports recommended by the Council are collectively referred to as the Chinook Salmon EDR, and are described below in the section titled: New Collection of Economic Data.

The new proposed Reports/Surveys are—

- Chinook Salmon PSC Allocation Compensated Transfer Report (CTR);
- Vessel Fuel Survey; and
- Vessel Master Survey.

NMFS will use the revised and new data to conduct analyses that include descriptive analysis and quantitative and qualitative comparisons of the annual and seasonal, changes in the pollock fleet under Amendment 91. Examples of some of the potential analyses with these data are described in the RIR/IRFA for this action (See **ADDRESSES**).

Proposed Revisions to Existing Collections for Chinook Salmon EDR Program

To implement the Chinook salmon EDR program, NMFS would revise existing recordkeeping and recording requirements to add data on movement of vessels in the Bering Sea pollock fishery to avoid Chinook salmon bycatch and data on transfers of Chinook salmon PSC and pollock to the IPA Annual Report.

The following documents would be amended for purposes of supplementing information for the Chinook salmon EDR:

- IPA Annual Report;
- AFA Cooperative Report;
- Catcher Vessel Trawl Gear Groundfish Daily Fishing Logbook (DFL);
- Catcher/processor Trawl Gear Electronic Logbook (ELB); and
- eLandings landing report.

Revisions to the IPA Annual Report

The IPA Annual Report would be revised to include requirements to submit information on the sub-allocation of Chinook salmon PSC and pollock to each participating vessel at the start of each fishing season, and the number of Chinook salmon PSC and amount of pollock caught at the end of a season. These revisions would also require submission of information on transfers of Chinook salmon PSC regardless of whether the transfers were ''compensated'' transfers.

While NMFS currently approves and tracks initial allocation and transfers of Chinook salmon PSC among the catcher/processor sector, mothership sector, inshore cooperatives, and CDQ groups under Amendment 91, this proposed action would require each IPA representative to report additional sub-allocations or transfers of Chinook salmon PSC within a sector-level entity or cooperative. NMFS would require a record of these sub-allocations and transfers of pollock between members of a sector or an inshore cooperative in the IPA Annual Report. NMFS anticipates that the parties to an IPA or the IPA representative will be informed of the number and amounts of Chinook salmon PSC transferred among parties to each IPA. Though NMFS will maintain a record of all initial allocations and transfers from entities authorized to receive Chinook salmon PSC, NMFS anticipates that the representative for an IPA may report some of those same allocation and transfer amounts in the IPA Annual Report to facilitate the accounting of sub-allocations to vessels and transfers between the members of an IPA.

Proposed Revisions to AFA Cooperative Report

NMFS would relocate the requirement for submitting some pollock catch data from the AFA Cooperative Annual Report to the IPA Annual Report, to provide a single location for Chinook salmon and pollock data on initial allocation, sub-allocations, NMFS-approved Chinook salmon PSC transfers, internal cooperative or sector-level entity Chinook salmon PSC transfers, and catch by season and year for each catcher vessel, catcher/processor, or mothership participating in an IPA. Pollock would be removed from the requirement at § 679.61(f)(2)(ii) to submit in the AFA Cooperative Annual Report the cooperative's actual retained and discarded catch of pollock, sideboard species, and PSC on an area-by-area and vessel-by-vessel basis. However, if members of an AFA cooperative elected to move all the allocations and sub-allocations, and transferred, retained and discarded catch of pollock and Chinook salmon PSC listed at § 679.21(f)(13)(ii)(E) and (f)(13)(ii)(F) to the AFA Cooperative

Annual Report, they would no longer need to report that data in the IPA Annual Report. If the members of an AFA inshore cooperative, mothership sector level entity, or catcher/processor sector level entity are not the same as the parties to an IPA for each AFA inshore cooperative, mothership sector-level entity, or catcher/processor sector level entity, then NMFS anticipates that all the data at § 679.21(f)(13)(ii)(E) would be included in the AFA Cooperative Annual Report under § 679.61(f)(2)(vii).

Proposed Revisions to eLandings, Daily Fishing Log, and ELB for Reporting Change in Location on Fishing Grounds

Revisions are proposed to various existing catch and production reports to require additional data describing the reasons that AFA vessels change locations in the CDQ and non-CDQ pollock fishery to avoid Chinook salmon bycatch. The proposed revisions would be:

- Whenever the operator of an AFA catcher vessel chooses to move the vessel primarily to avoid Chinook salmon bycatch, the operator would indicate each change in location for any haul by checking a vessel movement box in the trawl gear DFL.
- Whenever the operator of an AFA catcher/processor chooses to move the vessel primarily to avoid Chinook salmon bycatch, the operator would indicate each change in location for any haul by checking a vessel movement box in the catcher/processor trawl gear ELB.
- Whenever the operator of an AFA mothership receives notification that an AFA catcher vessel delivering pollock moved the vessel to avoid Chinook salmon bycatch, the operator would indicate each change in location for any haul by checking a vessel movement box in the eLandings landing report.

Proposed New Economic Data Collections

Each of the three proposed surveys/reports—the Chinook Salmon CTR, the Vessel Fuel Survey, and Vessel Master Survey—would be available in a fillable electronic format on the NMFS Alaska Region Web site. Persons responsible for submitting each of the three EDR data survey/reports differ based on the requirements listed in each form, but would include vessel owners, vessel leaseholders, or vessel masters of AFA vessels. Submitters would also include representatives for or participants in an AFA catcher/processor or mothership sector, inshore cooperative, the inshore open access fishery, CDQ groups, or parties to an IPA. Each of the forms would be submitted annually to NMFS or the NMFS-designated data collection agent by June 1, based on fishing conducted in the previous fishing year. For example, data from fishing in the 2012 Bering Sea pollock season would be submitted to the NMFS-designated data collection agent in the fillable Chinook salmon EDR forms by June 1, 2013.

Chinook Salmon PSC Allocation Compensated Transfer Report (CTR)

All persons who conducted a Chinook salmon PSC transfer that was paid for with an exchange of money (called a compensated transfer) would be required to submit an annual CTR detailing the quantity and amount paid for each compensated transfer. The persons conducting these transfers of Chinook salmon PSC would be an owner or leaseholder of an AFA-permitted vessel, or a representative for an AFA cooperative, sector-level entity, or CDQ group.

Each transfer would be identified as either an independent transfer of Chinook salmon PSC for monetary compensation or a transfer with a portion of the transfer that includes monetary compensation and a portion of the transfer that did not include monetary compensation. Each transfer would be identified as to type as follows:

Transaction type	Transaction description
1	Between 2 entities which are affiliated as defined by AFA.
2	Between 2 entities in the same cooperative but not affiliated as defined by AFA.
3	Between 2 entities in the same sector but not affiliated as defined by AFA or in the same cooperative.
4	Between 2 entities not part of the same sector or cooperative, or affiliated as defined by AFA.

The CTR would require each transfer of Chinook salmon PSC to include the transferor and transferee names, along with the NMFS identifier (NMFS person ID), date of the transfer, the amount transferred, and the price of the monetary compensated transfer. A Chinook salmon PSC transfer that did not involve monetary compensation, but had some form of compensation, would be indicated on the form, but without an estimate of transfer prices.

The purpose of the proposed CTR would be to account for Chinook salmon PSC transfers and the amount of money exchanged for transfers between AFA vessel owners and other entities transferring Chinook salmon PSC. NMFS would examine data reported for each transaction and compare the amount of Chinook salmon PSC transferred in each transaction, number of transactions by vessel type (sector and AFA cooperative), and time intervals of the transfers in a season or year. Also, this data would allow for tabulation of the average and variation in price paid for transactions by vessel operation type, sector, and AFA cooperative.

Vessel Fuel Survey

After each calendar year, each owner of an AFA-permitted vessel catching CDQ or non-CDQ pollock in the Bering Sea would submit to NMFS the Vessel Fuel Survey to report annual fuel use and cost in the Bering Sea pollock fishery. The owner would include identifying information on the certification page of the report, including a NMFS person ID. The Vessel Fuel Survey, which would be submitted by June 1 of the following year, would include average annual hourly fuel burned while fishing and transiting and annual fuel purchases in cost per gallon. Each of these values would be combined with other NMFS data (such as VMS and observer data reports) to estimate the costs of moving vessels to avoid Chinook salmon bycatch (including the fuel use during trawling, transit between trawls, and lost fishing time).

Vessel Master Survey

The proposed new Vessel Master Survey would be a qualitative assessment survey that would pose a series of questions to elicit vessel operator input on factors that impacted the vessel's performance during the year. The Vessel Master Survey would be conducted at the end of each fishing year. The owner of each AFA-permitted vessel would be responsible for submitting the Vessel Master Survey to NMFS on behalf of any person who is an operator, vessel master, or skipper of an AFA-permitted vessel. The owner of the AFA-permitted vessel would be required to verify that each person listed

on the Certification page for this form is a master of the AFA-permitted vessel.

The intent of the Vessel Master Survey would be to identify the purpose for decision-making during the pollock season with respect to fishing location choices, Chinook salmon bycatch incentives, and availability or costs of accessing Chinook salmon PSC allocations. The survey would be designed to obtain operator responses to conditions on the fishing grounds to gain information regarding the effect of IPAs and Chinook salmon bycatch measures on decision-making. The nine questions in the Vessel Master Survey would collect operator assessments of the past year's fishing performance regarding the causes for bycatch avoidance, factors impacting Chinook salmon bycatch rates, and the influence of the IPAs and AFA cooperatives on fishing and Chinook salmon bycatch avoidance behaviors.

Audit Procedure for Chinook Salmon EDR

NMFS would develop measures to verify data accuracy of the Chinook salmon EDR program. These measures would help NMFS to verify data submitted in the CTR, the Vessel Master Survey, and the Vessel Fuel Survey. The principal means to verify data and resolve questions would be through validation of data submitted in these three surveys against supporting records. NMFS staff would contact the EDR submitter and request confirmation of data submissions. The person submitting the EDR would need to respond within 20 days of the NMFS information request. Responses after 20 days would be considered untimely and may result in a violation and enforcement action.

For verification of the CTR form, NMFS could request any person who conducted a monetary compensated transfer of Chinook salmon PSC at § 679.65(b)(1) and (b)(2) to submit additional data to facilitate verification by NMFS and respond to additional questions. This could occur in instances where a random audit occurs or an audit is otherwise justified for the CTR. To carry out these audits, NMFS may retain under contract a designated data collection auditor (DDCA) who would be a professional auditor/accounting specialist, and who would review the data submitted in the EDR. The DDCA also could request financial documents substantiating the data submitted in the EDR. The DDCA would be subject to strict confidentiality requirements.

Uses of Data Collected Under This Proposed Rule

New data required from industry to complete the IPA Annual Report, Trawl Catcher Vessel DFL and ELB, and forms for the CTR, Vessel Fuel Survey, and Vessel Master Survey would increase the amount and type of data that NMFS and the Council use to analyze the effects of Amendment 91. This analysis of effects with new EDR data is intended to focus on the behavioral impacts of Amendment 91 to participants in the Bering Sea pollock fishery and potential changes in Chinook salmon bycatch. Specifically, applying these multiple data sources along with other NMFS data could provide insight into one or more of the following elements:

- The effects and impacts of the Amendment 91 IPAs, the PSC limits, and the performance standard;
- The effectiveness of the IPA incentives in times of high and low levels of Chinook salmon bycatch;
- The effectiveness of the performance standard to reduce Chinook salmon bycatch; and
- How Amendment 91 affects where, when, and how pollock fishing and Chinook salmon bycatch occur.

Additional information collected by this proposed action in the IPA Annual Report would provide quantitative and qualitative data on Chinook salmon and pollock sub-allocations and transfers. If the quantitative transfer and allocation data are submitted in a uniform and comparable manner for each IPA, analysis in conjunction with IPA Annual Report data could include descriptive statistics on the pollock and Chinook salmon bycatch, allocations, and transfers between participants in each of the above groups. This information could be displayed by season or annually, and if useful, data could be pooled over multiple years.

The additional Chinook salmon PSC transfer data in IPA reports may provide information about changes in fishing practices or the effectiveness of IPAs to reduce bycatch. For example, if IPA Report data provide a record of many pollock transfers to vessels with low Chinook salmon bycatch rates, this record of transfers may suggest that vessels with poor bycatch performance have an incentive to reduce their participation in the fishery in years of high bycatch. In addition, observations of the number of transfers to vessels that are approaching their individual share of the Chinook salmon PSC cap could help verify if PSC transferability contributes to a higher yield of pollock. Finally, if a portion of the vessels that are party to an IPA are prohibited by the agreement from fishing in valuable pollock areas of the Bering Sea, Chinook salmon PSC may be transferred to or away from vessels that continue to have access to those fishing areas. Some of these behavioral responses may be correlated with a particular incentive in a manner that could aid in the assessment of the effectiveness of Amendment 91.

NMFS would not require that new data in each IPA Annual Report be submitted in a structured format. For example, the proposed allocation and transfer data would be provided by each vessel, but could be displayed in a table or narrative format, or in a manner that is difficult to compare quantities of an allocation or transfer between parties in more than one IPA. Therefore, for each IPA Annual Report, IPA performance information may not be uniformly comparable, which could create consistency issues when comparing information between IPAs and could limit any statistical analysis with IPA Annual Report data. Thus, there may be analytical limits to the potential usefulness of this data for statistical analysis.

NMFS would use the proposed Bering Sea vessel movement information (denoting when a Bering Sea pollock vessel moved to avoid Chinook salmon bycatch prior to a haul) to compare Chinook salmon bycatch avoidance by vessel, and by vessel characteristics. Chinook salmon bycatch rates by vessel could be merged with the movement data by vessel to assess how bycatch rates change for each vessel prior to and following a change in fishing location. Vessel movement data combined with other management data, such as NMFS seasonal opening and closing dates or IPA-directed openings and closings of selected pollock fishing areas may assist in differentiating a vessel's voluntary movements to leave a groundfish statistical area to avoid Chinook salmon bycatch or movements that are required by IPA agreements. That information could contribute to evaluating how Amendment 91 affects where, when, and how pollock fishing and Chinook salmon bycatch occur. The industry-reported vessel movement data may be helpful for evaluating assumptions in statistical models that combine catch by location, VMS, and other data to explain the reasons or tradeoffs for a specific set of moves and fishing choices. That information could also assist with assessing conclusions drawn by industry in the IPA Annual Reports.

Differences in the willingness of individual vessels to move from areas with high Chinook salmon bycatch and to search for areas with lower bycatch

rates may reflect differences in the incentives created by an IPA. Alternatively, upon examination, these data and other information provided by cooperatives may reflect the amount of central coordination of fishing by area and time a cooperative applies to each member of the cooperative. While movement data are subjective, the data is intended to provide a better understanding of each vessel operator's perception of factors that impacted fishing decisions and are likely to provide information for NMFS and the Council to evaluate the effectiveness of IPAs and Amendment 91.

With new data from the CTRs and proposed revisions to the IPA Annual Reports, it would be possible to enumerate the number of potential trades of Chinook salmon by date and season as well as by vessel owner, leaseholder, or another party that did or did not participate in compensated Chinook salmon PSC transfers. The timing and patterns of the transfer data in comparison with the specific IPAs in effect by date, sector, and AFA cooperative, will potentially help to assess the value of Chinook salmon PSC in each year and how the IPAs may have impacted the value of PSC. Thus, if a large number of accurate monetary transfers are observed, NMFS may develop some insights on the two elements of the effects of certain incentives included in the IPAs, and the performance standard. Potential sources of bias in monetary transfers are explained below.

The proposed CTR data may help to verify some of the industry-reported information in the contracts and agreements for allocating Chinook salmon PSC within and among AFA sectors and cooperatives included in IPA Annual Reports and AFA Cooperative Reports. This will assist in understanding the overall effects and impacts of Amendment 91, by permitting transactions reported in other industry-reported sources to be compared to and reconciled with the transactions reported in the CTR.

If a sufficient number of Chinook salmon PSC transfers are reported in the CTR and if they are considered to be representative of actual transfer practices, this data should assist in determining the distribution of Chinook salmon PSC allocations and transfers in-season and over multiple years. When combined with additional data on entity affiliations the CTR could assist in determining if prices exchanged represent independent and arms-length transactions or if the prices are merely accounting measures within affiliated entities.

Where quantitative EDR program data is collected at the level of an individual vessel, merging data by vessel from multiple data sources may assist in estimating the costs associated with bycatch incentives. For example, data on the intra-sector or intra-cooperative allocations of PSC may be combined with data on Chinook salmon PSC and pollock transfers, to show the distribution and amounts of pollock and Chinook salmon PSC exchanged among vessels in a season. Travel costs of those vessels (see analysis of fuel data below) to avoid Chinook salmon bycatch, along with the prices reported for PSC transactions may be compared with the specific incentives in place for each vessel to gauge some of the costs of specific incentives.

Because a completed CTR is not expected to include all sources of compensation for Chinook salmon PSC transfers (prices are restricted to monetary compensated transfers) that is likely to limit the application of this data for analysis. For example, it is possible that operators of vessels or the representatives submitting the CTR will not use unpaired or independent monetary transactions to exchange Chinook salmon PSC. If the CTR respondents find it to be more efficient to bundle all or nearly all Chinook salmon transactions with pollock or other items of value, they may submit very few transactions or prices of Chinook salmon PSC. Also, if each independent Chinook salmon PSC transfer consists of both a monetary transfer component and a non-monetary transfer component, these observations may be less useful. Further, persons reporting data on Chinook salmon PSC transactions could intentionally bundle monetary and non-monetary transfers to obscure an observation of a compensated transfer. The possibility exists that these reporting constraints and potential reasons for biasing data submitted in the CTR would result in a sufficiently low number of reported transactions to significantly reduce the value of these data for examining Chinook salmon PSC prices. Non-monetary compensation is not included in the CTR or elsewhere in the EDR program, as the cost of collecting this data with sufficient accuracy and detail to allow for estimating an equivalent monetary value would be cost prohibitive [see CLASSIFICATION for more information].

Analyses of data from the Vessel Fuel Survey may range from basic comparisons of estimated fuel costs of fishing and transiting by vessel operation type or other vessel characteristic, to quantitative or statistical estimates of the fuel costs for Chinook salmon bycatch avoidance from specific salmon bycatch incentives. The data would allow for estimates of fuel used by a vessel when moving to areas with higher or lower areas of bycatch. NMFS has no other data on fuel consumption or average fuel price on a vessel-by-vessel basis for this fishery to address this question. Especially during periods of high Chinook salmon bycatch, these data may be used to estimate transit costs when vessels move to avoid areas where high Chinook salmon bycatch has been reported. The estimation could be accomplished by merging data from the Vessel Fuel Survey with other available data, including observer reports, VMS data, catch accounting, movement data, and IPA and AFA Cooperative Annual Reports to assess changes in fuel consumption when vessels move from areas of high or low Chinook salmon bycatch. Thus, these data would be useful for understanding the variation in fuel usage for some activities, which can aid in assessing fuel costs more generally in the fishery.

Variation in vessel fuel costs among vessels could affect the response of certain vessels to incentives or disincentives for avoiding Chinook salmon. For example, if it is less expensive for vessels with lower travel costs to travel farther to reach clean fishing grounds, those vessels may be more likely to engage in increased transiting activity between fishing locations. NMFS may examine vessel response to Chinook salmon encounter rates to determine whether these operational differences are affected by variations in fuel-based travel costs between vessels, which in turn may have implications for the effectiveness of some incentives developed in an IPA. NMFS could use these findings to assess the effects of Chinook salmon bycatch incentives and other questions listed in the purpose and need for this action, such as how Amendment 91 affects where, when, and how pollock fishing and Chinook salmon bycatch occur.

The proposed new Vessel Master Survey is designed to solicit subjective responses to questions on the decision-making process applied for avoiding Chinook salmon bycatch when fishing for pollock under Amendment 91. Part of the utility of these questions would be to allow for comparison of the subjective information in each response with other observed changes in fishing behavior and Chinook salmon bycatch. Where possible, NMFS will examine the effect of the behavioral influences reported in this survey in greater detail and corroborate the responses with

other data sources, such as observer data, VMS data, and catch accounting data.

The response to questions on bycatch avoidance may provide insight as to how IPAs affect fishing behavior, when catch accounting and other data are limited. For example, because Chinook salmon bycatch data cannot be attributed to each trawl catcher vessel's haul, which limits the usefulness of bycatch data to assess specific incentives, the qualitative responses in the Vessel Master Survey may provide vessel master assessments as to how IPA incentives impacted trawl catcher vessel avoidance of Chinook salmon bycatch.

The Chinook salmon EDR program is also intended to assess the accuracy of conclusions drawn by industry in the IPA Annual Report. Analysis of Vessel Master Survey data may contribute to some qualitative comparisons of a vessel master's response to these questions and information provided in industry IPA Annual Reports. Utilizing a vessel master's self-reported experiences and comparing that with current catch and VMS data available to NMFS should improve the opportunities for analysts to consider fishermen's experiences in formulating assessments of the Amendment 91 program.

Proposed Regulatory Amendments

Definitions

Section 679.2 would be revised by adding a definition of designated data collection auditor (DDCA) to apply to the use of a DDCA under § 679.65(e).

Vessel Movement Data

NMFS proposes to modify existing regulations to collect data indicating a change of fishing location primarily to avoid Chinook salmon bycatch.

Section 679.5(c)(4)(vi) describes catch-by-haul information required in the trawl gear catcher vessel DFL and the catcher/processor trawl Daily Cumulative Production Logbook (DCPL). A new paragraph (c)(4)(vi)(I) would be added to request the operator of a trawl gear catcher vessel to indicate each time the vessel moved to avoid Chinook salmon in the trawl gear catcher vessel DFL.

Section 679.5(e)(6) describes requirements for a mothership landing report. The eLandings mothership landing report would be revised to require the operator of a mothership to record vessel movement data provided by the trawl catcher vessel directed fishing for pollock in the Bering Sea and delivering to the mothership. Section 679.5(e)(6)(i)(A)(*12*) would be added to require the operator of a mothership to indicate whether prior to a haul, the operator of the catcher vessel using trawl gear moved its fishing location primarily to avoid Chinook salmon bycatch.

NMFS created a catcher/processor ELB that interfaces with eLandings. The catcher/processor trawl gear ELB will allow NMFS to determine any differences between movement related to avoidance of Chinook salmon and other vessel movement by identifying any tow prior to a move that is due primarily to Chinook salmon avoidance. Section 679.5(f)(1)(vii) would be revised to require that data on vessel movement to avoid Chinook salmon be entered into the catcher/processor ELB.

Section 679.5(f)(2)(ii), which describes the use of a DFL or DCPL as backup for the ELB in the event of a computer or ELB failure, would be replaced with text that provides general instructions to contact NMFS Inseason Management, when the Internet fails. This general instruction is necessary to assure a reasonable response to delays in transmission of commercial fishery information, including the movement of vessels to avoid Chinook salmon bycatch in the ELB.

Section 679.5(f)(7) describes the transmission of data in the ELB. There are two distinct methods and time limits for data transmission for the catcher vessel and the catcher/processor using an ELB. This introductory text would be removed to avoid duplicating text that follows in the distinct paragraphs.

Paragraph (f)(7)(i) would be corrected by revising the heading to read ''Catcher/processors'' because it pertains only to catcher/processors, not motherships. In addition, the transmission method would be corrected to read ''online,'' not ''email attachment.''

Paragraph (f)(7)(ii) would be corrected by adding a heading to read ''Catcher vessels'' to maintain format for parallel headings with paragraph (f)(7)(i) and replace the word ''export'' with ''transfer'' to provide a more exact term.

Prohibited Species Bycatch Management

Paragraph (f)(12)(vii) in § 679.21 would be redesignated as paragraphs (f)(13)(i) through (f)(13)(ii)(F) to reduce the number of paragraph-levels used under (f)(12). Paragraph (f)(13)(ii)(E) would describe requirements for data submittal on sub-allocations, transfers, and catch of pollock and Chinook salmon PSC in the IPA Annual Report.

Section 679.61(f)(2)(ii) would be revised to remove pollock from information required as this requirement is redundant with the reporting requirement in paragraph (f)(13)(ii)(E).

Section 679.61(f)(2)(vii) would be added to provide that AFA cooperatives report pollock and Chinook salmon PSC allocation and catch in the AFA annual cooperative report or in the IPA Annual Report, as also provided in § 679.21(f)(13)(ii)(E).

Chinook Salmon EDR

Section 679.65 would be added to describe the Chinook salmon EDR and the forms used to collect economic data for the Chinook salmon bycatch management program. In addition, an audit procedure for the Chinook salmon EDR would be added, including the use of a DDCA as defined under § 679.2.

Classification

Pursuant to sections 304(b)(1)(A) and 305(d) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

An IRFA was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, the reasons why it is being considered, and a statement of the objectives of and the legal basis for this action are included at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A summary of the remainder of the IRFA follows. A copy of this analysis is available from NMFS (see **ADDRESSES**).

The directly regulated entities for this proposed action are those members of the commercial fishing industry that participate in the directed pollock trawl fishery in the Bering Sea. These entities include the AFA-affiliated pollock fleet and the six CDQ groups that receive allocations of Bering Sea pollock. Under a conservative application of the Small Business Administration criteria and the best available data, six small entities out of an estimated 122 respondents are eligible to submit the transfer report (Table 1). To provide these estimates of the number of non-CDQ AFA-affiliated pollock entities that were not small, earnings from all Alaskan fisheries for 2010 were matched with the vessels that participated in the AFA-affiliated pollock fleet for that year.

TABLE 1—SUMMARY OF SMALL AND LARGE ENTITIES FOR REGULATORY FLEXIBILITY ACT PURPOSES AND NUMBER OF VESSELS, INSHORE PROCESSORS, AND CDQ GROUPS

Entity class	Units	Directly regulated by action	Small	Non-small	Total directly regulated
Catcher/processors	Vessels	Yes	0	16	
Motherships	Vessels	Yes	0	3	
Catcher vessels	Vessels	Yes	0	90	
Inshore processors	Plants (including fixed floating platforms)	Yes	0	7	
CDQ groups	Non-profit organizations	Yes	6	0	
Total small and non small entities.			6	116	122

All of the non-CDQ AFA-affiliated pollock entities directly regulated by the proposed action were members of AFA cooperatives in 2010 and, therefore, NMFS considers them ''affiliated'' large (non-small) entities for RFA purposes.

Due to their status as non-profit corporations, the six CDQ groups are identified as ''small'' entities. This proposed action directly regulates the six CDQ groups, and NMFS considers the CDQ groups to be small entities for RFA purposes. As described in regulations implementing the RFA (13 CFR 121.103) the CDQ groups' affiliations with other large entities do not define them as large entities. Complete descriptions of the CDQ groups, and the impacts of this action, are located in sections 2.5 and 6.10.3 of the Final Environmental Impact Statement/Regulatory Impact Review/ Final Regulatory Flexibility Analysis for Amendment 91, which may be obtained from *http://www.regulations.gov* or from the NMFS Alaska Region Web site at *http://alaskafisheries.noaa.gov.*

Four alternatives were considered in the RIR/IRFA for this proposed rule (See **ADDRESSES**). Alternative 1, the no action alternative, would not expand data collection for evaluating Amendment 91. Current data collected by NMFS would still allow for assessment of basic information such as the changes in the catch of Chinook salmon. IPA plans and IPA annual reports may also provide some industry impressions of the effects of Amendment 91 on Chinook salmon bycatch or effectiveness of the IPAs. Alternatives 2 and 3 included options for expanded data collection by implementing the use of ledger forms for recording Chinook salmon PSC or pollock allocations and transfers, the price for each transfer of Chinook salmon PSC or pollock, detailed fuel price and use data, vessel movement data, and a Vessel Master Survey. Alternative 4 (the preferred alternative) included flexible reporting of Chinook salmon and pollock allocations and transfers in the annual IPA report or AFA cooperative report, Chinook salmon bycatch quantities and prices of compensated Chinook salmon transfers in the CTR, average fuel use and prices in the Vessel Fuel Survey, vessel movement data in current recordkeeping and reporting collections, and vessel master impressions of the effects of Chinook salmon bycatch incentives in the Vessel Master Survey. The Council also considered and removed alternatives to collect more detailed revenue and cost data (including roe production, expanded Chinook transfer data, revenue data, and daily operating cost data).

Collection of the data in Alternatives 2 and 3 and in alternatives not advanced for analysis would expand the data available to study the effectiveness of salmon bycatch measures (including IPAs) across various segments of the fleets and would improve understanding of the effects of those measures on participants in the fisheries. Specifically, these detailed roe production, expanded Chinook salmon transfer data, revenue data, and daily operating cost data, as well as data from Alternatives 2 and 3 could be used to conduct more in-depth examination of revenue and cost tradeoffs of vessels when avoiding Chinook salmon bycatch.

Alternative 1 was not selected because it would not address the objectives of the Chinook EDR program to increase the quality and quantity of data for assessing the effects of Amendment 91 IPAs, the PSC limits, and the performance standard on when, where, and how pollock fishing and Chinook salmon bycatch occur.

While acknowledging that data in Alternatives 2 and 3, along with the additional detailed roe production expanded Chinook transfer data, revenue data, and daily operating cost data could increase the amount of information concerning the fishery and Chinook salmon bycatch avoidance, the Council elected to not select these data intensive alternatives. The Council did not advance these alternatives as well as additional alternatives for analysis. The Council determined that Amendment 91 incentives should be in operation for a period of time before NMFS could analyze how industry recordkeeping could be used to develop data collection instruments. The data forms required to collect information in Alternatives 2 and 3 and the additional roe, transfer and daily cost data would require additional development. Also, the Council determined the cost and burden of collecting the additional data would be substantial.

Alternative 4 was chosen because the limited scope of the data collected is feasible to implement in a timely manner, would likely increase the quality and quantity of data for assessing the effects of Amendment 91 IPAs, the PSC limits, and the performance standard on when, where, and how pollock fishing and Chinook salmon bycatch occur, and would permit a more expansive data collection in the future. Alternative 4 would have the least impact of the four alternatives on small entities while continuing to meet the objectives of the action.

Additional industry outreach and Council review of the EDR program was carried out to ensure that the Chinook salmon EDR program was compatible with industry recordkeeping procedures and consistent with the intent of the Council recommendations. In June 2010, the three EDR forms were reviewed and revised by members of the Bering Sea pollock industry in an industry workshop sponsored by NMFS. In October 2010, the Council reviewed the three revised data forms developed for this action, draft regulations, and the draft Paperwork Reduction Act submission. The Council voted unanimously that NMFS go forward with this proposed rule with minor,

clarifying revisions to the data collection forms.

The analysis did not identify any Federal rules that would duplicate, overlap, or conflict with the proposed rule.

In the CTR, NMFS expects the representative for each of the four sectors to actively track transfers throughout the year and report these in the fillable on-line CTR form once per year. For each individual Chinook transfer that consisted of a monetary exchange, each entity involved in a compensated transfer is required to submit an entry in the CTR to record transfer information. NMFS estimates that each entity will require 15 minutes to track each transfer and enter that data in either an internal tracking system provided to the representative for the sector, or in a separate CTR.

The CTR is estimated to be 90 percent electronic because most of these reports will be submitted as attachments to e-mails or via the Internet. Some reports may be submitted by fax.

The proposed new Vessel Master and Vessel Fuel Surveys would be completed at the end of the year and would be electronically submitted in a fillable on-line web form. The certification page would be submitted by mail, fax, or as an attachment to an e-mail. NMFS expects that many vessel masters (for the Vessel Master Survey), and vessel owners and leaseholders (for the Vessel Fuel Survey) may compile notes in season to respond to the specific survey questions at years end. The burden associated with tracking activity will vary depending on the circumstances encountered during the year.

OMB Collection of Information

This proposed rule contains collection-of-information requirements subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). These requirements have been submitted to OMB for approval. Burden estimates were developed for each of the four Office of Management and Budget collections that are revised or created for the proposed Chinook salmon EDR program. The proposed revised and new collections and reporting burdens are listed below by OMB control number.

OMB Control Number 0648–AKRL

Public reporting burden per response is estimated to average 23 minutes for a catcher vessel trawl gear DFL; and 35 minutes for an AFA catcher/processor trawl gear ELB—

OMB Control Number 0648–0401

Public reporting burden per response is estimated to average 40 hours for an IPA; 40 hours for an IPA Annual Report; and 8 hours for an AFA Annual Cooperative Report—

OMB Control Number 0648–0515

Public reporting burden per response is estimated to average 35 minutes for a mothership eLandings landing report—OMB Control Number 0648–NEW [EDR]

Public reporting burden per response is estimated to annually average 40 hours for a CTR; 8 hours for a Vessel Fuel Survey; and 3 hours for a Vessel Master Survey.

Reporting burden includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

NMFS seeks public comment regarding whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to NMFS (see **ADDRESSES**), e-mail to *OIRA_Submission@omb.eop.gov,* or fax to 202–395–7285.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Reporting and recordkeeping requirements.

Dated: July 11, 2011.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 679 is proposed to be amended as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

1. The authority citation for part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.;* 1801 *et seq.;* 3631 *et seq.,* Pub. L. 108–447.

2. In § 679.2 add a definition for ''Designated data collection auditor'' in alphabetical order to read as follows:

§ 679.2 Definitions.

* * * * *

Designated data collection auditor (DDCA) means the NMFS-designated contractor to perform the functions of a data collection auditor for the Chinook PSC Compensated Transfer Report.

* * * * *

3. In § 679.5,

A. Revise paragraphs (c)(4)(vi) introductory text, (f)(1)(vii), (f)(2)(ii), and (f)(7).

B. Add paragraph (c)(4)(vi)(I) and paragraph (e)(6)(i)(A)(*12*).

§ 679.5 Recordkeeping and reporting (R&R).

* * * * *

(c) * * *

(4) * * *

(vi) *Catch-by-haul information.* The operator must record the following information (see paragraphs (c)(4)(vi)(A) through (I) of this section) for each haul (see § 679.2). If no catch occurred for a given day, write ''no catch.''

* * * * *

(I) *Movement to Avoid Salmon.* If a catcher vessel is directed fishing for pollock in the Bering Sea, indicate with a check mark (X) whether, prior to the haul, the operator moved fishing location primarily to avoid salmon bycatch.

* * * * *

(e) * * *

(6) * * *

(i) * * *

(A) * * *

(*12*) For deliveries from catcher vessels directed fishing for pollock in the Bering Sea, indicate whether, prior to the haul, the operator of the catcher vessel moved fishing location primarily to avoid Chinook salmon bycatch.

* * * * *

(f) * * *

(1) * * *

(vii) *AFA and CDQ trawl catcher/processors.* The operator of an AFA catcher/processor or any catcher/processor harvesting pollock CDQ must use a combination of NMFS-approved catcher/processor trawl gear ELB and eLandings to record and report groundfish and PSC information. In the ELB, the operator must enter processor identification information; catch-by-haul information; prohibited species discard or disposition data for all salmon species in each haul; and indicate whether, prior to the haul, the

operator moved fishing location primarily to avoid Chinook salmon bycatch. In eLandings, the operator must enter processor identification, groundfish production data, and groundfish and prohibited species discard or disposition data for all prohibited species except salmon.

(2) * * *

(ii) *Reporting groundfish by ELB.* If the User is unable to submit commercial fishery information due to hardware, software, or Internet failure for a period longer than the required reporting time, contact NMFS Inseason Management at 907–586–7228 for instructions. When the hardware, software, or Internet is restored, the User must enter this same information into the electronic logbook (ELB) or other NMFS-approved software.

* * * * *

(7) *ELB data submission*—(i) *Catcher/processors.* The operator of a catcher/processor must transmit ELB data directly to NMFS online through eLandings or other NMFS-approved data transmission mechanism, by 2400 hours, A.l.t., each day to record the previous day's hauls.

(ii) *Catcher vessels.* The operator of a catcher vessel must transmit ELB data directly to NMFS as an e-mail attachment or to NMFS through a shoreside processor, SFP, or mothership who received his/her groundfish catch. Through a prior agreement with the catcher vessel, the operator of a mothership or the manager of a shoreside processor or SFP will forward the ELB data transfer to NMFS as an e-mail attachment within 24 hours of completing receipt of the catcher vessel's catch.

* * * * *

4. In § 679.21, paragraph (f)(12)(vii) is redesignated as paragraph (f)(13) and revised to read as follows:

§ 679.21 Prohibited Species Bycatch Management.

* * * * *

(f) * * *

(13) *IPA Annual Report.* The representative of each approved IPA must submit a written annual report to the Council at the address specified in § 679.61(f). The Council will make the annual report available to the public.

(i) *Submission deadline.* The IPA Annual Report must be postmarked or received by the Council no later than April 1 of each year following the year in which the IPA is first effective.

(ii) *Information requirements.* The IPA Annual Report must contain the following information:

(A) A comprehensive description of the incentive measures in effect in the previous year;

(B) A description of how these incentive measures affected individual vessels;

(C) An evaluation of whether incentive measures were effective in achieving salmon savings beyond levels that would have been achieved in absence of the measures;

(D) A description of any amendments to the terms of the IPA that were approved by NMFS since the last annual report and the reasons that the amendments to the IPA were made;

(E) Sub-allocation to each participating vessel of the number of Chinook salmon PSC and amount of pollock (mt) at the start of each fishing season, and number of Chinook salmon PSC and amount of pollock (mt) caught at the end of each season, unless reported under § 679.61(f)(2); and

(F) *In-season transfers.*

(*1*) *Transfers among entities.* For in-season transfer of Chinook salmon PSC or pollock among AFA cooperatives, entities eligible to receive Chinook salmon PSC allocations, or CDQ groups, provide the following information:

(*i*) Date of transfer;

(*ii*) Name of transferor;

(*iii*) Name of transferee;

(*iv*) Number of Chinook salmon transferred; and

(*v*) Amount of pollock (mt) transferred.

(*2*) *Transfers among IPA vessels.* Transfers among vessels participating in the IPA provide the following information:

(*i*) Date of transfer;

(*ii*) Name of transferor;

(*iii*) Name of transferee;

(*iv*) Number of Chinook salmon transferred; and

(v) Amount pollock (mt) transferred.

* * * * *

5. In § 679.61,

A. Revise the heading of paragraph (f), and paragraph (f)(2)(ii); and

B. Add paragraph (f)(2)(vii).

§ 679.61 Formation and operation of fishery cooperatives.

* * * * *

(f) *Annual reporting requirements.*

* * *

(2) * * *

(ii) The cooperative's actual retained and discarded catch of sideboard species and PSC, except for Chinook salmon PSC, on an area-by-area and vessel-by-vessel basis;

* * * * *

(vii) Sub-allocation to each participating vessel of the number of Chinook salmon PSC and amount of pollock (mt) at the start of each fishing season, and number of Chinook salmon PSC and amount of pollock (mt) retained and discarded at the end of each season, unless that data is reported in the IPA report at § 679.21 (f)(13)(ii)(E).

* * * * *

6. Section 679.65 is added to read as follows:

§ 679.65 Bering Sea Chinook Salmon Bycatch Management Program Economic Data Report (Chinook salmon EDR program).

(a) *Requirements.* NMFS developed the regulations under this § 679.65 to implement the Chinook salmon EDR program. Additional regulations that implement specific portions of the Chinook salmon EDR program are set out under paragraphs (a)(1) through (a)(4) of this section:

(1) *Daily fishing logbook (DFL), catcher vessel trawl gear.* See § 679.5(c)(4).

(2) *Electronic logbook (ELB), AFA and CDQ trawl catcher/processors.* See § 679.5(f) in combination with eLandings pursuant to § 679.5(e).

(3) *IPA Annual Report.* See § 679.21(f)(13).

(4) *AFA cooperative annual reporting requirement.* See § 679.61(f)(2).

(b) *Chinook salmon PSC Compensated Transfer Report (CTR).* (1) An owner or leaseholder of an AFA-permitted vessel and the representative of any entity that received an allocation of Chinook salmon PSC from NMFS must submit a CTR, Part 1, each calendar year, for the previous calendar year.

(2) Any person who transferred Chinook salmon PSC allocation after January 20, and paid or received money for the transfer, must submit a completed CTR (Part 1 and Part 2) for the previous calendar year.

(3) The CTR is available through the Internet on the NMFS Alaska Region Web site at *http://alaskafisheries.noaa.gov,* or by contacting NMFS at 206–526–6414.

(4) Each year, the completed CTR must be submitted electronically on or before 1700, A.l.t., on June 1, following the instructions on the form.

(c) *Vessel Fuel Survey.* (1) An owner or leaseholder of an AFA-permitted vessel must submit all completed Vessel Fuel Surveys for each vessel used to harvest pollock in the Bering Sea in a given year.

(2) The Vessel Fuel Survey is available through the Internet on the NMFS Alaska Region Web site at *http://alaskafisheries.noaa.gov,* or by contacting NMFS at 206–526–6414.

(3) The owner or leaseholder annually must submit a completed Vessel Fuel Survey, electronically on or before 1700, A.l.t., on June 1, following the instructions on the form.

(d) *Vessel Master Survey.* (1) For any AFA-permitted vessel used to harvest pollock in the Bering Sea in the previous year:

(i) The vessel master must complete the Vessel Master Survey, Part 1A.

(ii) An owner or leaseholder must complete the Vessel Master Survey, Part 1B.

(iii) An owner or leaseholder must submit all Vessel Master Surveys, Parts 1A and 1B completed by the owner and all of the masters electronically on or before 1700, A.l.t., on June 1, following the instructions on the form.

(2) The Vessel Master Survey is available through the Internet on the NMFS Alaska Region Web site at *http://alaskafisheries.noaa.gov,* or by contacting NMFS at 206–526–6414.

(e) *Chinook salmon EDR verification and audit procedures.* NMFS or the designated data collection agent (DDCA) will conduct verification of Chinook salmon EDR information with the persons identified at § 679.65(b)(1), (b)(2), (c)(1), (d)(1)(i), and (d)(1)(ii).

(1) The persons identified at § 679.65(b)(1), (b)(2), (c)(1), (d)(1)(i), and (d)(1)(ii) must respond to inquiries by NMFS and its DDCA for purposes of the CTR, within 20 days of the date of issuance of the inquiry.

(2) The persons identified at § 679.65(b)(1) and (b)(2) must provide copies of additional data to facilitate verification by NMFS and its DDCA for purposes of the CTR. These paper or electronic copies may include, but are not limited to, previously audited or reviewed financial statements, worksheets, tax returns, invoices, receipts, and other original documents substantiating the data submitted.

[FR Doc. 2011–17894 Filed 7–15–11; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 76, No. 137
Monday, July 18, 2011

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Specialty Crop Committee Stakeholder Listening Sessions

AGENCY: Research, Education, and Economics, USDA.

ACTION: Notice of stakeholder listening sessions.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App 2, the United States Department of Agriculture announces two stakeholder listening sessions of the Specialty Crop Committee, under the auspices of the National Agricultural Research, Extension, Education, and Economics Advisory Board.

DATES: The Specialty Crop Committee will hold two stakeholder listening sessions July 19, 2011 from 9 a.m.–12 noon and 3 p.m.–6 p.m.

ADDRESSES: The stakeholder listening sessions of the Specialty Crop Committee will take place on July 19, 2011, from 9 a.m.–12 p.m. at the Kellogg Hotel and Conference Center, Michigan, State University, 55 South Harrison Avenue, East Lansing, Michigan 48824, and on July 19, 2011, from 3–6 p.m. at the Amway Grand Plaza Hotel, 187 Monroe, NW., Grand Rapids, Michigan 49503.

The public may file written comments before or up to two weeks after the listening sessions with the contact person identified in this notice at: The National Agricultural Research, Extension, Education, and Economics Advisory Board Office, U.S. Department of Agriculture, Room 3901, South Building, 1400 Independence Avenue, SW., Washington, DC 20250–2255.

FOR FURTHER INFORMATION CONTACT: Rob Burk, Executive Director, National Agricultural Research, Extension, Education, and Economics Advisory Board; telephone: (202) 720–3684; fax: (202) 720–6199; or e-mail: *robert.burk@ars.usda.gov.*

SUPPLEMENTARY INFORMATION: The Specialty Crop Committee was established in accordance with the Specialty Crops Competitiveness Act of 2004 under Title III, Section 303 of Public Law 108–465. This Committee is a permanent committee of the National Agricultural Research, Extension, Education, and Economics Advisory Board (the Board). The Committee's charge is to study the scope and effectiveness of research, extension, and economics programs affecting the specialty crop industry. The congressional legislation defines ''specialty crops'' as fruits, vegetables, tree nuts, dried fruits and nursery crops (including floriculture). In order to carry out its responsibilities effectively, the Committee is holding these stakeholder listening sessions. The Committee seeks stakeholder input from industry and state representatives, national organizations and institutions, local producers, agricultural researchers and extension educators, and other groups interested in the issues with which the Specialty Crop Committee is charged. Comments on measures to improve the efficiency, productivity, profitability and economic stability of specialty crop producers; on regional or national data or information needed by the industry to evaluate its competitive position; and on measures designed to improve the competitiveness of research, extension and economics programs affecting the industry are particularly sought. The format will focus on several panel sessions, each relating to one or more specific issues delineated in the Committee's charge. Each panel will be followed with questions or comments by Committee members and from the floor. Opportunities for brief presentations and general discussion from the public participants will be provided.

Also, written comments by attendees and other interested stakeholders will be welcomed as additional public input before and up to two weeks following the listening sessions. All statements will become part of the official public record of the Board's Specialty Crop Committee.

Done at Washington, DC, this 8th day of June 2011.

Catherine Woteki,

Under Secretary, Research, Education, and Economics.

[FR Doc. 2011–17982 Filed 7–15–11; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Forest Service

Humboldt (NV) Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Humboldt (NV) Resource Advisory Committee will meet in Winnemucca, Nevada. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. The purpose of the meeting is to review projects and to decide on the implementaion and recommend funding allocations for selected projects.

DATES: The meeting will be held August 11, 2011, 10 a.m.

ADDRESSES: The meeting will be held at 1085 Fairgrounds Rd., UNR Extension Office, 4H Meeting Room, Winnemucca, Nevada 89445. Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION:**.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Santa Rosa Ranger District, 1200 E. Winnemucca Blvd., Winnemucca, NV 89445. Please call ahead to 775–623–5025 to facilitate entry into the building to view comments.

FOR FURTHER INFORMATION CONTACT: Jeff Ulrich, RAC Designated Federal Official, Santa Rosa Ranger District, 1200 E. Winnemucca Blvd., Winnemucca, Nevada 89445, 775–623–5025, e-mail *jlulrich@fs.fed.us.*

Individuals who use telecommunication devices for the deaf

(TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday. Requests for reasonable accomodation for access to the facility or procedings may be made by contacting the person listed **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: The following business will be conducted: Review and approve previous meeting's minutes and busines expenses, recommend and decide on funding allocations for proposed projects, and provide an opportunity for public comment.

More informaton is available at: https://fsplaces.fs.fed.us/fsfiles/unit/wo/secure_rural_schools.nsf. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by August 7, 2011 to be scheduled on the agenda.

Written comments and requests for time for oral comments must be sent to Santa Rosa Ranger District, 1200 E. Winnemucca Blvd., Winnemucca, Nevada 89445 or by e-mail to *sjingram@fs.fed.us* or via facsimile to 775–625–1200.

Dated: July 12, 2011.

Jeanne M. Higgins,

Forest Supervisor.

[FR Doc. 2011–17967 Filed 7–15–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–924]

Polyethylene Terephthalate Film, Sheet, and Strip From the People's Republic of China: Extension of Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') is extending the time limit for the preliminary results of the administrative review of polyethylene terephthalate film, sheet, and strip (''PET film'') from the People's Republic of China (''PRC''). This review covers the period November 1, 2009, through October 31, 2010.

DATES: *Effective Date:* July 18, 2011.

FOR FURTHER INFORMATION CONTACT: Thomas Martin or Jonathan Hill, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–3936 or (202) 482–3518, respectively.

Background

On December 28, 2010, the Department published in the **Federal Register** a notice of initiation of the second administrative review of the antidumping duty order on PET film from the PRC. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 75 FR 81565 (December 28, 2010). The preliminary results of this review are currently due no later than August 2, 2011.

Statutory Time Limits

In antidumping duty administrative reviews, section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), requires the Department to issue its preliminary results within 245 days after the last day of the anniversary month of an order for which a review is requested and to issue its final results within 120 days after the date on which the preliminary results are published. However, if it is not practicable to complete the review within these time periods, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the preliminary results to a maximum of 365 days after the last day of the anniversary month.

Extension of Time Limit for Preliminary Results of Review

The Department has determined that it is not practicable to complete the instant administrative review within the original time limits established by section 751(a)(3)(A) of the Act because we require additional time to evaluate the most appropriate surrogate values on the administrative record to use in this segment of the proceeding. Therefore, in accordance with section 751(a)(3)(A) of the Act, the Department is extending the time period for completing the preliminary results of the instant administrative review by 60 days. The new deadline is October 3, 2011.[1] The deadline for the final results of this review continues to be 120 days after the publication of the preliminary results.

We are issuing and publishing this notice in accordance with sections 751(a)(3)(A) and 777(i) of the Act.

Dated: July 9, 2011.

Christian Marsh

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–18041 Filed 7–15–11; 8:45 am]

BILLING CODE 3510–DS–P

[1] The 60 day extension falls on October 1, 2011 which is a Saturday. It is the Department's practice to issue a determination on the next business day when the statutory deadline falls on a weekend, federal holiday, or any other day when the Department is closed. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, as Amended,* 70 FR 24533 (May 10, 2005). Accordingly, the deadline for completion of the preliminary results is October 3, 2011.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–834]

Purified Carboxymethylcellulose From Mexico: Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On April 12, 2011, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on purified carboxymethylcellulose from Mexico. *See Purified Carboxymethylcellulose From Mexico: Notice of Preliminary Results of Antidumping Duty Administrative Review,* 76 FR 20313 (April 12, 2011) (*Preliminary Results*). The review covers one producer/exporter, Quimica Amtex S.A. de C.V. The period of review (POR) is July 1, 2009, through June 30, 2010. We invited interested parties to comment on our *Preliminary Results.* The Department received no comments concerning our *Preliminary Results;* therefore, our final results remain unchanged from our *Preliminary Results.* The final results are listed in the section ''Final Results of Review'' below.

DATES: *Effective Date:* July 18, 2011.

FOR FURTHER INFORMATION CONTACT: Mark Flessner or Robert James, AD/CVD Operations Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–6312 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 12, 2011, the Department published the preliminary results of this review in the **Federal Register**. *See Preliminary Results.* We invited parties to comment on the *Preliminary Results.* We received no comments or requests for a hearing.

Scope of the Order

The merchandise covered by the order is all purified carboxymethylcellulose (CMC), sometimes also referred to as purified sodium CMC, polyanionic cellulose, or cellulose gum, which is a white to off-white, non-toxic, odorless, biodegradable powder, comprising sodium CMC that has been refined and purified to a minimum assay of 90 percent. Purified CMC does not include unpurified or crude CMC, CMC Fluidized Polymer Suspensions, and CMC that is cross-linked through heat treatment. Purified CMC is CMC that has undergone one or more purification operations which, at a minimum, reduce the remaining salt and other by-product portion of the product to less than ten percent. The merchandise subject to this order is classified in the Harmonized Tariff Schedule of the United States at subheading 3912.31.00. This tariff classification is provided for convenience and customs purposes; however, the written description of the scope of the order is dispositive.

Final Results of Review

As noted above, the Department received no comments concerning the *Preliminary Results.* As there have been no changes from or comments on the *Preliminary Results,* there is no decision memorandum accompanying this **Federal Register** notice. For further details of the issues addressed in this proceeding, *see Preliminary Results.* The final weighted-average dumping margin for the period July 1, 2009, through June 30, 2010, is as follows:

Producer/exporter	Weighted-average margin (percentage)
Quimica Amtex, S.A. de C.V.	0.80

Assessment

The Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.,* at or above 0.50 percent). Pursuant to 19 CFR 351.106(c)(2), we will instruct CBP to liquidate without regard to antidumping duties any entries for which the assessment rate is *de minimis* (*i.e.,* less than 0.50 percent).

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003). This clarification will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know their merchandise was destined for the United States. This clarification will also apply to POR entries of subject merchandise produced by companies for which we rescind the review based on certifications of no shipments, because these companies certify that they made no POR shipments of subject merchandise for which they had knowledge of U.S. destination. In such instances, we will instruct CBP to liquidate unreviewed entries at the ''all-others'' rate established in the less-than-fair value (LTFV) investigation if there is no rate for the intermediate company(ies) involved in the transaction.

Cash Deposit Requirements

Because we revoked the order with an effective date of July 11, 2010, no cash deposits for estimated antidumping duties are required.[1]

Notification to Importers

This notice serves as a final reminder to importers of their responsibility, under 19 CFR 351.402(f)(2), to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 11, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–18042 Filed 7–15–11; 8:45 am]

BILLING CODE 3510–DS–P

[1] On May 20, 2011, the Department revoked the order, with an effective date of July 11, 2010. *See Purified Carboxymethylcellulose From Mexico and Sweden: Revocation of Antidumping Duty Orders,* 76 FR 29194 (May 20, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–703]

Granular Polytetrafluoroethylene Resin From Italy: Continuation of Antidumping Duty Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* July 18, 2011.

SUMMARY: As a result of the determinations by the Department of Commerce (''Department'') and the International Trade Commission (''ITC'') that revocation of the antidumping duty order on granular polytetrafluoroethylene resin (''PTFE resin'') from Italy would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, the Department is publishing a notice of continuation of the antidumping duty order.

FOR FURTHER INFORMATION CONTACT: Patricia Tran or Nancy Decker, AD/CVD Operations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–1503 and (202) 482–0196, respectively.

SUPPLEMENTARY INFORMATION: On November 1, 2010, the Department published in the **Federal Register** the notice of initiation of the third sunset review of the antidumping duty order on PTFE resin from Italy, pursuant to section 751(c)(2) of the Tariff Act of 1930, as amended (''the Act''). *See Initiation of Five-Year (''Sunset'') Review,* 75 FR 67082 (November 1, 2010). As a result of its review, the

Department determined that revocation of the antidumping duty order on PTFE resin from Italy would likely lead to a continuation or recurrence of dumping and, therefore, notified the ITC of the magnitude of the margins likely to prevail should the order be revoked. *See Granular Polytetrafluoroethylene Resin From Italy: Final Results of Expedited Sunset Review of the Antidumping Duty Order,* 76 FR 12939 (March 9, 2011).

On July 7, 2011, the ITC published its determination in the **Federal Register**, pursuant to section 751(c)(1) of the Act, that revocation of the antidumping duty order on PTFE resin from Italy would likely lead to a continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. *See Granular Polytetrafluoroethylene Resin From Italy,* 76 FR 39896 (July 7, 2011), and *USITC Publication 4240* (June 2011), Granular Polytetrafluoroethylene Resin From Italy, Investigation No. 731–TA–385, Third Review (Expedited).

Scope of the Order

The product covered by the order is PTFE resin, filled or unfilled. The order also covers PTFE wet raw polymer exported from Italy to the United States. *See Granular Polytetrafluoroethylene Resin From Italy; Final Affirmative Determination of Circumvention of Antidumping Duty Order,* 58 FR 26100 (April 30, 1993). The order excludes PTFE dispersions in water and fine powders. During the period covered by this review, such merchandise was classified under item number 3904.61.00 of the Harmonized Tariff Schedule of the United States (''HTSUS''). We are providing this HTSUS number for convenience and customs purposes only. The written description of the scope remains dispositive.

Continuation of the Order

As a result of the determinations by the Department and the ITC that revocation of the antidumping duty order would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby orders the continuation of the antidumping order on PTFE resin from Italy. U.S. Customs and Border Protection will continue to collect antidumping duty cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of the order will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to sections 751(c)(2) and 751(c)(6) of the Act, the Department intends to initiate the next five-year review of the order not later than 30 days prior to the fifth anniversary of the effective date of continuation.

This five-year (sunset) review and this notice are in accordance with section 751(c) of the Act and published pursuant to section 777(i)(1) of the Act.

Dated: July 12, 2011.

Christian Marsh,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–18039 Filed 7–15–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free-Trade Agreement, Article 1904 NAFTA Panel Reviews; Request for Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of First Request for Panel Review.

SUMMARY: On July 8, 2011, Jungbunzlauer Canada Inc. filed a First Request for Panel Review with the United States Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. Panel Review was requested of the Final Results of the 2008–2009 and 2009–2010 Antidumping Duty Administrative Review, made by the International Trade Administration, respecting Citric Acid and Certain Citrate Salts from Canada. This determination was published in the **Federal Register** (76 FR 34,044), on June 10, 2011. The NAFTA Secretariat has assigned Case Number USA–CDA–2011–1904–03 to this request.

FOR FURTHER INFORMATION CONTACT: Ellen M. Bohon, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, NW., Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free Trade Agreement (''Agreement'') established a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada, and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* (''Rules''). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

A first Request for Panel Review was filed with the United States Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement, on July 8, 2011, requesting a panel review of the determination and order described above.

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 39 within 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is August 8, 2011);

(b) A Party, investigating authority or interested person that does not file a Complaint but that intends to appear in support of any reviewable portion of the final determination may participate in the panel review by filing a Notice of Appearance in accordance with Rule 40 within 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is August 22, 2011); and

(c) The panel review shall be limited to the allegations of error of fact or law, including the jurisdiction of the investigating authority, that are set out in the Complaints filed in panel review and the procedural and substantive defenses raised in the panel review.

Dated: July 13, 2011

Ellen M. Bohon,

United States Secretary, NAFTA Secretariat.

[FR Doc. 2011–18005 Filed 7–15–11; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA574

South Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a meeting of the South Atlantic Fishery Management Council.

SUMMARY: The South Atlantic Fishery Management Council will hold a meeting of the full Council in August. A public comment session will be held as part of the meeting regarding agenda items. See **SUPPLEMENTARY INFORMATION** for additional details.

DATES: The Council meeting will be held August 9, 2011. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meeting will be held at the Charleston Marriott Hotel, 170 Lockwood Blvd., Charleston, SC 29403; telephone: (1–800) 968–3569 or (843) 723–3000; fax: (843) 723–0276. Copies of documents are available from Kim Iverson, Public Information Officer, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer; telephone: (843) 571–4366 or toll free at (866) SAFMC–10; fax: (843) 769–4520; e-mail: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION:

Meeting Date

1. Full Council Meeting 8 a.m.–6 p.m.: August 9, 2011

The Council will review Amendment 18 to the Coastal Migratory Pelagic Fishery Management Plan for the South Atlantic and Gulf of Mexico. The amendment addresses Annual Catch Limits (ACLs) and Accountability Measures (AMs) for the joint Gulf/South Atlantic fishery. After considering public comment, the Council may modify the document if appropriate. The Council is scheduled to approve the document for formal review by the Secretary of Commerce, contingent upon the approval of the amendment by the Gulf of Mexico Fishery Management Council.

The Council will review the recommendations of its Scientific and Statistical Committee and Law Enforcement Advisory Panel regarding the Comprehensive Annual Catch Limit (ACL) Amendment and Regulatory Amendment 11 to the Snapper Grouper Fishery Management Plan (FMP). The amendments will be modified based on public comment and, if appropriate, approved for formal review by the Secretary of Commerce. The Comprehensive ACL Amendment meets the mandates of the Magnuson-Stevens Act by establishing ACLs and AMs for species managed by the Council that are not currently undergoing overfishing. Regulatory Amendment 11 addresses options for ending overfishing of speckled hind and warsaw grouper, including modifications to current restrictions for waters deeper than 240 feet.

The Council will review Amendment 20A to the Snapper Grouper FMP addressing the management of wreckfish, modify as appropriate, and approve for public hearings.

Note: A public comment period will be held on August 9, 2011, beginning at 8:30 a.m., on Amendment 18 to the Coastal Migratory Pelagic FMP for the South Atlantic and Gulf of Mexico, the Comprehensive Annual Catch Limit Amendment, and Regulatory Amendment 11 to the Snapper Grouper FMP, followed by public comment regarding any other items on the Council agenda.

The Council will also discuss timing and priorities for the development of FMPs and amendments, review regional operation schedules, and provide guidance to staff.

Documents regarding these issues are available from the Council office (see **ADDRESSES**).

Although non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subjects of formal final Council action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Except for advertised (scheduled) public hearings and public comment, the times and sequence specified on this agenda are subject to change.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) by August 4, 2011.

Dated: July 13, 2011.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2011–17962 Filed 7–15–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RIN 0648–XA440]

National Policy for Distinguishing Serious From Non-Serious Injuries of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability; request for comments.

SUMMARY: NMFS developed a draft national policy, comprised of a Policy Directive and associated Procedural Directive, for distinguishing serious from non-serious injuries of marine mammals. The draft Directives were developed by reviewing injury determinations from 1997–2008, current scientific information, and a new analysis of existing NMFS data. NMFS solicits public comments on the draft Policy and Procedural Directives.

DATES: Comments must be received by *August 17, 2011.*

ADDRESSES: The draft Policy and Procedural Directives for distinguishing serious from non-serious injuries of marine mammals are available in electronic form via the Internet at *http://www.nmfs.noaa.gov/pr/laws/mmpa/* under ''Policies, Guidances and Regulations''.

Copies of the Policy and Procedural Directives may also be requested from Melissa Andersen, Office of Protected Resources, NMFS, 1315 East West Hwy, Silver Spring, MD 20910.

Send comments by any one of the following methods.

(1) *Electronic Submissions:* Submit all electronic comments through the Federal eRulemaking portal: *http://www.regulations.gov* (follow instructions for submitting comments).

(2) *Mail:* Chief, Marine Mammal and Sea Turtle Conservation Division, Attn: Policy for distinguishing serious from non-serious injuries of marine mammals, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (*e.g.,* name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected

information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields, if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Melissa Andersen, Office of Protected Resources, 301–713–2322.

SUPPLEMENTARY INFORMATION:

Background

The Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361 *et seq.*) requires NMFS to estimate annual levels of human-caused mortality and serious injury of marine mammal stocks (section 117) and to categorize commercial fisheries based on their level of incidental mortality and serious injury of marine mammals (section 118). Based on the results of a 1997 workshop discussing the impacts of injuries of marine mammals incidental to commercial fishing operations (Angliss and DeMaster, 1998) and specific regional experience with injury events, NMFS Regional Offices and Science Centers developed regional techniques for assessing and quantifying the serious injuries of marine mammals. Although these regional techniques helped to accomplish the MMPA's mandates, NMFS recognized the need for a nationally consistent and transparent process for effective conservation of marine mammal stocks and management of human activities impacting these stocks.

Accordingly, NMFS convened the Serious Injury Technical Workshop in 2007 to review performance under existing processes, and gather the best available and current scientific information (Andersen *et al.,* 2008). Based on results of the 2007 workshop and input from marine mammal scientists, veterinary experts, and the MMPA Scientific Review Groups, NMFS developed the draft Policy and Procedural Directives describing national guidance and criteria for distinguishing serious from non-serious injuries of marine mammals. The draft Directives will serve as the basis for analyzing marine mammal injury reports (*e.g.,* observer, disentanglement, and stranding program reports) and incorporating the results into marine mammal stock assessment reports (SAR) and marine mammal conservation management regimes (*e.g.,* MMPA List of Fisheries (LOF), take reduction plans (TRP), ship speed regulations).

Draft Policy and Procedural Directives

Interpretation of the Regulatory Definition of ''Serious Injury''

NMFS defined serious injury in regulations (50 CFR 229.2) as ''any injury that will likely result in mortality.'' While this definition provides guidance on which injuries should be considered serious injuries, it allows subjective interpretation of the likelihood that an injury will result in mortality. Therefore, the draft Policy Directive clarifies and provides justification for NMFS' interpretation of the regulatory definition of serious injury as any injury that is ''more likely than not'' to result in mortality, or any injury that presents a greater than 50 percent chance of death to a marine mammal.

Making and Documenting Injury Determinations

The draft Procedural Directive describes the annual process for making and documenting injury determinations. The annual process includes guidance for which NMFS personnel make the annual injury determinations; what information should be used in making injury determinations; information exchange between NMFS Science Centers; NMFS Regional Office and SRG review of the injury determinations; injury determination report preparation and clearance; and inclusion of injury determinations in the SARs and marine mammal conservation management regimes.

Accounting for Injury Cases Where the Outcome Cannot Be Determined

There are many reasons why the severity of a given marine mammal injury event cannot be determined (CBD). In some cases, reports on an injury event lack sufficient information to make an injury determination. In other cases, the severity of an injury may depend on any number of unknown factors. Lastly, the current state of veterinary knowledge or clinical data about the impact of certain injuries might be insufficient to make a determination. Therefore, the draft Procedural Directive outlines NMFS' approach for applying appropriate methods to assign CBD cases as either serious or non-serious injuries for management and reporting purposes. The approach includes methods that can be based on fishery observer data, when available, or historical information from any data source that provides a valid basis for analysis.

Accounting for Successful Mitigation Efforts

Marine mammals that become entangled in or hooked by fishing gear are sometimes released or break free from the gear, but remain hooked or entangled in a portion of the gear. In some instances, those entangled or hooked animals are sighted at a later date or time and NOAA undertakes mitigation efforts to disentangle or dehook the animal (*e.g.,* via the large whale disentanglement program). As a result of the 2007 workshop, NMFS revisited whether marine mammals that are successfully disentangled or dehooked at a later date or time should be considered when classifying fisheries on the LOF. Previously, if an entangled or hooked marine mammal was determined to be seriously injured from the entanglement/hooking but was later successfully disentangled/dehooked and determined to have only non-serious injuries once the gear was removed, the interaction was not included as a serious injury in the SAR because the animal was not removed from the population; thus, the interaction was also not used when classifying fisheries on the LOF. However, this previous approach does not accurately reflect the overall impact of commercial fisheries on marine mammal populations because, by not including disentangled animals in the number of seriously injured animals resulting from interactions with commercial fishing gear, it does not account for all serious injuries inflicted on marine mammals by commercial fishing. Further, this previous approach can lead to an underestimation of total serious injury and mortality of marine mammals because it relies on opportunistic detection and post-interaction intervention by NOAA to mitigate injury effects.

The draft Procedural Directive establishes NMFS' process for assessing and documenting these cases. Successful mitigation efforts (*i.e.,* a marine mammal is disentangled by a disentanglement program and is determined to have only non-serious injuries when released) will not change the pre-intervention injury determination for use in classifying fisheries on the LOF or for use in TRPs. In other words, if the animal was determined to be seriously injured from an entanglement prior to the disentanglement program's intervention, it is considered seriously injured for the purposes of commercial fisheries management, such as the LOF and TRPs. However, for the purposes of assessing the status of stocks in the

SARs, NMFS will record the level of injury determined after the mitigation effort to reflect the fact that the animal likely survived its injuries post-intervention and was not removed from the population.

Injury Categories and Criteria for Large Cetaceans, Small Cetaceans and Pinnipeds

The draft Procedural Directive describes the injury categories and criteria for distinguishing between serious and non-serious injuries of marine mammals. The criteria were developed separately for large cetaceans, small cetaceans, and pinnipeds because the types and impacts of injuries differ between these groups. For this reason, the draft Procedural Directive includes three separate sections that describe criteria for determining injury status specific to each species group, including three tables summarizing the injury categories and criteria with an associated injury determination. The process and criteria for determining injury status for large cetaceans differ from the process and criteria for small cetaceans and pinnipeds. The injury criteria and determinations for large cetaceans are largely based on an analysis of NMFS data on injury events with known outcomes (*i.e.,* survival or death of the animal), with the exception of a few criteria that are based on expert opinion or research presented at the 2007 NMFS Serious Injury Technical Workshop. In contrast, injury criteria and determinations for small cetaceans and pinnipeds are based almost entirely on expert opinion or research presented at the 2007 NMFS Serious Injury Technical Workshop because, unlike large cetaceans, data on injury events with known outcomes are not available for most small cetacean and pinniped species.

References

Andersen, M. S., K. A. Forney, T. V. N. Cole, T. Eagle, R. Angliss, K. Long, L. Barre, L. Van Atta, D. Borggaard, T. Rowles, B. Norberg, J. Whaley, and L. Engleby. 2008. Differentiating Serious and Non-Serious Injury of Marine Mammals: Report of the Serious Injury Technical Workshop, 10–13 September 2007, Seattle, Washington. U.S. Dep. Commer., NOAA Tech. Memo. NMFS–OPR–39. 94 p.

Angliss, R.P. and D.P. DeMaster. 1998. Differentiating Serious and Non-Serious Injury of Marine Mammals Taken Incidental to Commercial Fishing Operations. NOAA Tech Memo. NMFS–OPR–13, 48 p.

Dated: July 12, 2011.

James H. Lecky,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011–18037 Filed 7–15–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA566

Marine Mammals; File No. 15511

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that a permit has been issued to SeaWorld, LLC., 9205 South Center Loop, Suite 400 Orlando, FL 32819, to import one short-finned pilot whale for public display.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562) 980–4001; fax (562) 980–4018;

FOR FURTHER INFORMATION CONTACT: Kristy Beard or Jennifer Skidmore, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On July 2, 2010, notice was published in the **Federal Register** (75 FR 38457) that a request for a permit to import one short-finned pilot whale (*Globicephala macrorhynchus*) for public display had been submitted by the above-named applicant. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216). The permit is valid through July 31, 2012.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: July 11, 2011.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011–17909 Filed 7–15–11; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 10 a.m., Friday August 5, 2011.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance and Enforcement Matters. In the event that the times or dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Sauntia S. Warfield, 202–418–5084.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2011–18202 Filed 7–14–11; 4:15 pm]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 11 a.m., Tuesday August 9, 2011.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Rule Enforcement Review Meeting.

CONTACT PERSON FOR MORE INFORMATION: Sauntia S. Warfield, 202–418–5084.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2011–18203 Filed 7–14–11; 4:15 pm]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 10 a.m., Friday, August 19, 2011.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance and Enforcement Matters. In the event that the times or dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Sauntia S. Warfield, 202–418–5084.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2011–18205 Filed 7–14–11; 4:15 pm]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 10 a.m., Friday, August 26, 2011.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance and Enforcement Matters. In the event that the times or dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Sauntia S. Warfield, 202–418–5084.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2011–18206 Filed 7–14–11; 4:15 pm]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 10 a.m., Friday August 12, 2011.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance and Enforcement Matters. In the event that the times or dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Sauntia S. Warfield, 202–418–5084.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2011–18204 Filed 7–14–11; 4:15 pm]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 10–67]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. John Unglesbee, DSCA/DBO/CFM, (703) 601–6026.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 10–67 with attached transmittal, policy justification, and Sensitivity of Technology statement.

Dated: July 11, 2011.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUN 30 2011

The Honorable John A. Boehner
Speaker
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 10-67, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Egypt for defense articles and services estimated to cost $1.329 billion. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

William E. Landay III
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided under Separate Cover)

BILLING CODE 5001–06–C

Transmittal No. 10–67

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Egypt

(ii) *Total Estimated Value:*

Major Defense Equipment	$ .980 billion
Other	.349 billion
Total	1.329 billion

(iii) *Description and Quantity or Quantities of Articles or Services Under Consideration for Purchase:* 125 M1A1 Abrams tank kits for co-production, 125 M256 Armament Systems, 125 M2 .50 caliber machine guns, 250 M240 7.62mm machine guns, 125 AGT–1500 M1A1 series tank engines and transmissions, 120mm test cartridges, spare and repair parts, maintenance, support equipment, special tool and test equipment, personnel training and equipment, publications and technical documentation, U.S. Government and contractor engineering and logistics support services, and other related elements of logistics and program support. Articles may be provided in furtherance of a co-production agreement.

(iv) *Military Department:* Army (NFY, NFZ, VCV, VCW)

(v) *Prior Related Cases, if any:* numerous cases from 1988 through 2007

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Annex attached

(viii) *Date Report Delivered to Congress:*

* as defined in Section 47(6) of the Arms Export Control Act.

Policy Justification

Egypt—Co-Production of M1A1 Abrams Tank

The Government of Egypt has requested a possible sale that includes 125 M1A1 Abrams tank kits for co-production, 125 M256 Armament Systems, 125 M2 .50 caliber machine guns, 250 M240 7.62mm machine guns, 125 AGT–1500 M1A1 series tank engines and transmissions, 120mm test cartridges, spare and repair parts, maintenance, support equipment, special tool and test equipment, personnel training and equipment, publications and technical documentation, U.S. Government and contractor engineering and logistics support services, and other related elements of logistics and program support. Articles may be provided in furtherance of a co-production agreement. The estimated cost is $1.329 billion.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country that has been and continues to be an important force for political stability and economic progress in the Middle East.

The additional M1A1 tanks will provide Egypt with a modern tank fleet, enhancing its capability to meet current and future threats. This will contribute to Egypt's goal to update its military capability while further enhancing interoperability between Egypt, the U.S., and other allies. Egypt, which has co-produced the M1A1 Abrams tank, will have no difficulty absorbing the additional tanks.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractors will be General Dynamics in Sterling Heights, Michigan, Honeywell International Incorporated in Phoenix, Arizona, and Allison Transmission Motors in Indianapolis, Indiana. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require the assignment of approximately 4 U.S. government and 35 contractor representatives for up to three years in Egypt to manage this production and fielding program.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 10–67

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The M1A1 Thermal Imaging System (TIS) 2nd Generation Forward Looking Infrared (FLIR) constitutes a target acquisition system which, when operated with other tank systems, gives the tank crew a substantial advantage over a potential threat. The TIS provides the M1A1 crew with the ability to effectively aim and fire the tank main armament system under a broad range of adverse battlefield conditions. The hardware itself is Unclassified. The engineering design and manufacturing data associated with the detector and infrared (IR) optics and coatings are considered sensitive. The technical data package is Unclassified with exception of the specifications for target acquisition range (Confidential), nuclear hardening (Confidential, restricted data), and laser hardening (Secret).

2. The M1A1 Tank Special Armor and other special armors used in the hull and turret are classified at the Secret level. Major components of special armor are fabricated in sealed modules and in serialized removable subassemblies. Special armor components and associated vulnerability data for both chemical and kinetic energy rounds are classified Secret.

3. Most of the components of the training ammunition are not considered to be sensitive material or technology. These rounds could be reverse engineered given sufficiently capable analysis. Technical information available from testing and analysis of this ammunition could form the basis of research to develop more capable rounds.

4. The use of the Advanced Gas Turbine-1500 (AGT–1500) Gas Turbine Propulsion System in the MlA1 is a unique application of armored vehicle power-pack technology. The hardware is composed of the AGT–1500 engine and transmission, and is Unclassified. Manufacturing processes associated with the production of turbine blades, recuperator, bearings and shafts, and hydrostatic pump and motor, are proprietary and therefore commercially competition sensitive.

5. A major survivability feature of the Abrams tank is the compartmentalization of fuel and ammunition. Compartmentalization is the positive separation of the crew and critical components from combustible materials. In the event that the fuel or ammunition is ignited or deteriorated by an incoming threat round, the crew is fully protected by the compartmentalization. Sensitive information includes the performance of the ammunition compartments as well as the compartment design parameters.

6. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

[FR Doc. 2011–18011 Filed 7–15–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Final Notice of a Finding of No Significant Impact for a Programmatic Environmental Assessment Implementing a Wind Energy Program at Marine Forces Reserve Facilities Located Across the United States

AGENCY: Department of the Navy, DoD.

ACTION: Final Finding of No Significant Impact (FONSI) for a Programmatic Environmental Assessment (PEA) Implementing a Wind Energy Program at Marine Forces Reserve (MARFORRES) Facilities Located Across the United States.

SUMMARY: Pursuant to the Council on Environmental Quality Regulations (40 CFR parts 1500–1508) implementing procedural provisions of the National Environmental Policy Act (NEPA), 42 United States Code 4321, and the Marine Corps NEPA directive (Marine Corps Order P5090.2A), the Department of the Navy gives final notice that the FONSI for the PEA implementing the MARFORRES Wind Energy Program will not have a significant adverse impact on the environment. In accordance with 42 U.S.C. 4321 and 40 CFR 1501.4(e)(2), a preliminary FONSI for this action was published in the April 18, 2011 **Federal Register** (76 FR Page 21712). No comments were received regarding the preliminary FONSI. MARFORRES has reviewed the conclusion of the PEA, and agrees with the finding of no significant impact. This notice serves as the Final FONSI for the PEA implementing the MARFORRES Wind Energy Program. The preliminary FONSI and the PEA are adopted in final with no change.

Therefore, the preparation of an Environmental Impact Statement (EIS) is not required. Site-specific, focused Environmental Assessments (EA's) will be tiered from the PEA to evaluate site-specific impacts at individual MARFORRES facilities identified as having the potential for the development of wind energy.

DATES: *Effective date:* These findings are effective as of July 12, 2011.

FOR FURTHER INFORMATION CONTACT: Alain D. Flexer, Energy Manager, Marine Forces Reserve, 2000 Opelousas, New Orleans, LA 70146, 504–697–9571; (this is not a toll-free number).

Dated: July 12, 2011.

L.M. Senay,

Lieutenant, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2011–17980 Filed 7–15–11; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12711–003]

Ocean Renewable Power Company, LLC; Notice Concluding Pre-Filing Process and Approving Process Plan And Schedule

a. *Type of Filing:* Notice of Intent to File Application for License for a Hydrokinetic Pilot Project.

b. *Project No.:* 12711–003.

c. *Dated Filed:* July 24, 2009.

d. *Submitted By:* Ocean Renewable Power Company, LLC.

e. *Name of Project:* Cobscook Bay Tidal Energy Project.

f. *Location:* In Cobscook Bay, in Washington County, Maine. The project would not occupy federal lands.

g. *Filed Pursuant to:* 18 CFR 5.3 and 5.5 of the Commission's regulations.

h. *Applicant Contact:* Christopher R. Sauer, Ocean Renewable Power Company, LLC, 120 Exchange Street, Suite 508, Portland, Maine 04101, (207) 772–7707.

i. *FERC Contact:* Timothy Konnert (202) 502–6359.

j. Ocean Renewable Power Company, LLC (ORPC) has filed with the Commission: (1) A notice of intent (NOI) to file an application for a pilot hydrokinetic hydropower project and a draft license application with monitoring plans; (2) a request for waivers of certain Integrated Licensing Process (ILP) regulations necessary for expedited processing of a license application for a hydrokinetic pilot project; (3) a proposed process plan and schedule; and (4) a request to be designated as the non-federal representative for section 7 of the Endangered Species Act consultation and for section 106 consultation under the National Historic Preservation Act.

k. A notice was issued on August 7, 2009, soliciting comments on the draft license application from agencies and stakeholders. Comments were filed by federal and state agencies, and non-governmental organizations. No comments were filed opposing the request to waive the ILP regulations or the proposed process plan and schedule.

l. ORPC was designated as the non-federal representative for section 7 of the Endangered Species Act consultation and for section 106 consultation under the National Historic Preservation Act on August 7, 2009.

m. ORPC proposes a two-phased development approach for the Cobscook Bay Tidal Energy Project. The project would consist of: (1) A single 5-meter-diameter axial flow Kinetic System turbine generator unit (TGU) mounted on a triframe mount, with a rated capacity of 60 kilowatts (kW), in Phase 1; (2) four 5-meter-diameter axial flow Kinetic System TGUs mounted on triframe mounts, with a rated capacity of 60 kW each, in Phase 2; (3) a direct current power and data cable approximately 3,800 feet long (3,600 feet underwater and 200 feet on shore) extending from the TGUs to the onshore station house; (4) an on-shore building 32 feet wide by 35 feet long, housing the SatCon power inverter and the supervisory control and data acquisition (SCADA) system; and (5) appurtenant facilities for navigation safety and operation. The project would have a total rated capacity of 300 kW, with an estimated annual generation between 1,200,000 and 1,300,000 kilowatt-hours.

n. The pre-filing process has been concluded and the requisite regulations have been waived such that the process and schedule indicated below can be implemented.

o. Post-filing process schedule. The post-filing process will be conducted pursuant to the following schedule. Revisions to the schedule may be made as needed.

Milestones	Dates
Final license application expected	August 31, 2011.
Issue notice of acceptance and ready for environmental analysis and request for interventions	September 15, 2011.
Issue biological assessment	September 15, 2011.
Recommendations, conditions, comments and interventions due	October 15, 2011.
Issue notice of availability of environmental assessment	December 14, 2011.
Comments due and 10(j) resolution, if needed	January 13, 2011.

p. Register online at *http://ferc.gov/esubscribenow.htm* to be notified via e-mail of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: July 12, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–17992 Filed 7–15–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any

responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC, Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket No.	File date	Presenter or requester
1. CP11–46–000	7–6–11	Raymond Bransfield.
2. CP11–161–000	7–1–11	Kevin Bowman.[1]
3. CP11–485–000	6–28–11	Gertrude F. Johnson.
4. ER11–1791–000	6–20–11	Hon. Tim Walberg, *et al.*
5. P–2299–000	7–1–11	Hon. Chris Vierra.

[1] Record of telephone conversation.

Dated: July 12, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–17993 Filed 7–15–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11–506–000]

Texas Eastern Transmission, LP; Notice of Request Under Blanket Authorization

Take notice that on July 1, 2011, Texas Eastern Transmission, LP (Texas Eastern), filed an application pursuant to sections 157.205, 157.208, and 157.210 of the Commission's regulations, requesting authorization to uprate the existing electric compressor unit at its Kosciusko Compressor Station from 12,500 horsepower (hp) to 16,875 hp and effectively increase the certificated capacity at the Kosciusko Compressor Station by 4,375 hp from 47,500 hp to 51,875 hp, all as more fully set forth in the application which is on file with the Commission. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this prior notice should be directed to Lisa A. Connolly, General Manager, Rates & Certificates, Texas Eastern Transmission, LP, P.O. Box 1642, Houston, Texas 77251–1642, or telephone (713) 627–4488, or fax (713) 627–5947or by e-mail *laconnolly@spectraenergy.com.*

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a) (1) (iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

Dated: July 12, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–17988 Filed 7–15–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at Southwest Power Pool Regional Entity Trustee, Regional State Committee and Board of Directors Meetings

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of its staff may attend the meetings of the Southwest Power Pool, Inc. (SPP) Regional Entity Trustee (RE), Regional State Committee (RSC) and Board of Directors, as noted below. Their attendance is part of the Commission's ongoing outreach efforts.

All meetings will be held at the Kansas City Marriott Country Club Plaza, 4445 Main Street, Kansas City, MO 64111. The hotel phone number is (800) 810–3708.

SPP RE

July 25, 2011 (8:30 a.m.–2 p.m.).

SPP RSC

July 25, 2011 (1–5 p.m.).

SPP Board of Directors

July 26, 2011 (8 a.m.–3 p.m.).

The discussions may address matters at issue in the following proceedings:

Docket No. ER06–451, *Southwest Power Pool, Inc.*
Docket No. ER08–1419, *Southwest Power Pool, Inc.*
Docket No. ER09–659, *Southwest Power Pool, Inc.*
Docket No. ER09–1050, *Southwest Power Pool, Inc.*
Docket No. ER10–696, *Southwest Power Pool, Inc.*
Docket No. ER10–941, *Southwest Power Pool, Inc.*
Docket No. ER10–1069, *Southwest Power Pool, Inc.*
Docket No. ER10–1254, *Southwest Power Pool, Inc.*
Docket No. ER10–1269, *Southwest Power Pool, Inc.*
Docket No. ER10–1697, *Southwest Power Pool, Inc.*
Docket No. ER10–2244, *Southwest Power Pool, Inc.*
Docket No. ER11–2528, *Southwest Power Pool, Inc.*
Docket No. ER11–2711, *Southwest Power Pool, Inc.*
Docket No. ER11–2719, *Southwest Power Pool, Inc.*
Docket No. ER11–2725, *Southwest Power Pool, Inc.*
Docket No. ER11–2736, *Southwest Power Pool, Inc.*
Docket No. ER11–2758, *Southwest Power Pool, Inc.*
Docket No. ER11–2781, *Southwest Power Pool, Inc.*
Docket No. ER11–2783, *Southwest Power Pool, Inc.*
Docket No. ER11–2787, *Southwest Power Pool, Inc.*
Docket No. ER11–2828, *Southwest Power Pool, Inc.*
Docket No. ER11–2837, *Southwest Power Pool, Inc.*
Docket No. ER11–2861, *Southwest Power Pool, Inc.*
Docket No. ER11–2881, *Southwest Power Pool, Inc.*
Docket No. ER11–2916, *Southwest Power Pool, Inc.*
Docket No. ER11–3025, *Southwest Power Pool, Inc.*
Docket No. ER11–3065, *Southwest Power Pool, Inc.*
Docket No. ER11–3073, *Southwest Power Pool, Inc.*
Docket No. ER11–3130, *Southwest Power Pool, Inc.*
Docket No. ER11–3133, *Southwest Power Pool, Inc.*
Docket No. ER11–3154, *Southwest Power Pool, Inc.*
Docket No. ER11–3159, *Southwest Power Pool, Inc.*
Docket No. ER11–3230, *Southwest Power Pool, Inc.*
Docket No. ER11–3299, *Southwest Power Pool, Inc.*
Docket No. ER11–3331, *Southwest Power Pool, Inc.*
Docket No. ER11–3838, *Southwest Power Pool, Inc.*
Docket No. ER11–3601, *Southwest Power Pool, Inc.*
Docket No. ER11–3622, *Southwest Power Pool, Inc.*
Docket No. ER11–3627, *Southwest Power Pool, Inc.*
Docket No. ER11–3650, *Southwest Power Pool, Inc.*
Docket No. ER11–3665, *Southwest Power Pool, Inc.*
Docket No. ER11–3666, *Southwest Power Pool, Inc.*
Docket No. ER11–3672, *Southwest Power Pool, Inc.*
Docket No. ER11–3710, *Southwest Power Pool, Inc.*
Docket No. ER11–3776, *Southwest Power Pool, Inc.*
Docket No. ER11–3877, *Southwest Power Pool, Inc.*
Docket No. ER11–3952, *Southwest Power Pool, Inc.*
Docket No. ER11–3958, *Southwest Power Pool, Inc.*
Docket No. ER11–3967, *Southwest Power Pool, Inc.*
Docket No. ER11–3728, *Midwest Independent System Operator, Inc.*
Docket No. EL11–34, *Midwest Independent System Operator, Inc.*

These meetings are open to the public.

For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249–5937 or *patrick.clarey@ferc.gov*.

Dated: July 12, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–17990 Filed 7–15–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4009–001]

Henwood Associates, Inc.; White Mountain Ranch, LLC; Notice of Transfer of Exemption

By letter filed June 8, 2011, Henwood Associates, Inc. informed the Commission that its exemption from licensing for the Millner Creek Hydro Project No. 4009, originally issued July 16, 1981,[1] has been transferred to White Mountain Ranch, LLC. The project is located on the Millner Creek Water System in Mono County, California. The transfer of an exemption does not require Commission approval.

White Mountain Ranch, LLC, located at 30130 Cabrillo Avenue, Temecula, California, is now the exemptee of the Millner Creek Hydro Project No. 4009.

Dated: July 11, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–17987 Filed 7–15–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5730–019]

River Bounty, Inc.; Renew Hydro, LLC; Notice of Transfer of Exemption

1. By letters filed April 19, April 20, and May 4, 2011, River Bounty, Inc. informed the Commission that its exemption from licensing for the Oakland Hydroelectric Project No. 5730, originally issued June 9, 1982,[1] has been transferred to Renew Hydro, LLC. The project is located on the Susquehanna River in Susquehanna County, Pennsylvania. The transfer of an exemption does not require Commission approval.

2. Renew Hydro, LLC, located at 1800 Route 34, Suite 101, Wall, New Jersey, is now the exemptee of the Oakland Hydroelectric Project No. 5730.

Dated: July 11, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–17991 Filed 7–15–11; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9440–5]

Availability of the Incident Waste Management Planning and Response Tool

AGENCY: Environmental Protection Agency.

ACTION: Notice of Availability: External Peer Review Meeting.

[1] *Henwood Associates, Inc.,* 16 FERC ¶ 62,075 (1981).

[1] *American Hydro Power Co.,* 19 FERC ¶ 62,426 (1982).

SUMMARY: EPA has responsibilities for decontamination and waste disposal activities following a biological incident. The Incident Waste Management Planning and Response Tool ''IWMPRT'' was developed partly to satisfy requirements assigned under Homeland Security Presidential Directive 10 (HSPD–10), Biodefense in the 21st Century HSPD–10. In addition, HSPD–9 requires that, ''the Administrator of the Environmental Protection Agency, shall enhance recovery systems that are able to stabilize agriculture production, the food supply, and the economy, rapidly remove and effectively dispose of contaminated agriculture and food products or infected plants and animals, and decontaminate premises.''

EPA is announcing the availability of an upcoming meeting where the public will be invited to attend and comment on the IWMPRT. The tool is available at: *http://www2.ergweb.com/bdrtool/login.asp.* In addition, a symposium paper describing updates to the IWMPRT is mentioned and made available through this notice.

Time and Dates: August 17 and 18, 2011 from 9 a.m. to 4 p.m.

Place: The meeting will be held at the Marriott Courtyard Arlington Crystal City, 2899 Jefferson Davis Highway, Arlington, VA.

Status: Parts of this meeting will be open to the public on August 17th from 9a.m. to 4 p.m. An open discussion period for public comment will be held from 3 p.m. to 3:30. The rest of the meeting is closed to the public. Seating is limited. The deadline to register is August 12, 2011. If you are interested in attending the public session on August 17, 2011, please register on-line at *http://iwmprt.eventbrite.com/.*

FOR FURTHER INFORMATION CONTACT:

Technical Information: To obtain access to the IWMPRT or any technical questions, please contact Dr. Paul Lemieux, 919–541–0962;

Logistical Information: For logistical related questions or to submit written comments, please contact Eletha Brady-Roberts. Public review comments should be submitted by August 12, 2011 either via e-mail at *roberts.eletha@epa.gov* or mail to Eletha Brady-Roberts, National Homeland Security Research Center, Office of Research and Development, U.S. Environmental Protection Agency (NG16), 26 West Martin Luther King Drive, Cincinnati, Ohio 45268. Telephone number: 513–569–7662; Fax number: 513–487–2555.

SUPPLEMENTARY INFORMATION: Unique challenges exist for the handling, transport, and disposal of debris resulting from homeland security incidents, natural disasters or other national emergencies. Access to guidance for facilitating decision making in the safe and timely disposal of waste and debris is critical to helping restore a contaminated area and to prevent further contamination or spread of disease. The IWMPRT is a suite of decision support tools developed by the US EPA, in collaboration with other Federal and state Agencies as well as members of the private sector, which provides a quick reference to technical data, regulations, and other information that assists decision makers in guiding disposal decisions that are important for the protection of public health, and the environment. Moreover, the IWMPRT provides a waste quantity estimation tool and information on the: (1) types and quantities of materials and contaminants involved and (2) unique issues or challenges faced with ensuring public and worker safety in the safe and efficient removal, transport, and disposal of debris from an incident.

Symposium paper is available on—*http://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=210325&fed_org_id=1253&address=nhsrc/&view=desc&sortBy=pubDateYear&showCriteria=1&count=25&searchall=Disposal%20OR%20landfill%20OR%20leachate.*

Dated: July 6, 2011.

Jonathan G. Herrmann,

Director, National Homeland Security Research Center, Office of Research and Development, U.S. Environmental Protection Agency.

[FR Doc. 2011–18003 Filed 7–15–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9440–3]

Underground Injection Control Program; Hazardous Waste Injection Restrictions; Petition for Exemption—Class I Hazardous Waste Injection; ConocoPhillips Company, Borger, TX

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of a final decision on a no migration petition.

SUMMARY: Notice is hereby given that an exemption to the land disposal Restrictions, under the 1984 Hazardous and Solid Waste Amendments to the Resource Conservation and Recovery Act, has been granted to ConocoPhillips Company for one Class I injection well located at Borger, Texas. The company has adequately demonstrated to the satisfaction of the Environmental Protection Agency by the petition and supporting documentation that, to a reasonable degree of certainty, there will be no migration of hazardous constituents from the injection zone for as long as the waste remains hazardous. This final decision allows the underground injection by ConocoPhillips, of the specific restricted hazardous wastes identified in this exemption, into Class I hazardous waste injection well No. WDW–325 at the Borger Texas facility, until December 31, 2017, unless EPA moves to terminate this exemption. Additional conditions included in this final decision may be reviewed by contacting the Region 6 Ground Water/UIC Section. A public notice was issued May 19, 2011. The public comment period closed on July 5, 2011. No comments were received. This decision constitutes final Agency action and there is no Administrative appeal. This decision may be reviewed/appealed in compliance with the Administrative Procedure Act.

DATES: This action is effective as of July 8, 2011.

ADDRESSES: Copies of the petition and all pertinent information relating thereto are on file at the following location: Environmental Protection Agency, Region 6, Water Quality Protection Division, Source Water Protection Branch (6WQ–S), 1445 Ross Avenue, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Philip Dellinger, Chief Ground Water/UIC Section, EPA—Region 6, telephone (214) 665–7150.

Dated: July 8, 2011.

William Honker,

Acting, Division Director, Water Quality Protection Division.

[FR Doc. 2011–18001 Filed 7–15–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Update to Notice of Financial Institutions for Which the Federal Deposit Insurance Corporation Has Been Appointed Either Receiver, Liquidator, or Manager

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Update Listing of Financial Institutions in Liquidation.

SUMMARY: Notice is hereby given that the Federal Deposit Insurance

Corporation (Corporation) has been appointed the sole receiver for the following financial institutions effective as of the Date Closed as indicated in the listing. This list (as updated from time to time in the **Federal Register**) may be relied upon as ''of record'' notice that the Corporation has been appointed receiver for purposes of the statement of policy published in the July 2, 1992 issue of the **Federal Register** (57 FR 29491). For further information concerning the identification of any institutions which have been placed in liquidation, please visit the Corporation Web site at *http://www.fdic.gov/bank/individual/failed/banklist.html* or contact the Manager of Receivership Oversight in the appropriate service center.

Dated: July 11, 2011.

Federal Deposit Insurance Corporation.

Pamela Johnson,

Regulatory Editing Specialist.

INSTITUTIONS IN LIQUIDATION

[In alphabetical order]

FDIC Ref. No.	Bank name	City	State	Date closed
10373	Colorado Capital Bank	Castle Rock	CO	7/8/2011
10374	First Chicago Bank & Trust	Chicago	IL	7/8/2011
10375	Signature Bank	Windsor	CO	7/8/2011

[FR Doc. 2011–17969 Filed 7–15–11; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE AND TIME: *Thursday, July 21, 2011 at 10 a.m.*

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor)

STATUS: This meeting will be open to the public.

Items To Be Discussed

Correction and Approval of the Minutes for the Meeting of June 30, 2011.

Draft Advisory Opinion 2011–13: Democratic Senatorial Campaign Committee.

Audit Division Recommendation Memorandum on John Edwards for President.

Proposed Final Audit Report on the Georgia Federal Elections Committee.

Proposed Policy Statement Extending a Pilot Program for Requesting Consideration of Legal Questions by the Commission.

Management and Administrative Matters.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Commission Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the hearing date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer. *Telephone:* (202) 694–1220.

Shawn Woodhead Werth,

Secretary and Clerk of the Commission.

[FR Doc. 2011–18154 Filed 7–14–11; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS11–19]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council

ACTION: Notice of Meeting.

Description: In accordance with Section 1104 (b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for its regular meeting:

Location: OCC—250 E Street, SW., Room 8C, Washington, DC 20219.

Date: July 21, 2011.

Time: 10:30 a.m.

Status: Open.

Matters to be Considered

Summary Agenda

June 8, 2011 minutes—Open Session.

(No substantive discussion of the above items is anticipated. These matters will be resolved with a single vote unless a member of the ASC requests that an item be moved to the discussion agenda.)

Discussion Agenda

Appraisal Foundation 2010 Agreed Upon Procedures Grant Report.

Appraisal Foundation March 2011 Grant Reimbursement Request.

Idaho Compliance Review.

Tennessee Compliance Review.

Vermont Compliance Review.

Idaho Request for an Extension of the Effective Date of the Modified National Registry Fee.

AQB Compliance Status for Licensed Appraisers Listed on the National Registry.

How To Attend and Observe an ASC Meeting

E-mail your name, organization and contact information to *meetings@asc.gov.* You may also send a written request via U.S. Mail, fax or commercial carrier to the Executive Director of the ASC, 1401 H Street, NW., Ste. 760, Washington, DC 20005. The fax number is 202–289–4101. Your request must be received no later than 4:30 p.m., ET, on the Tuesday prior to the meeting. Attendees must have a valid government-issued photo ID and must agree to submit to reasonable security measures. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC meetings.

Dated: July 13, 2011.

James R. Park,

Executive Director.

[FR Doc. 2011–18034 Filed 7–15–11; 8:45 am]

BILLING CODE P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS11–20]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of meeting.

Description: In accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as

amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in closed session:

Location: OCC—250 E Street, SW., Room 8C, Washington, DC 20219.

Date: July 21, 2011.

Time: Immediately following the ASC open session.

Status: Closed.

Matters to be Considered:

June 8, 2011 minutes—Closed Session.

Preliminary discussion of State Compliance Reviews.

Dated: July 13, 2011.

James R. Park,

Executive Director.

[FR Doc. 2011–18035 Filed 7–15–11; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 2, 2011.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *The Dana Hale Nelson Family Irrevocable Trust; the Lisa K. Hale Family Irrevocable Trust; the Dana Hale Nelson Irrevocable Trust for Allison Lesta Nelson; the Dana Hale Nelson Irrevocable Trust for Hayley Elizabeth Nelson; the Dana Hale Nelson Irrevocable Trust for Kristen Adele Nelson, and the Lisa K. Hale Irrevocable Trust for Joseph Joshua Hodos, all of Mission Hills, Kansas; the Karen Hale Young Family Irrevocable Trust; the Max Alan Hale Family Irrevocable Trust; the Twin Meadow VHC Trust; the Karen Hale Young Irrevocable Trust for Rhys Adele Young; the Karen Hale Young Irrevocable Trust for Malia Jean Young; the Karen Hale Young Irrevocable Trust for Elle Joyce Young; the Karen Hale Young Irrevocable Trust for Tatum Diana Young; the Max Alan Hale Irrevocable Trust for Morgan Ann Hale; the Max Alan Hale Irrevocable Trust for Madison Adele Hale; the Max Alan Hale Irrevocable Trust for Keaton Mathew Hale; the Mollie Hale Carter Irrevocable Trust for Elizabeth Ann Carter, and the Mollie Hale Carter Irrevocable Trust for Jocelyn Renee Carter, all of Salina, Kansas;* to become members of the Hale Family Group, and to acquire voting shares of Sunflower Financial, Inc., and thereby indirectly acquire voting shares of Sunflower Bank, National Association, both in Salina, Kansas.

Board of Governors of the Federal Reserve System, July 13, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–17963 Filed 7–15–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0047; Docket No. 2011–0079; Sequence 4]

Federal Acquisition Regulation; Submission for OMB Review; Place of Performance

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), the Regulatory Secretariat (MVCB) will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning place of performance.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

DATES: Submit comments on or before August 17, 2011.

ADDRESSES: Submit comments identified by Information Collection 9000–0047, Place of Performance by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by inputting ''Information Collection 9000–0047, Place of Performance'', under the heading ''Enter Keyword or ID'' and selecting ''Search''. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0047, Place of Performance''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0047 Place of Performance'' on your attached document.
- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street, NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0047, Place of Performance.

Instructions: Please submit comments only and cite Information Collection 9000–0047 Place of Performance, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, Acquisition Policy Division at (202) 208–4949 or e-mail *michaelo.jackson@gsa.gov*.

A. Purpose

The information relative to the place of performance and owner of plant or facility, if other than the prospective contractor, is a basic requirement when contracting for supplies or services (including construction). This information is instrumental in determining bidder responsibility, responsiveness, and price reasonableness. A prospective contractor must affirmatively demonstrate its responsibility. Hence, the Government must be apprised of this information prior to award. The contracting officer must know the place of performance and the owner of the plant or facility to (1) Determine bidder responsibility; (2) determine price reasonableness; (3) conduct plant or source inspections; and (4) determine whether the prospective contractor is a manufacturer or a regular dealer. The information is used to determine the firm's eligibility for awards and to assure proper preparation of the contract. Contractors can complete the

provision electronically in the On-Line Representation and Certifications Application (ORCA); however, because the data being collected could change for a specific solicitation, contractors will still be required to submit place of performance information on an exceptional basis; that is, whenever the place of performance for a specific solicitation is different from the place of performance shown in ORCA.

B. Annual Reporting Burden

Respondents: 79,397.
Responses per Respondent: 14.
Total Responses: 1,111,558.
Hours per Response: .07.
Total Burden Hours: 77,810.
Obtaining copies of proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Branch (MVCB), 1275 First Street, NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0047, Place of Performance, in all correspondence.

Dated: July 7, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy.

[FR Doc. 2011–17979 Filed 7–15–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service (DHHS) is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA) will hold a meeting. The meeting will be conducted as a telephone conference call. The meeting will be open to the public through a conference call phone number.

DATES: The meeting will be on August 2, 2011 from 2 p.m. to approximately 3 p.m. E.S.T.

ADDRESSES: No in-person meeting; conference call only.

Conference Call: Domestic: 888–455–2653. *International:* 1–210–839–8485.
Access code: 1508564.

FOR FURTHER INFORMATION CONTACT: Mr. Melvin Joppy, Committee Manager, Presidential Advisory Council on HIV/AIDS, Department of Health and Human Services, 200 Independence Avenue, SW., Room 443H, Washington, DC 20201; (202) 690–5560. More detailed information about PACHA can be obtained by accessing the Council's Web site at *http://www.pacha.gov.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995 as amended by Executive Order 13009, dated June 14, 1996. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to (a) Promote effective prevention of HIV disease, (b) advance research on HIV and AIDS, and (c) promote quality services to persons living with HIV disease and AIDS. PACHA was established to serve solely as an advisory body to the Secretary of Health and Human Services.

The purpose of this conference call meeting is for PACHA members to discuss their ''game changing'' recommendations letter to the Secretary of HHS and the President in order to curb the HIV epidemic. A copy of the letter will be on the PACHA Web site by close of business Thursday, July 28, 2011. The meeting will be open to the public through a conference call phone number provided above. There will be a limited amount of open lines for the public; early registration is highly recommended. Individuals who need special assistance using this service, such as captioning of the conference call or other reasonable accommodations, should submit a request at least five days prior to the meeting. Members of the public who participate using the conference call phone number will be in a listen only status.

Members of the public will have the opportunity to provide comments. Pre-registration is required for public comment. Individuals who wish to participate in the public comment session must send a copy of their public comments to Melvin Joppy, Committee Manager, at *melvin.joppy@hhs.gov* by close of business Friday, July 29, 2011. Registration for public comment will not be accepted by telephone. Public comment will be limited to the first eight individuals who pre-register. Public comment will be limited to two minutes per speaker. Individuals not providing public comment during the conference call meeting may submit written comments to Melvin Joppy, Committee Manager, at *melvin.joppy@hhs.gov* by close of business Friday, August 5, 2011.

Dated: July 11, 2011.

Christopher H. Bates,

Executive Director, Presidential Advisory Council on HIV/AIDS.

[FR Doc. 2011–17926 Filed 7–15–11; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Appointment to the Chronic Fatigue Syndrome Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office on Women's Health.

ACTION: Notice.

Authority: 42 U.S.C. 271A, Section 222 of the Public Health Service (PHS) Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The Office of the Assistant Secretary for Health, Office on Women's Health, HHS, is seeking nominations of qualified candidates to be considered for appointment as a member of the Chronic Fatigue Syndrome Advisory Committee (CFSAC). CFSAC provides advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on a broad range of issues and topics related to chronic fatigue syndrome (CFS). The appointments of three Committee members are scheduled to end during the 2012 calendar year. Nominations of qualified candidates are being sought to fill these future vacancies.

DATES: Nominations to be considered for appointment to the Committee must be received no later August 17, 2011, by 5 p.m. EDT, at the address listed below.

ADDRESSES: All nominations should be mailed or delivered to Nancy C. Lee, M.D., Executive Secretary, Chronic Fatigue Syndrome Advisory Committee, c/o Office on Women's Health, Department of Health and Human Services, 200 Independence Avenue, SW., Room 712E, Washington, DC 20201. No nominations will be accepted by e-mail.

FOR FURTHER INFORMATION CONTACT: Nancy C. Lee, M.D., Office on Women's Health, Department of Health and Human Services, 200 Independence Avenue, SW., Room 712E, Washington, DC 20201; Telephone: (202) 690–7650. Inquiries also can be sent to *cfsac@hhs.gov.*

SUPPLEMENTARY INFORMATION: CFSAC was established on September 5, 2002. The Committee was established to advise, consult with, and make recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on a broad range of topics including: (1) The current state of knowledge and research and the relevant gaps in knowledge and research about the epidemiology, etiologies, biomarkers and risk factors relating to CFS, and identifying potential opportunities in these areas; (2) impact and implications of current and proposed diagnosis and treatment methods for CFS; (3) development and implementation of programs to inform the public, health care professionals, and the biomedical academic and research communities about CFS advances; and (4) partnering to improve the quality of life of CFS patients.

Nominations: The Office on Women's Health is requesting nominations to fill CFSAC positions that are scheduled to be vacated. The positions are scheduled to become vacant in April 2012. The Committee membership consists of 11 members. The Committee is composed of seven biomedical research scientists with demonstrated expertise in biomedical research applicable to CFS and four individuals with demonstrated expertise in health care delivery, private health care services or insurers, or voluntary organizations concerned with the problems of individuals with CFS. The scheduled vacancies affect both member categories.

Individuals selected for appointment to the Committee will serve as voting members. Individuals selected for appointment to the committee can be invited to serve terms of up to four years. Committee members receive a stipend for attending Committee meetings and also are authorized to receive per diem and reimbursement for travel expenses incurred to attend the meetings.

To qualify for consideration of appointment to the Committee, an individual must possess and demonstrate experience and expertise in the designated fields or disciplines, as well as expert knowledge of the broad issues and topics pertinent to CFS.

Nominations should be typewritten. The original nomination package should include: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes which qualify the nominee for being considered for appointment to the Committee), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address, and daytime telephone number, and contact information (specifically, home and/or work address, telephone number and e-mail address) for the nominated individual; and (3) a current copy of the nominated individual's *curriculum vitae* or resume. Nominations that do not provide these three elements will not be considered. Nominations of Federal employees should not be submitted; Federal employees will not be considered for appointment to the Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that a broad representation of geographic areas, gender, ethnic and minority groups, and people with disabilities are given consideration for membership on HHS Federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status. Potential candidates will be required to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible conflicts of interest.

Dated: July 12, 2011.

Nancy C. Lee,

Deputy Assistant Secretary for Health—Women's Health and Executive Secretary, Chronic Fatigue Syndrome Advisory Committee.

[FR Doc. 2011–18038 Filed 7–15–11; 8:45 am]

BILLING CODE 4150–42–P

DEPARTMENT OF HOMELAND SECURITY

Agency Information Collection Activities: Case Submission Form, Case Assistance Form

(Form DHS–7001), Online Ombudsman Form DHS–7001

AGENCY: Office of the Citizenship and Immigration Service Ombudsman, DHS.

ACTION: 60-Day Notice and request for comments; Revision of currently approved collection.

SUMMARY: The Department of Homeland Security, Office of the Citizenship and Immigration Service Ombudsman will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until September 16, 2011. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to Office of the Citizenship and Immigration Services Ombudsman, DHS, Attn.: Chief of Special Programs, Mail Stop 1225, Washington, DC 20528–1225. Comments may also be submitted to DHA via facsimile to 202–272–8352, 202–357–0042 or via e-mail at *rfs.regs@dhs.gov* or *cisombudsman@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Citizenship and Immigration Services (CIS) Ombudsman was created under section 452 of the Homeland Security Act of 2002 (Pub. L. 107–296) to: (1) Assist individuals and employers in resolving problems with the U.S. Citizenship and Immigration Services (USCIS); (2) to identify areas in which individuals and employers have problems in dealing with USCIS; and (3) to the extent possible, propose changes in the administrative practices of USCIS to mitigate problems. This form is used by an applicant who is experiencing problems with USCIS during the processing of an immigration benefit.

The information collected on this form will allow the CIS Ombudsman to identify the issue such as: (1) A case problem which is a request for information about a case that was filed with USCIS (''case problem''); or (2) the identification of a systemic issue that may or may not pertain to an individual case which the individual, attorney or employer is seeking to bring to the attention of the CIS Ombudsman (''trend''). For case problems, the CIS Ombudsman will refer case specific issues to the Customer Assistance Office for USCIS for further research, and review.

For trends received, the CIS Ombudsman notes the systemic issue identified in the correspondence which may or may not be incorporated into future recommendations submitted to the Director of USCIS pursuant to section 452(d)(4) of Public Law 107–296.

The use of this form provides the most efficient means for collecting and processing the required data. The CIS Ombudsman anticipates employing the use of information technology in collecting and processing information by offering the option for electronic submission of the DHS Form 7001 in

FY2012. The technology for electronic capture of this data is in the final phase of development with successful testing of a pilot version conducted in the 4th quarter of FY2010. We are requesting a two year approval for the form anticipating Government Paperwork Elimination Act compliance for electronic means for collections to be developed and deployed by FY2012. We plan to submit any required paperwork to amend this document for the electronic version of this form during FY2011. There has been no increase or decrease in the estimated annual burden hours previously reported for this information collection. There is no change in the information being collected, however there have been cosmetic changes to the form including punctuation and formatting. The title of the form has changed from ''Case Problem Submission Worksheet (CIS Ombudsman Form DHS–7001)'' to ''Case Assistance Form (Form DHS–7001)'' The name of the system has changed from ''Virtual Ombudsman System'' to ''Online Ombudsman Form DHS–7001''. The instructions have been updated to reflect the electronic submission options. Instructions for electronic submission will be posted on the CIS Ombudsman Web site at *http://www.dhs.gov/cisombudsman.*

The terms of clearance from the previously approved collection have been addressed by updates to the: (a) Privacy Impact Assessment for the Office of the Citizenship & Immigration Services Ombudsman (CISOMB) Virtual Ombudsman System (March 19, 2010); and the (b) Systems of Records Notice: 9110–9B Department of Homeland Security, Office of the Secretary [Docket No. DHS–2009–0146] Privacy Act of 1974; Department of Homeland Security Citizenship and Immigration Services Ombudsman—001 Virtual Ombudsman System (March 2010) to reflect the name change to Online Ombudsman Form DHS–7001 System of Records. These documents are currently under review by DHS HQ Privacy Office.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Analysis

Agency: Office of the Citizenship and Immigration Service Ombudsman, DHS.

Title: Case Submission Form.

OMB Number: 1601–0004.

Frequency: On Occasion.

Affected Public: Individuals or Household.

Number of Respondents: 2,600.

Estimated Time per Respondent: 1 Hour.

Total Burden Hours: 2,600.

Richard Spires,

Chief Information Officer.

[FR Doc. 2011–17934 Filed 7–15–11; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF HOMELAND SECURITY

Agency Information Collection Activities: BioWatch Filter Holder Log

AGENCY: Department of Homeland Security.

ACTION: 30-Day Notice and request for comments; Extension with change.

SUMMARY: The Department of Homeland Security, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). DHS previously published this information collection request (ICR) in the **Federal Register** on May 2, 2011 at 76 FR 24504, for a 60-day public comment period. No comments were received by DHS. The purpose of this notice is to allow additional 30-days for public comments.

DATES: Comments are encouraged and will be accepted until August 17, 2011. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to OMB Desk Officer, Department of Homeland Security and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

FOR FURTHER INFORMATION CONTACT: If additional information is required contact: The Department of Homeland Security, Attn.: Daniel Yereb, *djy1@dhs.gov,* 703–647–8052.

SUPPLEMENTARY INFORMATION: The Department of Homeland Security, Office of Health Affairs/OCMO Early Detection Division will collect information from BioWatch jurisdictions. The BioWatch Program operates aerosol collector equipment in approximately 30 U.S. jurisdictions to monitor for the presence of organisms that may be related to the deliberate release of a select subset of biological threat agents. Information is collected in writing by a representative of a BioWatch jurisdiction (either an employee, or a contractor) assigned responsibility for installing and removing filters from aerosol collection devices and transportation to local laboratories for sample analysis. A standard filter log form is completed for each sample and is archived by the BioWatch jurisdiction for a period of one year. The BioWatch Program reimburses participating jurisdictions for the cost of collection and laboratory analysis activities, including the preparation of the filter log form and other documentation. The creation of a written record for each sample is required to support law enforcement activities, including criminal prosecution in the case of a deliberate release of a biological agent.

Analysis

Agency: Department of Homeland Security.
Title: BioWatch Filter Holder Log.
OMB Number: 1601–0006.
Frequency: Daily.
Affected Public: State, Local, and Tribal Governments.
Number of Respondents: 522.
Estimated Time per Respondent: 0.0167 hours (1 minute).
Total Burden Hours: 3173 hours.

Richard Spires,

Chief Information Officer.

[FR Doc. 2011–17933 Filed 7–15–11; 8:45 am]

BILLING CODE 4410–9B–P

DEPARTMENT OF HOMELAND SECURITY

Agency Information Collection Activities: DHS Individual Complaint of Employment Discrimination

AGENCY: Department of Homeland Security.

ACTION: 30-Day Notice and request for comments; Extension without Change.

SUMMARY: The Department of Homeland Security, Office for Civil Rights and Civil Liberties, DHS will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). DHS previously published this information collection request (ICR) in the **Federal Register** on May 2, 2011 at 76 FR 24503 for a 60-day public comment period. No comments were received by DHS. The purpose of this notice is to allow additional 30-days for public comments.

DATES: Comments are encouraged and will be accepted until August 17, 2011. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to OMB Desk Officer, Department of Homeland Security and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806. The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

FOR FURTHER INFORMATION CONTACT: If additional information is required contact: The Department of Homeland Security (DHS), *Attn:* Denise Moore, *denise.moore@dhs.gov,* 202–254–8230.

SUPPLEMENTARY INFORMATION: It is the policy of the Government of the United States to provide equal opportunity in employment for all persons, to prohibit discrimination in employment because of race, color, religion, sex, national origin, age, disability, protected genetic information, sexual orientation, or status as a parent, and to promote the full realization of equal employment opportunity (EEO) through a continuing affirmative program in each agency.

Persons who claim to have been subjected to these types of discrimination, or to retaliation for opposing these types of discrimination or for participating in any stage of administrative or judicial proceedings relating to them, can seek a remedy under Title VII of the Civil Rights Act (Title VII) (42 U.S.C. 2000e *et seq.*) (race, color, religion, sex, national origin), the Age Discrimination in Employment Act (ADEA) (29 U.S.C. 621 *et seq.*) (age), the Equal Pay Act (29 U.S.C. 206(d)) (sex), the Rehabilitation Act (29 U.S.C. 791 *et seq.*) (disability), the Genetic Information Nondiscrimination Act (GINA) (42 U.S.C. 2000ff *et seq.*) (genetic information), and Executive Order 11478 (as amended by Executive Orders 13087 and 13152) (sexual orientation or status as a parent).

The Department of Homeland Security (DHS), Office for Civil Rights and Civil Liberties (CRCL) adjudicates discrimination complaints filed by current and former DHS employees, as well as applicants for employment to DHS. The complaint adjudication process for statutory rights is outlined in the Equal Employment Opportunity Commission (EEOC) regulations found at Title 29, Code of Federal Regulations Part 1614 and EEO Management Directive 110. For complaints regarding sexual orientation or status as a parent, DHS follows the same procedures as for statutory rights, to the extent permitted by law.

The recordkeeping provisions are designed to ensure that a current employee, former employee, or applicant for employment claiming to be aggrieved or that person's attorney provide a signed statement that is sufficiently precise to identify the aggrieved individual and the agency and to describe generally the action(s) or practice(s) that form the basis of the complaint. The complaint must also contain a telephone number and address where the complainant or the representative can be contacted. The complaint form is used for original allegations of discrimination but also for amendments to underlying complaints of discrimination. The form also determines whether the person is willing to participate in mediation or other available types of alternative dispute resolution (ADR) to resolve their complaint; Congress has enacted legislation to encourage the use of ADR in the federal sector and the form ensures that such an option is considered at this preliminary stage of the EEO complaint process.

A complainant may access the complaint form on the agency web site and may submit a completed complaint form electronically to the relevant Component's EEO Office. The complaint form can then be directly uploaded into the DHS EEO Enterprise Complaints Tracking System, also known as ''iComplaints.''

There is no change or adjustment to the burden associated with the collection of information associated with the DHS complaint form.

DHS is proposing to make one change to the DHS compliant form. This change is the need to add a new checkbox that says ''pregnancy'' under and slightly intended from the existing checkbox that says ''sex'' on the form. Pregnancy discrimination is a form of sex discrimination, which is covered under Title VII. So this information is already included in data gathered in EEO complaints; adding the separate check box just more clearly identifies a sub-category. This form modification is in accordance with new instructions from EEOC—requiring all government agencies to specifically identify this type of information on our complaint forms.

Analysis

Agency: Department of Homeland Security, DHS.

Title: DHS Individual Complaint of Employment Discrimination.

OMB Number: 1610–0001.

Frequency: Annually.

Affected Public: Federal Government.

Number of Respondents: 1200.

Estimated Time per Respondent: 0.5 hours (30 minutes).

Total Burden Hours: 600 hours.

Total Burden Cost (capital/startup): $0.00.

Total Burden Cost (operating/maintaining): $30,246.00.

Richard Spires,

Chief Information Officer.

[FR Doc. 2011–17936 Filed 7–15–11; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Agency Information Collection Activities: Minimum Standards for Driver's Licenses and Identification Cards Acceptable by Federal Agencies for Official Purposes

AGENCY: Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Revision of a currently approved collection.

SUMMARY: The Department of Homeland Security, Office of the Secretary, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until September 16, 2011. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to Office of the Secretary, DHS Attn.: Steve Kozar *Steven.Kozar@hq.dhs.gov,* (202) 447–3368.

SUPPLEMENTARY INFORMATION: The REAL ID Act of 2005 (the Act) prohibits Federal agencies from accepting state-issued drivers' licenses or identification cards for any official purpose—defined by the Act and regulations as boarding commercial aircraft, accessing Federal facilities, or entering nuclear power plants—unless the license or card is issued by a state that meets the requirements set forth in the Act. Title II of Division B of Public Law 109–13, codified at 49 U.S.C. 30301 note. The REAL ID regulations, which DHS issued in January 2008, establish the minimum standards that states must meet to comply with the Act. *See* 73 FR 5272, also 6 CFR part 37 (Jan. 29, 2008). These include requirements for presentation and verification of documents to establish identity and lawful status, standards for document issuance and security, and physical security requirements for driver's license production facilities. For a state to achieve full compliance, the Department of Homeland Security (DHS) must make a final determination on or before January 15, 2013, that the state has met the requirements contained in the regulations and is compliant with the Act. The regulations include new information reporting and record keeping requirements for states seeking a full compliance determination by DHS. As discussed in more detail below, states seeking DHS's full compliance determination must certify that they are meeting certain standards in the issuance of driver's licenses and identification cards and submit security plans covering physical security of document production and storage facilities as well as security of personally identifiable information. 6 CFR 37.55(a). States also must conduct background checks and training for employees involved in the document production and issuance processes and retain and store applicant photographs and other source documents. 6 CFR 37.31 and 37.45. States must recertify compliance with REAL ID every three years on a rolling basis as determined by the Secretary of Homeland Security. 6 CFR 37.55.

Certification Process Generally—Section 202(a)(2) of the REAL ID Act requires the Secretary to determine whether a state is meeting its requirements, ''based on certifications made by the State to the Secretary.'' To assist DHS in making a final compliance determination, 37.55 of the rule requires the submission of the following materials:

(1) A certification by the highest level Executive official in the state overseeing the DMV that the state has implemented a program for issuing driver's licenses and identification cards in compliance with the REAL ID Act.

(2) A letter from the Attorney General of the state confirming the state has the legal authority to impose requirements necessary to meet the standards.

(3) A description of a state's exceptions process to accept alternate documents to establish identity and lawful status and wavier process used when conducting background checks for individuals involved in the document production process.

(4) The state's security plan.

Additionally, after a final compliance determination by DHS, states must recertify compliance every three years on a rolling basis as determined by DHS. 6 CFR 37.55(b).

State REAL ID programs will be subject to DHS review to determine whether the state meets the requirements for compliance. States must cooperate with DHS's compliance review and provide any reasonable information requested by DHS relevant to determining compliance. Under the rule, DHS may inspect sites associated with the enrollment of applicants and the production, manufacture, personalization, and issuance of driver's licenses or identification cards. DHS also may conduct interviews of employees and contractors involved in the document issuance, verification, and production processes. 6 CFR 37.59(a).

Following a review of a state's certification package, DHS may make a preliminary determination that the State needs to take corrective actions to achieve full compliance. In such cases, a state may have to respond to DHS and explain the actions it took or plans to take to correct any deficiencies cited in the preliminary determination or alternatively, detail why the DHS preliminary determination is incorrect. 6 CFR 37.59(b).

Security plans—In order for states to be in compliance with the Act, they must ensure the security of production facilities and materials and conduct background checks and fraudulent document training for employees involved in document issuance and production. REAL ID Act section 202(d)(7)–(9). The Act also requires compliant licenses and identification cards to include features to prevent tampering, counterfeiting, or duplication. REAL ID Act section 202(b). To document compliance with these requirements the regulations require states to prepare a security plan and submit it as part of their certification package. 6 CFR 37.41. At a minimum, the security plan must address steps the state is taking to ensure:

- The physical security of production materials and storage and production facilities;
- Security of personally identifiable information maintained at DMVs including a privacy policy and standards and procedures for document retention and destruction;
- Document security features including a description of the use of biometrics and the technical standards used;
- Facility access control including credentialing and background checks;

- Fraudulent document and security awareness training;
- Emergency response;
- Internal audit controls; and
- An affirmation that the state possesses the authority and means to protect the confidentiality of REAL ID documents issued in support of criminal justice agencies or similar programs.

The security plan also must include a report on card security and integrity.

Background checks and waiver process—Within its security plans, the rule requires states to outline their approach to conducting background checks of certain DMV employees involved in the card production process. 6 CFR 37.45. Specifically, states are required to perform background checks on persons who are involved in the manufacture or production of REAL ID driver's licenses and identification cards, as well as on individuals who have the ability to affect the identity information that appears on the driver's license or identification card and on current employees who will be assigned to such positions. The background check must include a name-based and fingerprint-based criminal history records check, an employment eligibility check, and for newer employees a prior employment reference check. The regulation permits a state to establish procedures to allow for a waiver for certain background check requirements in cases, for example, where the employee has been arrested, but no final disposition of the matter has been reached.

Exceptions process—Under the rule, a state DMV may choose to establish written, defined exceptions process for persons who, for reasons beyond their control, are unable to present all necessary documents and must rely on alternate documents to establish identity, date of birth, or SSN (including not having an SSN). 6 CFR 37.11(h). Alternative documents to demonstrate lawful status will only be allowed to demonstrate U.S. citizenship. The state must retain copies or images of the alternate documents accepted under the exceptions process and submit a report with a copy of the exceptions process as part of its certification package.

Recordkeeping—The rule requires states to maintain photographs of applicants and records of certain source documents. Paper or microfiche copies of these documents must be retained for a minimum of seven years. Digital images of these documents must be retained for a minimum of ten years. 6 CFR 37.31.

The collection of the information will support the information needs of DHS in its efforts to determine state compliance with requirements for issuing REAL ID driver's licenses and identification cards. States may submit the required documents in any format that they choose. DHS has not defined specific format submission requirements for states. DHS will use all of the submitted documentation to evaluate State progress in implementing the requirements of the REAL ID final rule. DHS has used information provided under the current collection to grant extensions and track state progress.

Submission of the security plan helps to ensure the integrity of the license and identification card issuance and production process and outlines the measures taken to protect personal information collected, maintained, and used by state DMVs. Additionally, the collection will assist other Federal and state agencies conducting or assisting with necessary background and immigration checks for certain employees. The purpose of the name-based and fingerprint based CHRC requirement is to ensure the suitability and trustworthiness of individuals who have the ability to affect the identity information that appears on the license; have access to the production process; or who are involved in the manufacture or issuance of the licenses and identification cards.

In compliance with GPEA, states will be permitted to submit the required information for their security plans, certification packages, and written exceptions processes electronically. States will be permitted to submit electronic signatures but must keep the original signature on file. Additionally, because they contain sensitive security information (SSI), the security plans must be handled and protected in accordance with 49 CFR Part 1520. 6 CFR 37.41(c). The final rule does not dictate how States must submit their employees' fingerprints to the FBI for background checks; however it is assumed States will do so via electronic means or another means determined by the FBI.

This is a revision to the original REAL ID information request that covered submissions of material compliance checklists and requests for extensions to meet the requirements of the regulation. This collection is being revised to cover the collection of information required under the regulation for full compliance, including recordkeeping requirements and employee background checks, and to include information to assist DHS in making full compliance determinations. States seeking certification of full compliance with the REAL ID Act must follow the certification requirements described in 37.55 of the regulation and referenced in the response to question one of this supporting statement. There are no new or additional costs associated with this revised information collection. All costs were included in the REAL ID final rule that was published in January 2008. There has been an increase in annual burden hours associated with this collection. This increase in burden is a result of the collection of information required for full compliance. The number of respondents also has increased from 51 to 56, as the previously approved collection did not include the five U.S. Territories (Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, the Virgin Islands, and American Samoa).

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Office of the Secretary, DHS.

Title: REAL ID: Minimum Standards for Driver's Licenses and Identification Cards Acceptable by Federal Agencies.

OMB Number: 1601–0005.

Frequency: Once.

Affected Public: State, Local, and Tribal Governments.

Number of Respondents: 56.

Estimated Time per Respondent: 1,098 hours.

Total Burden Hours: 443,606.

Richard Spires,

Chief Information Officer.

[FR Doc. 2011–17935 Filed 7–15–11; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2011–0586]

Application for Recertification of Cook Inlet Regional Citizens' Advisory Council

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Coast Guard announces the availability of, and seeks comments on, the application for recertification submitted by the Cook Inlet Regional Citizen's Advisory Council (CIRCAC) for September 1, 2011, through August 31, 2012. Under the Oil Terminal and Tanker Environmental Oversight Act of 1990, the Coast Guard may certify on an annual basis, an alternative voluntary advisory group in lieu of a Regional Citizens' Advisory Council for Cook Inlet, Alaska. This advisory group monitors the activities of terminal facilities and crude oil tankers under the Cook Inlet program established by the statute. The current certification for CIRCAC will expire August 31, 2011.

DATES: Public comments on CIRCAC's recertification application must reach the Seventeenth Coast Guard District on or before September 1, 2011.

ADDRESSES: You may submit comments identified by docket number USCG–2011–0586 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this recertification, call or e-mail LCDR Mike Franklin, Seventeenth Coast Guard District (dpi); telephone (907) 463–2821; e-mail *Michael.R.Franklin@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Request for Comments

Public Participation and Request for Comments

We encourage you to participate in this application for recertification by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this notice of availability (USCG–2011–0586), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2011–0586'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8.5 by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may withhold recertification or grant a conditional recertification based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2011–0586'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

The Coast Guard does not plan to hold a public meeting. But you may submit a request for one on or before August 1st, 2011 using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid the process of thoroughly considering the application for recertification, we will hold one at a time and place announced by a later notice in the **Federal Register.**

Background and Purpose

The Coast Guard published guidelines on December 31, 1992 (57 FR 62600), to assist groups seeking recertification under the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (33 U.S.C. 2732) (the Act). The Coast Guard issued a policy statement on July 7, 1993 (58 FR 36504), to clarify the factors that the Coast Guard would be considering in making its determination as to whether advisory groups should be certified in accordance with the Act; and the procedures which the Coast Guard would follow in meeting its certification responsibilities under the Act. Most recently, on September 16, 2002 (67 FR 58440), the Coast Guard changed its

policy on recertification procedures for regional citizen's advisory council by requiring applicants to provide comprehensive information every three years. For the two years in between, applicants only submit information describing substantive changes to the information provided at the last triennial recertification. This is the year in this triennial cycle that CIRCAC must provide comprehensive information.

At the conclusion of the comment period, September 1, 2011, the Coast Guard will review all application materials and comments received and will take one of the following actions:

(a) Recertify the advisory group under 33 U.S.C. 2732(o).

(b) Issue a conditional recertification for a period of 90 days, with a statement of any discrepancies, which must be corrected to qualify for recertification for the remainder of the year.

(c) Deny recertification of the advisory group if the Coast Guard finds that the group is not broadly representative of the interests and communities in the area or is not adequately fostering the goals and purposes of 33 U.S.C. 2732.

The Coast Guard will notify CIRCAC by letter of the action taken on their respective applications. A notice will be published in the **Federal Register** to advise the public of the Coast Guard's determination.

Dated: June 24, 2011.

T.P. Ostebo,

Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.

[FR Doc. 2011–17981 Filed 7–15–11; 8:45 am]

BILLING CODE 9110–04–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *In Re Certain Dynamic Random Access Memory and Nand Flash Memory Devices and Products Containing Same,* DN 2829; the Commission is soliciting comments on any public interest issues raised by the complaint.

FOR FURTHER INFORMATION CONTACT: James R. Holbein, Secretary to the Commission, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint filed on behalf of Intellectual Ventures Management LLC, Invention Investment Fund I, L.P., Invention Investment Fund II, LLC, Intellectual Ventures I LLC, and Intellectual Ventures II LLC on July 12, 2011. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain dynamic random access memory and nand flash memory devices and products containing same. The complaint names as respondents Hynix Semiconductor Inc. of South Korea; Hynix Semiconductor America, Inc. of San Jose, CA; Elpida Memory Inc. of Japan; Elpida Memory (USA) Inc. of Sunnyvale, CA; Acer Inc. of Taiwan; Acer America Corp. of San Jose, CA; ADATA Technology Co., Ltd. of Taiwan; ADATA Technology (U.S.A) Co., Ltd. of Hacienda Heights, CA; Asustek Computer Inc. of Taiwan; Asus Computer International Inc. of Fremont, CA; Dell, Inc. of Round Rock, TX; Hewlett-Packard Company of Palo Alto, CA; Kingston Technology Co., Inc. of Fountain Valley, CA; Logitech International S.A. of Switzerland; Logitech, Inc. of Fremont, CA; Pantech Co, Ltd. of South Korea; Pantech Wireless Inc. of Atlanta, GA; Best Buy Co., Inc. of Richfield, MN; and Wal-Mart Stores, Inc. of Bentonville, AR.

The complainant, proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five pages in length, on any public interest issues raised by the complaint. Comments should address whether issuance of an exclusion order and/or a cease and desist order in this investigation would negatively affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the potential orders;

(iii) Indicate the extent to which like or directly competitive articles are produced in the United States or are otherwise available in the United States, with respect to the articles potentially subject to the orders; and

(iv) Indicate whether Complainant, Complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to an exclusion order and a cease and desist order within a commercially reasonable time.

Written submissions must be filed no later than by close of business, five business days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Submissions should refer to the docket number (''Docket No. 2829'') in a prominent place on the cover page and/or the first page. The Commission's rules authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf*). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the

Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50(a)(4) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50(a)(4)).

Issued: July 12, 2011.

By order of the Commission.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–17932 Filed 7–15–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–787]

In the Matter of Certain Motion-Sensitive Sound Effects Devices and Image Display Devices and Components and Products Containing Same II; Notice of Institution of Investigation; Institution of Investigation Pursuant to 19 U.S.C. 1337

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 13, 2011, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Ogma, LLC of Longview, Texas. Supplements to the complaint were filed on June 17 and 29, 2011. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain motion-sensitive sound effects devices and image display devices and components and products containing same by reason of infringement of certain claims of U.S. Patent No. 6,150,947 (''the '947 patent'') and U.S. Patent No. 5,825,427 (''the '427 patent''). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue an exclusion order and cease and desist orders.

ADDRESSES: The complaint and supplements, except for any confidential information contained therein, are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2011).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on July 11, 2011, *Ordered That*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain motion-sensitive sound effects devices and image display devices and components and products containing same that infringe one or more of claims 1, 9, and 19 of the '947 patent or claims 1 and 2 of the '427 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: Ogma, LLC, 3301 W. Marshall Avenue, Longview, TX 75604.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

3M Company, 3M Center, St. Paul, MN 55144.

Bensussen Deutsch & Associates, Inc., d/b/a Power A, 15525 Woodinville-Redmond Road, NE., Woodinville, WA 98072.

Casio America, Inc., 570 Mount Pleasant Avenue, Dover, NJ 07801.

Casio Computer Co., Ltd., 6–2, Hon-machi 1-chome, Shibuya-ku, Tokyo 151–8543, Japan.

Christie Digital Systems USA, Inc., 10550 Camden Drive, Cypress, CA 90630.

Eiki International, Inc., 30251 Esperanza, Rancho Santa Margarita, CA 92688.

Intec, Inc., 7600 Corporate Center Dr., Suite 400, Miami, FL 33126.

Mitsubishi Electric Corporation, Tokyo Building, 2–7–3, Marunouchi, Chiyoda-ku, Tokyo 100–8310, Japan.

Mitsubishi Electric & Electronics USA, Inc., 5665 Plaza Drive, Cypress, CA 90630.

Optoma Corporation, 5F., No. 108, Minchiuan Road, Shindian City, Taipei, Taiwan.

Optoma Technology, Inc., 715 Sycamore Drive, Milpitas, CA 95035.

Performance Designed Products LLC, 14144 Ventura Boulevard, Suite 200, Sherman Oaks, CA 91423.

Planar Systems, Inc., 1195 NW. Compton Drive, Beaverton, OR 97006.

Supersonic, Inc., 6555 Bandini Boulevard, Commerce, CA 90040.

Toshiba Corporation, 1–1, Shibaura 1-chome, Minato-ku, Tokyo 105–8001, Japan.

Toshiba America Information Systems, Inc., 9740 Irvine Boulevard, Irvine, CA 92618–1697.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Honorable E. James Gildea is designated as the presiding administrative law judge.

The Commission has determined to assign this investigation to Judge Gildea, who is the presiding administrative law judge in *Certain Motion-Sensitive Sound Effects Devices and Image Display Devices and Components and Products Containing Same,* Inv. No. 337–TA–773, in view of the overlapping subject matter in the two investigations. The presiding administrative law judge is authorized to consolidate Inv. No. 337–TA–773 and this investigation if he deems it appropriate.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to

19 CFR 201.16(d)–(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: July 13, 2011.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–17966 Filed 7–15–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1127 (Final) (Remand)]

Certain Lightweight Thermal Paper From Germany; Remand Proceedings

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The U.S. International Trade Commission (''Commission'') hereby gives notice of the court-ordered remand of its final determination in Investigation No. 731–TA–1127 concerning certain lightweight thermal paper (''LWTP'') from Germany. For further information concerning the conduct of this proceeding and rules of general application, consult the Commission's Rules of Practice and Procedure, Part 201, subparts A through E (19 CFR part 201), and part 207, subpart A (19 CFR part 207).

DATES: *Effective Date:* July 1, 2011.

FOR FURTHER INFORMATION CONTACT: Christopher Cassise, Office of Investigations, telephone 202–708–5408, or Marc A. Bernstein, Office of General Counsel, telephone 202–205–3087, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov).* The public record of Investigation No. 731–TA–1127 may be viewed on the Commission's electronic docket (''EDIS'') at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—In November 2008, the Commission determined that a domestic industry was threatened with material injury by reason of imports of certain lightweight thermal paper from Germany that the Department of Commerce found were sold at less than fair value (LTFV). Papierfabrik August Koehler AG and Koehler America, Inc. (collectively ''Koehler''), respectively an exporter and importer of LWTP from Germany, contested the Commission's determination before the Court of International Trade (CIT). The CIT affirmed the Commission's determination. *Papierfabrik August Koehler AG* v. *United States,* 675 F. Supp.2d 1172 (Ct. Int'l Trade 2009). On appeal, the United States Court of Appeals for the Federal Circuit vacated the judgment of the CIT. The Federal Circuit held that the Commission improperly failed to consider certain materials Koehler introduced, consisting of a worksheet prepared in the Commerce dumping investigation containing intermediate dumping margin calculations concerning certain types of LWTP, including LWTP having basis weight of 48 grams per square meter (''48 gram LWTP''). *Papierfabrik August Koehler AG* v. *United States,* App. No. 2010–1147 (Fed. Cir. January 11, 2011) (non-precedential opinion). The Federal Circuit subsequently denied the Commission's petition for rehearing and rehearing *en banc. Paperfabrik August Koehler AG* v. *United States,* App. No. 2010–1147 (Fed. Cir. May 18, 2011). On June 15, 2011, the CIT remanded this matter to the Commission. It ordered the Commission to take ''action consistent with the [Federal Circuit] decision'' and ''to revise its final determination with respect to the threat of material injury from subject merchandise from Germany, in accordance with the decision [of the Federal Circuit]. The Commission shall specifically explain how its decision to deny Koehler's request to exclude a subset of subject merchandise from the Commission's threat of material injury determination complies with the Court of Appeals' interpretation of 19 U.S.C. 1673d(c)(1)(A) and the decision in *Algoma Steel Corp.* v. *United States,* 865 F.2d 240 (Fed. Cir. 1989).'' *Papierfabrik August Koehler AG* v. *United States,* Slip. Op. 11–67 (Ct. Int'l Trade June 15, 2011).

Participation in the proceeding.—Only those persons who were interested parties to the original investigation (*i.e.,* persons listed on the Commission Secretary's service list) and participated in the appeal proceedings before the Federal Circuit may participate in the remand proceeding. Such persons need not re-file their appearance notices or protective order applications to participate in the remand proceeding. Business proprietary information (''BPI'') referred to during the remand proceeding will be governed, as appropriate, by the administrative protective order issued in the original investigation.

Written submissions.—The Commission is reopening the record to obtain additional information pertinent to the issue on which the CIT has directed a remand. In addition, the Commission will permit the parties to file comments pertaining to any new factual information and the following issues:

1. The nature of the action the opinion of the Federal Circuit and the remand instructions of the CIT require the Commission to take on remand.

2. What factual findings and legal conclusions the Commission should make in light of the information in the remand record from Department of Commerce proceedings concerning dumping of imports of 48 gram LWTP from Germany.

Comments should be limited to no more than twenty (20) double-spaced and single-sided pages of textual material. The parties may not submit any new factual information in their comments and may not address any issue other than those listed above. Any such comments must be filed with the Commission no later than August 5, 2011.

All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to

the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (Nov. 8, 2002).

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Parties are also advised to consult with the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and Part 207, subpart A (19 CFR Part 207) for provisions of general applicability concerning written submissions to the Commission.

Issued: July 12, 2011.

By order of the Commission.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–17937 Filed 7–15–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–617]

In the Matter of Certain Digital Television Products and Certain Products Containing Same and Methods of Using Same; Notice of Commission Determination to Rescind a Limited Exclusion Order and Cease and Desist Orders as to Certain Respondents

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to rescind the limited exclusion order and cease and desist orders issued in the above-captioned investigation as to TPV Technology, Ltd.; TPV International (USA), Inc.; Top Victory Electronics (Taiwan) Co., Ltd.; and Envision Peripherals, Inc. (collectively, ''the TPV respondents'') based on a settlement agreement.

FOR FURTHER INFORMATION CONTACT: Daniel E. Valencia, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–1999. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 15, 2007, based on a complaint filed by Funai Electric Co., Ltd. of Japan and Funai Corporation of Rutherford, New Jersey (collectively ''Funai''), alleging violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital televisions and certain products containing same by reason of infringement of certain claims of United States Patent Nos. 5,329,369 (''the '369 patent'') and 6,115,074 (''the '074 patent''). The complaint named several respondents including the TPV respondents; and Vizio, Inc. and AmTran Technology Co., Ltd. (collectively, ''the Vizio respondents).

On April 10, 2009, the Commission made its final determination in the investigation finding a violation of section 337 with regard to the '074 patent and no violation with respect to the '369 patent. The Commission issued a limited exclusion order and several cease and desist orders.

On August 9, 2010, the Commission determined to rescind the limited exclusion order and cease and desist orders as to the Vizio respondents based on a joint motion regarding a settlement between Funai and the Vizio respondents.

On December 21, 2010, the Commission modified the limited exclusion order and cease and desist orders based on a decision of the United States Court of Appeals for the Federal Circuit in *Vizio, Inc.* v. *Int'l Trade Comm'n,* 605 F.3d 1330 (Fed. Cir. 2010). On May 31, 2011, Funai and the TPV respondents filed a joint petition to rescind the modified remedial orders as to the TPV respondents. According to the joint petition, these parties have settled their dispute.

The Commission has determined that the settlement satisfies the requirement of Commission Rule 210.76 (a)(1) (19 CFR 210.76(a)(1)) that there be changed conditions of fact or law. The Commission therefore has issued an order rescinding the limited exclusion order and cease and desist orders previously issued in this investigation as to the TPV respondents. The Commission's remedial orders remain in effect against the following respondents: Syntax-Brillian Corporation; Taiwan Kolin Co., Ltd.; Proview International Holdings, Ltd.; Proview Technology (Shenzhen) Co., Ltd.; and Proview Technology, Ltd.

The authority for the Commission's determination is contained in Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.76(a)(1) of the Commission's Rules of Practice and Procedure (19 CFR 210.76(a)(1)).

By order of the Commission.

Issued: July 13, 2011.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–17999 Filed 7–15–11; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under The Resource Conservation and Recovery Act (RCRA)

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on July 8, 2011, a proposed Consent Decree in *United States and State of Florida Department of Environmental Protection* v. *Hi-Acres, LLC, d/b/a Foremost Fertilizer,* Civil Action No. 5:11–cv–00389–WTH–KRS, was lodged with the United States District Court for the Middle District of Florida, Ocala Division.

The Consent Decree represents the settlement of claims brought by the United States and State of Florida Department of Environmental Protection (''FDEP'') for violations by Hi-Acres at a retail sales outlet for pesticides, herbicides, and fertilizers located in Leesburg, Lake County, Florida. The Complaint alleged, *inter alia,* violations of the Resource Conservation and Recovery Act (''RCRA'') Section 3008(a), 42 U.S.C. 6928(a), and the federal regulations promulgated at 40 CFR Parts 260 through 279; the authorized hazardous waste management regulations of the State of Florida, relating to the generation, transportation, treatment, storage, handling and disposal of hazardous wastes, Fla. Admin. Code Chapter 63–740, et seq; and Fla. Stat. § 403.727; and of RCRA Section 3004(d), 42 U.S.C. 6924(d), and Fla. Stat. Chapter 403

(Environmental Control), Part IV. (Resource Recovery Management), relating to the disposal of hazardous wastes restricted from land disposal.

Under the Consent Decree, Hi-Acres must commence site rehabilitation in accordance with State of Florida rules and regulations for all solid waste management units and areas of contamination that are identified on the appendix to the Consent Decree. Hi-Acres is required to provide any necessary revisions to its Contamination Assessment Protection Plan, along with any proposed alternate schedules for completing the required work. Hi-Acres will be required under the Consent Decree to submit periodic status reports to FDEP. Once the site is cleaned up, Hi-Acres shall submit to FDEP a site rehabilitation completion report. Hi-Acres will further be required to submit a plan for all necessary environmental monitoring to ensure the effectiveness of the on-going cleanup, including groundwater monitoring. Hi-Acres will be required to pay a penalty of $400,000, evenly split between EPA and the FDEP, along with interest, per the terms of the Consent Decree.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States and State of Florida Department of Environmental Protection* v. *Hi-Acres, LLC, d/b/a Foremost Fertilizer, Inc.* D.J. Ref. 90–7–1–09265.

The Consent Decree may be examined at U.S. EPA Region 4, Atlanta Federal Center, 61 Forsyth Street, Atlanta, Georgia 30303. During the public comment period, the Consent Decree, may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $9.75 (for the Consent Decree only) and $17.00 for the Consent Decree and all exhibits thereto) (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by email or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–17927 Filed 7–15–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Evaluation of the Adult and Dislocated Worker Program in the Workforce Investment Act

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the proposed Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, ''Evaluation of the Adult and Dislocated Worker Program in the Workforce Investment Act,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35).

DATES: Submit comments on or before August 17, 2011.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an e-mail to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, Employment and Training Administration (ETA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), e-mail: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by e-mail at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: To determine whether the adult and dislocated worker services funded by Title I of the Workforce Investment Act (WIA) are effective, the ETA is undertaking the WIA Random Assignment Impact Evaluation of the Adult and Dislocated Worker Programs. The evaluation will address the following research questions:

- Does access to WIA intensive and training services-both individually and combined-lead adults and dislocated workers to achieve better educational, employment, earnings, and self-sufficiency outcomes than they would achieve in the absence of access to those services?
- Does the effectiveness of the WIA vary by population subgroup? Is there variation by sex, age, race/ethnicity, unemployment insurance receipt, education level, previous employment history, adult and dislocated worker status, and veteran and disability status?
- How does the implementation of the WIA vary by Local Workforce Investment Area? Does the effectiveness of the WIA vary by how it is implemented? To what extent do implementation differences explain variations in the WIA's effectiveness?
- Do the benefits from WIA services exceed program costs? Do the benefits of intensive services exceed their costs? Do the benefits of training exceed its costs? Do the benefits exceed the costs for adults? Do they for dislocated workers?

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB control number. *See* 5 CFR 1320.5(a) and 1320.6. For additional information, see the related notice published in the **Federal Register** on November 10, 2010 (75 FR 69126).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should reference OMB Control Number

201101–1205–001. The OMB is particularly interested in comments that:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: Employment and Training Administration (ETA).

Type of Review: New Collection (Request for a new OMB Control Number).

Title of Collection: Evaluation of the Adult and Dislocated Worker Program in the Workforce Investment Act.

OMB Reference Number: 201101–1205–001.

Affected Public: Individuals or Households; State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 69,350.

Total Estimated Number of Responses: 70,430.

Total Estimated Annual Burden Hours: 34,133.

Total Estimated Annual Other Costs Burden: $0.

Dated: July 12, 2011.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2011–18008 Filed 7–15–11; 8:45 am]

BILLING CODE 4510–FN–P

MERIT SYSTEMS PROTECTION BOARD

Public Availability of the Merit Systems Protection Board's FY 2010 Service Contract Inventory

AGENCY: Merit Systems Protection Board.

ACTION: Notice.

SUMMARY: The Merit Systems Protection Board (MSPB) is publishing this notice to advise the public of the availability of its FY 2010 Service Contract Inventory as required by Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117). This inventory provides information on service contract actions over $25,000 awarded in FY 2010. The inventory was developed in accordance with guidance issued on November 5, 2010 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). The OFPP's guidance is available at: *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf.* The MSPB's inventory is posted on its Web site at *http://www.mspb.gov/contact/contracting.htm.*

FOR FURTHER INFORMATION CONTACT: Veronica Bullock, Merit Systems Protection Board, Office of Financial and Administrative Management, 1615 M Street, NW., Washington, DC 20419; telephone 202–254–4406; e-mail *veronica.bullock@mspb.gov.*

William D. Spencer,

Clerk of the Board.

[FR Doc. 2011–17976 Filed 7–15–11; 8:45 am]

BILLING CODE 7400–01–P

POSTAL REGULATORY COMMISSION

[Docket No. R2010–4R; Order No. 757]

Rate Adjustment Remand

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a proceeding to address the causation standard in exigent rate adjustments. This notice provides information on legal developments associated with this proceeding, addresses preliminary procedural matters, and invites public comment.

DATES: *Comments are due:* July 25, 2011; *reply comments are due:* August 1, 2011.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION:

Regulatory History: 75 FR 40853 (July 14, 2010).

On May 24, 2011, the United States Court of Appeals for the District of Columbia Circuit issued its opinion in *United States Postal Service* v. *Postal Regulatory Commission,* 640 F.3d 1263 (D.C. Cir. 2011). The court denied in part and granted in part a Postal Service petition for review of the Commission's September 30, 2010 order denying a Postal Service request for an exigent rate adjustment under 39 U.S.C. 3622(d)(1)(E).[1] 640 F.3d at 1268.

On July 11, 2011, the court issued its mandate remanding the case to the Commission. The Commission is issuing this order to promptly establish procedures for receiving initial and reply comments that address the causation standard applicable to exigent rate adjustment requests submitted under 39 U.S.C. 3622(d)(1)(E).[2]

Background. On July 6, 2010, the Postal Service filed a request for an exigent rate adjustment pursuant to 39 U.S.C. 3622(d)(1)(E).[3] This was the first such request filed by the Postal Service. The Exigent Request alleged that ''extraordinary or exceptional circumstances'' had occurred—namely, the recent recession and related declines in mail volume—and that the Postal Service was entitled to an exigent rate adjustment. *Id.* at 6.

After holding public hearings and considering initial and reply comments filed by the Postal Service and other interested persons, the Commission issued Order No. 547 denying the Postal Service's Exigent Request. The Commission analyzed the plain meaning of ''due to'' in section 3622(d)(1)(E), interpreting the phrase as requiring that a ''proposed adjustment * * * be causally related to the alleged extraordinary or exceptional circumstance.'' Order No. 547 at 54. The Commission found that the recent recession and its impact on postal

[1] Order Denying Request for Exigent Rate Adjustments, September 30, 2010 (Order No. 547).

[2] Section 3622(d)(1)(E) provides in relevant part as follows:

''[R]ates may be adjusted on an expedited basis *due to* either extraordinary or exceptional circumstances, provided that the Commission determines * * * that such adjustment is reasonable and equitable and necessary to enable the Postal Service, under best practices of honest, efficient, and economical management, to maintain and continue the development of postal services of the kind and quality adapted to the needs of the United States.'' (emphasis added).

[3] Exigent Request of the United States Postal Service, July 6, 2010 (Exigent Request).

volumes qualified as an ''extraordinary or exceptional'' circumstance. *Id.* at 50. However, it ruled that the Postal Service had failed to demonstrate that the proposed rate adjustments were ''due to'' the ''extraordinary or exceptional'' circumstance, as required by section 3622(d)(1)(E), because it did not show how the rate increases related to exigent circumstances that purportedly gave rise to them. *Id.* at 53, 60. Accordingly, the Commission denied the requested exigent rate adjustment. *Id.* at 87.

The court's opinion. On appeal, the court affirmed the Commission's conclusion that the plain meaning of the words ''due to'' in section 3622(d)(1)(E) requires a causal relationship between the amount of the requested adjustment and the impact of the extraordinary or exceptional circumstances.[4] The court confirmed that, ''under the plain meaning of [section 3622(d)(1)(E)], a rate may be 'adjusted on an expedited basis' only *because of* 'extraordinary or exceptional circumstances.' '' *Id.* (emphasis in original).

The court nevertheless concluded that the plain meaning of the ''due to'' phrase does not adequately express how close the relationship between the proposed adjustment and the exigent circumstance must be.[5] In the court's view, the ''due to'' phrase in section 3622(d)(1)(E) is ambiguous because the phrase can mean ''due *in part* to'' as well as ''due *only* to.'' *Id.* (emphasis in original).

Because the phrase ''due to'' is ambiguous as a standard of causation, the court held that the Commission could not properly reject the Exigent Request based on a plain meaning interpretation of the phrase.[6] Thus, it granted the Postal Service's petition in part and remanded the case to the Commission to satisfy its obligation ''to fill the statutory gap by determining how closely the amount of the adjustments must match the amount of the revenue lost as a result of the exigent circumstances.'' *Id.*

The Commission's response. As directed by the court, the Commission will proceed to apply its expertise and interpret the phrase ''due to'' to determine how closely the amount of an exigent rate adjustment must match the amount of revenue lost as a result of an exigent circumstance. *Id.; see Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.,* 467 U.S. 837, 842–43 (1984).

The Commission establishes Docket No. R2010–4R to consider issues on remand. Docket Nos. R2010–4 and R2010–4R are part of the same proceeding. The Commission shall consider all documents filed to date in Docket No. R2010–4 as part of the record in Docket No. R2010–4R.

To ensure that the Postal Service and other interested persons have an opportunity to make their views known regarding the proper interpretation of ''due to'' as the standard of causation in 39 U.S.C. 3622(d)(1)(E), the Commission hereby provides for submission of initial and reply comments on this topic. Initial comments are due no later than July 25, 2011. Reply comments are due no later than August 1, 2011. All comments and other documents related to issues on remand must be filed under Docket No. R2010–4R.

It is ordered:

1. The Commission establishes Docket No. R2010–4R to consider issues on remand.

2. James Waclawski will continue to serve as officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Initial comments addressing the proper interpretation of ''due to'' as a standard of causation in 39 U.S.C. 3622(d)(1)(E) are due no later than July 25, 2011.

4. Reply comments addressing matters raised in initial comments are due no later than August 1, 2011.

5. All comments and other documents related to issues on remand must be filed under Docket No. R2010–4R.

6. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2011–17924 Filed 7–15–11; 8:45 am]

BILLING CODE 7710–FW–P

[4] 640 F.3d at 1267 (''[W]e agree with the Commission that the plain meaning of 'due to' mandates a causal relationship between the amount of a requested adjustment and the exigent circumstances' impact on the Postal Service.'').

[5] *Id.* at 1268 (''[A]lthough ['due to'] has a plain meaning regarding causal connection *vel non,* * * * it has no similar plain meaning regarding the closeness of the causal connection.'').

[6] *Id.* The court rejected the Commission's plain meaning interpretation as ''requiring that the Postal Service match the amount of the proposed adjustments *precisely* to the amount of revenue lost as a result of the exigent circumstances.'' *Id.* (emphasis in original).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 29723; File No. 812–13143]

HighMark Funds and HighMark Capital Management, Inc.; Notice of Application

July 12, 2011.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act and rule 18f–2 under the Act.

SUMMARY OF THE APPLICATION: Applicants request an order that would permit them to enter into and materially amend sub-advisory agreements without shareholder approval.

APPLICANTS: HighMark Funds and HighMark Capital Management, Inc. (''HMCM'').

DATES: *Filing Dates:* The application was filed on December 14, 2004, and amended on February 17, 2010, and January 14, 2011. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 5, 2011, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090. Applicants: HighMark Funds, 350 California Street, Suite 1600, San Francisco, California 94104; HMCM, 350 California Street, San Francisco, California 94104.

FOR FURTHER INFORMATION CONTACT: Lewis B. Reich, Senior Counsel, at (202) 551–6919, or Jennifer L. Sawin, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. HighMark Funds is a registered open-end management investment company organized as a Massachusetts business trust and currently offers 29 series (each, a ''Fund''), each with its own investment objective, restrictions and policies.[1]

2. HMCM, a California corporation with its principal office in San Francisco, is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). HMCM is a subsidiary of Union Bank, N.A., which is a subsidiary of UnionBanCal Corporation, which is wholly owned by The Bank of Tokyo-Mitsubishi UFJ Ltd., which is a wholly-owned subsidiary of Mitsubishi UFJ Financial Group, Inc. HMCM serves as the investment adviser to the currently existing Funds pursuant to an investment advisory agreement with HighMark Funds (an ''Advisory Agreement'') approved by board of trustees of the HighMark Funds (the ''Board''), including a majority of the trustees who are not ''interested persons'' of HighMark Funds as defined in section 2(a)(19) of the Act (the ''Independent Trustees''), and by the shareholders of each Fund in accordance sections 15(a) and (c) of the Act and rule 18f–2 thereunder.[2]

3. Under the Advisory Agreement, the Adviser is responsible for providing a continuous investment program for each Multi-Manager Fund and determining what securities and other investments will be purchased, retained or sold by each Multi-Manager Fund, consistent with the Multi-Manager Fund's objectives, policies, and restrictions. As compensation for its investment management services, the Adviser receives the fee specified in the Advisory Agreement with respect to each Multi-Manager Fund based on the Multi-Manager Fund's average daily net assets. The Advisory Agreement permits the Adviser to retain one or more sub-advisers (each a ''Sub-Adviser'') pursuant to investment sub-advisory agreements at the Adviser's own expense, for the purpose of managing all or a portion of the assets of a Multi-Manager Fund. Each Sub-Adviser is, or will be, an investment adviser registered under the Advisers Act. Each Sub-Adviser is and will be responsible, subject to the general supervision of the Adviser and the Board, for supervising and administering the Multi-Manager Fund's investment program with respect to the portion of the Multi-Manager Fund's assets assigned to it. The Adviser will evaluate and recommend Sub-Advisers to the Board and will monitor and evaluate each Sub-Adviser's investment programs, performance and compliance. The Adviser will recommend to the Board whether sub-advisory agreements should be renewed, modified or terminated.

4. Applicants request an order to permit the Adviser, subject to Board approval, to enter into and materially amend sub-advisory agreements for Multi-Manager Funds without shareholder approval. The requested relief will not apply with respect to any Sub-Adviser that is an affiliated person, as defined in section 2(a)(3) of the Act, of a Multi-Manager Fund or of the Adviser, other than by reason of serving as Sub-Adviser to one or more Multi-Manager Funds (''Affiliated Sub-Adviser'').

Applicants' Legal Analysis

1. Section 15(a) of the Act provides, in relevant part, that it is unlawful for any person to act as an investment adviser to a registered investment company except pursuant to a written contract that has been approved by a vote of a majority of the company's outstanding voting securities. Rule 18f-2 under the Act provides that each series or class of stock in a series investment company affected by a matter must approve the matter if the Act requires shareholder approval.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or from any rule thereunder, if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief satisfies this standard for the reasons below.

3. Applicants state that the shareholders of a Multi-Manager Fund expect the Adviser, under the overall supervision of the Board and the Independent Trustees, to take responsibility for overseeing the Sub-Advisers and recommending their hiring, termination, and replacement. Applicants assert that, from the perspective of the investor, the role of the Sub-Advisers with respect to the Multi-Manager Funds is substantially equivalent to the role of the individual portfolio managers employed by traditional investment company advisory firms. In the absence of exemptive relief from Section 15(a) of the Act, when a new Sub-Adviser is proposed for retention by a Multi-Manager Fund, shareholders would be required to approve the sub-advisory agreement with that Sub-Adviser. Similarly, approval by the shareholders of the affected Multi-Manager Fund would be required in order to amend an existing sub-advisory agreement in any material respect or in order to continue to retain an existing Sub-Adviser whose sub-advisory agreement is ''assigned'' as a result of a change of control. Applicants state that obtaining shareholder approval is costly and slow, so the relief requested would benefit the Multi-Manager Funds and their shareholders by reducing these expenses and enabling the Multi-Manager Funds to operate more efficiently. Applicants also note that each Advisory Agreement will remain fully subject to the requirements in sections 15(a) and 15(c) of the Act and rule 18f–2 under the Act, including the requirement for shareholder approval.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Before a Multi-Manager Fund may rely on the order requested in the application, the operation of the Multi-Manager Fund in the manner described in the application will be approved by a majority of the Multi-Manager Fund's outstanding voting securities, as defined in the Act, or, in the case of a Multi-Manager Fund whose public shareholders purchase shares on the basis of a prospectus containing the

[1] Applicants request that any relief granted pursuant to the application apply also to any existing or future registered open-end management investment company or series thereof that (a) Is advised by HMCM or any entity controlling, controlled by or under common control with HMCM or its successors (HMCM and each such entity an ''Adviser''); (b) uses the manager of managers structure described in the application; and (c) complies with the terms and conditions in the application (any such registered open-end management investment company or series thereof, a ''Multi-Manager Fund''). HighMark Funds is the only existing investment company that currently intends to rely on the requested order. All Multi-Manager Funds that currently intend to rely on the requested order are named in the Application. If the name of any Multi-Manager Fund contains the name of any Sub-Adviser (as defined below), the name of the Adviser that serves as the primary adviser to that Multi-Manager Fund will precede the name of the Sub-Adviser.

[2] The term ''Advisory Agreement'' also refers to any other agreement pursuant to which an Adviser serves as the investment adviser to a Multi-Manager Fund. The term ''Board'' includes the board of trustees or directors of any Multi-Manager Fund.

disclosure contemplated by condition 2 below, by the initial shareholder(s) before offering shares of the Multi-Manager Fund to the public.

2. Each Multi-Manager Fund relying on the requested order will disclose in its prospectus the existence, substance, and effect of any order granted pursuant to the application. In addition, each Multi-Manager Fund will hold itself out to the public as employing the manager of managers structure described in the application. The prospectus will prominently disclose that the Adviser has ultimate responsibility (subject to oversight by the Board) to oversee Sub-Advisers and recommend their hiring, termination and replacement.

3. Within 90 days of the hiring of any new Sub-Adviser, shareholders of the affected Multi-Manager Fund will be furnished all of the information about the new Sub-Adviser that would be included in a proxy statement. To meet this obligation the Multi-Manager Fund will, within 90 days of hiring a new Sub-Adviser, provide shareholders of the affected Multi-Manager Fund with an information statement meeting the requirements of Regulation 14C, Schedule 14C and Item 22 of Schedule 14A under the Securities Exchange Act of 1934, as amended.

4. The Adviser will not enter into a sub-advisory agreement with any Affiliated Sub-Adviser without such agreement, including the compensation to be paid thereunder, being approved by the shareholders of the applicable Multi-Manager Fund.

5. At all times, at least a majority of the Board will be Independent Trustees, and the nomination of new or additional Independent Trustees will be at the discretion of the then existing Independent Trustees.

6. When a change of Sub-Adviser is proposed for a Multi-Manager Fund with an Affiliated Sub-Adviser, the Board, including a majority of the Independent Trustees, will make a separate finding, reflected in the Board minutes, that such change is in the best interests of the Multi-Manager Fund and its shareholders and does not involve a conflict of interest from which the Adviser or an Affiliated Sub-Adviser derives an inappropriate advantage.

7. The Adviser will provide general management services to each Multi-Manager Fund, including overall supervisory responsibility for the general management and investment of the Multi-Manager Fund's assets, and, subject to review and approval by the Board, will: (i) set the Multi-Manager Fund's overall investment strategies; (ii) evaluate, select and recommend Sub-Advisers to manage all or a part of the Multi-Manager Fund's assets; (iii) when appropriate, allocate and reallocate the Multi-Manager Fund's assets among multiple Sub-Advisers; (iv) monitor and evaluate the Sub-Advisers' performance; and (v) implement procedures reasonably designed to ensure that the Sub-Advisers comply with the Multi-Manager Fund's investment objectives, policies and restrictions.

8. No trustee or officer of a Multi-Manager Fund or director or officer of the Adviser will own directly or indirectly (other than through a pooled investment vehicle that is not controlled by such person) any interest in a Sub-Adviser, except for: (i) ownership of interests in the Adviser or any entity that controls, is controlled by or is under common control with the Adviser; or (ii) ownership of less than 1% of the outstanding securities of any class of equity or debt of a publicly-traded company that is either a Sub-Adviser or an entity that controls, is controlled by, or is under common control with a Sub-Adviser.

9. In the event the Commission adopts a rule under the Act providing substantially similar relief to that in the order requested in the application, the requested order will expire on the effective date of that rule.

For the Commission, by the Division of Investment Management, under delegated authority.

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17956 Filed 7–15–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Federal Register Citation of Previous Announcement: [76 FR 40948, July 12, 2011].

STATUS: Closed Meeting.

PLACE: 100 F Street, NW., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: July 14, 2011 at 2 p.m.

CHANGE IN THE MEETING: Deletion of Items.

The following items will not be considered during the Closed Meeting on Thursday, July 14, 2011:

Adjudicatory Matters.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: July 14, 2011.

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–18067 Filed 7–14–11; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Federal Register Citation of Previous Announcement: [76 FR 41534, July 14, 2011].

STATUS: Open Meeting.

PLACE: 100 F Street, NE., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: Thursday, July 14, 2011.

CHANGE IN THE MEETING: Cancellation of Meeting.

The Open Meeting scheduled for Thursday, July 14, 2011 at 10 a.m. has been cancelled.

For further information please contact the Office of the Secretary at (202) 551–5400.

Dated: July 13, 2011.

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–18051 Filed 7–14–11; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64863; File No. SR–Phlx–2011–94]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by NASDAQ OMX PHLX LLC Relating to the Options Floor Broker Subsidy

July 12, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2011, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Section VII of its Fee Schedule entitled the ''Options Floor Broker Subsidy.''

The Exchange also proposes to make an amendment to Section III of the Fee Schedule entitled ''Singly Listed Options.''

While changes to the Fee Schedule pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative on July 1, 2011.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqtrader.com/micro.aspx?id=PHLXfilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the computation for eligible contracts. The Exchange proposes to amend the eligible contract computation to limit the eligible contracts where a Firm is also obtaining the benefit of the Firm Related Equity Option Cap (''Cap'').[3] The Exchange believes that the benefit of the Cap should be taken into account in the eligible contract computation.

The Exchange currently pays an Options Floor Broker Subsidy (''Subsidy'') to member organizations with Exchange registered floor brokers that enter eligible contracts into the Exchange's Floor Broker Management System (''FBMS'').[4] The Subsidy is paid based on the contract volume on Customer-to-non-Customer as well as non-Customer-to-non-Customer transactions for that month. Only the volume from orders entered by floor brokers into FBMS and subsequently executed on the Exchange qualifies. The Exchange pays a Subsidy based on a monthly total of all eligible contracts as follows:

PER ELIGIBLE CONTRACT MONTHLY VOLUME SUBSIDY PAYMENT

Tier I	Tier II	Tier III	Tier IV
0 to 1,250,000	1,250,001 to 2,250,000	2,250,001 to 5,250,000	5,250,001 and greater.
$0.00 per contract	$0.03 per contract	$0.05 per contract	$0.09 per contract.

In computing the monthly eligible contracts, the Exchange currently excludes: (i) Customer-to-Customer executions; (ii) dividend,[5] merger[6] and short stock interest[7] strategies; and (iii) firm facilitation transactions.[8] The Subsidy applies to contracts that are executed as part of a Complex Order.[9] Where two or more member organizations with Exchange registered floor brokers each enter one side of a transaction into FBMS, the executed contracts are divided equally among qualifying member organizations that participate in that transaction.

The Exchange is proposing to amend the computation of eligible contracts to also exclude: (i) Firm-to-Customer executions, where the Firm has reached the Cap; and (ii) Firm-to-Firm executions, where both sides have reached the Cap. The Exchange also proposes to amend Section VII to capitalize the word ''Customer'' and make other technical amendments.

Additionally, the Exchange is proposing to amend Section III of the Fee Schedule entitled ''Singly Listed Options.'' Specifically, the Exchange proposes to remove the list of Alpha Index Options symbols (''Alpha Symbols''). The Alpha Symbols are subject to change.[10] The Exchange provides a list of Alpha Symbols, which are subject to the Alpha Index Options Fee, at *http://*

[3] The Firm Related Equity Option Cap is currently $75,000. Firm equity option transaction charges and QCC Transaction Fees, in the aggregate, for one billing month will not exceed the Firm Related Equity Option Cap per member organization when such members are trading in their own proprietary account. The Firm equity options transaction charges will be waived for members executing facilitation orders pursuant to Exchange Rule 1064 when such members are trading in their own proprietary account. Members and member organizations must notify the Exchange in writing of all accounts in which the member is not trading in its own proprietary account. The Exchange will not make adjustments to billing invoices where transactions are commingled in accounts which are not subject to the Firm Related Equity Option Cap. In addition, Firms that (i) Are on the contra-side of an electronically-delivered and executed Customer complex order; and (ii) have reached the Firm Related Equity Option Cap will be assessed a $0.05 per contract fee. *See* Section II of the Exchange's Fee Schedule.

[4] FBMS is designed to enable floor brokers and/or their employees to enter, route, and report transactions stemming from options orders received on the Exchange. FBMS also is designed to establish an electronic audit trail for options orders represented and executed by floor brokers on the Exchange. *See* Exchange Rule 1080, commentary .06.

[5] A dividend strategy is defined as transactions done to achieve a dividend arbitrage involving the purchase, sale and exercise of in-the-money options of the same class, executed the first business day prior to the date on which the underlying stock goes ex-dividend. *See* Section II of the Fee Schedule.

[6] A merger strategy is defined as transactions done to achieve a merger arbitrage involving the purchase, sale and exercise of options of the same class and expiration date, executed the first business day prior to the date on which shareholders of record are required to elect their respective form of consideration, *i.e.,* cash or stock. *See* Section II of the Fee Schedule.

[7] A short stock interest strategy is defined as transactions done to achieve a short stock interest arbitrage involving the purchase, sale and exercise of in-the-money options of the same class. *See* Section II of the Fee Schedule.

[8] A facilitation occurs when a floor broker holds an options order for a public customer and a contra-side order for the same option series and, after providing an opportunity for all persons in the trading crowd to participate in the transaction, executes both orders as a facilitation cross. *See* Exchange Rule 1064.

[9] A Complex Order is any order involving the simultaneous purchase and/or sale of two or more different options series in the same underlying security, priced at a net debit or credit based on the relative prices of the individual components, for the same account, for the purpose of executing a particular investment strategy. Furthermore, a Complex Order can also be a stock-option order, which is an order to buy or sell a stated number of units of an underlying stock or ETF coupled with the purchase or sale of options contract(s). *See* Exchange Rule 1080, Commentary .08(a)(i).

[10] The Exchange would file a proposed rule change with the Commission each time it proposes to amend the Alpha Symbols which are subject to the Alpha Index Options Fee in Section III of the Fee Schedule.

www.nasdaqomxtrader.com/Micro.aspx?id=Alpha.

While changes to the Fee Schedule pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative on July 1, 2011.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [11] in general, and furthers the objectives of Section 6(b)(4) of the Act [12] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members.

The Exchange believes that the proposed amendments to the Subsidy are equitable and reasonable because member organizations with Exchange registered floor brokers would continue to be provided an equal opportunity to receive a Subsidy. The Exchange believes that amending the computation to exclude Firm-to-Customer executions and Firm-to-Firm executions where the Firm sides have reached the Cap is reasonable because the Exchange would not be paying a Subsidy on executions that incur no transaction fees. In addition, the Exchange believes that amending the computation to exclude Firm-to-Customer executions and Firm-to-Firm executions where the Firm sides have reached the Firm Related Equity Option Cap is equitable because the exclusions apply uniformly to all member organizations. Finally, the Exchange does not believe that this Subsidy is unreasonable or discriminatory because any floor broker is afforded the opportunity of meeting the volume criteria.

The Exchange believes that its proposal to amend Section III of the Fee Schedule to remove the list of Alpha Symbols is both reasonable and equitable because the list of symbols is readily available on the Exchange's Web site. Since the Alpha Symbols are subject to change, the Exchange believes that the list of current symbols on the Exchange's Web site is the most appropriate and current source of information for the complete list of Alpha Symbols subject to the Alpha Index Options Fee.[13]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[14] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2011–94 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2011–94. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–Phlx–2011–94 and should be submitted on or before August 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17911 Filed 7–15–11; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] This list is kept up to date and current with any rule changes that are filed with the Commission.

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64861; File No. SR–ISE–2011–38]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to a Market Maker Incentive Plan for Foreign Currency Options

July 12, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2011, the International Securities Exchange, LLC (the ''Exchange'' or the ''ISE'') filed with the Securities and Exchange Commission the proposed rule change, as described in Items I and II below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The ISE is proposing to extend an incentive plan for market makers in a number of foreign currency options (''FX Options'') traded on the Exchange. The text of the proposed rule change is available on the Exchange's Web site (*http://www.ise.com*), at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to extend an incentive plan for market makers in options on the New Zealand dollar (''NZD''), the Mexican peso (''PZO''), the Swedish krona (''SKA''), the Brazilian real (''BRB''), the Australian dollar (''AUX''), the British pound (''BPX''), the Canadian dollar (''CDD''), the euro (''EUI''), the Japanese yen (''YUK'') and the Swiss franc (''SFC'').[3] On August 3, 2009, the Exchange adopted an incentive plan applicable to market makers in NZD, PZO and SKA,[4] and on January 19, 2010, added BRB to the incentive plan,[5] and on March 1, 2011, added AUX, BPX, CDD, EUI, YUK and SFC.[6] The Exchange has since extended the date by which market makers may join the incentive plan[7] and now proposes to do so again.

In order to promote trading in these FX Options, the Exchange has an incentive plan pursuant to which the Exchange waives the transaction fees for the Early Adopter[8] FXPMM[9] and all Early Adopter FXCMMs[10] that make a market in NZD, PZO SKA, BRB, AUX, BPX, CDD, EUI, YUK and SFC for as long as the incentive plan is in effect. Further, pursuant to a revenue sharing agreement entered into between an Early Adopter Market Maker and ISE, the Exchange pays the Early Adopter FXPMM forty percent (40%) of the transaction fees collected on any customer trade in NZD, PZO SKA, BRB, AUX, BPX, CDD, EUI, YUK and SFC and pays up to ten (10) Early Adopter FXCMMs that participate in the incentive plan twenty percent (20%) of the transaction fees collected for trades between a customer and that FXCMM. Market makers that do not participate in the incentive plan are charged regular transaction fees for trades in these products. In order to participate in the incentive plan, market makers are currently required to enter into the incentive plan no later than June 30, 2011. The Exchange now proposes to extend the date by which market makers may enter into the incentive plan to September 30, 2011.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[11] in general, and furthers the objectives of Section 6(b)(4),[12] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities.

The Exchange believes the proposed rule change is equitable as it will permit all market makers to explore the opportunity to join the incentive plan for an additional three months. The Exchange believes the proposed rule change is reasonable because the extension of the incentive plan for three months will permit additional market makers to join the incentive plan which in turn will generate additional order flow to the Exchange by creating incentives to trade these FX Options as well as defray operational costs for Early Adopter Market Makers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[13] At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File

[3] The Commission previously approved the trading of options on NZD, PZO, SKA, BRB, AUX, BPX, CDD, EUI, YUK and SFC. *See* Securities Exchange Act Release No. 55575 (April 3, 2007), 72 FR 17963 (April 10, 2007) (SR–ISE–2006–59).

[4] *See* Securities Exchange Act Release No. 60536 (August 19, 2009), 74 FR 43204 (August 26, 2009) (SR–ISE–2009–59).

[5] *See* Securities Exchange Act Release No. 61459 (February 1, 2010), 75 FR 6248 (February 8, 2010) (SR–ISE–2010–07).

[6] *See* Securities Exchange Act Release No. 64012 (March 2, 2011), 76 FR 12778 (March 8, 2011) (SR–ISE–2011–11).

[7] *See* Securities Exchange Act Release Nos. 60810 (October 9, 2009), 74 FR 53527 (October 19, 2009) (SR–ISE–2009–80), 61334 (January 12, 2010), 75 FR 2913 (January 19, 2010) (SR–ISE–2009–115), 61851 (April 6, 2010), 75 FR 18565 (April 12, 2010) (SR–ISE–2010–27), 62503 (July 15, 2010), 75 FR 42812 (July 22, 2010) (SR–ISE–2010–71), 36045 (October 5, 2010), 75 FR 62900 (October 13, 2010) (SR–ISE–2010–100), 63639 (January 4, 2011), 76 FR 1488 (January 10, 2011) (SR–ISE–2010–121) and 64202 (April 6, 2011), 76 FR 20431 (April 12, 2011) (SR–ISE–2011–16).

[8] Participants in the incentive plan are known on the Exchange's Schedule of Fees as Early Adopter Market Makers.

[9] A FXPMM is a primary market maker selected by the Exchange that trades and quotes in FX Options only. *See* ISE Rule 2213.

[10] A FXCMM is a competitive market maker selected by the Exchange that trades and quotes in FX Options only. *See* ISE Rule 2213.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

Number SR–ISE–2011–38 on the subject line.

Paper Comments

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2011–38. This file number should be included on the subject line if e-mail is used.

To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room,100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2011–38, and should be submitted on or before August 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17917 Filed 7–15–11; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64859; File No. SR–NYSEAmex–2011–47)

Self-Regulatory Organizations; NYSE Amex LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Extending the Operative Date of NYSE Amex Equities Rule 92(c)(3) From August 1, 2011 to September 12, 2011

July 12, 2011.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 1, 2011, NYSE Amex LLC (the ''Exchange'' or ''NYSE Amex'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the operative date of NYSE Amex Equities Rule 92(c)(3) from August 1, 2011 to September 12, 2011. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, on the Commission's Web site at *http://www.sec.gov,* and *http://www.nyse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to extend the delayed operative date of NYSE Amex Equities Rule 92(c)(3) from August 1, 2011 to September 12, 2011. The Exchange believes that this extension will provide the time necessary for the Exchange and the Financial Industry Regulatory Authority, Inc. (''FINRA'') to harmonize their respective rules concerning customer order protection to achieve a standardized industry practice.

Background

On July 5, 2007, the Commission approved amendments to NYSE Rule 92 to permit riskless principal trading at the Exchange.[4] These amendments were filed in part to begin the harmonization process between NYSE Rule 92 and FINRA's Manning Rule.[5] In connection with those amendments, the Exchange implemented for an operative date of January 16, 2008, NYSE Rule 92(c)(3), which permits Exchange member organizations to submit riskless principal orders to the Exchange, but requires them to submit to a designated Exchange database a report of the execution of the facilitated order. That rule also requires members to submit to that same database sufficient information to provide an electronic link of the execution of the facilitated order to all of the underlying orders.

For purposes of NYSE Rule 92(c)(3), the Exchange informed member organizations that when executing riskless principal transactions, firms must submit order execution reports to the Exchange's Front End Systemic Capture (''FESC'') database linking the execution of the riskless principal order on the Exchange to the specific underlying orders. The information provided must be sufficient for both member firms and the Exchange to reconstruct in a time-sequenced manner all orders, including allocations to the underlying orders, with respect to which a member organization is claiming the riskless principal exception.

Because the rule change required both the Exchange and member organizations to make certain changes to their trading and order management systems, the NYSE filed to delay to May 14, 2008 the

[4] *See* Securities Exchange Act Release No. 56017 (July 5, 2007), 72 FR 38110 (July 12, 2007) (SR–NYSE–2007–21).

[5] *See* NASD Rule 2111 and IM–2110–2.

operative date of the NYSE Rule 92(c)(3) requirements, including submitting end-of-day allocation reports for riskless principal transactions and using the riskless principal account type indicator.[6] The NYSE filed for additional extensions of the operative date of NYSE Rule 92(c)(3) to August 1, 2011.[7] Because NYSE Amex adopted NYSE Rule 92 in its then current form,[8] the delayed operative date for the NYSE Rule 92(c)(3) reporting requirements also applied for NYSE Amex Equities Rule 92(c)(3) reporting requirements and the Exchange filed for additional extensions of the operative date, the most recent of which was an extension to August 1, 2011.[9]

Request for Extension [10]

FINRA and the Exchange have been working diligently on fully harmonizing their respective rules. On December 10, 2009, FINRA filed with the Commission its rule proposal to adopt a new industry standard for customer order protection as proposed FINRA Rule 5320.[11] On February 11, 2011, the Commission approved FINRA Rule 5320.[12] In order to provide time to implement programming changes associated with the proposed new rule, FINRA Rule 5320 becomes effective on September 12, 2011.[13] The Exchange intends to file a proposed rule change to adopt rule text that is substantially similar to FINRA Rule 5320 and implement it on the same date as FINRA.

The Exchange continues to believe that pending full harmonization of the respective customer order protection rules, it would be premature to require firms to meet the current NYSE Amex Equities Rule 92(c)(3) FESC reporting requirements.[14] Indeed, having differing reporting standards for riskless principal orders would be inconsistent with the overall goal of the harmonization process. Accordingly, the Exchange is proposing to delay the operative date for NYSE Amex Equities Rule 92(c)(3) from August 1, 2011 to September 12, 2011.

During that period, the Exchange will continue to require that, as of the date each member organization implements riskless principal routing, the member organization have in place systems and controls that allow them to easily match and tie riskless principal execution on the Exchange to the underlying orders and that they be able to provide this information to the Exchange upon request. To make clear that this requirement continues, the Exchange proposes to amend supplementary material .95 to NYSE Amex Equities Rule 92 to specifically provide that the NYSE Amex Equities Rule 92(c)(3) reporting requirements are suspended until September 12, 2011 and that member organizations are required to have in place such systems and controls relating to their riskless principal executions on the Exchange. Moreover, the Exchange will coordinate with FINRA to examine for compliance with the rule requirements for those firms that engage in riskless principal trading under NYSE Amex Equities Rule 92(c).

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[15] in general, and furthers the objectives of Section 6(b)(5) of the Act,[16] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes the proposed extension provides the Exchange, the NYSE, and FINRA the time necessary to develop a harmonized rule concerning customer order protection that will enable member organizations to participate in the national market system without unnecessary impediments.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act [17] and Rule 19b–4(f)(6) thereunder.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule

[6] *See* Securities Exchange Act Release No. 56968 (Dec. 14, 2007), 72 FR 72432 (Dec. 20, 2007) (SR–NYSE–2007–114).

[7] *See* Securities Exchange Act Release Nos. 57682 (Apr. 17, 2008), 73 FR 22193 (Apr. 24, 2008) (SR–NYSE–2008–29); 59621 (Mar. 23, 2009), 74 FR 14179 (Mar. 30, 2009) (SR–NYSE–2009–30); 60396 (July 30, 2009), 74 FR 39126 (Aug. 5, 2009) (SR–NYSE–2009–73); 61251 (Dec. 29, 2009), 75 FR 482 (Jan. 5, 2010) (SR–NYSE–2009–129); 62541 (July 21, 2010), 75 FR 44042 (July 27, 2010) (SR–NYSE–2010–52); and 63455 (Dec. 7. 2010), 75 FR 77687 (Dec. 13, 2010) (SR–NYSE–2010–76).

[8] The NYSE Amex Equities Rules, which became operative on December 1, 2008, are substantially identical to the current NYSE Rules 1–1004 and the Exchange continues to update the NYSE Amex Equities Rules as necessary to conform with rule changes to corresponding NYSE Rules filed by the NYSE. *See* Securities Exchange Act Release Nos. 58705 (Oct. 1, 2008), 73 FR 58995 (Oct. 8, 2008) (SR–Amex–2008–63); 58833 (Oct. 22, 2008), 73 FR 64642 (Oct. 30, 2008) (SR–NYSE–2008–106); 58839 (Oct. 23, 2008), 73 FR 64645 (October 30, 2008) (SR–NYSEALTR–2008–03); 59022 (Nov. 26, 2008), 73 FR 73683 (Dec. 3, 2008) (SR–NYSEALTR–2008–10); and 59027 (Nov. 28, 2008), 73 FR 73681 (Dec. 3, 2008) (SR–NYSEALTR–2008–11).

[9] *See* Securities Exchange Act Release Nos. 59620 (Mar. 23, 2009), 74 FR 14176 (Mar. 30, 2009) (SR–NYSEALTR–2009–29); 60397 (July 30, 2009), 74 FR 39128 (Aug. 5, 2009) (SR–NYSEAmex–2009–48); 61250 (Dec. 29, 2009), 75 FR 477 (Jan. 5, 2010) (SR–NYSEAmex–2009–92); and 62540 (July 21, 2010), 75 FR 44040 (July 27, 2010) (SR–NYSEAmex–2010–70), 75 FR 77685 (Dec. 13, 2010) (SR–NYSEAmex–2010–111).

[10] NYSE has filed a companion rule filing to conform its Rules to the changes proposed in this filing. *See* SR–NYSE–2011–32, formally submitted July 1, 2011.

[11] *See* Securities Exchange Act Release No. 61168 (Dec. 15, 2009), 74 FR 68084 (Dec. 22, 2009) (SR–FINRA–2009–90).

[12] *See* Securities Exchange Act Release No. 63895 (Feb. 11, 2011), 76 FR 9386 (Feb. 17, 2011) (SR–FINRA–2009–90).

[13] *See* FINRA Regulatory Notice 11–24.

[14] The Exchange notes that it would also need to make technological changes to implement the proposed FESC reporting solution for Rule 92(c)(3).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the self-regulatory organization to submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSEAmex–2011–47 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAmex–2011–47. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAmex–2011–47 and should be submitted on or before August 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17958 Filed 7–15–11; 8:45 am]

BILLING CODE 8011–01–P

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64864; File No. SR–DTC–2011–06]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of Proposed Rule Change To Amend Rules Relating to the Early Redemption of Certificates of Deposit

July 12, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b-4 thereunder[2] notice is hereby given that on July 1, 2011, The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared primarily by DTC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The purpose of DTC's proposed rule change is to amend its Redemption Service Guide as it relates to the early redemption of certain Certificates of Deposit held at DTC.[3]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DTC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. DTC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[4]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Recently, several issuers of Certificates of Deposit (''CDs'') have contacted DTC in an attempt to redeem or call their CDs prior to the maturity date. The master certificate of these CDs did not expressly specify that they were callable or subject to redemption. In some instances, the issuer offered to pay DTC participants the principal plus interest through the date of maturity. In other instances, the issuer offered to pay principal plus interest only through the date of redemption. Because the master certificates did not expressly indicate the CDs could be redeemed early, a number of DTC participants expressed their concerns that the CDs had been sold to investors without disclosing the possibility of early redemption.

Over the past several months, DTC has worked with the industry, including the Retail Fixed Income Committee of The Securities Industry and Financial Markets Association (''SIFMA''), to better understand the issues related to the early termination of CDs that do not contain express early termination provisions. As a result of these consultations, DTC is now proposing to amend its Redemption Service Guide to state that DTC will not process early redemptions or calls on CDs unless (i) There is an explicit provision in the master certificate that permits early termination by the issuer and specifies the payment to be made in connection therewith or (ii) written consent to an early redemption in a form designed by DTC is obtained by the issuer from all of the holders of the CD. Furthermore, in the event that an issuer sends such payment to DTC in contravention of the proposed rule, DTC will return the payment to the issuer, less any costs associated with facilitating the attempted redemption and return of funds.

The proposed rule change is consistent with the requirements of the Act, as amended, (''Act'') and the rules and regulations thereunder applicable to DTC because it clarifies the terms and conditions under which DTC will permit the early redemption of certain CDs and thus facilitates the prompt and accurate clearance and settlement of transactions involving these CDs.

(B) Self-Regulatory Organization's Statement on Burden on Competition

DTC does not believe that the proposed rule change would impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. DTC will notify the Commission of any written comments received by DTC.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The text of the proposed rule change is attached as Exhibit 5 to DTC's filing, which is available at *http://www.dtcc.com/downloads/legal/rule_filings/2010/dtc/2011-06.pdf.*

[4] The Commission has modified the text of the summaries prepared by DTC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within forty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) As the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–DTC–2011–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submission should refer to File Number SR–DTC–2011–06. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549–1090, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filings will also be available for inspection and copying at the principal office of DTC and on DTC's Web site at *http://www.dtcc.com/downloads/legal/rule_filings/2011/dtc/2011-06.pdf.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–DTC–2011–06 and should be submitted on or before [insert date 21 days from publication in the Federal Register].

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[5]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17957 Filed 7–15–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64860; File No. SR–NYSE–2011–32]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Extending the Operative Date of NYSE Rule 92(c)(3) From August 1, 2011 to September 12, 2011

July 12, 2011.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that July 1, 2011, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the operative date of NYSE Rule 92(c)(3) from August 1, 2011 to September 12, 201 [sic]. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, on the Commission's Web site at *http://www.sec.gov,* and *http://www.nyse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to extend the delayed operative date of NYSE Rule 92(c)(3) from August 1, 2011 to September 12, 2011. The Exchange believes that this extension will provide the time necessary for the Exchange and the Financial Industry Regulatory Authority, Inc. (''FINRA'') to harmonize their respective rules concerning customer order protection to achieve a standardized industry practice.

Background

On July 5, 2007, the Commission approved amendments to NYSE Rule 92 to permit riskless principal trading at the Exchange.[4] These amendments were filed in part to begin the harmonization process between Rule 92 and FINRA's Manning Rule.[5] In connection with those amendments, the Exchange implemented for an operative date of January 16, 2008, NYSE Rule 92(c)(3), which permits Exchange member organizations to submit riskless principal orders to the Exchange, but requires them to submit to a designated Exchange database a report of the execution of the facilitated order. That rule also requires members to submit to that same database sufficient information to provide an electronic link of the execution of the facilitated order to all of the underlying orders.

For purposes of NYSE Rule 92(c)(3), the Exchange informed member

[5] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 56017 (July 5, 2007), 72 FR 38110 (July 12, 2007) (SR–NYSE–2007–21).

[5] *See* NASD Rule 2111 and IM–2110–2.

organizations that when executing riskless principal transactions, firms must submit order execution reports to the Exchange's Front End Systemic Capture (''FESC'') database linking the execution of the riskless principal order on the Exchange to the specific underlying orders. The information provided must be sufficient for both member firms and the Exchange to reconstruct in a time-sequenced manner all orders, including allocations to the underlying orders, with respect to which a member organization is claiming the riskless principal exception.

Because the rule change required both the Exchange and member organizations to make certain changes to their trading and order management systems, the NYSE filed to delay to May 14, 2008 the operative date of the NYSE Rule 92(c)(3) requirements, including submitting end-of-day allocation reports for riskless principal transactions and using the riskless principal account type indicator.[6] The Exchange filed for additional extensions of the operative date of Rule 92(c)(3), the most recent of which was an extension to August 1, 2011.[7]

Request for Extension [8]

FINRA and the Exchange have been working diligently on fully harmonizing their respective rules. On December 10, 2009, FINRA filed with the Commission its rule proposal to adopt a new industry standard for customer order protection as proposed FINRA Rule 5320.[9] On February 11, 2011, the Commission approved FINRA Rule 5320.[10] In order to provide time to implement programming changes associated with the proposed new rule, FINRA Rule 5320 becomes effective on September 12, 2011.[11] The Exchange intends to file a proposed rule change to adopt rule text that is substantially similar to FINRA Rule 5320 and implement it on the same date as FINRA.

The Exchange continues to believe that pending full harmonization of the respective customer order protection rules, it would be premature to require firms to meet the current Rule 92(c)(3) FESC reporting requirements.[12] Indeed, having differing reporting standards for riskless principal orders would be inconsistent with the overall goal of the harmonization process. Accordingly, the Exchange is proposing to delay the operative date for NYSE Rule 92(c)(3) from August 1, 2011 to September 12, 2011.

During that period, the Exchange will continue to require that, as of the date each member organization implements riskless principal routing, the member organization have in place systems and controls that allow them to easily match and tie riskless principal execution on the Exchange to the underlying orders and that they be able to provide this information to the Exchange upon request. To make clear that this requirement continues, the Exchange proposes to amend supplementary material .95 to Rule 92 to specifically provide that the Rule 92(c)(3) reporting requirements are suspended until September 12, 2011 and that member organizations are required to have in place such systems and controls relating to their riskless principal executions on the Exchange. Moreover, the Exchange will coordinate with FINRA to examine for compliance with the rule requirements for those firms that engage in riskless principal trading under Rule 92(c).

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[13] in general, and furthers the objectives of Section 6(b)(5) of the Act,[14] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes the proposed extension provides the Exchange and FINRA the time necessary to develop a harmonized rule concerning customer order protection that will enable member organizations to participate in the national market system without unnecessary impediments.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and Rule 19b–4(f)(6) thereunder.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[6] *See* Securities Exchange Act Release No. 56968 (Dec. 14, 2007), 72 FR 72432 (Dec. 20, 2007) (SR–NYSE–2007–114).

[7] *See* Securities Exchange Act Release Nos. 57682 (Apr. 17, 2008), 73 FR 22193 (Apr. 24, 2008) (SR–NYSE–2008–29); 59621 (Mar. 23, 2009), 74 FR 14179 (Mar. 30, 2009) (SR–NYSE–2009–30); 60396 (July 30, 2009), 74 FR 39126 (Aug. 5, 2009) (SR–NYSE–2009–73); 61251 (Dec. 29, 2009), 75 FR 482 (Jan. 5, 2010) (SR–NYSE–2009–129); 62541 (July 21, 2010), 75 FR 44042 (July 27, 2010) (SR–NYSE–2010–52); and 63455 (Dec. 7. 2010), 75 FR 77687 (Dec. 13, 2010) (SR–NYSE–2010–76).

[8] NYSE Amex LLC has filed a companion rule filing to conform its Equities Rules to the changes proposed in this filing. *See* SR–NYSEAmex–2011–47, formally submitted June 30, 2011.

[9] *See* Securities Exchange Act Release No. 61168 (Dec. 15, 2009), 74 FR 68084 (Dec. 22, 2009) (SR–FINRA–2009–90).

[10] *See* Securities Exchange Act Release No. 63895 (Feb. 11, 2011), 76 FR 9386 (Feb. 17, 2011) (SR–FINRA–2009–90).

[11] *See* FINRA Regulatory Notice 11–24.

[12] The Exchange notes that it would also need to make technological changes to implement the proposed FESC reporting solution for Rule 92(c)(3).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the self-regulatory organization to submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Electronic Comments

• Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

• Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2011–32 on the subject line.

Paper Comments

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2011–32. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2011–32 and should be submitted on or before August 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17955 Filed 7–15–11; 8:45 am]

BILLING CODE 8011–01–P

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64858; File No. SR–NASDAQ–2011–094]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7034 To Extend the Waiver of Certain Co-Location Installation Fees for an Additional Month

July 12, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 1, 2011, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7034 to extend the waiver of fees assessed for the installation of certain co-location services for an additional month. The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com/,* at the Exchange's principal office, at the Commission's Public Reference Room, and at the Commission's Web site at *http://www.sec.gov.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7034 to extend for a one-month period the initial waiver of fees assessed for the installation of certain co-location services, in order to provide its existing and potential new customers a full opportunity to avail themselves of the waiver. The initial waiver of fees for the installation of certain co-location services commenced June 1, 2011 and ended June 30, 2011.[3] Since the initial waiver, there has been significant demand for the select co-location services by existing customers, as well as new customers. However, the Exchange has become aware that a significant number of new and existing customers are unable to complete their requests by June 30, 2011 due to the need for additional time to order new equipment to be housed in the cabinets, or, to complete the internal approval process for the ongoing monthly fees that will be incurred as part of the service. Therefore, the Exchange proposes to extend the waiver of fees until July 29, 2011 (the ''extended period''). Beginning August 1, 2011, the above-referenced waived fees will revert to the amount in effect prior to June 1, 2011. The Exchange proposes to extend the waiver of the following installation fees during the extended period:

1. Rule 7034(a): installation fees for new cabinets with power.

2. Rule 7034(b): installation fees for external telecommunication, inter-cabinet connectivity, connectivity to NASDAQ and market data connectivity related to an order for a new cabinet. However, the one-time telecommunication connectivity expedite fee[4] will not be waived during the extended period.

3. Rule 7034(c): installation fees for cabinet power related to an order for a new cabinet.

4. Rule 7034(d): installation fees for cooling fans, perforated floor tiles and fiber downspouts, which are necessary items to support a higher density cabinet and fiber cross connects, relating to an order for a new cabinet placed during the extended period. Installation fees for other items that are

[3] *See* Securities Exchange Act Release No. 64630 (June 8, 2011), 76 FR 34783 (June 14, 2011) (SR–NASDAQ–2011–074).

[4] The one-time telecommunication connectivity expedite fee is a fee for an optional request to complete the installation in a shorter time period than the install timeframes.

customized or options are not waived during the extended period.

The following requirements must be met to receive the waiver of the installation fee:

1. The new cabinet order must be placed in the CoLo Console [5] during the extended period; and

2. The new cabinet must be live within 90 days of the date of the order.[6]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[7] in general, and with Section 6(b)(4) of the Act,[8] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the Exchange operates or controls. The proposed fee waiver is reasonable because it provides an opportunity for all new customers and all existing customer [sic] that desire additional cabinet space to obtain that space without incurring fees. This decrease in fees provided a savings of over $100,000 to customers that took advantage of the fee waiver during the month of June. In addition, the Exchange believes that the fee waiver results in an equitable allocation of fees among the members of the Exchange. Specifically, the Exchange believes that by encouraging new and existing co-location customers to increase their presence in the Exchange's data center, the Exchange will generate additional order execution and data consumption activity. If it materializes, such an increase in activity would assist the Exchange in controlling the charges it imposes on members generally for their use of a variety of Exchange services. The waiver of fees is also equitably allocated since all existing and potential co-location customers may avail themselves of the waiver during the period of availability. Notably, during June 2011, the preponderance of customers availing themselves of the waiver were existing, rather than new customers, demonstrating the benefit of the program to a variety of members. Finally, extending the program for a month will ensure that several customers that have expressed an interest in expanding their data center presence but that have not yet been able to do so will have the opportunity to benefit from the waiver.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The Exchange believes that the extension of the waiver of fees for certain co-location services is equitable because all customers may avail themselves of the waiver.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[9] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2011–094 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2011–94. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).*

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–NASDAQ–2011–094 and should be submitted on or before August 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17954 Filed 7–15–11; 8:45 am]

BILLING CODE 8011–01–P

[5] The ''CoLo Console'' is web-based ordering tool that is utilized by NASDAQ to place co-location orders.

[6] Exchange staff generally installs and makes operational a new cabinet within 90 days of the date of the order (the ''live date''). The estimated live date is communicated to the customer. However, there may be instances where the customer desires the live date to be later than the estimated live date provided by Exchange staff. In such instances, the live date cannot extend beyond 90 days of the date of the order.

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

BioMETRX, Inc., Biopure Corp. (n/k/a PBBPC, Inc.), Distributed Energy Systems Corp., Fortified Holdings Corp., Knobias, Inc., and One IP Voice, Inc. (n/k/a Indian Hill Holdings Corporation); Order of Suspension of Trading

July 14, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of BioMETRX, Inc. because it has not filed any periodic reports since the period ended September 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Biopure Corp. (n/k/a PBBPC, Inc.) because it has not filed any periodic reports since the period ended April 30, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Distributed Energy Systems Corp. because it has not filed any periodic reports since the period ended March 31, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Fortified Holdings Corp. because it has not filed any periodic reports since the period ended September 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Knobias, Inc. because it has not filed any periodic reports since the period ended September 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of One IP Voice, Inc. (n/k/a Indian Hill Holdings Corporation) because it has not filed any periodic reports since the period ended September 30, 2006.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies. Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on July 14, 2011, through 11:59 p.m. EDT on July 27, 2011.

By the Commission.

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–18085 Filed 7–14–11; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Order of Suspension of Trading; In the Matter of M.B.A. Holdings, Inc., Medicor Ltd., MidgardXXI, Inc., MidNet, Inc., Nettel Holdings, Inc., and Nexicon, Inc., File No. 500–1

July 14, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of M.B.A. Holdings, Inc. because it has not filed any periodic reports since the period ended July 31, 2006.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Medicor Ltd. because it has not filed any periodic reports since the period ended September 30, 2006.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of MidgardXXI, Inc. because it has not filed any periodic reports since the period ended September 30, 2006.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of MidNet, Inc., because it has not filed any periodic reports since the period ended September 30, 2006.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Nettel Holdings, Inc. because it has not filed any periodic reports since it filed a registration statement on March 31, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Nexicon, Inc. because it has not filed any periodic reports since it filed a registration statement on December 31, 2005.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. E.D.T. on July 14, 2011, through 11:59 p.m. E.D.T. on July 27, 2011.

By the Commission.

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–18068 Filed 7–14–11; 11:15 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12678 and #12679]

Arkansas Disaster #AR–00050

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Arkansas (FEMA–4000–DR), dated 07/08/2011.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 05/24/2011 through 05/26/2011.

Effective Date: 07/08/2011.

Physical Loan Application Deadline Date: 09/06/2011.

Economic Injury (EIDL) Loan Application Deadline Date: 04/09/2012.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/08/2011, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Franklin, Johnson.

Contiguous Counties (Economic Injury Loans Only):

Arkansas: Crawford, Logan, Madison, Newton, Pope, Sebastian.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere:	5.375
Homeowners Without Credit Available Elsewhere:	2.688

	Percent
Businesses With Credit Available Elsewhere:	6.000
Businesses Without Credit Available Elsewhere:	4.000
Non-Profit Organizations With Credit Available Elsewhere:	3.250
Non-Profit Organizations Without Credit Available Elsewhere:	3.000
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere:	4.000
Non-Profit Organizations Without Credit Available Elsewhere:	3.000

The number assigned to this disaster for physical damage is 12678B and for economic injury is 126790.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2011–17944 Filed 7–15–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12684 and #12685]

Vermont Disaster #VT–00020

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Vermont (FEMA–4001–DR), dated 07/08/2011.

Incident: Severe Storms and Flooding.

Incident Period: 05/26/2011 through 05/27/2011.

Effective Date: 07/08/2011.

Physical Loan Application Deadline Date: 09/06/2011.

Economic Injury (EIDL) Loan Application Deadline Date: 04/09/2012.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/08/2011, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Caledonia.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.000
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	3.000

The number assigned to this disaster for physical damage is 126846 and for economic injury is 126856.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2011–17948 Filed 7–15–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12677]

Arizona Disaster #AZ–00017 Declaration of Economic Injury

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the State of Arizona, dated 07/11/2011.

Incident: Wallow Fire.

Incident Period: 05/29/2011 and continuing.

Effective Date: 07/11/2011.

EIDL Loan Application Deadline Date: 04/11/2012.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for economic injury disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Apache.

Contiguous Counties:

Arizona: Graham, Greenlee, Navajo.

Colorado: Montezuma.

New Mexico: Catron, Cibola, McKinley, San Juan.

Utah: San Juan.

The Interest Rates are:

	Percent
Businesses And Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	3.000
The number assigned to this disaster for economic injury is 126770.	
The States which received an EIDL Declaration # are Arizona, Colorado, New Mexico, Utah.	

(Catalog of Federal Domestic Assistance Number 59002)

Dated: July 11, 2011.

Karen G. Mills,

Administrator.

[FR Doc. 2011–17949 Filed 7–15–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12680 and #12681]

Arkansas Disaster #AR–00051

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Arkansas (FEMA–4000–DR), dated 07/08/2011.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 05/24/2011 through 05/26/2011.

Effective Date: 07/08/2011.

Physical Loan Application Deadline Date: 09/06/2011.

Economic Injury (EIDL) Loan Application Deadline Date: 04/09/2012.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration,

409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/08/2011, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Crawford, Franklin, Johnson.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere ...	3.250
Non-Profit Organizations Without Credit Available Elsewhere	3.000
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	3.000

The number assigned to this disaster for physical damage is 12680B and for economic injury is 12681B.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2011–17947 Filed 7–15–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12675 and #12676]

Arizona Disaster #AZ–00016

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Arizona dated 07/11/2011.

Incident: Monument Fire.

Incident Period: 06/12/2011 and continuing.

Effective Date: 07/11/2011.

Physical Loan Application Deadline Date: 09/09/2011.

Economic Injury (EIDL) Loan Application Deadline Date: 04/11/2012.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Cochise.

Contiguous Counties:

Arizona: Graham, Greenlee, Pima, Santa Cruz.

New Mexico: Hidalgo.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	5.375
Homeowners Without Credit Available Elsewhere	2.688
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere ...	3.250
Non-Profit Organizations Without Credit Available Elsewhere	3.000
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	3.000

The number assigned to this disaster for physical damage is 12675 5 and for economic injury is 12676 0.

The States which received an EIDL Declaration # are Arizona; New Mexico.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: July 11, 2011.

Karen G. Mills,

Administrator.

[FR Doc. 2011–17945 Filed 7–15–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12682 and #12683]

Vermont Disaster #VT–00017

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Vermont (FEMA–4001–DR), dated 07/08/2011.

Incident: Severe Storms and Flooding.

Incident Period: 05/26/2011 through 05/27/2011.

Effective Date: 07/08/2011.

Physical Loan Application Deadline Date: 09/06/2011.

Economic Injury (EIDL) Loan Application Deadline Date: 04/09/2012.

ADDRESSES: Submit completed loan applications to:

U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/08/2011, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: (Physical Damage and Economic Injury Loans): Caledonia, Washington.

Contiguous Counties: (Economic Injury Loans Only):

Vermont: Addison, Chittenden, Essex, Lamoille, Orange, Orleans.

New Hampshire: Grafton.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688
Businesses with Credit Available Elsewhere	6.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.000
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.000

The number assigned to this disaster for physical damage is 126826 and for economic injury is 126830.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2011–17946 Filed 7–15–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Small Business Size Standards: Waiver of the Nonmanufacturer Rule

AGENCY: U.S. Small Business Administration.

ACTION: Notice of Denial to Waive the Nonmanufacturer Rule for Eyeglass Frames.

SUMMARY: The U. S. Small Business Administration (SBA) is denying a request for a class waiver of the Nonmanufacturer Rule for Optical Eyeglass Frames, Product Service Code (PSC) 6540 (Ophthalmic Instruments, Equipment, and Supplies), under the North American Industry Classification System (NAICS) code 339115 (Ophthalmic Goods Manufacturing) based on SBA's discovery of one small business manufacturer. Denying this waiver will require recipients of Federal contracts set aside for small businesses, Service-Disabled Veteran-Owned (SDVO) small businesses, Participants in SBA's 8(a) Business Development (BD) Program, or Women-Owned Small Business (WOSB) concerns to provide the products of small business manufacturers or processors on such contracts, unless an individual waiver in connection with a specific contract is requested and granted.

DATES: This action is effective August 2, 2011.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Garcia, Procurement Analyst, by telephone at (202) 205–6842; by FAX at (202) 481–1630; or by e-mail at *amy.garcia@sba.gov.*

SUPPLEMENTARY INFORMATION: Section 8(a)(17) of the Small Business Act (Act), 15 U.S.C. 637(a)(17), and SBA's implementing regulations require that recipients of Federal supply contracts set aside for small businesses, SDVO small businesses, Participants in the SBA's 8(a) BD Program, or WOSB concerns, provide the product of a small business manufacturer or processor, if the recipient is other than the actual manufacturer or processor of the product. This requirement is commonly referred to as the Nonmanufacturer Rule. 13 CFR 121.406(b), 125.15(c). Section 8(a)(17)(b)(iv) of the Act authorizes SBA to waive the Nonmanufacturer Rule for any ''class of products'' for which there are no small business manufacturers or processors available to participate in the Federal market.

In order to be considered available to participate in the Federal market for a class of products, a small business manufacturer must have submitted a proposal for a contract solicitation or received a contract from the Federal Government within the last 24 months. 13 CFR 121.1202(c). The SBA defines ''class of products'' based on the Office of Management and Budget's NAICS. In addition, SBA uses PSCs to further identify particular products within the NAICS code to which a waiver would apply. The SBA may then identify a specific item within a PSC and NAICS to which a class waiver would apply.

The SBA received a request on February 15, 2011, to waive the Nonmanufacturer Rule for Optical Eyeglass Frames, PSC 6540 (Ophthalmic Instruments, Equipment, and Supplies), under NAICS code 339115 (Ophthalmic Goods Manufacturing). In response, on April 27, 2011, SBA published in the **Federal Register** a notice of intent to waive the Nonmanufacturer Rule for Optical Eyeglass Frames (76 FR 10106). SBA explained in the notice that it was soliciting comments and sources of small business manufacturers of this class of products. In response to the April 27, 2011 notice, SBA received comments from a small business manufacturer indicating that it has furnished this product to the Federal government. Accordingly, based on the available information, SBA has determined that there are one or more small business manufacturers of this class of products, and, is therefore denying the class waiver of the Nonmanufacturer Rule for Optical Eyeglass Frames, PSC 6540 (Ophthalmic Instruments, Equipment, and Supplies), under NAICS code 339115 (Ophthalmic Goods Manufacturing).

John W. Klein,

Acting Director, Office of Government Contracting.

[FR Doc. 2011–17950 Filed 7–15–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Small Business Size Standards; Waiver of the Nonmanufacturer Rule

AGENCY: U.S. Small Business Administration.

ACTION: Notice of Retraction of a Class Waiver

SUMMARY: The U.S. Small Business Administration (SBA) is terminating a waiver of the Nonmanufacturer Rule for Service Code (PSC) 9130, Liquid Propellants—Petroleum Base, under North American Industry Classification System (NAICS) code 324110 (Petroleum Refineries), based on SBA's discovery of small business manufacturers. Terminating this waiver will require recipients of Federal contracts set aside for small businesses, Service-Disabled Veteran-Owned (SDVO) small businesses, Participants in SBA's 8(a) Business Development (BD) Program, or Women-Owned Small Business (WOSB) concerns to provide the products of small business manufacturers or processors on such contracts.

DATES: This action is effective August 2, 2011.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Garcia, Procurement Analyst, by telephone at (202) 205–6842; by Fax at (202) 481–1630; or by e-mail at *amy.garcia@sba.gov.*

SUPPLEMENTARY INFORMATION: Section 8(a)(17) of the Small Business Act (Act), 15 U.S.C. 637(a)(17), and SBA's implementing regulations require that recipients of Federal supply contracts set aside for small businesses, SDVO small businesses, Participants in the SBA's 8(a) BD Program, or WOSBs, provide the product of a small business manufacturer or processor, if the recipient is other than the actual manufacturer or processor of the product. This requirement is commonly referred to as the Nonmanufacturer Rule. 13 CFR 121.406(b), 125.15(c), 127.505. Section 8(a)(17)(b)(iv) of the Act authorizes SBA to waive the Nonmanufacturer Rule for any ''class of products'' for which there are no small business manufacturers or processors available to participate in the Federal market.

In order to be considered available to participate in the Federal market for a class of products, a small business manufacturer must have submitted a proposal for a contract solicitation or received a contract from the Federal Government within the last 24 months. 13 CFR 121.1202(c). The SBA defines ''class of products'' based on the Office of Management and Budget's NAICS. SBA also uses product service codes to further define a class of products with an industry.

On June 8, 2009, SBA granted a class waiver for liquid propellants-petroleum. 74 FR 27202. Liquid propellants-petroleum based are identified in NAICS code 324110 under PSC 9130. Soon after the class waiver was

published, SBA was notified by the Defense Logistics Agency, Defense Energy Support Center (DESC), Fort Belvoir, VA, that the agency has awarded prime contracts to, or received offers from, small business refiners. On August 4, 2009, SBA published a proposed Notice of Retraction of a Waiver from the Nonmanufacturer Rule for PSC 9130 (Liquid Propellants—Petroleum Base), under NAICS code 324110 (Petroleum Refineries) seeking comments on the proposed retraction of waiver. 74 FR 18584. A final Notice of Retraction of a Waiver was not published. Consequently, on June 3, 2011, SBA again issued a **Federal Register** notice of its intent to retract the class waiver (76 FR 13777), seeking comments on the proposed retraction.

SBA received two responses to this notice, one from a Federal agency and one from a small business nonmanufacturer. One nonmanufacturer objected to the proposed termination of the waiver. However, the nonmanufacturer did not provide evidence that small business manufacturers are not available to participate in the Federal marketplace. Instead, the nonmanufacturer indicated termination of the class waiver may hinder its ability to compete for set-asides in certain circumstances. However, the underlying purpose of the Small Business Act's manufacturing requirements is to encourage small business manufacturing. Thus, if small business manufacturers exist that can satisfy a particular requirement, then an offeror must supply the product of a small business manufacturer. If these performance requirements cannot be met, a contracting officer may request an individual waiver in connection with a specific contract. A class waiver is only appropriate if no small business manufacturer is available to participate in the Federal marketplace, and based on available evidence, small business manufacturers are participating in this Federal marketplace for this item. In a letter to SBA dated June 20, 2011, DLA identified seven (7) small business refiners to which DLA has awarded prime contracts to, or received offers from, who participate in the Federal market.

Therefore, SBA is retracting the Nonmanufacturer Rule class waiver previously granted for PSC 9130 (Liquid Propellants—Petroleum Base), under NAICS code 324110 (Petroleum Refineries).

John W. Klein,

(Acting) Director, Office of Government Contracting.

[FR Doc. 2011–17951 Filed 7–15–11; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 7526]

Culturally Significant Objects Imported for Exhibition Determinations: ''Rembrandt and the Face of Jesus''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Rembrandt and the Face of Jesus,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Philadelphia Museum of Art, Philadelphia, PA, from on or about July 28, 2011, until on or about October 30, 2011; the Detroit Institute of Arts, Detroit, MI, from on or about November 11, 2011, until on about February 12, 2012, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: July 12, 2011.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2011–18056 Filed 7–15–11; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 7527]

Culturally Significant Objects Imported for Exhibition Determinations: ''Lyonel Feininger: Photographs, 1928–1939''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Lyonel Feininger: Photographs: 1928–1939,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The J. Paul Getty Museum, Los Angeles, CA, from on or about October 25, 2011, until on or about March 11, 2012; Harvard Art Museums, Cambridge, MA, from on or about March 30, 2012, until on or about June 2, 2012, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: July 12, 2011.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2011–18055 Filed 7–15–11; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 7525]

Lifting of Sanctions on Person Associated With the A.Q. Khan Nuclear Procurement Network

AGENCY: Bureau of International Security and Nonproliferation, Department of State.

ACTION: Notice.

SUMMARY: A determination has been made to lift the measures imposed on Shah Hakim Shahnazim Zain pursuant to the Nuclear Proliferation Prevention Act (NPPA), Section 821 of the Foreign Relations Authorization Act for Fiscal Years 1994–1995 (22 U.S.C. 6301), the Export-Import Bank Act of 1945 (as amended) Section 2(b)(4) (12 U.S.C. 635 (b)(4)), and Executive Order 12938 of November 14, 1994 as amended by Executive Order 13094 of July 28, 1998.

DATES: *Effective Date:* July 18, 2011.

FOR FURTHER INFORMATION CONTACT: Director, Office of Counterproliferation Initiatives, Bureau of International Security and Nonproliferation, Department of State, Washington, DC 20520, Tel.: 202/647–7895.

SUPPLEMENTARY INFORMATION: The restrictions were first imposed on January 16, 2009 (see 74 FR 3126, Jan 16, 2009; Public Notice 6486).

Dated: July 12, 2011.

Vann H. Van Diepen,

Acting Assistant Secretary of State, International Security and Nonproliferation, Department of State.

[FR Doc. 2011–18057 Filed 7–15–11; 8:45 am]

BILLING CODE 4710–27–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: May 1, 2011, through May 31, 2011.

ADDRESSES: Susquehanna River Basin Commission, 1721 North Front Street, Harrisburg, PA 17102–2391.

FOR FURTHER INFORMATION CONTACT: Richard A. Cairo, General Counsel, telephone: (717) 238–0423, ext. 306; fax: (717) 238–2436; e-mail: *rcairo@srbc.net* or Stephanie L. Richardson, Secretary to the Commission, telephone: (717) 238–0423, ext. 304; fax: (717) 238–2436; e-mail: *srichardson@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(f) for the time period specified above:

Approvals By Rule Issued Under 18 CFR 806.22(f)

1. Pennsylvania General Energy Company, LLC, Pad ID: COP Tract 293 Pad F, ABR–201105001, Cummings Township, Lycoming County, Pa.; Consumptive Use of up to 3.000 mgd; Approval Date: May 6, 2011.

2. Cabot Oil & Gas Corporation, Pad ID: Augustine P1, ABR–201105002, Springville Township, Susquehanna County, Pa.; Consumptive Use of up to 3.575 mgd; Approval Date: May 9, 2011.

3. Chesapeake Appalachia, LLC, Pad ID: Ramblinrose, ABR–201105003, Tuscarora Township, Bradford County, Pa.; Consumptive Use of up to 7.500 mgd; Approval Date: May 10, 2011.

4. Chesapeake Appalachia, LLC, Pad ID: Hess, ABR–201105004, Rome Township, Bradford County, Pa.; Consumptive Use of up to 7.500 mgd; Approval Date: May 10, 2011.

5. Chief Oil & Gas LLC, Pad ID: Jerauld Drilling Pad #1, ABR–201105005, Lenox Township, Susquehanna County, Pa.; Consumptive Use of up to 2.000 mgd; Approval Date: May 13, 2011.

6. Anadarko E&P Company LP, Pad ID: COP Tract 728 Pad H, ABR–201105006, Watson Township, Lycoming County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 13, 2011.

7. Anadarko E&P Company LP, Pad ID: COP Tract 728 Pad G, ABR–201105007, Watson Township, Lycoming County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 13, 2011.

8. EQT Production Company, Pad ID: Stoney Brook, ABR–201105008, Jay Township, Elk County, Pa.; Consumptive Use of up to 3.000 mgd; Approval Date: May 17, 2011.

9. Seneca Resources Corporation, Pad ID: DCNR 100 PAD E, ABR–201105009, McIntyre Township, Lycoming County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 18, 2011.

10. Williams Production Appalachia LLC, Pad ID: Nayavich Well Pad, ABR–201105010, Sugarloaf Township, Columbia County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 18, 2011.

11. Chesapeake Appalachia, LLC, Pad ID: LRJ, ABR–201105011, Rush Township, Susquehanna County, Pa.; Consumptive Use of up to 7.500 mgd; Approval Date: May 19, 2011.

12. Talisman Energy USA Inc., Pad ID: 03 081 Bergeys, ABR–201105012, Wells Township, Bradford County, Pa.; Consumptive Use of up to 6.000 mgd; Approval Date: May 19, 2011.

13. Anadarko E&P Company LP, Pad ID: Lycoming H&FC Pad E, ABR–201105013, Cogan House Township, Lycoming County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 20, 2011.

14. Anadarko E&P Company LP, Pad ID: Larrys Creek F&G Pad C, ABR–201105014, Cummings Township, Lycoming County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 20, 2011.

15. Cabot Oil & Gas Corporation, Pad ID: LopatofskyJ P1, ABR–201105015, Springville Township, Susquehanna County, Pa.; Consumptive Use of up to 3.575 mgd; Approval Date: May 23, 2011.

16. SWEPI LP, Pad ID: Biegalski 592, ABR–201105016, Richmond Township, Tioga County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 24, 2011.

17. SWEPI LP, Pad ID: Sanchis 1129, ABR–201105017, Farmington Township, Tioga County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 24, 2011.

18. SWEPI LP, Pad ID: Showalter 822, ABR–201105018, Chatham Township, Tioga County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 24, 2011.

19. Great Plains Operating, LLC dba Great Mountain Operating, Pad ID: Sturgis–B, ABR–201105019, Gallagher Township, Clinton County, Pa.; Consumptive Use of up to 6.000 mgd; Approval Date: May 25, 2011.

20. Williams Production Appalachia LLC, Pad ID: Sadecki Well Pad, ABR–201105020, Liberty Township, Susquehanna County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 26, 2011.

21. XTO Energy Incorporated, Pad ID: Glidewell Unit A, ABR–201105021, Pine Township, Columbia County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 26, 2011.

22. Chesapeake Appalachia, LLC, Pad ID: Packard, ABR–201105022, Sheshequin Township, Bradford County, Pa.; Consumptive Use of up to 7.500 mgd; Approval Date: May 26, 2011.

23. Chesapeake Appalachia, LLC, Pad ID: Lomison Inc., ABR–201105023, Burlington Township, Bradford County, Pa.; Consumptive Use of up to 7.500 mgd; Approval Date: May 26, 2011.

24. EQT Production Co., Pad ID: Phoenix P, ABR–201105024, Duncan Township, Tioga County, Pa.; Consumptive Use of up to 3.000 mgd; Approval Date: May 31, 2011.

25. SM Energy Company, Pad ID: Young Pad #4, ABR–201105025, Portage Township, Potter County, Pa.; Consumptive Use of up to 6.000 mgd: Approval Date: May 31, 2011.

26. Williams Production Appalachia LLC, Pad ID: Mitchell Well Pad, ABR–201105026, Franklin Township, Susquehanna County, Pa.; Consumptive Use of up to 4.000 mgd; Approval Date: May 31, 2011.

27. Chesapeake Appalachia, LLC, Pad ID: Karp, ABR–201105027, Lemon Township, Wyoming County, Pa.; Consumptive Use of up to 7.500 mgd; Approval Date: May 31, 2011.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: July 7, 2011.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2011–17925 Filed 7–15–11; 8:45 am]

BILLING CODE 7040–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Allocation of Additional Fiscal Year (FY) 2011 In-Quota Volume for Raw Cane Sugar

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) is providing notice of country-by-country allocations of additional fiscal year (FY) 2011 in-quota quantity of the tariff-rate quota (TRQ) for imported raw cane sugar. USTR is also reallocating a portion of the unused original FY 2011 TRQ.

DATES: *Effective Date:* July 18, 2011.

ADDRESSES: Inquiries may be mailed or delivered to Julie Scott, Policy Analyst, Office of Agricultural Affairs, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC 20508.

FOR FURTHER INFORMATION CONTACT: Julie Scott, Office of Agricultural Affairs, 202–395–6127.

SUPPLEMENTARY INFORMATION: Pursuant to Additional U.S. Note 5 to chapter 17 of the Harmonized Tariff Schedule of the United States (HTS), the United States maintains TRQs for imports of raw cane and refined sugar.

Section 404(d)(3) of the Uruguay Round Agreements Act (19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a TRQ for any agricultural product among supplying countries or customs areas. The President delegated this authority to the United States Trade Representative under Presidential Proclamation 6763 (60 FR 1007).

On June 21, 2011, the Secretary of Agriculture announced an additional in-quota quantity of the FY 2011 TRQ for imported raw cane sugar for the remainder of FY 2011 (ending September 30, 2011) in the amount of 108,862 metric tons * raw value (MTRV). This quantity is in addition to the minimum amount to which the United States is committed pursuant to the World Trade Organization (WTO) Uruguay Round Agreements (1,117,195 MTRV). Based on consultations with quota holders, USTR is allocating the 108,862 MTRV to the following countries in the amounts specified below:

Country	FY 2011 additional allocation
Argentina	7,636
Australia	14,740
Belize	1,954
Bolivia	1,421
Brazil	25,750
Colombia	4,262
Costa Rica	2,664
Ecuador	1,954
El Salvador	4,617
Guatemala	8,524
Guyana	2,131
India	1,421
Malawi	1,776
Mozambique	2,309
Nicaragua	3,729
Panama	5,150
Peru	7,281
Philippines	2,841
South Africa	4,085
Thailand	2,486
Zimbabwe	2,131

Additionally, based on follow-up country consultations, the Office of the United States Trade Representative also today is reallocating 16,807 MTRV of the minimum amount of the original TRQ for raw cane sugar, to the Philippines. This results in an overall increased allocation of 19,648 MTRV for the Philippines.

These allocations are based on the countries' historical shipments to the United States. The allocations of the raw cane sugar TRQ to countries that are net importers of sugar are conditioned on receipt of the appropriate verifications of origin and certificates for quota eligibility must accompany imports from any country for which an allocation has been provided.

* Conversion factor: 1 metric ton = 1.10231125 short tons.

Ronald Kirk,

United States Trade Representative.

[FR Doc. 2011–17857 Filed 7–15–11; 8:45 am]

BILLING CODE 3190–W1–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Commercial Space Transportation Advisory Committee—Public Teleconference

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Space Transportation Operations Working Group of the Commercial Space Transportation Advisory Committee Teleconference.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App. 2), notice is hereby given of a teleconference of the Space Transportation Operations Working Group (STOWG) of the Commercial Space Transportation Advisory Committee (COMSTAC). The teleconference will take place on Thursday, August 4, 2011, starting at 1 p.m. Eastern Daylight Time. Individuals who plan to participate should contact Susan Lender, Designated Federal Officer (DFO), (the Contact Person listed below) by phone or e-mail for the teleconference call in number.

The proposed agenda for this teleconference consists of the following topics: Final discussion of the CONOPS report on reentry debris, final discussion of the Economic Impact of complying with orbital debris standards, updates on the European Code of Conduct and the Long Term Sustainability of Space effort by the United Nations Committee for Peaceful Uses of Outer Space, and any new business items that members want to consider.

Interested members of the public may submit relevant written statements for the COMSTAC members to consider under the advisory process. Statements may concern the issues and agenda items mentioned above or additional issues that may be relevant for the U.S. commercial space transportation industry. Interested parties wishing to submit written statements should

contact Susan Lender, DFO, (the Contact Person listed below) in writing (mail or e-mail) by July 28, 2011, so that the information can be made available to COMSTAC members for their review and consideration before the August 4, 2011, teleconference. Written statements should be supplied in the following formats: One hard copy with original signature or one electronic copy via e-mail.

An agenda will be posted on the FAA Web site at *http://www.faa.gov/go/ast.*

Individuals who plan to participate and need special assistance should inform the Contact Person listed below in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Susan Lender (AST–5), Office of Commercial Space Transportation (AST), 800 Independence Avenue, SW., Room 331, Washington, DC 20591, telephone (202) 267–8029; E-mail *susan.lender@faa.gov.* Complete information regarding COMSTAC is available on the FAA Web site at: *http://www.faa.gov/about/office_org/headquarters_offices/ast/advisory_committee/.*

Issued in Washington, DC, July 7, 2011.

James Van Laak,

Deputy Associate Administrator for Commercial Space Transportation.

[FR Doc. 2011–17977 Filed 7–15–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by the California Department of Transportation (Caltrans), pursuant to 23 U.S.C. 327.

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans, and USACE that are final within the meaning of 23 U.S.C. 139(*l*)(1). The actions relate to a proposed highway project at the Genesee Avenue Interchange on Interstate 5 (I–5) in the City and County of San Diego, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before January 14, 2012. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Bruce L. April, Deputy District Director—Environmental, Caltrans District 11, 4050 Taylor Street, MS 242, San Diego, CA 92110. Regular Office Hours: 8 am to 5 pm. Telephone: (619) 688–0100 Email: *Bruce_April@dot.ca.gov*.

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that Caltrans has taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: The I–5/Genesee Avenue Interchange (IC) Reconstruction Project. This project would include replacement of the Genesee Avenue Overcrossing (OC) with a new OC that would be wider to accommodate additional lanes to relieve a ''bottleneck'' on Genesee and to improve pedestrian and bicycle access, and would be longer and higher to accommodate possible future widening of I–5; widening of IC ramps; widening of ramps at Sorrento Valley Road (the next IC to north); construction of auxiliary lanes; replacement of Voigt Drive OC (the next OC to south); realignment of a portion of nearby Gilman Drive; installation of new ramp meters; and, construction of a bicycle path along I–5. The project is located in the City and County of San Diego and project length along I–5 is a total of approximately three (3) kilometers [two (2) miles]. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Environmental Assessment (EA) with Finding of No Significant Impact (FONSI) for the project, approved on June 29, 2011, and in other documents in the FHWA project records. The EA, FONSI, and other project records are available by contacting Caltrans at the address provided above. The Caltrans EA and FONSI can be viewed and downloaded from the project web site at *http://www.dot.ca.gov/dist11/envir.htm.*

Pending Federal actions include:

1. Section 401 Water Quality Certification from the San Diego Regional Water Quality Control Board (RWQCB), under Section 401 of the Clean Water Act.

2. Section 404 Permit pursuant to the Memorandum of Understanding among FHWA; Caltrans; U.S. Army, Corps of Engineers (USACE); U.S. Fish and Wildlife Service (USFWS) and the National Marine Fisheries Service for the National Environmental Policy Act (NEPA) and the Clean Water Act, Section 404 Integration Process for Federal Aid Surface Transportation Projects in California (NEPA/404 MOU).

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. Council on Environmental Quality Regulations
2. National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4321 *et seq.*
3. Federal-Aid Highway Act of 1970, 23 U.S.C 109
4. Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), Public Law 109–59
5. Clean Air Act Amendments of 1990 (CAAA)
6. Clean Water Act of 1977 and 1987
7. Federal Water Pollution Control Act of 1972 (see Clean Water Act of 1977 & 1987)
8. Federal Land Policy and Management Act of 1976 (Paleontological Resources)
9. Noise Control Act of 1972
10. Safe Drinking Water Act of 1944, as amended
11. Endangered Species Act of 1973
12. Executive Order 11990, Protection of Wetlands
13. Executive Order 13112, Invasive Species
14. Executive Order 13186, Migratory Birds
15. Fish and Wildlife Coordination Act of 1934, as amended
16. Migratory Bird Treaty Act
17. Water Bank Act Wetlands Mitigation Banks, ISTEA 1991, Sections 1006–1007
18. Wildflowers, Surface Transportation and Uniform Relocation Act of 1987 Section 130
19. Coastal Zone Management Act of 1972
20. Coastal Zone Management Act Reauthorization Amendments of 1990
21. Executive Order 11988, Floodplain Management
22. Department of Transportation (DOT) Executive Order 5650.2—Floodplain Management and Protection (April 23, 1979)
23. Rivers and Harbors Appropriation Act of 1899, Sections 9 and 10
24. Title VI of the Civil Rights Act of 1964, as amended

25. Act for the Preservation of American Antiquities (1906)
26. Archaeological and Historical Preservation Act of 1974
27. Archeological Resources Protection Act of 1979
28. National Historic Preservation Act of 1966, as amended (Section 106)
29. Native American Graves Protection and Repatriation Act of 1990
30. 23 CFR 771: Environmental Impact and Related Procedures
31. NEPA/404 Integration MOU (2006)
32. Director's Title VI Statement

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Issued on: July 12, 2011.

Manuel E. Sánchez,

Senior Transportation Engineer/Border Engineer, Federal Highway Administration, San Diego, California.

[FR Doc. 2011–17964 Filed 7–15–11; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Final Federal Agency Actions on Proposed Highway in North Carolina

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by Army Corps of Engineers (USACE).

SUMMARY: This notice announces actions taken by the USACE that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to a proposed highway project, the Monroe Connector/Bypass, from US 74 near I–485 in Mecklenburg County, North Carolina, to US 74 between the towns of Wingate and Marshville in Union County, North Carolina. The Monroe Connector/Bypass is also known as State Transportation Improvement Program Project R–3329/R–2559. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions that are covered by this notice will be barred unless the claim is filed on or before January 17, 2012. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA: Mr. George Hoops, P.E., Major Projects Engineer, Federal Highway Administration, 310 New Bern Avenue, Suite 410, Raleigh, North Carolina 27601–1418, *Telephone:* (919) 747–7022; *e-mail: george.hoops@dot.gov*. FHWA North Carolina Division Office's normal business hours are 8 a.m. to 5 p.m. (Eastern Time). For the North Carolina Turnpike Authority (NCTA): Ms. Jennifer Harris, P.E., Director of Planning and Environmental Studies, North Carolina Turnpike Authority (NCTA), 1578 Mail Service Center, Raleigh, North Carolina 27699, *Telephone:* (919) 707–2700; *e-mail: jhharris1@ncdot.gov*. NCTA's normal business hours are 8 a.m. to 5 p.m. (Eastern Time). For USACE: Ms. Liz Hair, Project Manager, US Army Corps of Engineers, Asheville Regulatory Field Office, 151 Patton Avenue, Room 208, Asheville, North Carolina 28801, *Telephone:* (828) 271–7980; *e-mail: sarah.e.hair@usace.army.mil*. USACE's normal business hours are 8 a.m. to 5 p.m. (Eastern Time)

SUPPLEMENTARY INFORMATION: On September 27, 2010, the FHWA published a ''Notice of Final Federal Agency Actions on Proposed Highway in North Carolina'' in the **Federal Register** in Volume 75, Number 186 for the following highway project: The Monroe Connector/Bypass, a 20 mile long, multi-lane, fully access-controlled, new location toll road located in Mecklenburg and Union Counties, North Carolina. The purpose of the project is to improve mobility and capacity within the project study area by providing a facility for the US 74 corridor from near I–485 in Mecklenburg County to between the towns of Wingate and Marshville in Union County that allows for high-speed regional travel consistent with the designations of the North Carolina Strategic Highway Corridor program and the North Carolina Intrastate System, while maintaining access to properties along existing US 74. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Impact Statement (FEIS) for the project, approved on May 25, 2010, and the FHWA Record of Decision (ROD) issued on August 27, 2010 approving the Monroe Connector/Bypass project, and in other documents in the FHWA administrative record. The FEIS, ROD, and other documents in the FHWA administrative record file are available by contacting the FHWA or NCTA at the addresses provided above. Notice is hereby given that, subsequent to the earlier FHWA notice, the USACE has taken final agency actions within the meaning of 23 U.S.C. 139(l)(1) by issuing permits and approvals for the highway project. Specifically, the USACE issued an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) on April 5, 2011, and on April 15, 2011, issued a permit for the Monroe Connector/Bypass project. Both of these documents can be viewed at the following link: *http://www.saw.usace.army.mil/Wetlands/Projects/MonroeBypass/index.html.* The actions by the USACE, and the laws under which such actions were taken, are described in the USACE decisions and its project records, referenced as Department of the Army Permit Number 2009–00876. That information is available by contacting the USACE at the address or Web site provided above. This notice does not apply to any Federal agency actions and decisions addressed in the ''Notice of Final Federal Agency Actions on Proposed Highway in North Carolina'' previously published in the **Federal Register** on September 27, 2010.

Information about the project also is available from the FHWA and the NCTA at the addresses provided above. The FEIS and ROD can be viewed and downloaded from the ''Project Library'' link on the project Web site at *http://www.ncturnpike.org/projects/monroe* or viewed at the offices of the North Carolina Turnpike Authority. The USACE decision can be viewed and downloaded from the project Web site at *http://www.ncturnpike.org/projects/monroe/documents.asp*.

This notice applies to all USACE final actions taken after the issuance date of the FHWA **Federal Register** notice described above. The laws under which actions were taken include, but are not limited to:

1. *Wetlands and Water Resources:* Clean Water Act (Section 404, Section 401, Section 319) [33 U.S.C. 1251–1377].

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: July 12, 2011.

George W. Hoops,

Major Projects Engineer, Federal Highway Administration, Raleigh, North Carolina.

[FR Doc. 2011–18060 Filed 7–15–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0097]

Pilot Program on the North American Free Trade Agreement (NAFTA) Long-Haul Trucking Provisions; Correction

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice; correction.

SUMMARY: The Federal Motor Carrier Safety Administration published a document in the **Federal Register** of July 8, 2011, concerning a response to comments in regards to an April 8, 2011 notice announcing a pilot program on the North American Free Trade Agreement (NAFTA) long-haul trucking provisions. The document contained an incorrect phone number.

FOR FURTHER INFORMATION CONTACT: Marcelo Perez, (512) 916–5440, extension 228.

Correction

In the **Federal Register** of July 8, 2011, in FR Doc. 2011–16886, on page 40420, in the third column, correct the **FOR FURTHER INFORMATION CONTACT** caption to read:

FOR FURTHER INFORMATION CONTACT: Mr. Marcelo Perez, FMCSA, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001. Telephone (512) 916–5440, extension 228; e-mail *marcelo.perez@dot.gov.*

Issued on: July 13, 2011.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2011–18033 Filed 7–15–11; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2011–0075]

Pipeline Safety: Issuance of Draft Decision on Det Norske Veritas (USA), Inc.'s Petition for Approval of the Process Hazard Analysis Software Tool—Unified Dispersion Model

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice.

SUMMARY: This notice advises owners and operators of liquefied natural gas facilities and other interested parties that the Administrator has issued a Draft Decision on Det Norske Veritas (DNV) (USA), Inc.'s petition for approval of the Process Hazard Analysis Software Tool—Unified Dispersion Model (PHAST–UDM). The Draft Decision is available for public inspection at Docket No. PHMSA–2011–0075 at *http://www.regulations.gov.* Any comments received by August 11, 2011, will be considered before a Final Decision is issued. Late comments will be considered to the extent practicable.

DATES: Submit comments by August 11, 2011.

ADDRESSES: Comments should reference Docket No. PHMSA–2011–0075 and may be submitted in the following ways:

- *E-Gov Web site: http://www.regulations.gov.* This Web site allows the public to enter comments on any **Federal Register** notice issued by any agency. Follow the instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Management Facility, M–30, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.
- *Hand Delivery:* U.S. Department of Transportation, Docket Management Facility, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: Identify the docket number PHMSA–2011–0075 at the beginning of your comments. Note that all comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided. You should know that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). Therefore, you may want to review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477) or visit *http://www.regulations.gov* before submitting any such comments.

Docket: For access to the docket or to read background documents or comments go to *http://www.regulations.gov* at any time or to Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: ''Comments on PHMSA–2011–0075.'' The Docket Clerk will date stamp the postcard prior to returning it to you via the U.S. mail. Please note that due to delays in the delivery of U.S. mail to Federal offices in Washington, DC, we recommend that persons consider an alternative method (Internet, fax, or professional delivery service) of submitting comments to the docket and ensuring their timely receipt at DOT.

Note: Comments are posted without changes or edits to *http://www.regulations.gov,* including any personal information provided. There is a privacy statement published on *http://www.regulations.gov.* Any comments received by August 11, 2011, will be considered before a Final Decision is issued. Late comments will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Charles Helm by telephone at 405–954–7219 or by e-mail at *Charles.Helm@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On October 25, 2010, DNV (USA), Inc., filed a petition for approval of the PHAST–UDM at 49 CFR 190.9 and 193.2059(a). Those regulations permit the Administrator to approve the use of alternative vapor gas dispersion models in siting liquefied natural gas facilities.

On July 12, 2011, the Administrator issued a Draft Decision proposing to approve DNV's petition. The Draft Decision is available for public inspection under PHMSA Docket No. 2011–0075 at *http://www.regulations.gov.*

Issued in Washington, DC, on July 12, 2011.

Jeffrey D. Wiese,

Associate Administrator for Pipeline Safety.

[FR Doc. 2011–18036 Filed 7–15–11; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35533]

East Penn Railroad, L.L.C.; Lease and Operation Exemption; Norfolk Southern Railway Company

Under 49 CFR 1011.7(a)(2)(x)(A), the Director of the Office of Proceedings (Director) is delegated the authority to determine whether to issue notices of exemption for lease transactions under 49 U.S.C. 10902. However, the Board reserves to itself the consideration and

disposition of all matters involving issues of general transportation importance. *See* 49 CFR 1011.2(a)(6). Accordingly, the Board is revoking the delegation to the Director with respect to the issuance of this notice of exemption. The Board has determined that this lease and operation notice of exemption should be issued, and does so here.

East Penn Railroad, L.L.C. (ESPN), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease from Norfolk Southern Railway Company (NSR) and to operate approximately 5.2 miles of rail line in York, Penn.[1] Pursuant to the lease agreement, ESPN will lease: (1) The York Industrial Track between milepost YR 7.50 and YR 12.31 (4.81 miles in length); and (2) the Wye Track between milepost YR 12.31 and milepost 12.70 (0.39 miles in length), which connects the York Industrial Track to NSR's line.[2]

As required under 49 CFR 1150.43(h), ESPN has disclosed that the lease agreement between it and NSR contains an interchange commitment provision that enables ESPN to reduce its lease payments by receiving a credit for each car interchanged with NSR. ESPN states that NSR initially proposed a fixed rental payment with no option to reduce the rent, but ESPN requested a lease credit option to give it an opportunity to earn a lower rental payment, which would enable it to invest in improvements on the leased lines and thereby increase traffic levels. According to ESPN, the interchange point with NSR is York.

ESPN certifies that the projected annual revenues resulting from the proposed transaction will not result in ESPN becoming a Class II or Class I rail carrier and will not exceed $5 million annually.

The transaction is expected to be consummated on or after July 31, 2011, the effective date of the exemption (30 days after the verified notice of exemption was filed).

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than July 22, 2011 (at least 7 days before the exemption becomes effective).

[1] ESPN's has filed a lease agreement and an interchange agreement under seal pursuant to 49 CFR 1150.43(h)(1)(ii).

[2] ESPN states that it will also be leasing from NSR certain real property located under the Wye Track and a service road extending from Windsor Street.

An original and 10 copies of all pleadings, referring to Docket No. FD 35533 must be filed with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Karl Morell, Ball Janik LLP, Suite 225, 655 Fifteenth Street, NW., Washington, DC 20005.

Board decisions and notices are available at our Web site at ''*http://www.stb.dot.gov.*''

It is ordered:

1. The delegation of authority to the Director of the Office of Proceedings, under 49 CFR 1011.7(a)(2(x)(A), to determine whether to issue a notice of exemption in this proceeding is revoked.

2. This decision is effective on the date of service.

Decided: July 12, 2011.

By the Board, Chairman Elliott, Vice Chairman Begeman, and Commissioner Mulvey. Commissioner Mulvey dissented with a separate expression.

Commissioner Mulvey, dissenting:

I disagree with the Board's decision to allow this transaction to be processed under the class exemption procedures. I would like to have more information about the likely impact of the proposed interchange commitment before deciding whether to permit the transaction to go forward. In support of the interchange commitment provision, ESPN asserts only that it requested a ''lease credit'' option from NSR so that ESPN would better be able to invest in line improvements. This generic refrain, which has been used in a number of recent Board proceedings, sheds no light on whether a provision discouraging interchange with other carriers is inconsistent with the public interest in this case.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–17872 Filed 7–15–11; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF VETERANS AFFAIRS

Announcement of Competition Under the America COMPETES Reauthorization Act of 2011

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: To encourage widespread use of Blue Button personal health records (PHRs) outside Federal health care programs to benefit Veterans who receive care from non-VA providers, the Secretary of Veterans Affairs (VA) announces a prize competition under Section 105 of the America COMPETES Reauthorization Act of 2011, Public Law 111–358 (2011).

DATES: Competition begins July 18, 2011, and ends when a winner is announced or on October 18, 2011, whichever occurs first, unless the term of the contest is extended as provided in this Notice.

FOR INFORMATION CONTACT: James M. Speros at the Office of the Secretary, Department of Veterans Affairs at (202) 461–7214. (**Note:** This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: In collaboration with other Federal agencies and non-governmental entities the Department of Veterans Affairs (VA) developed and has implemented an online PHR functionality known as Blue Button℠. VA's Blue Button℠ PHR allows Veterans who are registered users of VA's My HealtheVet internet portal to download extracts of their own medical information to their home computers. Blue Button℠; PHR downloads can be printed or saved on computers and portable storage devices. Veterans can then choose to share this data with other health care providers, caregivers, or people they trust.

The Department of Defense has implemented a Blue Button℠ PHR for beneficiaries of its Tricare program and patients in the Military Health System; the Centers for Medicare and Medicaid Services has implemented a Blue Button℠ PHR that allows Medicare beneficiaries to download data about claims for Medicare-covered services. Other health benefit plans, health insurers and health service providers offer Blue Button℠ PHRs to their patients and customers.

Blue Button℠ PHRs provide a simple, convenient, and secure means for storing personal health data in an internet-based service (including the download and upload of this information). Blue Button℠ PHRs are currently used by more than 350,000 people—including 300,000 Veterans who receive care through the VA health system. VA believes Blue Button℠ PHRs have now been sufficiently tested and proven useful to be made available for use throughout the United States by Veterans who receive their care from non-VA facilities and providers and by the public generally.

Blue Button℠ PHRs keep the kind of information that patients need when they ''fill in the clipboard'' when visiting a physician or other licensed health care provider. Blue Button℠ PHRs may also include clinical information from a sponsoring physician's clinical electronic health records. Some PHRs are compilations of data that patients receive from multiple

physicians, other care providers, health plans, or hospitals.

VA's health care system currently provides care to approximately eight million Veterans; some of these Veterans and the remainder of the 28 million Veterans in the United States receive some or all of their care from providers outside the VA health care system. VA believes all Veterans—not just those who receive all their care from VA—would benefit from and should have access to a Blue Button℠ PHR which is interoperable with the VA Blue Button℠ PHR. Making a Blue Button℠ PHR available to all Veterans advances VA's mission of improving the health care and health status of Veterans.

VA anticipates that Blue Button℠ PHRs will both empower patients and be useful both within and outside the Federal government. Users can include governmental and non-governmental health plans, health systems, hospitals, physicians, and other clinical providers. Blue Button℠ PHRs can help professionals and hospitals provide Veterans and other patients with an electronic copy of specified health information, including clinical summaries of office visits and discharge instructions. Blue Button℠ PHRs can also support electronic exchange of key clinical information between care providers when authorized by patients.

In addition to enhancing provider and health plan relationships with patients, the use of Blue Button℠ PHRs may help licensed health care providers and organizations to achieve the meaningful use of electronic health records, as set forth in 42 CFR 496.6(d)(12), (14) and (15) (professionals), and 42 CFR 496(f)(11), (12) and (13) (hospitals).

Competition Details

Subject of the competition. The objective of this competition is the widespread installation and actual use of a simple internet-based application which allows physicians and other licensed clinical professionals (LCPs) to sponsor and offer to their patients, including Veterans, a Blue Button℠ personal electronic health record (PHR).

Amount of the prize. The prize to be awarded to the winner of this competition is $50,000.

Competition Rules

(1) *Basis on which the winner will be selected.* The winner of this competition will be the first entrant that can document that:

(a) It has created an internet-based application which allows LCPs to sponsor and offer to their patients, including Veterans, a Blue Button℠ PHR, and

(b) The Blue Button℠ PHR application has actually been installed on public-facing internet sites by 25,000 LCPs within the United States and is actually available for use by all patients of those LCPs, including Veterans.

(i) To qualify as an installation sponsored by an LCP, the Blue Button℠ PHR application must be installed on the LCP's internet site or the Internet site of the organization with which the LCP is affiliated, must be freely accessible to all patients of the LCP, including Veterans, and must be operable at the time of judging.

(ii) If the Blue Button℠ PHR application is installed on the internet site of an organization with which the LCP is one of multiple LCP practitioners, then the total number of LCPs affiliated with the organization will be counted toward the required number of installations if it is freely accessible and usable by all patients who receive services from the organization. *Important:* Before a prize is awarded to them, participants will be required to submit a written approval and confirmation of installation from any LCP organization through which 100 or more practitioners will be offering the Blue Button℠ PHR. The written approval and confirmation must be signed by the chief executive officer or equivalent of the LCP organization.

(c) The Blue Button℠ PHR application meets the following criteria:

(i) It provides patients with a simple, convenient and secure means for entering and storing their personal health data and retrieving that data via download.

(ii) It supports downloads in, at a minimum, in ASCII and .pdf formats. The ASCII download format will be identical to and interoperable with the VA ASCII-based Blue Button℠ text file and can read and write to the VA format. This format can be found at *http://www.va.gov/bluebutton.*

(iii) LCPs and LCP organizations can easily install the application and make it available to patients as an internet-based service.

(iv) The Blue Button℠ and related Service Marks are used exclusively to identify the application and all of its components and functionalities.

(1) To install the application, the sponsoring LCP or LCP organization (1) Agrees to VA Blue Button℠ end user license terms and to transmittal to VA of information necessary to identify the LCP or LCP organization as an end-user licensee. The application must support automated transmission of such identifying information to VA.

(2) See ''Intellectual Property,'' below, for additional information about the Blue Button℠ Service Marks.

(v) The application can and does verify the identity of a recipient of any health information and the authority of the recipient to receive any data in the PHR, and, specifically, shall comply with the HIPAA Security Rule, *i.e.,* 45 CFR 164.312(a) (access control), 45 CFR 164.312(c)(1) (data integrity), and 45 CFR 164.312(e)(1) (transmission security).

(d) The Blue Button℠ PHR application may also, but is not required to:

(i) Include additional data fields based on the nature or types of clinical services provided by the sponsoring LCP or LCP organization, or

(ii) Offer additional functions, such as allowing LCPs or LCP organizations to export clinical information to a patient's PHR; allowing patients to electronically transmit PHR data to their LCP or LCP organization; and allowing LCPs or LCP organizations, when authorized by a patient, to electronically transfer the patient's PHR data via NHIN Direct to another LCP or health institution.

(2) *Alternate basis for selecting winner.*

(a) If the competition judge decides that no single entrant has met all required criteria for winning the contest, VA may determine that two or more, and up to 10, participants who have in the aggregate installed the Blue Button℠ PHR application on the internet sites of 25,000 LCPs, either individually or through LCP organizations, should be declared winners and share the prize.

(b) In the absence of an individual winner, VA will rank entries from highest to lowest based on the number of verified LCP installations, and if 25,000 LCP installations, either individually or through LCP organizations, can be achieved by aggregating two or more, up to a maximum of 10 of the entries, starting from the top-ranked entry, the entrants will be eligible to share in the prize, if,

(i) *All Participants submit an entry on or before October 18, 2011 or the end of the contest if extended by formal announcement;*

(ii) Entries meet all requirements of this contest except only the requirement for 25,000 installations by a single entrant.

(c) If VA determines that multiple entries should be declared winners and share the prize, the prize amount will be prorated among the winning entries based on the number of verified installations, and in no event will the

total amount of all prizes awarded exceed $50,000.

(3) *Definitions.* For purposes of this competition:

(a) A ''LCP'' is an individual licensed to provide health care and health services, without direction or supervision and who qualifies for and has received a National Provider Identifier (NPI) from the Centers for Medicare and Medicaid Services. Examples of LCPs include physicians, psychologists, dentists, and, when delivery of health care or services without supervision is authorized by the individual's license, nurse practitioners, physician's assistants, certified nurse-midwives and licensed independent social workers.

(b) A LCP may be ''affiliated'' with an organization (LCP organization) with or through which the LCP actively engages in the practice of the health profession for which the LCP is licensed. Examples include multi-physician practice groups, partnerships or professional corporations in which the principals are actively engaged in the practice of medical or health care. Membership in or engagement in professional or trade associations are not ''affiliations'' which qualify for this competition.

(4) *Contest period.*

(a) This contest will begin on July 18, 2011.

(b) This contest will end on the earlier of:

(i) The date VA announces a winning entry has been submitted, or

(c) October 18, 2011, unless VA extends the period of this contest by notice published in the **Federal Register** on or before October 18, 2011.

(d) If no winning entry is submitted on or before October 18, 2011 or during any extension of the period of this contest, the prize will not be awarded.

(5) *To participate in this competition, contestants must:*

(a) Obtain from VA a license to use the Blue Button℠ and related Service Marks (Marks) in connection with this competition and otherwise. This license must be obtained prior to any use of the Blue Button℠ and related Marks.

(i) VA will issue a non-exclusive royalty-free license to use the Blue Button℠ and related Marks to any participant or end user who requests a license via www.va.gov/bluebutton/apps/license, provides the required identifying information and agrees to VA's license terms.

(ii) *Important:* Participants who use the Blue Button℠ and related Marks, whether in connection with this competition or otherwise prior to obtaining a license from VA, or who use the Marks other than as authorized under license terms, are disqualified from this competition and not eligible to win any prize.

(iii) See ''Intellectual Property,'' below, for additional information about the Blue Button℠ Service Marks.

(b) Submit an entry via *http://challenge.gov/VAi2/198-blue-button-for-all-americans* which includes each of the following in the electronic formats specified:

(i) A narrative describing the participant's PHR application, its functionality and its installation at the required number of LCP- or LCP organization-sponsored Internet sites. The narrative will state the date and time when the participant obtained a license to use the Blue Button℠ and related Marks and the serial number of the Blue Button℠ use license issued by VA. The narrative will be in a format completely compatible with Microsoft Word 2007, not exceeding five 8½ x 11″ pages in length using Arial or Calibri 11 point font and one-inch margins.

(ii) A link to a Web site from which VA can download the application, in source or object code at the option of the participant. By submitting an entry in this competition, participant expressly authorizes VA, its employees and agents to download, install and use the application for purposes of determining whether the submitted application meets the requirements of this competition.

(iii) A listing of all LCPs and LCP organizations who or which have installed the participant's application identified by the Blue Button℠ Marks, and made it freely available for use by the LCP's patients, including Veterans.

(1) The listing will be in a format completely compatible with Microsoft Excel 2007 and contain the information set forth in the template found at *http://challenge.gov/VAi2/198-blue-button-for-all-americans.* This information will be used to verify that the required number of LCPs or LCP organizations have installed the participant's application, and may be used to support licensing of VA's Blue Button℠ Marks to each end user.

(iv) Information necessary to contact the participant in the event the participant is an apparent winner or there are questions about the information submitted, including name, street address, e-mail address and telephone number.

(6) *Eligibility to participate in the competition.* To be eligible to win a prize in this competition, an individual or entity:

(a) In the case of an individual, must be a citizen or permanent resident of the United States; and if an entity, must be incorporated in and maintain a primary place of business in the United States.

(b) Must have complied with all requirements of this Notice and all requirements established by Section 105 of the America COMPETES Act of 2011, Public Law 111–358.

(c) May not be a Federal entity or Federal employee acting within the scope of his or her employment.

(d) Must agree to assume any and all risks and waive any claims against the Federal government and its related entities, except in case of willful misconduct, for any injury, death, damage, or loss of property revenue or profits, whether direct, indirect, or consequential, arising from their participation in this competition, whether the injury, death, damage or loss arises through negligence or otherwise. *Provided, however,* that participants will not be required to waive claims against VA arising out of the unauthorized use of or disclosure by the agency of the intellectual property, trade secrets or confidential information of the participant.

(i) Participants shall be responsible for obtaining their own insurance to cover claims by any third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with or participation in the competition.

(7) *Procedures for obtaining additional information.*

(a) During the period of this competition, VA will operate and maintain a moderated blog at *http://challenge.gov/VAi2/198-blue-button-for-all-americans* to which participants may submit questions and receive official guidance from VA.

(b) VA may choose not to respond to any question or comment or to delete questions or comments which it determines are not relevant to the competition.

(c) All participants are bound by official guidance on the blog if posted prior to submission of a participant's entry.

(8) *Judge and Judging Procedures.*

(a) The judge of this competition will be the Director of the VA Innovation Initiative, acting in his or her official capacity. If the judge is disqualified or unable to fulfill his or her duties, VA reserves the right to substitute another official as judge. Notice of such substitution will be published in the **Federal Register**. Specific tasks related to the judging process may be delegated to other VA employees.

(b) VA may use any technical means it determines suitable to test the functionality and usability of the

entrant's Blue Button℠ PHR application.

(c) VA may use any analytical means it determines suitable to determine whether the entrant's Blue Button℠ PHR application has been installed by, and is freely available to patients of, the required number of LCPs or LCP organizations. The methods VA may use include but are not limited to assessment of a statistical sample of internet site addresses submitted by an entrant, the results of which may be generalized to the entire population. As provided in Section 3(b)(ii), above, internet sites must be operable at the time of judging.

(d) Determination of whether a participant is the ''first'' to document it has met all of the criteria for selection as a winner of this competition will be based on the date and time of VA's receipt of the submission of the entries. If two apparently winning entries are submitted at exactly the same date and time, the entry of the entrant which first obtained a license to use the Blue Button℠ Marks will be designated the ''first'' entry.

(e) VA will use the information submitted in the entry to contact an apparent winner. If VA is unsuccessful in contacting the apparent winner after a minimum of 10 attempts over the course of a 10-day period, it may disqualify the participant and either (1) Award the prize to another participant or (2) terminate this competition without awarding any prize.

(f) Prior to final designation as the winner of this competition, the apparent winner will be required to submit documentation:

(i) If an individual, that the person is a citizen or permanent resident of the United States; and if an entity, that is it incorporated in and maintains a place of business in the United States;

(ii) Of written approval and confirmation of installation signed by the chief executive officer or equivalent of any LCP organization through which 100 or more practitioners are offering the Blue Button℠ PHR; and

(iii) Of financial account information sufficient to support electronic transfer of the prize amount consistent with VA fiscal policy and the issuance of an IRS Form 1099. The information submitted will be used for these purposes only.

(g) Decisions of the judge are final.

(9) *Intellectual property.*

(a) The winner of the competition will, in consideration of the prize to be awarded, grant to VA a perpetual non-exclusive, royalty-free license to use any and all intellectual property pertaining to the winning entry (Winning IP) for any governmental purpose, including the right to permit such use by any other agency or agencies of the Federal government. All other rights to the Winning IP will be retained by the winner of the competition.

(b) VA may, in its sole and exclusive discretion, choose to negotiate with any non-winning entrant for a license to use any intellectual property developed by a participant for this competition.

(c) ''Blue Button,'' the Blue Button logo and the slogan ''Download My Data'' are Service Marks (Marks) of the Department of Veterans Affairs, an agency of the United States Government (reg. app. pending), which reserves all rights pertaining to its Marks. Any unlicensed use of the Blue Button℠ Marks or use inconsistent with the terms of license issued by or on behalf of VA constitutes infringement of VA's intellectual property and subjects the infringer to all penalties provided by law.

(i) ''Use,'' as used in Sections 6 and 10(c) above, means use in commerce of any reproduction, counterfeit, copy, or colorable imitation of the Blue Button℠ Marks in connection with the sale, offering for sale, distribution, or advertising of any goods or services related to the electronic storage or transmittal of health or health-related data. Use also means application of any reproduction, counterfeit, copy, or colorable imitation of the Blue Button℠ Marks to labels, signs, prints, packages, wrappers, receptacles or advertisements intended to be used in commerce upon or in connection with the sale, offering for sale, distribution, or advertising any goods or services related to the electronic storage or transmittal of health or health-related data.

(d) Additional information about the Blue Button℠ PHR functionality is available at *http://www.va.gov/bluebutton/, http://www.myhealth.va.gov/,* and *http://www.whitehouse.gov/open/innovations/BlueButton.*

Dated: July 13, 2011.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

[FR Doc. 2011–18014 Filed 7–15–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Rehabilitation Research and Development Service Scientific Merit Review Board; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that a meeting of the Rehabilitation Research and Development Service Scientific Merit Review Board will be held August 9–11 and 16–18, 2011, at the Sheraton Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, VA, from 8 a.m. to 5 p.m. each day. The following subcommittees of the Board will meet to evaluate merit review applications:

August 9—Rehabilitation Engineering and Prosthetics/Orthotics; Regenerative Medicine.

August 9–10—Aging & Neurodegenerative Disease; Psychological Health and Social Reintegration.

August 9–11—Brain Injury; Musculoskeletal/Orthopedic Rehabilitation.

August 16—Rehabilitation Engineering and Prosthetics/Orthotics.

August 16–17—Psychological Health and Social Reintegration; Sensory Systems/Communication; Spinal Cord Injury; and Career Development Award Program.

August 18—Rehabilitation Research and Development Centers of Excellence.

The purpose of the Board is to review rehabilitation research and development applications and advises the Director, Rehabilitation Research and Development Service, and the Chief Research and Development Officer on the scientific and technical merit, the mission relevance, and the protection of human and animal subjects.

A general session of each subcommittee meeting will be open to the public for approximately one hour at the start of each meeting to cover administrative matters and to discuss the general status of the program. The remaining portion of each subcommittee meeting will be closed to the public for the discussion, examination, reference to, and oral review of the research applications and critiques.

During the closed potion of each meeting, discussion and recommendations will include qualifications of the personnel conducting the studies (the disclosure of which would constitute a clearly unwarranted invasion of personal privacy), as well as research information (the premature disclosure of which would likely compromise significantly the implementation of proposed agency action regarding such research projects). As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).

Those who plan to attend the general session should contact Tiffany Asqueri, Designated Federal Officer, Rehabilitation Research and Development Service, at Department of

Veterans Affairs (10P9R), 810 Vermont Avenue, NW., Washington, DC 20420, or e-mail *tiffany.asqueri@va.gov* at least five days before the meeting. For further information, please call Mrs. Asqueri at (202) 443–5757.

By Direction of the Secretary.

Dated: July 12, 2011.

Vivian Drake,

Acting Committee Management Officer.

[FR Doc. 2011–17942 Filed 7–15–11; 8:45 am]

BILLING CODE

DEPARTMENT OF VETERANS AFFAIRS

Health Services Research and Development Service Merit Review Board; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that a meeting of the Health Services Research and Development Service Merit Review Board will be held August 30–31, 2011, at the Red Lion Hotel on Fifth Avenue, 1415 5th Avenue, Seattle, WA. Various subcommittees of the Board will meet. Each subcommittee meeting of the Merit Review Board will be open to the public the first day for approximately one half-hour from 8 a.m. until 8:30 a.m. to cover administrative matters and to discuss the general status of the program. The remaining portion of the meetings will be closed. The closed portion of each meeting will involve discussion, examination, reference to, and oral review of the research proposals and critiques.

The purpose of the Board is to review research and development applications involving the measurement and evaluation of health care services, the testing of new methods of health care delivery and management, and nursing research. Applications are reviewed for scientific and technical merit. Recommendations regarding funding are submitted to the Chief Research and Development Officer.

On August 30, the subcommittees on Nursing Research Initiatives and Research Best Practices will convene from 8 a.m. to 3 p.m.; and the Career Development Award will convene from 8 a.m. to 5:30 p.m. On August 31, the subcommittee on Career Development Award will reconvene from 8 a.m. to 3 p.m. and six subcommittees on Health Services Research (HSR 1—Medical Care and Clinical Management; HSR 2—Determinants of Patient Response to Care; HSR 3—Informatics and Research Methods Development; HSR 4—Mental and Behavioral Health; HSR 5—Health Care System Organization and Delivery; and HSR 6—Post-acute and Long-term Care) will convene from 8 a.m. to 5:30 p.m.

During the closed portion of each meeting, discussion and recommendations will include qualifications of the personnel conducting the studies (the disclosure of which would constitute a clearly unwarranted invasion of personal privacy), as well as research information (the premature disclosure of which would likely compromise significantly the implementation of proposed agency action regarding such research projects). As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing portions of each meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).

Those who plan to attend the open session should contact Kristy Benton-Grover, Scientific Merit Review Program Manager, at Department of Veterans Affairs, Health Services Research and Development (10P9H), 810 Vermont Avenue, NW., Washington, DC 20420, or e-mail at *Kristy.benton-grover@va.gov.* For further information, please call Mrs. Benton-Grover at (202) 443–5728.

By Direction of the Secretary.

Dated: July 12, 2011.

Vivian Drake,

Acting Committee Management Officer.

[FR Doc. 2011–17952 Filed 7–15–11; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 76 Monday,
No. 137 July 18, 2011

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services
42 CFR Parts 410, 411, 416 et al.

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 416, 419, 489, and 495

[CMS–1525–P]

RIN 0938–AQ26

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) to implement applicable statutory requirements and changes arising from our continuing experience with this system. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the OPPS. These proposed changes would be applicable to services furnished on or after January 1, 2012.

In addition, this proposed rule would update the revised Medicare ambulatory surgical center (ASC) payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In this proposed rule, we set forth the proposed relative payment weights and payment amounts for services furnished in ASCs, specific HCPCS codes to which these proposed changes would apply, and other proposed ratesetting information for the CY 2012 ASC payment system. These proposed changes would be applicable to services furnished on or after January 1, 2012.

We are proposing to revise the requirements for the Hospital Outpatient Quality Reporting (IQR) Program, add new requirements for ASC Quality Reporting System, and make additional changes to provisions of the Hospital Inpatient Value-Based Purchasing (VBP) Program.

We also are proposing to allow eligible hospitals and CAHs participating in the Medicare Electronic Health Record (EHR) Incentive Program to meet the clinical quality measure reporting requirement of the EHR Incentive Program for payment year 2012 by participating in the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot.

In addition, we are proposing to make changes to the rules governing the whole hospital and rural provider exceptions to the physician self-referral prohibition for expansion of facility capacity and changes to provider agreement regulations on patient notification requirements.

DATES: *Comment Period:* To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on August 30, 2011.

ADDRESSES: In commenting, please refer to file code CMS–1525–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically*. You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail*. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1525–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail*. You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1525–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier*. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION, CONTACT:

Paula Smith, (410) 786–0378, Hospital outpatient prospective payment issues.

Char Thompson, (410) 786–0378, Ambulatory surgical center issues.

Michele Franklin, (410) 786–4533, and Jana Lindquist, (410) 786–4533, Partial hospitalization and community mental health center issues.

James Poyer, (410) 786–2261, Reporting of Hospital Outpatient Quality Reporting (OQR) and ASC Quality Reporting Program issues.

Teresa Schell, (410) 786–8651, Physician Ownership and Investment in Hospitals issues.

Georganne Kuberski, (410) 786–0799, Patient Notification Requirements issues.

James Poyer, (410) 786–2261, and Ernessa Brawley (410) 786–2075, Hospital Value-Based Purchasing (VBP) Program issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have

been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys)*, a service of the U.S. Government Printing Office. This database can be accessed via the Internet at *http://www.gpo.gov/fdsys/*.

Addenda Available Only Through the Internet on the CMS Web Site

In the past, a majority of the Addenda referred to throughout the preamble of our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with this CY 2012 rule, all of the Addenda will no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda will be published and available only on the CMS Web site. The Addenda relating to the OPPS are available at: *http://www.cms.hhs.gov/HospitalOutpatientPPS*. The Addenda relating to the ASC payment system are available at: *http://www/cms.hhs.gov/ASCPayment/*. For complete details on the availability of the Addenda referenced in this proposed rule, we refer readers to section XVII. Readers who experience any problems accessing any of the Addenda that are posted on the CMS Web site identified above should contact Charles Braver at (410) 786–0378.

Alphabetical List of Acronyms Appearing in This Federal Register Document

ACEP American College of Emergency Physicians
AHA American Hospital Association
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
AMA American Medical Association
AMP Average Manufacturer Price
AOA American Osteopathic Association
APC Ambulatory Payment Classification
ARRA American Recovery and Reinvestment Act of 2009, Pub. L. 111–5
ASC Ambulatory Surgical Center
ASP Average Sales Price
AWP Average Wholesale Price
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Pub. L. 106–113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106–554
BLS Bureau of Labor Statistics
CAH Critical Access Hospital
CAP Competitive Acquisition Program
CBSA Core-Based Statistical Area
CCN CMS Certification Number
CCR Cost-to-Charge Ratio
CDC Centers for Disease Control
CERT Comprehensive Error Rate Testing
CLFS Clinical Laboratory Fee Schedule
CMHC Community Mental Health Center
CMS Centers for Medicare & Medicaid Services
CPT [Physicians'] Current Procedural Terminology, Fourth Edition, 2009, copyrighted by the American Medical Association
CQM Clinical Quality Measure
CR Cardiac Rehabilitation
CY Calendar Year
DFO Designated Federal Official
DHS Designated Health Service
DRA Deficit Reduction Act of 2005, Pub. L. 109–171
DSH Disproportionate Share Hospital
EACH Essential Access Community Hospital
E/M Evaluation and Management
EHR Electronic Health Record
ESRD End-Stage Renal Disease
FACA Federal Advisory Committee Act, Pub. L. 92–463
FAR Federal Acquisition Regulations
FDA Food and Drug Administration
FFS Fee-for-Service
FSS Federal Supply Schedule
FY Fiscal Year
GAO Government Accountability Office
HAC Hospital-Acquired Condition
HAI Healthcare-Associated Infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCERA Health Care and Education Reconciliation Act of 2010, Pub. L. 111–152
HCP Healthcare Personnel
HCPCS Healthcare Common Procedure Coding System
HCRIS Hospital Cost Report Information System
HHA Home Health Agency
HIPAA Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191
HOPD Hospital OutPatient Department
Hospital OQR Hospital Outpatient Quality Reporting
ICR Intensive Cardiac Rehabilitation
IDE Investigational Device Exemption
IHS Indian Health Service
I/OCE Integrated Outpatient Code Editor
IOL Intraocular Lens
IPPS [Hospital] Inpatient Prospective Payment System
MAC Medicare Administrative Contractor
MedPAC Medicare Payment Advisory Commission
MIEA–TRHCA Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006, Pub. L. 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110–275
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Pub. L. 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. 110–173
MPFS Medicare Physician Fee Schedule
MSA Metropolitan Statistical Area
NCCI National Correct Coding Initiative
NHSN National Healthcare Safety Network
NCD National Coverage Determination
NQF National Quality Forum
NTIOL New Technology Intraocular Lens
OIG [HHS] Office of the Inspector General
OMB Office of Management and Budget
OPD [Hospital] Outpatient Department
OPPS [Hospital] Outpatient Prospective Payment System
OQR Outpatient Quality Reporting
PBD Provider-Based Department
PHP Partial Hospitalization Program
PPI Producer Price Index
PPS Prospective Payment System
PR Pulmonary Rehabilitation
PRA Paperwork Reduction Act
QAPI Quality Assessment and Performance Improvement
QIO Quality Improvement Organization
RAC Recovery Audit Contractor
RFA Regulatory Flexibility Act
Hospital IQR Hospital Inpatient Quality Reporting
Hospital OQR Hospital Outpatient Quality Reporting
RHHI Regional Home Health Intermediary
SBA Small Business Administration
SCH Sole Community Hospital
SDP Single Drug Pricer
SI Status Indicator
TEP Technical Expert Panel
TOPs Transitional Outpatient Payments
VBP Value-Based Purchasing
WAC Wholesale Acquisition Cost

In this document, we address two payment systems under the Medicare program: The Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) payment system. In addition, we are proposing to make changes to the rules governing limitations on certain physician referrals to hospitals in which physicians have an ownership or investment interest, the provider agreement regulations on patient notification requirements, and the rules governing the Hospital Inpatient Value-Based Purchasing (VBP) Program. The provisions relating to the OPPS are included in sections I. through XII. and

section XIV. and sections XVII. through XXI. of this proposed rule. Addenda A, B, C, D1, D2, E, L, M, and N, which relate to the OPPS, are referenced in section XVII. of this proposed rule and are available via the Internet on the CMS Web site at the URL indicated in section XVII. The provisions related to the ASC payment system are included in sections XIII., XIV., and XVII. through XXI. of this proposed rule. Addenda AA, BB, DD1, DD2, and EE, which relate to the ASC payment system, are referenced in section XVII. of this proposed rule and are available via the Internet on the CMS Web site at the URL indicated in section XVII. The provisions relating to physician referrals to hospitals in which physicians have an ownership or investment interest and to the provider agreement regulations on patient notification requirements are included in section XV., and the provisions relating to the Hospital Inpatient VBP Program are included in section XVI. of this proposed rule.

Table of Contents

Regulation Text

I. Background and Summary of the CY 2012 OPPS/ASC Proposed Rule

A. Legislative and Regulatory Authority for the Hospital Outpatient Prospective Payment System

When Title XVIII of the Social Security Act (the Act) was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1,

2000. Implementing regulations for the OPPS are located at 42 CFR part 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; and most recently the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010. (These two public laws are collectively known as the Affordable Care Act, and most recently the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309).)

Under the OPPS, we pay for hospital outpatient services on a rate-per-service basis that varies according to the ambulatory payment classification (APC) group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which include certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC group. The OPPS includes payment for most hospital outpatient services, except those identified in section I.B. of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by community mental health centers (CMHCs)) and hospital outpatient services that are furnished to inpatients who have exhausted their Part A benefits, or who are otherwise not in a covered Part A stay.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the median cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

B. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercised the authority granted under the statute to also exclude from the OPPS those services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD composite rate; and services and procedures that require an inpatient stay that are paid under the hospital inpatient prospective payment system (IPPS). We set forth the services that are excluded from payment under the OPPS in 42 CFR 419.22 of the regulations.

Under § 419.20(b) of the regulations, we specify the types of hospitals and entities that are excluded from payment under the OPPS. These excluded entities include: Maryland hospitals, but only for services that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act; critical access hospitals (CAHs); hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service (IHS) hospitals.

C. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/*. The CY 2011 OPPS/ASC final rule with comment period appears in the November 24,

2010 **Federal Register** (75 FR 71800). In that final rule with comment period, we revised the OPPS to update the payment weights and conversion factor for services payable under the CY 2011 OPPS on the basis of claims data from January 1, 2009, through December 31, 2009, and to implement certain provisions of the Affordable Care Act. In addition, we responded to public comments received on the provisions of the CY 2010 final rule with comment period (74 FR 60316) pertaining to the APC assignment of HCPCS codes identified in Addendum B to that rule with the new interim (''NI'') comment indicator, and public comments received on the August 3, 2010 OPPS/ASC proposed rule for CY 2011 (75 FR 46170).

D. Advisory Panel on Ambulatory Payment Classification (APC) Groups

1. Authority of the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the APC Panel)

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an outside panel of experts to review the clinical integrity of the payment groups and their weights under the OPPS. The Act further specifies that the panel will act in an advisory capacity. The APC Panel, discussed under section I.D.2. of this proposed rule, fulfills these requirements. The APC Panel is not restricted to using data compiled by CMS, and it may use data collected or developed by organizations outside the Department in conducting its review.

2. Establishment of the APC Panel

On November 21, 2000, the Secretary signed the initial charter establishing the APC Panel. This expert panel, which may be composed of up to 15 representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) subject to the OPPS, reviews clinical data and advises CMS about the clinical integrity of the APC groups and their payment weights. The APC Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). Since its initial chartering, the Secretary has renewed the APC Panel's charter five times: on November 1, 2002; on November 1, 2004; on November 21, 2006; on November 2, 2008 and November 12, 2010. The current charter specifies, among other requirements, that: the APC Panel continues to be technical in nature; is governed by the provisions of the FACA; may convene up to three meetings per year; has a Designated Federal Official (DFO); and is chaired by a Federal Official designated by the Secretary.

The current APC Panel membership and other information pertaining to the APC Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS Web site at: *http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.*

3. APC Panel Meetings and Organizational Structure

The APC Panel first met on February 27 through March 1, 2001. Since the initial meeting, the APC Panel has held multiple meetings, with the last meeting taking place on February 28–March 1, 2011. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for APC Panel membership and to announce new members.

The APC Panel has established an operational structure that, in part, includes the use of three subcommittees to facilitate its required APC review process. The three current subcommittees are the Data Subcommittee, the Visits and Observation Subcommittee, and the Subcommittee for APC Groups and Status Indicator (SI) Assignments (previously known as the Packaging Subcommittee).

The Data Subcommittee is responsible for studying the data issues confronting the APC Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the APC Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS (for example, APC configurations and APC payment weights). The Subcommittee for APC Groups and SI Assignments advises the Panel on the following issues: the appropriate SIs to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid; and the appropriate APCs to be assigned to HCPCS codes regarding services for which separate payment is made.

Each of these subcommittees was established by a majority vote from the full APC Panel during a scheduled APC Panel meeting, and the APC Panel recommended that the subcommittees continue at the February/March 2011 APC Panel meeting. We accept those recommendations of the APC Panel. All subcommittee recommendations are discussed and voted upon by the full APC Panel.

Discussions of the other recommendations made by the APC Panel at the February/March 2011 APC Panel meeting are included in the sections of this proposed rule that are specific to each recommendation. For discussions of earlier APC Panel meetings and recommendations, we refer readers to previously published hospital OPPS/ASC proposed and final rules, the CMS Web site mentioned earlier in this section, and the FACA database at: *http://fido.gov/facadatabase/public.asp.*

E. Summary of the Major Contents of This CY 2012 OPPS/ASC Proposed Rule

In this proposed rule, we set forth proposed changes to the Medicare hospital OPPS for CY 2012 to implement statutory requirements and changes arising from our continuing experience with the system. In addition, we set forth proposed changes to the revised Medicare ASC payment system for CY 2012, including proposed updated payment weights, covered surgical procedures, and covered ancillary items and services based on the proposed OPPS update. In addition, we are proposing to make changes to the rules governing limitations on certain physician referrals to hospitals in which physicians have an ownership or investment interest, provider agreement regulations on patient notification requirements, and the rules governing the Hospital Inpatient Value-Based Purchasing (VBP) Program.

The following is a summary of the major changes that we are proposing to make for CY 2012:

1. Proposed Updates Affecting OPPS Payments

In section II. of this proposed rule, we set forth—

- The methodology used to recalibrate the proposed APC relative payment weights.
- The proposed changes to packaged services.
- The proposed update to the conversion factor used to determine payment rates under the OPPS. In this section, we are proposing changes in the amounts and factors for calculating the full annual update increase to the conversion factor.
- The proposed retention of our current policy to use the IPPS wage indices to adjust, for geographic wage differences, the portion of the OPPS payment rate and the copayment

standardized amount attributable to labor-related cost.

- The proposed update of statewide average default CCRs.
- The proposed application of hold harmless transitional outpatient payments (TOPs) for certain small rural hospitals, extended by section 3121 of the Affordable Care Act.
- The proposed payment adjustment for rural SCHs.
- The proposed calculation of the hospital outpatient outlier payment.
- The calculation of the proposed national unadjusted Medicare OPPS payment.
- The proposed beneficiary copayments for OPPS services.

2. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

In section III. of this proposed rule, we discuss—

- The proposed additions of new HCPCS codes to APCs.
- The proposed establishment of a number of new APCs.
- Our analyses of Medicare claims data and certain recommendations of the APC Panel.
- The application of the 2 times rule and proposed exceptions to it.
- The proposed changes to specific APCs.
- The proposed movement of procedures from New Technology APCs to clinical APCs.

3. Proposed OPPS Payment for Devices

In section IV. of this proposed rule, we discuss the proposed pass-through payment for specific categories of devices and the proposed adjustment for devices furnished at no cost or with partial or full credit.

4. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

In section V. of this proposed rule, we discuss the proposed CY 2012 OPPS payment for drugs, biologicals, and radiopharmaceuticals, including the proposed payment for drugs, biologicals, and radiopharmaceuticals with and without pass-through status.

5. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

In section VI. of this proposed rule, we discuss the estimate of CY 2012 OPPS transitional pass-through spending for drugs, biologicals, and devices.

6. Proposed OPPS Payment for Hospital Outpatient Visits

In section VII. of this proposed rule, we set forth our proposed policies for the payment of clinic and emergency department visits and critical care services based on claims data.

7. Proposed Payment for Partial Hospitalization Services

In section VIII. of this proposed rule, we set forth our proposed payment for partial hospitalization services, including the proposed separate threshold for outlier payments for CMHCs.

8. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

In section IX. of this proposed rule, we discuss the procedures that we are proposing to remove from the inpatient list and assign to APCs for payment under the OPPS.

9. Proposed Policies on Supervision Standards for Outpatient Services in Hospitals and CAHs

In section X. of this proposed rule, we discuss proposed policy changes relating to the supervision of outpatient services furnished in hospitals and CAHs.

10. Proposed OPPS Payment Status and Comment Indicators

In section XI. of this proposed rule, we discuss our proposed changes to the definitions of status indicators assigned to APCs and present our proposed comment indicators.

11. OPPS Policy and Payment Recommendations

In section XII. of this proposed rule, we address recommendations made by the Medicare Payment Advisory Commission (MedPAC) in its March 2011 report to Congress, by the Office of Inspector General (OIG), and by the APC Panel regarding the OPPS for CY 2012.

12. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

In section XIII. of this proposed rule, we discuss the proposed updates of the revised ASC payment system and payment rates for CY 2012.

13. Reporting Quality Data for Annual Payment Rate Updates

In section XIV. of this proposed rule, we discuss the proposed measures for reporting hospital outpatient quality data for the OPD fee schedule increase factor for CY 2013 and subsequent calendar years; set forth the requirements for data collection and submission; and discuss the reduction to the OPPS OPD fee schedule increase factor for hospitals that fail to meet the Hospital OQR Program requirements. We also discuss proposed measures for reporting ASC quality data for the annual payment update factor for CYs 2014, 2015, and 2016; and set forth the requirements for data collection and submission for the annual payment update.

14. Proposed Changes to EHR Incentive Program for Eligible Hospitals and CAHs Regarding Electronic Submission of Clinical Quality Measures (CQMs)

In section XIV.J. of this proposed rule, we are proposing to allow eligible hospitals and CAHs participating in the Medicare EHR Incentive Program to meet the CQM reporting requirement of the EHR Incentive Program for payment year 2012 by participating in the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot.

15. Proposed Changes to Provisions Relating to Physician Self-Referral Prohibition and Provider Agreement Regulations on Patient Notification Requirements

In section XV. of this proposed rule, we present our proposed exception process for expansion of facility capacity under the whole hospital and rural provider exceptions to the physician self-referral law, and proposed changes to the provider agreement regulations on patient notification requirements.

16. Additional Proposed Changes Relating to the Hospital Inpatient VBP Program

In section XVI. of this proposed rule, we present our proposed requirements for the FY 2014 Hospital Inpatient VBP Program.

17. Economic and Federalism Analyses

In sections XX. and XXI. of this proposed rule, we set forth an analysis of the regulatory and federalism impacts that the proposed changes would have on affected entities and beneficiaries.

F. Public Comments Received on the CY 2011 OPPS/ASC Final Rule With Comment Period

We received approximately 43 timely pieces of correspondence on the CY 2011 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 24, 2010 (75 FR 71800), some of which contained multiple comments on the interim APC assignments and/or status indicators of HCPCS codes identified with comment indicator ''NI'' in Addendum B to that final rule with comment period. We will

present summaries of those public comments on topics open to comment in the CY 2012 OPPS/ASC final rule with comment period and our responses to them under appropriate headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review and revise the relative payment weights for APCs at least annually. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For the CY 2012 OPPS, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2012, and before January 1, 2013 (CY 2012), using the same basic methodology that we described in the CY 2011 OPPS/ASC final rule with comment period. That is, we are proposing to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights. For the purpose of recalibrating the proposed APC relative payment weights for CY 2012, we used approximately 138 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for hospital outpatient department services furnished on or after January 1, 2010, and before January 1, 2011. (For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/HORD/*.)

Of the 138 million final action claims for services provided in hospital outpatient settings used to calculate the proposed CY 2012 OPPS payment rates for this proposed rule, approximately 105 million claims were the type of bill potentially appropriate for use in setting rates for OPPS services (but did not necessarily contain services payable under the OPPS). Of the 105 million claims, approximately 3 million claims were not for services paid under the OPPS or were excluded as not appropriate for use (for example, erroneous cost-to-charge ratios (CCRs) or no HCPCS codes reported on the claim). From the remaining approximately 102 million claims, we created approximately 100 million single records, of which approximately 67 million were ''pseudo'' single or ''single session'' claims (created from approximately 23 million multiple procedure claims using the process we discuss later in this section). Approximately 888,000 claims were trimmed out on cost or units in excess of ±3 standard deviations from the geometric mean, yielding approximately 99 million single bills for median setting. As described in section II.A.2. of this proposed rule, our data development process is designed with the goal of using appropriate cost information in setting the APC relative weights. The bypass process is described in section II.A.1.b. of this proposed rule. This section discusses how we develop ''pseudo'' single procedure claims (as defined below), with the intention of using more appropriate data from the available claims. In some cases, the bypass process allows us to use some portion of the submitted claim for cost estimation purposes, while the remaining information on the claim continues to be unusable. Consistent with the goal of using appropriate information in our data development process, we are proposing to only use claims (or portions of each claim) that are appropriate for ratesetting purposes. Ultimately, we were able to use for CY 2012 ratesetting some portion of approximately 94 percent of the CY 2010 claims containing services payable under the OPPS.

The proposed APC relative weights and payments for CY 2012 in Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) were calculated using claims from CY 2010 that were processed before January 1, 2011, and continue to be based on the median hospital costs for services in the APC groups. Under the proposed methodology, we select claims for services paid under the OPPS and match these claims to the most recent cost report filed by the individual hospitals represented in our claims data. We continue to believe that it is appropriate to use the most current full calendar year claims data and the most recently submitted cost reports to calculate the median costs underpinning the APC relative payment weights and the CY 2012 payment rates.

b. Proposed Use of Single and Multiple Procedure Claims

For CY 2012, in general, we are proposing to continue to use single procedure claims to set the medians on which the APC relative payment weights would be based, with some exceptions as discussed below in this section. We generally use single procedure claims to set the median costs for APCs because we believe that the OPPS relative weights on which payment rates are based should be derived from the costs of furnishing one unit of one procedure and because, in many circumstances, we are unable to ensure that packaged costs can be appropriately allocated across multiple procedures performed on the same date of service.

It is generally desirable to use the data from as many claims as possible to recalibrate the APC relative payment weights, including those claims for multiple procedures. As we have for several years, we are proposing to continue to use date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims. Through bypassing specified codes that we believe do not have significant packaged costs, we are able to use more data from multiple procedure claims. In many cases, this enabled us to create multiple ''pseudo'' single procedure claims from claims that were submitted as multiple procedure claims spanning multiple dates of service, or claims that contained numerous separately paid procedures reported on the same date on one claim. We refer to these newly created single procedure claims as ''pseudo'' single procedure claims. The history of our use of a bypass list to generate ''pseudo'' single procedure claims is well documented, most recently in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71811 through 71822). In addition, for CY 2008, we increased packaging and created the first composite APCs. We have continued our packaging policies and the creation of composite APCs for CY 2009, 2010, and 2011, and we are proposing to continue them for CY 2012. Increased packaging and creation of composite APCs also increased the number of bills that we were able to use for median calculation by enabling us to use claims that contained multiple major procedures that previously would not have been usable. Further, for CY 2009, we expanded the composite APC model to one additional clinical area, multiple imaging services (73 FR 68559 through 68569), which also increased

the number of bills we were able to use to calculate APC median costs. We have continued the composite APCs for multiple imaging services for CYs 2010 and 2011, and we are proposing to continue to create them for CY 2012. We refer readers to section II.A.2.e. of this proposed rule for discussion of the use of claims to establish median costs for composite APCs.

We are proposing to continue to apply these processes to enable us to use as much claims data as possible for ratesetting for the CY 2012 OPPS. This methodology enabled us to create, for this proposed rule, approximately 67 million ''pseudo'' single procedure claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.e.(5) of the proposed rule for further discussion), to add to the approximately 33 million ''natural'' single procedure claims. For this proposed rule, ''pseudo'' single procedure and ''single session'' procedure bills represented approximately 67 percent of all single procedure bills used to calculate median costs.

For CY 2012, we are proposing to bypass 460 HCPCS codes for CY 2012 that are identified in Addendum N to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site). Since the inception of the bypass list, which is the list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims, we have calculated the percent of ''natural'' single bills that contained packaging for each HCPCS code and the amount of packaging on each ''natural'' single bill for each code. Each year, we generally retain the codes on the previous year's bypass list and use the updated year's data (for CY 2012, data available for the February 28–March 1, 2011 APC Panel meeting from CY 2010 claims processed through September 30, 2010, and CY 2009 claims data processed through June 30, 2010, used to model the payment rates for CY 2011) to determine whether it would be appropriate to propose to add additional codes to the previous year's bypass list. For CY 2012, we are proposing to continue to bypass all of the HCPCS codes on the CY 2011 OPPS bypass list because they continue to meet the established empirical criteria for the bypass list. We updated HCPCS codes on the CY 2011 bypass list that were mapped to new HCPCS codes for CY 2012 ratesetting by evaluating data for the replacement codes under the empirical criteria described below and also removing the HCPCS codes that we are proposing to be deleted for CY 2012, which are listed in Table 1 of this proposed rule. We also are proposing to remove HCPCS codes that are not separately paid under the OPPS because the purpose of the bypass list is to obtain more data for those codes relevant to ratesetting. None of these deleted codes were ''overlap bypass codes'' (those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs). We also are proposing to add to the bypass list for CY 2012 all HCPCS codes not on the CY 2011 bypass list that, using either the CY 2011 final rule data (CY 2009 claims) or the February 28–March 1, 2011 APC Panel data (first 9 months of CY 2010 claims), met the empirical criteria for the bypass list that are summarized below. The entire list proposed for CY 2012 (including the codes that remain on the bypass list from prior years) is open to public comment. Because we must make some assumptions about packaging in the multiple procedure claims in order to assess a HCPCS code for addition to the bypass list, we assumed that the representation of packaging on ''natural'' single procedure claims for any given code is comparable to packaging for that code in the multiple procedure claims. The proposed criteria for the bypass list are:

- There are 100 or more ''natural'' single procedure claims for the code. This number of single procedure claims ensures that observed outcomes are sufficiently representative of packaging that might occur in the multiple claims.
- Five percent or fewer of the ''natural'' single procedure claims for the code have packaged costs on that single procedure claim for the code. This criterion results in limiting the amount of packaging being redistributed to the separately payable procedures remaining on the claim after the bypass code is removed and ensures that the costs associated with the bypass code represent the cost of the bypassed service.
- The median cost of packaging observed in the ''natural'' single procedure claims is equal to or less than $55. This criterion also limits the amount of error in redistributed costs. During the assessment of claims against the bypass criteria, we do not know the dollar value of the packaged cost that should be appropriately attributed to the other procedures on the claim. Therefore, ensuring that redistributed costs associated with a bypass code are small in amount and volume protects the validity of cost estimates for low cost services billed with the bypassed service.

In response to comments to the CY 2010 OPPS/ASC proposed rule requesting that the packaged cost threshold be updated, we considered whether it would be appropriate to update the $50 packaged cost threshold for inflation when examining potential bypass list additions. As discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60328), the real value of this packaged cost threshold criterion has declined due to inflation, making the packaged cost threshold more restrictive over time when considering additions to the bypass list. Therefore, adjusting the threshold by the market basket would prevent continuing decline in the threshold's real value. For CY 2011, based on CY 2009 claims data, we proposed to apply the final market basket of 3.6 percent published in the CY 2009 OPPS/ASC final rule with comment period (73 FR 26584) to the $50 packaged cost threshold used in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60325). This calculation led us to a proposed packaged cost threshold for bypass list additions for CY 2011 of $50 ($51.80 rounded to $50). We stated that we believe that applying the market basket from the year of claims data to the packaged cost threshold, rounded to the nearest $5 increment, would appropriately account for the effects of inflation when considering additions to the bypass list because the market basket increase percentage reflects the extent to which the price of inputs for hospital services has increased compared to the price of inputs for hospital services in the prior year. We are proposing for CY 2012, based on the same rationale described for the CY 2011 OPPS/ASC final rule with comment period (75 CFR 71812), to continue to update the packaged cost threshold by the market basket. By applying the final CY 2011 market basket increase of 1.85 percent to the prior non-rounded dollar threshold of $51.80 (75 FR 71812), we determined that the threshold increases for CY 2012 to $55 ($52.76 rounded to $55, the nearest $5 increment). Therefore, we are proposing to set the median packaged cost threshold on the CY 2010 claims at $55 for a code to be considered for addition to the CY 2012 OPPS bypass list.

- The code is not a code for an unlisted service.

In addition, we are proposing to continue to include, on the bypass list, HCPCS codes that CMS medical advisors believe have minimal associated packaging based on their clinical assessment of the complete CY 2012 OPPS proposal. Some of these

codes were identified by CMS medical advisors and some were identified in prior years by commenters with specialized knowledge of the packaging associated with specific services. We also are proposing to continue to include on the bypass list certain HCPCS codes in order to purposefully direct the assignment of packaged costs to a companion code where services always appear together and where there would otherwise be few single procedure claims available for ratesetting. For example, we have previously discussed our reasoning for adding HCPCS code G0390 (Trauma response team associated with hospital critical care service) and the CPT codes for additional hours of drug administration to the bypass list (73 FR 68513 and 71 FR 68117 through 68118).

As a result of the multiple imaging composite APCs that we established in CY 2009, the program logic for creating ''pseudo'' single procedure claims from bypassed codes that are also members of multiple imaging composite APCs changed. When creating the set of ''pseudo'' single procedure claims, claims that contain ''overlap bypass codes'' (those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs) were identified first. These HCPCS codes were then processed to create multiple imaging composite ''single session'' bills, that is, claims containing HCPCS codes from only one imaging family, thus suppressing the initial use of these codes as bypass codes. However, these ''overlap bypass codes'' were retained on the bypass list because, at the end of the ''pseudo'' single processing logic, we reassessed the claims without suppression of the ''overlap bypass codes'' under our longstanding ''pseudo'' single process to determine whether we could convert additional claims to ''pseudo'' single procedure claims. (We refer readers to section II.A.2.b. of this proposed rule for further discussion of the treatment of ''overlap bypass codes.'') This process also created multiple imaging composite ''single session'' bills that could be used for calculating composite APC median costs. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in Addendum N to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

Addendum N to this proposed rule includes the proposed list of bypass codes for CY 2012. The list of bypass codes contains codes that were reported on claims for services in CY 2010 and, therefore, includes codes that were in effect in 2010 and used for billing but were deleted for CY 2011. We retained these deleted bypass codes on the proposed CY 2012 bypass list because these codes existed in CY 2010 and were covered OPD services in that period, and CY 2010 claims data are used to calculate 2012 payment rates. Keeping these deleted bypass codes on the bypass list potentially allowed us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that were members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add for CY 2012 are identified by asterisks (*) in the fourth column of Addendum N.

Table 1 below contains the list of codes that we are proposing to remove from the CY 2012 bypass list because these codes were either deleted from the HCPCS before CY 2010 (and therefore were not covered OPD services in CY2010) or were not separately payable codes under the proposed CY 2012 OPPS because these codes are not used for ratesetting (and therefore would not need to be bypassed). None of these proposed deleted codes were ''overlap bypass'' codes.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2012 BYPASS LIST

HCPCS Code	HCPCS Short descriptor
29220	Strapping of low back
78350	Bone mineral, single photon
90816	Psytx, hosp, 20–30 min
90818	Psytx, hosp, 45–50 min
90826	Intac psytx, hosp, 45–50 min
99241	Office consultation
99242	Office consultation
99243	Office consultation
99244	Office consultation
99245	Office consultation
0144T	CT heart wo dye; qual calc

c. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2012, we are proposing to continue to use the hospital-specific overall ancillary and departmental CCRs to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC median costs on which the proposed CY 2012 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2010 claims data from the most recent available hospital cost reports, in most cases, cost reports beginning in CY 2009. For the CY 2012 OPPS proposed rates, we used the set of claims processed during CY 2010. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/03_crosswalk.asp#TopOfPage*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2010 (the year of the claims data we used to calculate the proposed CY 2012 OPPS payment rates). For CY 2010, the National Uniform Billing Committee added revenue codes 860 (Magnetoencephalography (MEG); general classification) and 861 (Magnetoencephalography (MEG)). For purposes of applying a CCR to charges reported under revenue codes 860 and 861, we are proposing to use nonstandard Medicare cost report cost center 3280 (Electrocardiogram (EKG) and Electroencephalography (EEG)) as the primary cost center and to use standard cost center 5400 (Electroencephalography (EEG)) as the secondary cost center. We believe that MEG, which evaluates brain activity, is similar to EEG, which also evaluates brain activity, and that the few hospitals that furnish MEG are likely to furnish it in the same department of the hospital in which they furnish EEG services. Therefore, we believe that the CCRs that we apply to the EEG revenue codes are more likely to result in a more accurate estimated cost for MEG than would the application of the hospital-specific overall ancillary CCR. For hospitals that report charges under revenue code 860 or 861 but do not report costs on their cost report under cost center 3280 or 5400, we are proposing to apply the hospital-specific overall CCR to the charges reported under revenue code 860 or 861 for purposes of estimating the cost of these services. We note that revenue codes with effective dates in CY 2011 are not relevant to this process because these new revenue codes were not applicable to claims for services furnished during CY 2010.

In accordance with our longstanding policy, we calculated CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculated CCRs was the hospital-specific departmental level.

For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). One longstanding exception to this general methodology for calculation of CCRs used for converting charges to costs on each claim is the calculation of median blood costs, as discussed in section II.A.2.d.(2) of this proposed rule and which has been our standard policy since the CY 2005 OPPS.

For the CCR calculation process, we used the same general approach that we used in developing the final APC rates for CY 2007 and thereafter, using the revised CCR calculation that excluded the costs of paramedical education programs and weighted the outpatient charges by the volume of outpatient services furnished by the hospital. We refer readers to the CY 2007 OPPS/ASC final rule with comment period for more information (71 FR 67983 through 67985). We first limited the population of cost reports to only those for hospitals that filed outpatient claims in CY 2010 before determining whether the CCRs for such hospitals were valid.

We then calculated the CCRs for each cost center and the overall ancillary CCR for each hospital for which we had claims data. We did this using hospital-specific data from the Hospital Cost Report Information System (HCRIS). We used the most recent available cost report data, in most cases, cost reports with cost reporting periods beginning in CY 2009. For this proposed rule, we are using the most recently submitted cost reports to calculate the CCRs to be used to calculate median costs for the proposed CY 2012 OPPS payment rates. If the most recent available cost report was submitted but not settled, we looked at the last settled cost report to determine the ratio of submitted to settled cost using the overall ancillary CCR, and we then adjusted the most recent available submitted, but not settled, cost report using that ratio. We then calculated both an overall ancillary CCR and cost center-specific CCRs for each hospital. We used the overall ancillary CCR referenced in this section II.A.1.c. of this proposed rule for all purposes that require use of an overall ancillary CCR. We are proposing to continue this longstanding methodology for the calculation of median costs for CY 2012.

Since the implementation of the OPPS, some commenters have raised concerns about potential bias in the OPPS cost-based weights due to ''charge compression,'' which is the practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services. As a result, the cost-based weights may reflect some aggregation bias, undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR, is applied to items of widely varying costs in the same cost center.

To explore this issue, in August 2006, we awarded a contract to RTI International (RTI) to study the effects of charge compression in calculating the IPPS cost-based relative weights, particularly with regard to the impact on inpatient diagnosis-related group (DRG) payments, and to consider methods to better capture the variation in cost and charges for individual services when calculating costs for the IPPS relative weights across services in the same cost center. RTI issued a report in March 2007 with its findings on charge compression, which is available on the CMS Web site at: *http://www.cms.gov/reports/downloads/Dalton.pdf*. Although this report was focused largely on charge compression in the context of the IPPS cost-based relative weights, because several of the findings were relevant to the OPPS, we discussed that report in the CY 2008 OPPS/ASC proposed rule (72 FR 42641 through 42643) and discussed those findings again in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66599 through 66602).

In August 2007, we contracted with RTI to evaluate the cost estimation process for the OPPS relative weights because its 2007 report had concentrated on IPPS DRG cost-based relative weights. The results of RTI's analyses had implications for both the OPPS APC cost-based relative weights and the IPPS MS–DRG (Medicare severity) cost-based relative weights. The RTI final report can be found on RTI's Web site at: *http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf*. For a complete discussion of the RTI recommendations, public comments, and our responses, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527).

We addressed the RTI finding that there was aggregation bias in both the IPPS and the OPPS cost estimation of expensive and inexpensive medical supplies in the FY 2009 IPPS final rule. Specifically, we finalized our proposal for both the OPPS and IPPS to create one cost center for ''Medical Supplies Charged to Patients'' and one cost center for ''Implantable Devices Charged to Patients,'' essentially splitting the then current CCR for ''Medical Supplies and Equipment'' into one CCR for low-cost medical supplies and another CCR for high-cost implantable devices in order to mitigate some of the effects of charge compression. Accordingly, in Transmittal 20 of the Provider Reimbursement Manual, Part II (PRM–II), Chapter 36, Form CMS–2552–96, which was issued in July 2009, we created a new subscripted Line 55.01 on Worksheet A for the ''Implantable Devices Charged to Patients'' cost center. This new subscripted cost center, placed under the standard line for ''Medical Supplies Charged to Patients,'' is available for use for cost reporting periods beginning on or after May 1, 2009. A subscripted cost center is the addition of a separate new cost center line and description which bears a logical relationship to the standard cost center line and is located immediately following a standard cost center line. Subscripting a cost center line adds flexibility and cost center expansion capability to the cost report. For example, Line 55 of Worksheet A on Form CMS 2552–96 (the Medicare hospital cost report) is ''Medical Supplies Charged to Patients.'' The additional cost center, which isolates the costs of ''Implantable Medical Supplies Charged to Patients'', was created by adding subscripted Line 55.01 to Worksheet A and is defined as capturing the costs and charges billed with the following UB–04 revenue codes: 0275 (Pacemaker); 0276 (Intraocular lens); 0278 (other implants); and 0624 (FDA investigations devices) (73 FR 48458).

In preparation for the FY 2012 IPPS proposed rule and this CY 2012 OPPS proposed rule, we have assessed the availability of data in the ''Implantable Devices Charged to Patients'' cost center. In order to develop a robust analysis regarding the use of cost data from the ''Implantable Devices Charged to Patients'' cost center, we believe that it is necessary to have a critical mass of cost reports filed with data in this cost center. The cost center for ''Implantable Devices Charged to Patients'' is effective for cost reporting periods beginning on or after May 1, 2009. We have checked the availability of CY 2009 cost reports in the December 31, 2010 quarter ending update of HCRIS, which is the latest upload of CY 2009 cost report data that we could use for this proposed rule. We have determined that there are only 437 hospitals that have completed the ''Implantable Devices Charged to Patients'' cost center (out of approximately 3,500 IPPS hospitals). We do not believe this is a sufficient

amount of data from which to generate a meaningful analysis. Therefore, we are not proposing to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for Implantable Devices Charged to Patients for use in calculating the OPPS relative weights for CY 2012. We will reassess the availability of data for the ''Implantable Devices Charged to Patients'' cost center for the CY 2013 OPPS rulemaking cycle. Because there is approximately a 3-year lag in the availability of cost report data for IPPS and OPPS ratesetting purposes in a given calendar year, we believe we may be able to use data from the revised Medicare hospital cost report form to estimate costs from charges for implantable devices for the CY 2013 OPPS relative weights. For a complete discussion of the rationale for the creation of the new cost center for ''Implantable Devices Charged to Patients,'' public comments, and our responses, we refer readers to the FY 2009 IPPS final rule (73 FR 48458 through 45467).

In the CY 2009 OPPS/ASC final rule with comment period, we indicated that we would be making some other OPPS-specific changes in response to the RTI report recommendations. Specifically, these changes included modifications to the cost reporting software and the addition of three new nonstandard cost centers. With regard to modifying the cost reporting preparation software in order to offer additional descriptions for nonstandard cost centers to improve the accuracy of reporting for nonstandard cost centers, we indicated that the change would be made for the next release of the cost report software. These changes have been made to the cost reporting software with the implementation of CMS Transmittal 21, under Chapter 36 of the PRM–II, available on the CMS Web site at: *http://www.cms.hhs.gov/Manuals/PBM/,* which is effective for cost reporting periods ending on or after October 1, 2009.

We also indicated that we intended to add new nonstandard cost centers for ''Cardiac Rehabilitation,'' ''Hyperbaric Oxygen Therapy,'' and ''Lithotripsy.'' We note that, in January 2010, CMS issued Transmittal 21 which updated the PRM–II, Chapter 36, Form CMS–2552–96. One of the updates in this transmittal established nonstandard cost centers for ''Cardiac Rehabilitation,'' ''Hyperbaric Oxygen Therapy,'' and ''Lithotripsy'' for use on Worksheet A. These three new nonstandard cost centers became available for cost reporting periods ending on or after October 1, 2009, and are included in the revenue code to cost center crosswalk we are proposing to use for calculating payment rates for CY 2012 OPPS. Specifically, the nonstandard cost centers are: 3120 (Cardiac Catheterization Laboratory); 3230 (CAT Scan); 3430 (Magnetic Resonance Imaging (MRI)). The revenue code to cost center crosswalk that we are proposing to use for purposes of estimating the median costs of items and services for the CY 2012 OPPS is available for review and continuous comment (outside of comment on this proposed rule) on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/03_crosswalk.asp#TopOfPage.*

Furthermore, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create new standard cost centers for ''Computed Tomography (CT),'' ''Magnetic Resonance Imaging (MRI),'' and ''Cardiac Catheterization,'' and to require that hospitals report the costs and charges for these services under new cost centers on the revised Medicare cost report Form CMS 2552–10. As we discussed in the FY 2009 IPPS/LTCH PPS and CY 2009 OPPS/ASC proposed and final rules, RTI found that the costs and charges of CT scans, MRI, and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI also concluded that both the IPPS and OPPS relative weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRI, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the cost from charges on claims data. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a more detailed discussion on the reasons for the creation of standard cost centers for CT scans, MRI, and cardiac catheterization.) The new standard cost centers for MRI, CT scans, and cardiac catheterization are effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10. CMS issued the new hospital cost report Form CMS–2552–10 on December 30, 2010. The new cost report form can be accessed at the CMS Web site at: *https://www.cms.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS021935&intNumPerPage=10.* Once at this Web site, users should double click on ''Chapter 40.''

We believe that improved cost report software, the incorporation of new standard and nonstandard cost centers, and the elimination of outdated requirements will improve the accuracy of the cost data contained in the electronic cost report data files and, therefore, the accuracy of our cost estimation processes for the OPPS relative weights. We will continue our standard practice of examining ways in which we can improve the accuracy of our cost estimation processes.

2. Proposed Data Development Process and Calculation of Median Costs

In this section of this proposed rule, we discuss the use of claims to calculate proposed OPPS payment rates for CY 2012. The hospital OPPS page on the CMS Web site on which this proposed rule is posted provides an accounting of claims used in the development of the proposed payment rates at: *http://www.cms.gov/HospitalOutpatientPPS.* The accounting of claims used in the development of this proposed rule is included on the CMS Web site under supplemental materials for this CY 2012 OPPS/ASC proposed rule. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available for purchase under a CMS data use agreement. Our CMS Web site, *http://www.cms.gov/HospitalOutpatientPPS,* includes information about purchasing the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–9–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2010 claims that were used to calculate the proposed payment rates for the CY 2012 OPPS.

We used the methodology described in sections II.A.2.a. through II.A.2.e. of this proposed rule to calculate the median costs we use to establish the relative weights used in calculating the proposed OPPS payment rates for CY 2012 shown in Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC median costs to scaled payment weights.

a. Claims Preparation

For this proposed rule, we used the CY 2010 hospital outpatient claims

processed before January 1, 2011, to calculate the median costs of APCs that underpin the proposed relative weights for CY 2012. To begin the calculation of the relative weights for CY 2012, we pulled all claims for outpatient services furnished in CY 2010 from the national claims history file. This is not the population of claims paid under the OPPS, but all outpatient claims (including, for example, critical access hospital (CAH) claims and hospital claims for clinical laboratory services for persons who are neither inpatients nor outpatients of the hospital).

We then excluded claims with condition codes 04, 20, 21, and 77 because these are claims that providers submitted to Medicare knowing that no payment would be made. For example, providers submit claims with a condition code 21 to elicit an official denial notice from Medicare and document that a service is not covered. We then excluded claims for services furnished in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands because hospitals in those geographic areas are not paid under the OPPS, and, therefore, we do not use claims for services furnished in these areas in ratesetting.

We divided the remaining claims into the three groups shown below. Groups 2 and 3 comprise the 105 million claims that contain hospital bill types paid under the OPPS.

1. Claims that were not bill types 12X, 13X (hospital bill types), 14X (laboratory specimen bill types), or 76X (CMHC bill types). Other bill types are not paid under the OPPS and, therefore, these claims were not used to set OPPS payment.

2. Claims that were bill types 12X, 13X or 14X. Claims with bill types 12X and 13X are hospital outpatient claims. Claims with bill type 14X are laboratory specimen claims, of which we use a subset for the limited number of services in these claims that are paid under the OPPS.

3. Claims that were bill type 76X (CMHC).

To convert charges on the claims to estimated cost, we multiplied the charges on each claim by the appropriate hospital-specific CCR associated with the revenue code for the charge as discussed in section II.A.1.c. of this proposed rule. We then flagged and excluded CAH claims (which are not paid under the OPPS) and claims from hospitals with invalid CCRs. The latter included claims from hospitals without a CCR; those from hospitals paid an all-inclusive rate; those from hospitals with obviously erroneous CCRs (greater than 90 or less than 0.0001); and those from hospitals with overall ancillary CCRs that were identified as outliers (3 standard deviations from the geometric mean after removing error CCRs). In addition, we trimmed the CCRs at the cost center (that is, departmental) level by removing the CCRs for each cost center as outliers if they exceeded +/− 3 standard deviations from the geometric mean. We used a four-tiered hierarchy of cost center CCRs, which is the revenue code-to-cost center crosswalk, to match a cost center to every possible revenue code appearing in the outpatient claims that is relevant to OPPS services, with the top tier being the most common cost center and the last tier being the default CCR. If a hospital's cost center CCR was deleted by trimming, we set the CCR for that cost center to ''missing'' so that another cost center CCR in the revenue center hierarchy could apply. If no other cost center CCR could apply to the revenue code on the claim, we used the hospital's overall ancillary CCR for the revenue code in question as the default CCR. For example, if a visit was reported under the clinic revenue code but the hospital did not have a clinic cost center, we mapped the hospital-specific overall ancillary CCR to the clinic revenue code. The revenue code-to-cost center crosswalk is available for inspection and comment on the CMS Web site: *http://www.cms.gov/HospitalOutpatientPPS*. Revenue codes that we do not use to set medians or to model impacts are identified with an ''N'' in the revenue code-to-cost center crosswalk.

We applied the CCRs as described above to claims with bill type 12X, 13X, or 14X, excluding all claims from CAHs and hospitals in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands and claims from all hospitals for which CCRs were flagged as invalid.

We identified claims with condition code 41 as partial hospitalization services of hospitals and moved them to another file. We note that the separate file containing partial hospitalization claims is included in the files that are available for purchase as discussed above.

We then excluded claims without a HCPCS code. We moved to another file claims that contained nothing but influenza and pneumococcal pneumonia (PPV) vaccines. Influenza and PPV vaccines are paid at reasonable cost and, therefore, these claims are not used to set OPPS rates.

We next copied line-item costs for drugs, blood, and brachytherapy sources to a separate file (the lines stay on the claim, but are copied onto another file). No claims were deleted when we copied these lines onto another file. These line-items are used to calculate a per unit mean and median cost and a per day mean and median cost for drugs and nonimplantable biologicals, therapeutic radiopharmaceutical agents, and brachytherapy sources, as well as other information used to set payment rates, such as a unit-to-day ratio for drugs.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60517), we first adopted a policy to redistribute some portion of total cost of packaged drugs and biologicals to the separately payable drugs and biologicals as acquisition and pharmacy overhead and handling costs. As discussed further in section V.B.3. of this proposed rule, we are proposing to continue this policy for CY 2012. Therefore, we used the line-item cost data for drugs and biologicals for which we had a HCPCS code with ASP pricing information to calculate the ASP+X values, first for all drugs and biologicals with HCPCS codes, whether separately paid or packaged, and then for separately payable drugs and biologicals and for packaged drugs and biologicals, respectively, by taking the ratio of total claim cost for each group relative to total ASP dollars (per unit of each drug or biological HCPCS code's April 2011 ASP amount multiplied by total units for each drug or biological in the CY 2010 claims data). These values are ASP+11 percent (for all drugs and biologicals with HCPCS codes, whether separately paid or packaged), ASP–2 percent (for drugs and biologicals that are separately paid), and ASP+188 percent (for drugs and biologicals that have HCPCS codes and that are packaged), respectively. As we discuss in section V.B.3. of this proposed rule, we are proposing to redistribute $161 million of the total cost in our claims data for coded packaged drugs and biologicals with an ASP to payment for separately payable drugs and biologicals. We also are proposing to redistribute an additional $54 million from the cost of uncoded packaged drugs billed under pharmacy revenue code series 025X (Pharmacy (also see 063X, an extension of 025X)), 026X (IV Therapy), and 063X (Pharmacy—Extension of 025X). This total excludes the cost of diagnostic and therapeutic radiopharmaceuticals because they are not reported under pharmacy revenue codes or under the pharmacy cost center on the hospital cost report. Our CY 2012 proposal to redistribute $215 million in estimated costs from coded and uncoded packaged drugs to separately payable drugs represents the $200 million in total packaged drug costs

redistributed from the CY 2011 OPPS/ASC final rule with comment period (75 FR 71967), updated by the PPI for Pharmaceuticals for Human Use.

Redistributing a total of $161 million in pharmacy overhead cost from packaged drugs and biologicals reduces the $705 million cost of packaged drugs and biologicals with HCPCS codes and ASPs to $544 million, approximately a 23-percent reduction. Redistributing $54 million from the cost of uncoded packaged drugs and biologicals reduces the $502 million cost of uncoded drugs and biologicals to $448 million, approximately an 11-percent reduction. To implement our proposed CY 2012 policy to redistribute $161 million from the pharmacy overhead cost of coded packaged drugs and biologicals to separately payable drugs and biologicals and $54 million from the cost of uncoded packaged drugs, we multiplied the cost of each packaged drug or biological with a HCPCS code and ASP pricing information in our CY 2010 claims data by 0.77, and we multiplied all uncoded packaged pharmacy drug costs in our CY 2010 claims data, excluding those for diagnostic radiopharmaceuticals, by 0.89. We also added the redistributed $215 million to the total cost of separately payable drugs and biologicals in our CY 2010 claims data, which increased the relationship between the total cost for separately payable drugs and biologicals and ASP dollars for the same drugs and biologicals from ASP − 2 percent to ASP+4 percent. We refer readers to section V.B.3. of this proposed rule for a complete discussion of our proposed policy to pay for separately paid drugs and biologicals and pharmacy overhead for CY 2012.

We then removed line-items that were not paid during claim processing, presumably for a line-item rejection or denial. The number of edits for valid OPPS payment in the Integrated Outpatient Code Editor (I/OCE) and elsewhere has grown significantly in the past few years, especially with the implementation of the full spectrum of National Correct Coding Initiative (NCCI) edits. To ensure that we are using valid claims that represent the cost of payable services to set payment rates, we removed line-items with an OPPS status indicator that were not paid during claims processing in the claim year, but have a status indicator of ''S,'' ''T,'' ''V,'' or ''X'' in the proposed year's payment system. This logic preserves charges for services that would not have been paid in the claim year but for which some estimate of cost is needed for the proposed year, such as services newly proposed to come off the inpatient list for CY 2011 that were assigned status indicator ''C'' in the claim year. It also preserves charges for packaged services so that the costs can be included in the cost of the services with which they are reported, even if the CPT codes for the packaged services were not paid because the service is part of another service that was reported on the same claim or the code otherwise violates claims processing edits.

For CY 2012, we are proposing to continue the policy we implemented for CY 2011 to exclude line-item data for pass-through drugs and biologicals (status indicator ''G'' for CY 2010) and nonpass-through drugs and biologicals (status indicator ''K'' for CY 2010) where the charges reported on the claim for the line were either denied or rejected during claims processing. Removing lines that were eligible for payment but were not paid ensures that we are using appropriate data. The trim avoids using cost data on lines that we believe were defective or invalid because those rejected or denied lines did not meet the Medicare requirements for payment. For example, edits may reject a line for a separately paid drug because the number of units billed exceeded the number of units that would be reasonable and, therefore, is likely a billing error (for example, a line reporting 55 units of a drug for which 5 units is known to be a fatal dose). As with our trimming in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71828) of line items with a status indicator of ''S,'' ''T,'' ''V,'' or ''X,'' we believe that unpaid line-items represent services that are invalidly reported and, therefore, should not be used for ratesetting. We believe that removing lines with valid status indicators that were edited and not paid during claims processing increases the accuracy of the single bills used to determine the mean unit costs for use in the ASP+X calculation described in section V.B.3. of this proposed rule with comment period.

b. Splitting Claims and Creation of ''Pseudo'' Single Procedure Claims

(1) Splitting Claims

We then split the remaining claims into five groups: single majors; multiple majors; single minors; multiple minors; and other claims. (Specific definitions of these groups follow below.) For CY 2012, we are proposing to continue our current policy of defining major procedures as any HCPCS code having a status indicator of ''S,'' ''T,'' ''V,'' or ''X;'' defining minor procedures as any code having a status indicator of ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N,'' and classifying ''other'' procedures as any code having a status indicator other than one that we have classified as major or minor. For CY 2012, we are proposing to continue assigning status indicator ''R'' to blood and blood products; status indicator ''U'' to brachytherapy sources; status indicator ''Q1'' to all ''STVX-packaged codes;'' status indicator ''Q2'' to all ''T-packaged codes;'' and status indicator ''Q3'' to all codes that may be paid through a composite APC based on composite-specific criteria or paid separately through single code APCs when the criteria are not met. As discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68709), we established status indicators ''Q1,'' ''Q2,'' and ''Q3'' to facilitate identification of the different categories of codes. We are proposing to treat these codes in the same manner for data purposes for CY 2012 as we have treated them since CY 2008. Specifically, we are proposing to continue to evaluate whether the criteria for separate payment of codes with status indicator ''Q1'' or ''Q2'' are met in determining whether they are treated as major or minor codes. Codes with status indicator ''Q1'' or ''Q2'' are carried through the data either with status indicator ''N'' as packaged or, if they meet the criteria for separate payment, they are given the status indicator of the APC to which they are assigned and are considered as ''pseudo'' single procedure claims for major codes. Codes assigned status indicator ''Q3'' are paid under individual APCs unless they occur in the combinations that qualify for payment as composite APCs and, therefore, they carry the status indicator of the individual APC to which they are assigned through the data process and are treated as major codes during both the split and ''pseudo'' single creation process. The calculation of the median costs for composite APCs from multiple procedure major claims is discussed in section II.A.2.e. of this proposed rule.

Specifically, we divided the remaining claims into the following five groups:

1. *Single Procedure Major Claims:* Claims with a single separately payable procedure (that is, status indicator ''S,'' ''T,'' ''V,'' or ''X,'' which includes codes with status indicator ''Q3''); claims with one unit of a status indicator ''Q1'' code (''STVX-packaged'') where there was no code with status indicator ''S,'' ''T,'' ''V,'' or ''X'' on the same claim on the same date; or claims with one unit of a status indicator ''Q2'' code (''T-packaged'') where there was no code with a status indicator ''T'' on the same claim on the same date.

2. *Multiple Procedure Major Claims:* Claims with more than one separately payable procedure (that is, status indicator ''S,'' ''T,'' ''V,'' or ''X,'' which includes codes with status indicator ''Q3''), or multiple units of one payable procedure. These claims include those codes with a status indicator ''Q2'' code (''T-packaged'') where there was no procedure with a status indicator ''T'' on the same claim on the same date of service but where there was another separately paid procedure on the same claim with the same date of service (that is, another code with status indicator ''S,'' ''V,'' or ''X''). We also include, in this set, claims that contained one unit of one code when the bilateral modifier was appended to the code and the code was conditionally or independently bilateral. In these cases, the claims represented more than one unit of the service described by the code, notwithstanding that only one unit was billed.

3. *Single Procedure Minor Claims:* Claims with a single HCPCS code that was assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N'' and not status indicator ''Q1'' (''STVX-packaged'') or status indicator ''Q2'' (''T-packaged'') code.

4. *Multiple Procedure Minor Claims:* Claims with multiple HCPCS codes that are assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N;'' claims that contain more than one code with status indicator ''Q1'' (''STVX-packaged'') or more than one unit of a code with status indicator ''Q1'' but no codes with status indicator ''S,'' ''T,'' ''V,'' or ''X'' on the same date of service; or claims that contain more than one code with status indicator ''Q2'' (T-packaged), or ''Q2'' and ''Q1,'' or more than one unit of a code with status indicator ''Q2'' but no code with status indicator ''T'' on the same date of service.

5. *Non-OPPS Claims:* Claims that contain no services payable under the OPPS (that is, all status indicators other than those listed for major or minor status). These claims were excluded from the files used for the OPPS. Non-OPPS claims have codes paid under other fee schedules, for example, durable medical equipment or clinical laboratory tests, and do not contain a code for a separately payable or packaged OPPS service. Non-OPPS claims include claims for therapy services paid sometimes under the OPPS but billed, in these non-OPPS cases, with revenue codes indicating that the therapy services would be paid under the Medicare Physician Fee Schedule (MPFS).

The claims listed in numbers 1, 2, 3, and 4 above are included in the data file that can be purchased as described above. Claims that contain codes to which we have assigned status indicators ''Q1'' (''STVX-packaged'') and ''Q2'' (''T-packaged'') appear in the data for the single major file, the multiple major file, and the multiple minor file used in this proposed rule. Claims that contain codes to which we have assigned status indicator ''Q3'' (composite APC members) appear in both the data of the single and multiple major files used in this proposed rule, depending on the specific composite calculation.

(2) Creation of ''Pseudo'' Single Procedure Claims

To develop ''pseudo'' single procedure claims for this proposed rule, we examined both the multiple procedure major claims and the multiple procedure minor claims. We first examined the multiple major procedure claims for dates of service to determine if we could break them into ''pseudo'' single procedure claims using the dates of service for all lines on the claim. If we could create claims with single major procedures by using dates of service, we created a single procedure claim record for each separately payable procedure on a different date of service (that is, a ''pseudo'' single).

We also used the bypass codes listed in Addendum N to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) and discussed in section II.A.1.b. of this proposed rule to remove separately payable procedures which we determined contained limited or no packaged costs or that were otherwise suitable for inclusion on the bypass list from a multiple procedure bill. As discussed above, we ignore the ''overlap bypass codes,'' that is, those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs, in this initial assessment for ''pseudo'' single procedure claims. The proposed CY 2012 ''overlap bypass codes'' are listed in Addendum N to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site). When one of the two separately payable procedures on a multiple procedure claim was on the bypass list, we split the claim into two ''pseudo'' single procedure claim records. The single procedure claim record that contained the bypass code did not retain packaged services. The single procedure claim record that contained the other separately payable procedure (but no bypass code) retained the packaged revenue code charges and the packaged HCPCS code charges. We also removed lines that contained multiple units of codes on the bypass list and treated them as ''pseudo'' single procedure claims by dividing the cost for the multiple units by the number of units on the line. Where one unit of a single, separately payable procedure code remained on the claim after removal of the multiple units of the bypass code, we created a ''pseudo'' single procedure claim from that residual claim record, which retained the costs of packaged revenue codes and packaged HCPCS codes. This enabled us to use claims that would otherwise be multiple procedure claims and could not be used.

We then assessed the claims to determine if the criteria for the multiple imaging composite APCs, discussed in section II.A.2.e.(5) of this proposed rule, were met. Where the criteria for the imaging composite APCs were met, we created a ''single session'' claim for the applicable imaging composite service and determined whether we could use the claim in ratesetting. For HCPCS codes that are both conditionally packaged and are members of a multiple imaging composite APC, we first assessed whether the code would be packaged and, if so, the code ceased to be available for further assessment as part of the composite APC. Because the packaged code would not be a separately payable procedure, we considered it to be unavailable for use in setting the composite APC median cost. Having identified ''single session'' claims for the imaging composite APCs, we reassessed the claim to determine if, after removal of all lines for bypass codes, including the ''overlap bypass codes,'' a single unit of a single separately payable code remained on the claim. If so, we attributed the packaged costs on the claim to the single unit of the single remaining separately payable code other than the bypass code to create a ''pseudo'' single procedure claim. We also identified line-items of overlap bypass codes as a ''pseudo'' single procedure claim. This allowed us to use more claims data for ratesetting purposes.

We also examined the multiple procedure minor claims to determine whether we could create ''pseudo'' single procedure claims. Specifically, where the claim contained multiple codes with status indicator ''Q1'' (''STVX-packaged'') on the same date of service or contained multiple units of a single code with status indicator ''Q1,'' we selected the status indicator ''Q1'' HCPCS code that had the highest CY

2011 relative weight, set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q1.'' We then packaged all costs for the following into a single cost for the ''Q1'' HCPCS code that had the highest CY 2011 relative weight to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q1'' HCPCS code with the highest CY 2011 relative weight; other codes with status indicator ''Q1''; and all other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from the data status indicator of ''N'' to the status indicator of the APC to which the selected procedure was assigned for further data processing and considered this claim as a major procedure claim. We used this claim in the calculation of the APC median cost for the status indicator ''Q1'' HCPCS code.

Similarly, where a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') or multiple units of a single code with status indicator ''Q2,'' we selected the status indicator ''Q2'' HCPCS code that had the highest CY 2011 relative weight, set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the ''Q2'' HCPCS code that had the highest CY 2011 relative weight to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2011 relative weight; other codes with status indicator ''Q2''; and other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned, and we considered this claim as a major procedure claim.

Where a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') and status indicator ''Q1'' (''STVX-packaged''), we selected the T-packaged status indicator ''Q2'' HCPCS code that had the highest relative weight for CY 2011 and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the selected (''T packaged'') HCPCS code to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2011 relative weight; other codes with status indicator ''Q2''; codes with status indicator ''Q1'' (''STVX-packaged''); and other packaged HCPCS codes and packaged revenue code costs. We favor status indicator ''Q2'' over ''Q1'' HCPCS codes because ''Q2'' HCPCS codes have higher CY 2011 relative weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2011 relative weight, it would become the primary code for the simulated single bill process. We changed the status indicator for the selected status indicator ''Q2'' (''T-packaged'') code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned and we considered this claim as a major procedure claim.

We then applied our process for creating ''pseudo'' single procedure claims to the conditionally packaged codes that do not meet the criteria for packaging, which enabled us to create single procedure claims from them, where they meet the criteria for single procedure claims. Conditionally packaged codes are identified using status indicators ''Q1'' and ''Q2,'' and are described in section XI.A.1. of this proposed rule.

Lastly, we excluded those claims that we were not able to convert to single procedure claims even after applying all of the techniques for creation of ''pseudo'' single procedure claims to multiple procedure major claims and to multiple procedure minor claims. As has been our practice in recent years, we also excluded claims that contained codes that were viewed as independently or conditionally bilateral and that contained the bilateral modifier (Modifier 50 (Bilateral procedure)) because the line-item cost for the code represented the cost of two units of the procedure, notwithstanding that hospitals billed the code with a unit of one.

We are proposing to continue to apply this methodology for the purpose of creating pseudo single procedure claims for CY 2012 OPPS.

c. Completion of Claim Records and Median Cost Calculations

We then packaged the costs of packaged HCPCS codes (codes with status indicator ''N'' listed in Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) and the costs of those lines for codes with status indicator ''Q1'' or ''Q2'' when they are not separately paid), and the costs of the services reported under packaged revenue codes in Table 2 below that appeared on the claim without a HCPCS code into the cost of the single major procedure remaining on the claim.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66606), for the CY 2008 OPPS, we adopted an APC Panel recommendation that CMS should review the final list of packaged revenue codes for consistency with OPPS policy and ensure that future versions of the I/OCE edit accordingly. As we have in the past, we will continue to compare the final list of packaged revenue codes that we adopt for CY 2012 to the revenue codes that the I/OCE will package for CY 2012 to ensure consistency.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68531), we replaced the NUBC standard abbreviations for the revenue codes listed in Table 2 of the CY 2009 OPPS/ASC proposed rule with the most current NUBC descriptions of the revenue code categories and subcategories to better articulate the meanings of the revenue codes without changing the proposed list of revenue codes. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60362 through 60363), we finalized changes to the packaged revenue code list based on our examination of the updated NUBC codes and public comment to the CY 2010 proposed list of packaged revenue codes. For CY 2012, as we did for CY 2011, we reviewed the changes to revenue codes that were effective during CY 2010 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we would propose to package for the CY 2012 OPPS. We believe that the charges reported under the revenue codes listed in Table 2 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2012, we are proposing to continue to package the costs that we derive from the charges reported without HCPCS code under the revenue codes displayed in Table 2 below for purposes of calculating the median costs on which the CY 2012 OPPS are based.

TABLE 2—PROPOSED CY 2012 PACKAGED REVENUE CODES

Revenue code	Description
0250	Pharmacy; General Classification.
0251	Pharmacy; Generic Drugs.
0252	Pharmacy; Non-Generic Drugs.
0254	Pharmacy; Drugs Incident to Other Diagnostic Services.
0255	Pharmacy; Drugs Incident to Radiology.
0257	Pharmacy; Non-Prescription.
0258	Pharmacy; IV Solutions.
0259	Pharmacy; Other Pharmacy.
0260	IV Therapy; General Classification.
0261	IV Therapy; Infusion Pump.
0262	IV Therapy; IV Therapy/Pharmacy Svcs.
0263	IV Therapy; IV Therapy/Drug/Supply Delivery.
0264	IV Therapy; IV Therapy/Supplies.
0269	IV Therapy; Other IV Therapy.
0270	Medical/Surgical Supplies and Devices; General Classification.
0271	Medical/Surgical Supplies and Devices; Non-sterile Supply.
0272	Medical/Surgical Supplies and Devices; Sterile Supply.
0275	Medical/Surgical Supplies and Devices; Pacemaker.
0276	Medical/Surgical Supplies and Devices; Intraocular Lens.
0278	Medical/Surgical Supplies and Devices; Other Implants.
0279	Medical/Surgical Supplies and Devices; Other Supplies/Devices.
0280	Oncology; General Classification.
0289	Oncology; Other Oncology.
0343	Nuclear Medicine; Diagnostic Radiopharmaceuticals.
0344	Nuclear Medicine; Therapeutic Radiopharmaceuticals.
0370	Anesthesia; General Classification.
0371	Anesthesia; Anesthesia Incident to Radiology.
0372	Anesthesia; Anesthesia Incident to Other DX Services.
0379	Anesthesia; Other Anesthesia.
0390	Administration, Processing and Storage for Blood and Blood Components; General Classification.
0392	Administration, Processing and Storage for Blood and Blood Components; Processing and Storage.
0399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling.
0621	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Radiology.
0622	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Other DX Services.
0623	Medical Supplies—Extension of 027X, Surgical Dressings.
0624	Medical Surgical Supplies—Extension of 027X; FDA Investigational Devices.
0630	Pharmacy—Extension of 025X; Reserved.
0631	Pharmacy—Extension of 025X; Single Source Drug.
0632	Pharmacy—Extension of 025X; Multiple Source Drug.
0633	Pharmacy—Extension of 025X; Restrictive Prescription.
0681	Trauma Response; Level I Trauma.
0682	Trauma Response; Level II Trauma.
0683	Trauma Response; Level III Trauma.
0684	Trauma Response; Level IV Trauma.
0689	Trauma Response; Other.
0700	Cast Room; General Classification.
0710	Recovery Room; General Classification.
0720	Labor Room/Delivery; General Classification.
0721	Labor Room/Delivery; Labor.
0732	EKG/ECG (Electrocardiogram); Telemetry.
0762	Specialty Services; Observation Hours.
0801	Inpatient Renal Dialysis; Inpatient Hemodialysis.
0802	Inpatient Renal Dialysis; Inpatient Peritoneal Dialysis (Non-CAPD).
0803	Inpatient Renal Dialysis; Inpatient Continuous Ambulatory Peritoneal Dialysis (CAPD).
0804	Inpatient Renal Dialysis; Inpatient Continuous Cycling Peritoneal Dialysis (CCPD).
0809	Inpatient Renal Dialysis; Other Inpatient Dialysis.
0810	Acquisition of Body Components; General Classification.
0819	Inpatient Renal Dialysis; Other Donor.
0821	Hemodialysis—Outpatient or Home; Hemodialysis Composite or Other Rate.
0824	Hemodialysis—Outpatient or Home; Maintenance—100%.
0825	Hemodialysis—Outpatient or Home; Support Services.
0829	Hemodialysis—Outpatient or Home; Other OP Hemodialysis.

TABLE 2—PROPOSED CY 2012 PACKAGED REVENUE CODES—Continued

Revenue code	Description
0942	Other Therapeutic Services (also see 095X, an extension of 094x); Education/Training.
0943	Other Therapeutic Services (also see 095X, an extension of 094X), Cardiac Rehabilitation.
0948	Other Therapeutic Services (also see 095X, an extension of 094X), Pulmonary Rehabilitation.

In accordance with our longstanding policy, we are proposing to continue to exclude: (1) Claims that had zero costs after summing all costs on the claim; and (2) claims containing packaging flag number 3. Effective for services furnished on or after July 1, 2004, the I/OCE assigned packaging flag number 3 to claims on which hospitals submitted token charges less than $1.01 for a service with status indicator ''S'' or ''T'' (a major separately payable service under the OPPS) for which the fiscal intermediary or MAC was required to allocate the sum of charges for services with a status indicator equaling ''S'' or ''T'' based on the relative weight of the APC to which each code was assigned. We do not believe that these charges, which were token charges as submitted by the hospital, are valid reflections of hospital resources. Therefore, we deleted these claims. We also deleted claims for which the charges equaled the revenue center payment (that is, the Medicare payment) on the assumption that, where the charge equaled the payment, to apply a CCR to the charge would not yield a valid estimate of relative provider cost. We are proposing to continue these processes for the CY 2012 OPPS.

For the remaining claims, we then standardized 60 percent of the costs of the claim (which we have previously determined to be the labor-related portion) for geographic differences in labor input costs. We made this adjustment by determining the wage index that applied to the hospital that furnished the service and dividing the cost for the separately paid HCPCS code furnished by the hospital by that wage index. The claims accounting that we provide for the proposed and final rule contains the formula we use to standardize the total cost for the effects of the wage index. As has been our policy since the inception of the OPPS, we are proposing to use the pre-reclassified wage indices for standardization because we believe that they better reflect the true costs of items and services in the area in which the hospital is located than the post-reclassification wage indices and, therefore, would result in the most accurate unadjusted median costs.

In accordance with our longstanding practice, we also excluded single and pseudo single procedure claims for which the total cost on the claim was outside 3 standard deviations from the geometric mean of units for each HCPCS code on the bypass list (because, as discussed above, we used claims that contain multiple units of the bypass codes).

After removing claims for hospitals with error CCRs, claims without HCPCS codes, claims for immunizations not covered under the OPPS, and claims for services not paid under the OPPS, approximately 102 million claims were left. Using these 102 million claims, we created approximately 100 million single and ''pseudo'' single procedure claims, of which we used slightly more than 99.5 million single bills (after trimming out approximately 888,000 claims as discussed above in this section) in the proposed CY 2012 median development and ratesetting.

We used these claims to calculate the proposed CY 2012 median costs for each separately payable HCPCS code and each APC. The comparison of HCPCS code-specific and APC medians determines the applicability of the 2 times rule. Section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median (or mean cost, if elected by the Secretary) for an item or service in the group is more than 2 times greater than the lowest median cost for an item or service within the same group (the 2 times rule). We note that, for purposes of identifying significant HCPCS for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC median cost to be significant (75 FR 71832). This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing median costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC median. Unlisted codes are not used in establishing the percent of claims contributing to the APC, nor are their costs used in the calculation of the APC median. Finally, we reviewed the median costs for the services for which we are proposing to pay separately under this proposed rule, and we reassigned HCPCS codes to different APCs where it was necessary to ensure clinical and resource homogeneity within the APCs. Section III. of this proposed rule includes a discussion of many of the HCPCS code assignment changes that resulted from examination of the median costs and for other reasons. The APC medians were recalculated after we reassigned the affected HCPCS codes. Both the HCPCS code-specific medians and the APC medians were weighted to account for the inclusion of multiple units of the bypass codes in the creation of ''pseudo'' single procedure claims.

As we discuss in sections II.A.2.d. and II.A.2.e. and in section VIII.B. of this proposed rule, in some cases, APC median costs are calculated using variations of the process outlined above. Specifically, section II.A.2.d. of this proposed rule addresses the proposed calculation of single APC criteria-based median costs. Section II.A.2.e. of this proposed rule discusses the proposed calculation of composite APC criteria-based median costs. Section VIII.B. of this proposed rule addresses the methodology for calculating the proposed median costs for partial hospitalization services.

APC Panel Recommendations Regarding Data Development: At the February 28–March 1, 2011 APC Panel Meeting, we provided the APC Panel Data Subcommittee with a list of all APCs fluctuating by greater than 10 percent when comparing the CY 2011

OPPS final rule median costs based on CY 2009 claims processed through June 30, 2010, to those based on CY 2010 OPPS/ASC final rule data (CY 2008 claims processed through June 30, 2009). We included explanatory data where possible to allow the Data Subcommittee to focus on APC median changes that required more investigation, based on its request (75 FR 71834). The APC Panel Data Subcommittee reviewed the fluctuations in the APC median costs but did not express particular concerns with the median cost changes.

We also provided the APC Panel Data Subcommittee with a summary of cost and CCR data related to the Myocardial Positron Emission Tomography (PET) imaging APC, APC 0307, as well as the associated diagnostic radiopharmaceutical, Rb82 rubidium, based on a request for data related to the decline in the APC median cost from the CY 2010 OPPS final rule to the CY 2011 OPPS proposed rule. The Data Subcommittee noted a decline in the CCRs associated with the HCPCS codes in APC 0307, as well as declines in the line-item costs of the associated diagnostic radiopharmaceutical.

At the February 28–March 1, 2011 APC Panel Meeting, the APC Panel made a number of recommendations related to the data process. The Panel's recommendations and our responses follow.

Recommendation 1: The Panel commends the CMS staff for responding to the data requests of the Data Subcommittee.

CMS Response to Recommendation 1: We appreciate this recommendation.

Recommendation 2: The Panel recommends that the work of the Data Subcommittee continue.

CMS Response to Recommendation 2: We are accepting this recommendation.

Recommendation 3: The Panel recommends that Agatha Nolen, D.Ph., M.S., F.A.S.H.P., serve as acting chairperson for the winter 2011 meeting of the Data Subcommittee.

CMS Response to Recommendation 3: We are accepting this recommendation.

d. Proposed Calculation of Single Procedure APC Criteria-Based Median Costs

(1) Device-Dependent APCs

Device-dependent APCs are populated by HCPCS codes that usually, but not always, require that a device be implanted or used to perform the procedure. For a full history of how we have calculated payment rates for device-dependent APCs in previous years and a detailed discussion of how we developed the standard device-dependent APC ratesetting methodology, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66739 through 66742). Overviews of the procedure-to-device edits and device-to-procedure edits used in ratesetting for device-dependent APCs are available in the CY 2005 OPPS final rule with comment period (69 FR 65761 through 65763) and the CY 2007 OPPS/ASC final rule with comment period (71 FR 68070 through 68071).

For CY 2012, we are proposing to use the standard methodology for calculating median costs for device-dependent APCs that was finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71834 through 71837). (We refer readers to sections II.D.6. and II.A.e.6. of this proposed rule for detailed explanations of the proposed nonstandard methodology regarding cardiac resynchronization therapy.) This methodology utilizes claims data that generally represent the full cost of the required device. Specifically, we are proposing to calculate the median costs for device-dependent APCs for CY 2012 using only the subset of single procedure claims from CY 2010 claims data that pass the procedure-to-device and device-to-procedure edits; do not contain token charges (less than $1.01) for devices; do not contain the ''FB'' modifier signifying that the device was furnished without cost to the provider, supplier, or practitioner, or where a full credit was received; and do not contain the ''FC'' modifier signifying that the hospital received partial credit for the device. The procedure-to-device edits require that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code, while the device-to-procedure edits require that a claim that contains one of a specified set of device codes also contain an appropriate procedure code. We continue to believe the standard methodology for calculating median costs for device-dependent APCs gives us the most appropriate median costs for device-dependent APCs in which the hospital incurs the full cost of the device.

Table 3 below lists the APCs for which we are proposing to use our standard device-dependent APC ratesetting methodology (as explained in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71834 through 71837)) for CY 2012. We note that there are five proposed device-dependent APC title changes and one proposed deletion for CY 2012. As discussed in detail in section II.A.2.d.(6) of this proposed rule, we are proposing to change the title of APC 0083 from ''Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty'' to ''Level I Endovascular Revascularization of the Lower Extremity''; the title of APC 0229 from ''Transcatheter Placement of Intravascular Shunt and Stents'' to ''Level II Endovascular Revascularization of the Lower Extremity''; and the title of APC 0319 from ''Endovascular Revascularization of the Lower Extremity'' to ''Level III Endovascular Revascularization of the Lower Extremity.'' We also are proposing to change the title of APC 0040 from ''Percutaneous Implantation of Neurostimulator Electrodes'' to ''Level I Implantation/Revision/Replacement of Neurostimulator Electrodes,'' and the title of APC 0061 from ''Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes'' to ''Level II Implantation/Revision/Replacement of Neurostimulator Electrodes,'' as discussed in section III.D.1. of this proposed rule. In addition, as discussed in section II.A.2.e.(6) of this proposed rule, we are proposing to delete APC 0418 (Insertion of Left Ventricular Pacing Electrode) for CY 2012.

As we discuss in detail in section III.D.6. of this proposed rule, we are proposing to limit the payment for services that are assigned to APC 0108 to the proposed IPPS standardized payment amount for MS–DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization and without Medical Complications and Comorbidities) because we do not believe that it would be equitable to pay more under the OPPS for services assigned to APC 0108 than under the IPPS. In other words, we are proposing to pay APC 0108 at the lesser of the APC 0108 median cost or the IPPS standardized payment rate for MS–DRG 227. We are proposing to continue to apply the device edits and other standard features of the device-dependent APCs to APC 0108, but we are proposing to limit the payment amount under the OPPS to the amount of payment established for MS–DRG 227 under the IPPS.

We refer readers to Addendum A to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) for the proposed payment rates for these APCs for CY 2012.

TABLE 3—PROPOSED CY 2012 DEVICE-DEPENDENT APCS

Proposed CY 2012 APC	Proposed CY 2012 status indicator	Proposed CY 2012 APC title
0039	S	Level I Implantation of Neurostimulator Generator.
0040	S	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.
0061	S	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes.
0082	T	Coronary or Non-Coronary Atherectomy.
0083	T	Level I Endovascular Revascularization of the Lower Extremity.
0084	S	Level I Electrophysiologic Procedures.
0085	T	Level II Electrophysiologic Procedures.
0086	T	Level III Electrophysiologic Procedures.
0089	T	Insertion/Replacement of Permanent Pacemaker and Electrodes.
0090	T	Insertion/Replacement of Pacemaker Pulse Generator.
0104	T	Transcatheter Placement of Intracoronary Stents.
0106	T	Insertion/Replacement of Pacemaker Leads and/or Electrodes.
0107	T	Insertion of Cardioverter-Defibrillator.
0108*	T	Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes.
0115	T	Cannula/Access Device Procedures.
0202	T	Level VII Female Reproductive Procedures.
0227	T	Implantation of Drug Infusion Device.
0229	T	Level II Endovascular Revascularization of the Lower Extremity.
0259	T	Level VII ENT Procedures.
0293	T	Level V Anterior Segment Eye Procedures.
0315	S	Level II Implantation of Neurostimulator Generator.
0318	S	Implantation of Cranial Neurostimulator Pulse Generator and Electrode.
0319	T	Level III Endovascular Revascularization of the Lower Extremity.
0384	T	GI Procedures with Stents.
0385	S	Level I Prosthetic Urological Procedures.
0386	S	Level II Prosthetic Urological Procedures.
0425	T	Level II Arthroplasty or Implantation with Prosthesis.
0427	T	Level II Tube or Catheter Changes or Repositioning.
0622	T	Level II Vascular Access Procedures.
0623	T	Level III Vascular Access Procedures.
0648	T	Level IV Breast Surgery.
0652	T	Insertion of Intraperitoneal and Pleural Catheters.
0653	T	Vascular Reconstruction/Fistula Repair with Device.
0654	T	Insertion/Replacement of a Permanent Dual Chamber Pacemaker.
0655	T	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker.
0656	T	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0674	T	Prostate Cryoablation.
0680	S	Insertion of Patient Activated Event Recorders.

*OPPS CY 2012 payment for APC 0108 is proposed to be paid at the lesser of the APC 0108 median cost or the standardized payment rate for MS–DRG 227 under the IPPS. We refer readers to section III.D.6. of this proposed rule for more information.

(2) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

For CY 2012, we are proposing to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, in order to address the differences in CCRs and to better reflect hospitals' costs, we are proposing to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We would then apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We calculated the median costs upon which the proposed CY 2012 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific

simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe the hospital-specific, blood-specific CCR methodology best responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We believe that continuing with this methodology in CY 2012 would result in median costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We refer readers to Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) for the proposed CY 2012 payment rates for blood and blood products (which are identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

(3) Allergy Tests (APCs 0370 and 0381)

We are proposing to continue with our methodology of differentiating single allergy tests (''per test'') from multiple allergy tests (''per visit'') by assigning these services to two different APCs to provide accurate payments for these tests in CY 2012. Multiple allergy tests are currently assigned to APC 0370 (Allergy Tests), with a median cost calculated based on the standard OPPS methodology. For CY 2012, we are proposing to continue to use the standard OPPS methodology to set the APC payment rate for APC 0370, which has a proposed APC median cost of approximately $97 based on 283 claims.

We provided billing guidance in CY 2006 in Transmittal 804 (issued on January 3, 2006) specifically clarifying that hospitals should report charges for the CPT codes that describe single allergy tests to reflect charges ''per test'' rather than ''per visit'' and should bill the appropriate number of units (as defined in the CPT code descriptor) of these CPT codes to describe all of the tests provided. Services assigned to APC 0381 (Single Allergy Tests) reflect the CPT codes that describe single allergy tests in which CPT instructions direct providers to specify the number of tests performed, whereas the procedures in APC 0370 describe multiple allergy tests per encounter; therefore, for these procedures, only one unit of the service is billed even if multiple tests are performed. Our CY 2010 claims data available for this proposed rule for APC 0381 do not reflect improved and more consistent hospital billing practices of ''per test'' for single allergy tests. The median cost of APC 0381 calculated for this proposed rule according to the standard single claims OPPS methodology, is approximately $51, significantly higher than the CY 2011 OPPS/ASC final rule median cost of approximately $33 that was calculated according to the ''per unit'' methodology, and greater than we would expect for these procedures that are to be reported ''per test'' with the appropriate number of units. Some claims for single allergy tests still appear to provide charges that represent a ''per visit'' charge, rather than a ''per test'' charge. Therefore, consistent with our payment policy for single allergy tests since CY 2006, we calculated a proposed ''per unit'' median cost for APC 0381, based upon 601 claims containing multiple units or multiple occurrences of a single CPT code. The proposed CY 2012 median cost for APC 0381 using the ''per unit'' methodology is approximately $34. For a full discussion of the ''per unit'' methodology for APC 0381, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66737).

(4) Hyperbaric Oxygen Therapy (APC 0659)

Since the implementation of OPPS in August 2000, the OPPS has recognized HCPCS code C1300 (Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval) for hyperbaric oxygen therapy (HBOT) provided in the hospital outpatient setting. In the CY 2005 final rule with comment period (69 FR 65758 through 65759), we finalized a ''per unit'' median cost calculation for APC 0659 (Hyperbaric Oxygen) using only claims with multiple units or multiple occurrences of HCPCS code C1300 because delivery of a typical HBOT service requires more than 30-minutes. We observed that claims with only a single occurrence of the code were anomalies, either because they reflected terminated sessions or because they were incorrectly coded with a single unit. In the same rule, we also established that HBOT would not generally be furnished with additional services that might be packaged under the standard OPPS APC median cost methodology. This enabled us to use claims with multiple units or multiple occurrences. Finally, we also used each hospital's overall CCR to estimate costs for HCPCS code C1300 from billed charges rather than the CCR for the respiratory therapy or other departmental cost centers. Our rationale for using the hospital's overall CCR can be found in the CY 2005 OPPS final rule with comment period (69 FR 65758 through 65759). The public comments on the CY 2005 OPPS proposed rule effectively demonstrated that hospitals report the costs and charges for HBOT in a wide variety of cost centers. Since CY 2005, we have used this methodology to estimate the median cost for HBOT. The median costs of HBOT using this methodology have been relatively stable for several years.

For CY 2012, we are proposing to continue using the same methodology to estimate a ''per unit'' median cost for HCPCS code C1300. This methodology results in a proposed APC median cost of approximately $107 using 370,519 claims with multiple units or multiple occurrences for HCPCS code C1300 for CY 2012.

(5) Payment for Ancillary Outpatient Services When Patient Expires (APC 0375)

In the November 1, 2002 final rule with comment period (67 FR 66798), we discussed the creation of the new HCPCS modifier ''–CA'' to address situations where a procedure on the OPPS inpatient list must be performed to resuscitate or stabilize a patient (whose status is that of an outpatient) with an emergent, life-threatening condition, and the patient dies before being admitted as an inpatient. HCPCS modifier ''–CA'' is defined as a procedure payable only in the inpatient setting when performed emergently on an outpatient who expires prior to admission. In Transmittal A–02–129, issued on January 3, 2003, we instructed hospitals on the use of this modifier. For a complete description of the history of the policy and the development of the payment methodology for these services, we refer readers to the CY 2007 OPPS final rule with comment period (71 FR 68157 through 68158).

For CY 2012, we are proposing to continue to use our established ratesetting methodology for calculating the median cost of APC 0375 (Ancillary Outpatient Services When Patient Expires) and to continue to make one payment under APC 0375 for the

services that meet the specific conditions for using HCPCS modifier ''–CA.'' That is, we are proposing to calculate the relative payment weight for APC 0375 by using all claims reporting a status indicator ''C'' (inpatient procedures)appended with HCPCS modifier ''–CA.'' For the history and detailed explanation of the methodology, we refer readers to the CY 2004 OPPS final rule (68 FR 63467 through 63468), We continue to believe that this established ratesetting methodology results in the most appropriate aggregate median cost for the ancillary services provided in these unusual clinical situations.

We believe that hospitals are reporting the HCPCS modifier ''–CA'' according to the policy initially established in CY 2003. We note that the claims frequency for APC 0375 has been relatively stable over the past few years. We note that the median cost for APC 0375 has decreased based on the CY 2010 OPPS claims data used for the development of the proposed rates for CY 2012 compared to that for CY 2011. Variation in the median cost for APC 0375 is expected because of the small number of claims and because the specific cases are grouped by the presence of the HCPCS modifier ''–CA'' appended to an inpatient only procedure and not according to the standard APC criteria of clinical and resource homogeneity. Cost variation for APC 0375 from year to year is anticipated and acceptable as long as hospitals continue judicious reporting of the HCPCS modifier ''–CA.'' Table 4 below shows the number of claims, and the median costs for APC 0375 for CYs 2007, 2008, 2009, 2010, and 2011, and the proposed median cost for APC 0375 for CY 2012. For CY 2012, we are proposing a median cost of approximately $5,711 for APC 0375 based on 155 claims.

TABLE 4—CLAIMS FOR ANCILLARY OUTPATIENT SERVICES WHEN PATIENT EXPIRES (–CA MODIFIER) FOR CYS 2007 THROUGH 2012

Prospective payment year	Number of claims	APC median cost
CY 2007	260	$3,549
CY 2008	183	4,945
CY 2009	168	5,545
CY 2010	182	5,911
CY 2011	168	6,304
CY 2012	155	5,711*

*Proposed median cost.

(6) Endovascular Revascularization of the Lower Extremity (APCs 0083, 0229, and 0319)

For the CY 2011 update, the AMA's CPT Editorial Panel created 16 new CPT codes in the Endovascular Revascularization section of the 2011 CPT code book to describe endovascular revascularization procedures of the lower extremity performed for occlusive disease. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71841 through 71845), we discussed the process and methodology by which we assigned the new CY 2011 endovascular revascularization CPT codes to APCs that we believe are comparable with respect to clinical characteristics and resources required to furnish the services. Specifically, we were able to use the existing CY 2009 hospital outpatient claims data and most recent cost report data to create simulated medians for 12 of the 16 new separately payable codes for CY 2011. Because the endovascular revascularization CPT codes are new for CY 2011, we used our CY 2009 single and ''pseudo'' single claims data to simulate the new CY 2011 CPT code definitions. As shown in Table 7 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71844), many of the new endovascular revascularization CPT codes were previously reported using a combination of CY 2009 CPT codes. In order to simulate median costs, we selected claims that we believe meet the definition for each of the new endovascular revascularization CPT codes. Table 7 showed the criteria we applied to select a claim to be used in the calculation of the median cost for the new codes (shown in Column A). As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71842), we developed these criteria based on our clinicians' understanding of services that were reported by CY 2009 CPT codes that, in various combinations, reflect the services provided that are described by the new CPT codes for CY 2011.

After determining the simulated median costs for the procedures, we assigned each CPT code to appropriate APCs based on their clinical homogeneity and resource use. Of the 16 new codes, we assigned 9 CPT codes to APC 0083 (Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty) and 5 CPT codes to APC 0229 (Transcatheter Placement of Intravascular Shunts), and created new APC 0319 (Endovascular Revascularization of the Lower Extremity) for 2 CPT codes. Table 8 of the CY 2011 OPPS/ASC final rule with comment period displayed their final CY 2011 APC assignments and CPT median costs (75 FR 71845). We noted that because these CPT codes are new for CY 2011, they are identified with comment indicator ''NI'' in Addendum B to the CY 2011 OPPS/ASC final rule with comment period to identify them as a new interim APC assignment for the new year and subject to public comment. We specifically requested public comment on our methodology for simulating the median costs for these new CY 2011 CPT codes in addition to public comments on the payment rates themselves (75 FR 71845).

At its February 28–March 1, 2011 meeting, the APC Panel recommended that CMS provide data to allow the Panel to investigate and monitor the APC weights for the lower extremity revascularization procedures in light of CPT coding changes for CY 2011. We are accepting the APC Panel's recommendation and will provide additional data to the Panel at an upcoming meeting.

For CY 2012, we are proposing to continue with the CY 2011 methodology that was described previously in this section in determining the APC assignments for the CPT codes that describe endovascular revascularization of the lower extremity. The predecessor endovascular revascularization CPT codes were in existence prior to CY 2011 and were assigned to APCs based on claims data and cost report data. Given that these data are available for the services described by the predecessor endovascular revascularization CPT codes, we are proposing to continue for CY 2012 to use the existing hospital outpatient claims and cost report data from the previous endovascular revascularization CPT codes to simulate an estimated median cost for the new endovascular revascularization CPT codes in determining the appropriate APC assignments. As has been our practice since the implementation of the OPPS in 2000, we review our latest claims data for ratesetting and, if necessary, revise the APC assignments for the upcoming year. In this case, review of the procedures with significant claims data in APC 0083 showed a 2 times rule violation. Specifically, APC 0083, as it was initially configured, showed that the range of the CPT median costs for the procedures with significant claims data was approximately between $3,252 (for CPT code 35476 (Transluminal balloon angioplasty, percutaneous; venous)) and $7,174 (for CPT code 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with

transluminal stent placement(s), includes angioplasty within the same vessel, when performed)), resulting in a 2 times rule violation. Because of its median cost, we believe that CPT code 37221 would be more appropriately placed in APC 0229, which had an initial estimated median cost of approximately $8,606, based on the clinical and resource characteristics of other procedures also assigned to APC 0229. Therefore, for CY 2012, we are proposing to revise the APC assignment for CPT code 37221, from APC 0083 to APC 0229, to accurately reflect the cost and clinical feature of the procedure. This proposed reassignment of CPT code 37221 from APC 0083 to APC 0029 eliminates the 2 times rule violation for APC 0083 noted above. Based on this reconfiguration, the CY 2010 claims data available for this proposed rule were used to calculate a median cost of approximately $4,683 for APC 0083, approximately $8,218 for APC 0229, and approximately $14,556 for APC 0319. All three proposed median costs for CY 2012 are significantly greater than the CY 2011 OPPS/ASC final rule median costs of approximately $3,740 for APC 0083, approximately $7,940 for APC 0229, and approximately $13,751 for APC 0319.

In addition, we are proposing to revise the APC titles for APCs 0083, 0229, and 0319 to better describe the procedures assigned to these APCs. Specifically, we are proposing to revise the APC title for APC 0083 from ''Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty'' to ''Level I Endovascular Revascularization of the Lower Extremity''; for APC 0229, from ''Transcatheter Placement of Intravascular Shunt and Stents'' to ''Level II Endovascular Revascularization of the Lower Extremity''; and for APC 0319, from ''Endovascular Revascularization of the Lower Extremity'' to ''Level III Endovascular Revascularization of the Lower Extremity.''

We are soliciting public comments on the proposed status indicators and APC assignments for the endovascular revascularization of the lower extremity CPT codes. Table 5 below lists the endovascular revascularization of the lower extremity CPT codes along with their proposed status indicator and APC assignments for CY 2012.

TABLE 5—PROPOSED APCS TO WHICH ENDOVASCULAR REVASCULARIZATION OF THE LOWER EXTREMITY CPT CODES WOULD BE ASSIGNED FOR CY 2012

CY 2011 HCPCS code	CY 2011 short descriptor	CY 2011 SI	CY 2011 APC	Proposed CY 2012 SI	Proposed CY 2012 APC
37220	Iliac revasc	T	0083	T	0083
37221	Iliac revasc w/stent	T	0083	T	0229
37222	Iliac revasc add-on	T	0083	T	0083
37223	Iliac revasc w/stent add-on	T	0083	T	0083
37224	Fem/popl revas w/tla	T	0083	T	0083
37225	Fem/popl revas w/ather	T	0229	T	0229
37226	Fem/popl revasc w/stent	T	0229	T	0229
37227	Fem/popl revasc stnt & ather	T	0319	T	0319
37228	Tib/per revasc w/tla	T	0083	T	0083
37229	Tib/per revasc w/ather	T	0229	T	0229
37230	Tib/per revasc w/stent	T	0229	T	0229
37231	Tib/per revasc stent & ather	T	0319	T	0319
37232	Tib/per revasc add-on	T	0083	T	0083
37233	Tibper revasc w/ather add-on	T	0229	T	0229
37234	Revsc opn/prq tib/pero stent	T	0083	T	0083
37235	Tib/per revasc stnt & ather	T	0083	T	0083

(7) Non-Congenital Cardiac Catheterization (APC 0080)

For CY 2011, the AMA CPT Editorial Panel deleted 19 non-congenital cardiac catheterization-related CPT codes and replaced them with 20 new CPT codes in the Cardiac Catheterization and Injection-Related section of the 2011 CPT Code Book to describe more precisely the specific services provided during cardiac catheterization procedures. In particular, the CPT Editorial Panel deleted 19 non-congenital cardiac catheterization-related CPT codes from the 93500 series and created 14 new CPT codes in the 93400 series and 6 in the 93500 series. We discussed these coding changes in detail in the CY 2011 OPPS/ASC final rule with comment period, along with the process by which we assigned the new CPT codes to APCs that we believe are comparable with respect to clinical characteristics and resources required to furnish the cardiac catheterization services described by the new CPT codes (75 FR 71846 through 71849). As discussed in the final rule with comment period, we were able to use the existing CY 2009 hospital outpatient claims data and the most recent cost report data to create simulated medians for the new separately payable CPT codes for CY 2011. Specifically, to estimate the hospital costs associated with the 20 new non-congenital cardiac catheterization-related CPT codes based on their CY 2011 descriptors, we used claims and cost report data from CY 2009. Because of the substantive coding changes associated with the new non-congenital cardiac catheterization-related CPT codes for CY 2011, we used our CY 2009 single and ''pseudo'' single claims data to simulate the new CY 2011 CPT code definitions. We stated that many of the new CPT codes were previously reported using multiple CY 2009 CPT codes, and we provided a crosswalk of the new CY 2011 cardiac catheterization CPT codes mapped to the CY 2009 cardiac catheterization CPT codes in Table 11 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71849). Table 11 showed the criteria we applied to select a claim to be used in the calculation of the median cost for the new codes (shown in column A). As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71847 through 71848), we developed these criteria based on our clinicians' understanding of services that were reported by CY 2009 CPT codes that, in various combinations, reflect the services provided that are described in the new CPT codes. We used approximately 175,000 claims for the new non-congenital catheterization-related CPT codes, together with the single and ''pseudo'' single procedure claims for the remaining congenital

catheterization-related CPT codes in APC 0080, to calculate CPT level median costs and the median cost for APC 0080 of approximately $2,698. We noted that, because the CPT codes listed in Table 11 are new for CY 2011, they were identified with comment indicator ''NI'' in Addendum B of that final rule with comment period to identify them as subject to public comment. We specifically requested public comment on our methodology for simulating the median costs for these new CY 2011 CPT codes, in addition to public comments on the payment rates themselves (75 FR 71848).

For CY 2012, we are proposing to continue with the CY 2011 methodology in determining the APC assignments for the cardiac catheterization CPT codes. The predecessor cardiac catheterization CPT codes were in existence prior to CY 2011 and were assigned to APC 0080 based on claims data and cost report data. Given that these data are available for the services described by the predecessor cardiac catheterization CPT codes, for CY 2012, we are proposing to continue to use the existing hospital outpatient claims and cost report data from the predecessor cardiac catheterization CPT codes to simulate an estimated median cost for the new cardiac catheterization CPT codes in determining the appropriate APC assignments. As has been our practice since the implementation of the OPPS in 2000, we review our latest claims data for ratesetting and, if necessary, revise the APC assignments for the upcoming year. Based on analysis of the CY 2010 claims data available for this proposed rule, the proposed median cost for APC 0080 is approximately $2,822 for CY 2012, which is slightly greater than the median cost of approximately $2,698 for the CY 2011 OPPS/ASC final rule with comment period. For CY 2012, we are not proposing any changes to the CY 2011 APC assignments of any of the codes assigned to APC 0080 because the claims data available for this proposed rule support continuation of these APC assignments.

We are soliciting public comments on the proposed status indicators and the APC assignments for the CY 2012 cardiac catheterization CPT codes. Table 6 below lists the CY 2011 cardiac catheterization CPT codes along with their proposed status indicators, APC assignments, and payment rates for CY 2012.

TABLE 6—PROPOSED APCs TO WHICH NON-CONGENITAL CARDIAC CATHETERIZATION CPT CODES WOULD BE ASSIGNED FOR CY 2012

CY 2011 HCPCS Code	CY 2011 short descriptor	CY 2011 SI	CY 2011 APC	Proposed CY 2012 SI	Proposed CY 2012 APC
93451	Right heart cath	T	0080	T	0080
93452	Left hrt cath w/ventrclgrphy	T	0080	T	0080
93453	R&l hrt cath w/ventriclgrphy	T	0080	T	0080
93454	Coronary artery angio s&i	T	0080	T	0080
93455	Coronary art/grft angio s&i	T	0080	T	0080
93456	R hrt coronary artery angio	T	0080	T	0080
93457	R hrt art/grft angio	T	0080	T	0080
93458	L hrt artery/ventricle angio	T	0080	T	0080
93459	L hrt art/grft angio	T	0080	T	0080
93460	R&l hrt art/ventricle angio	T	0080	T	0080
93461	R&l hrt art/ventricle angio	T	0080	T	0080
93462	L hrt cath trnsptl puncture	T	0080	T	0080
93463	Drug admin & hemodynmic meas	N	NA	N	NA
93464	Exercise w/hemodynamic meas	N	NA	N	NA
93563	Inject congenital card cath	N	NA	N	NA
93564	Inject hrt congntl art/grft	N	NA	N	NA
93565	Inject l ventr/atrial angio	N	NA	N	NA
93566	Inject r ventr/atrial angio	N	NA	N	NA
93567	Inject suprvlv aortography	N	NA	N	NA
93568	Inject pulm art hrt cath	N	NA	N	NA

(8) Cranial Neurostimulator and Electrodes (APC 0318)

For CY 2011, the AMA CPT Editorial Panel created a new CPT code 64568 (Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator) and indicates that it describes the services formerly included in the combinations of (1) CPT code 64573 (Incision for implantation of neurostimulator electrodes; cranial nerve) and CPT code 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array); or (2) CPT code 64573 and CPT code 61886 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays). As we discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71850), our standard process for assigning new CPT codes to APCs is to assign the code to the APC that we believe contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. A new CPT code is given a comment indicator of ''NI'' to identify it as a new interim APC assignment for the first year and the APC assignment for the new code is then open to public comment. In some, but not all, cases, we are able to use the existing data from established codes to simulate an estimated median cost for the new code to guide us in the assignment of the new code to an APC. For CY 2011, in the case of the new neurostimulator electrode and pulse generator implantation CPT code, we were able to use the existing CY 2009 claims and most current cost report data to create a simulated median cost.

Specifically, to estimate the hospital costs of CPT code 64568 based on its CY 2011 descriptor, we used CY 2009 claims and the most recent cost report data, using the single and ''pseudo'' single claims within this data set to simulate the definition of this service. We selected claims with CPT code 64573 on which CPT code 61885 or 61886 was also present and consistent

with the description of the new CPT code 64568. We treated the summed costs on these claims as if they were a single procedure claim for CPT code 64568. We created an estimated median cost of approximately $22,562 for CPT code 64568 from 298 single claims to set a final payment rate for CY 2011 for the new code. We created APC 0318 (Implantation of Cranial Neurostimulator Pulse Generator and Electrode) for CY 2011, to which CPT code 64568 is the only procedure assigned. APC 0225 (Implantation of Neurostimulator Electrodes, Cranial Nerve), which contained only the predecessor CPT code 64573, was deleted effective January 1, 2011. We noted that, because CPT code 64568 is new for CY 2011, it was identified with comment indicator ''NI'' in Addendum B of the CY 2011 OPPS/ASC final rule with comment period to identify it as subject to public comment. We specifically requested public comment on our methodology for simulating the median costs for this new CY 2011 CPT code, in addition to public comments on the payment rate itself (75 FR 71850).

For CY 2012, we are proposing to use the same methodology we used in CY 2011 to estimate the hospital costs of CPT code 64568. We created an estimated median cost of approximately $24,267 for CPT code 64568 from 332 single claims to set a proposed payment rate for APC 0318 for CY 2012. We are proposing to maintain CPT code 64568 as the only code assigned to APC 0318 for CY 2012. We continue to request public comment on our proposed methodology for simulating the median cost for this CPT code introduced in CY 2011, in addition to public comments on the proposed payment rate itself.

(9) Brachytherapy Sources

(A) Background

Section 1833(t)(2)(H) of the Act, as added by section 621(b)(2)(C) of Public Law 108–173 (MMA), mandated the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The additional groups must reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished and include separate groups for palladium-103 and iodine-125 sources.

Section 1833(t)(16)(C) of the Act, as added by section 621(b)(1) of Public Law 108–173, established payment for brachytherapy sources furnished from January 1, 2004 through December 31, 2006, based on a hospital's charges for each brachytherapy source furnished adjusted to cost. Under section 1833(t)(16)(C) of the Act, charges for the brachytherapy sources may not be used in determining any outlier payments under the OPPS for that period in which payment is based on charges adjusted to cost. Consistent with our practice under the OPPS to exclude items paid at cost from budget neutrality consideration, these items were excluded from budget neutrality for that time period as well.

Subsequent to the MMA, various amendments to the Act were made that resulted in the extension of the payment period for brachytherapy sources based on a hospital's charges adjusted to cost through December 31, 2009. The CY 2011 OPPS/ASC final rule with comment period summarizes these amendments to the Act and our proposals to pay for brachytherapy sources at prospective payment rates based on their source specific median costs from CY 2007 through CY 2009 (75 FR 71977 through 71981).

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60533 through 60537), we adopted for CY 2010 the general OPPS prospective payment methodology for brachytherapy sources, consistent with section 1833(t)(2)(C) of the Act, with payment rates based on source-specific median costs. For CY 2011, we continued to use the general OPPS prospective payment methodology for brachytherapy sources, consistent with section 1833(t)(2)(C) of the Act (75 FR 71980). We also finalized our proposals to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537 and 75 FR 71980) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was superseded by section 142 of Pub. L. 110–275). That policy is intended to enable us to assign future new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

Consistent with our policy regarding APC payments made on a prospective basis, for CYs 2010 and 2011, we finalized proposals to subject brachytherapy sources to outlier payments under section 1833(t)(5) of the Act, and also to subject brachytherapy source payment weights to scaling for purposes of budget neutrality (75 FR 71980 through 71981 and 75 FR 60537). Hospitals could receive outlier payments for brachytherapy sources if the costs of furnishing brachytherapy sources meet the criteria for outlier payment. In addition, as noted in the CY 2010 and CY 2011 OPPS/ASC final rules with comment period (74 FR 60534 and 75 FR 71978 and 71979, respectively), implementation of prospective payments for brachytherapy sources provided opportunities for eligible hospitals to receive additional payments in CY 2010 and CY 2011 under certain circumstances through the 7.1 percent rural adjustment, as described in section II.E. of this final rule with comment period.

(B) Proposed OPPS Payment Policy

As we have stated previously (72 FR 66780, 73 FR 41502, 74 FR 60533 through 60534, and 75 FR 71978), we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons. The general OPPS payment methodology uses median costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by eliminating some of the extremely high and low payment amounts resulting from payment based on hospitals' charges adjusted to cost. We believe that the OPPS prospective payment methodology, as opposed to payment based on hospitals' charges adjusted to cost, would also provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS.

For CY 2012, we are proposing to use the median costs from CY 2010 claims data for setting the proposed CY 2012 payment rates for brachytherapy sources, as we are proposing for most other items and services that will be paid under the CY 2012 OPPS. We are proposing to continue the other payment policies for brachytherapy sources we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We are proposing to pay for the stranded and non-stranded NOS codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per source basis (as opposed, for example, to a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment

period (72 FR 66785). The proposed payment methodology for NOS sources would provide payment to a hospital for new sources and, at the same time, encourage interested parties to quickly bring new sources to our attention so that specific coding and payment could be established.

We also are proposing to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was superseded for a period of time by section 142 of Public Law 110–275). That policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

Consistent with our policy regarding APC payments made on a prospective basis, as we did for CY 2011, we are proposing to subject brachytherapy sources to outlier payments under section 1833(t)(5) of the Act, and also to subject brachytherapy source payment weights to scaling for purposes of budget neutrality. Hospitals can receive outlier payments for brachytherapy sources if the costs of furnishing brachytherapy sources meet the criteria for outlier payment. In addition, as noted in the CY 2010 and CY 2011 OPPS/ASC final rules with comment period (74 FR 60534 and 75 FR 71978 through 71979, respectively), implementation of prospective payments for brachytherapy sources would provide opportunities for eligible hospitals to receive additional payments in CY 2012 under certain circumstances through the 7.1 percent rural adjustment, as described in section II.E. of this proposed rule.

Therefore, we are proposing to pay for brachytherapy sources at prospective payment rates based on their source-specific median costs for CY 2012. We refer readers to Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) for the proposed CY 2012 payment rates for brachytherapy sources, identified with status indicator ''U.'' For more detailed discussion of the legislative history surrounding brachytherapy sources and our proposed and final policies for CY 2004 through CY 2011, we refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 71977 through 71981).

We continue to invite hospitals and other parties to submit recommendations to us for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. Such recommendations should be directed to the Division of Outpatient Care, Mail Stop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

e. Proposed Calculation of Composite APC Criteria-Based Median Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide only necessary, high quality care and to provide that care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite APC policies for extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for a full discussion of the development of the composite APC methodology (72 FR 66611 through 66614 and 66650 through 66652).

For CY 2012, we are proposing to continue, with some modifications, our established composite APC policies for extended assessment and management, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, and multiple imaging services, as discussed in sections II.A.2.e.(1), II.A.2.e.(2), II.A.2.e.(3), II.A.2.e.(4), and II.A.2.e.(5), respectively, of this proposed rule. We also are proposing to create a new composite APC for cardiac resynchronization therapy services, as discussed in section II.A.2.e.(6) of this proposed rule.

(1) Extended Assessment and Management Composite APCs (APCs 8002 and 8003)

For CY 2012, we are proposing to continue to include composite APC 8002 (Level I Extended Assessment and Management Composite) and composite APC 8003 (Level II Extended Assessment and Management Composite) in the OPPS. For CY 2008, we created these two composite APCs to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (an extended visit). In most circumstances, observation services are supportive and ancillary to the other services provided to a patient. In the circumstances when observation care is provided in conjunction with a high level visit or direct referral and is an integral part of a patient's extended encounter of care, payment is made for the entire care encounter through one of two composite APCs as appropriate.

As defined for the CY 2008 OPPS, composite APC 8002 describes an encounter for care provided to a patient that includes a high level (Level 5) clinic visit or direct referral for observation services in conjunction with observation services of substantial duration (72 FR 66648 through 66649). Composite APC 8003 describes an encounter for care provided to a patient that includes a high level (Level 4 or 5) Type A emergency department visit, a high level (Level 5) Type B emergency department visit, or critical care services in conjunction with observation services of substantial duration. HCPCS code G0378 (Observation services, per hour) is assigned status indicator ''N,'' signifying that its payment is always packaged. As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66648 through 66649), the Integrated Outpatient Code Editor (I/OCE) evaluates every claim received to determine if payment through a composite APC is appropriate. If payment through a composite APC is inappropriate, the I/OCE, in conjunction with the OPPS Pricer, determines the appropriate status indicator, APC, and payment for every code on a claim. The specific criteria that must be met for the two extended assessment and

management composite APCs to be paid are provided below in the description of the claims that were selected for the calculation of the proposed CY 2012 median costs for these composite APCs. We are not proposing to change these criteria for the CY 2012 OPPS.

When we created composite APCs 8002 and 8003 for CY 2008, we retained as general reporting requirements for all observation services those criteria related to physician order and evaluation, documentation, and observation beginning and ending time as listed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66812). These are more general requirements that encourage hospitals to provide medically reasonable and necessary care and help to ensure the proper reporting of observation services on correctly coded hospital claims that reflect the full charges associated with all hospital resources utilized to provide the reported services. We also issued guidance clarifying the correct method for reporting the starting time for observation services (sections 290.2.2 through 290.5 in the Medicare Claims Processing Manual (Pub. 100–4), Chapter 4, through Transmittal 1745, Change Request 6492, issued May 22, 2009 and implemented July 6, 2009). We are not proposing to change these reporting requirements for the CY 2012 OPPS.

For CY 2012, we are proposing to continue the extended assessment and management composite APC payment methodology for APCs 8002 and 8003. We continue to believe that the composite APCs 8002 and 8003 and related policies provide the most appropriate means of paying for these services. We are proposing to calculate the median costs for APCs 8002 and 8003 using all single and ''pseudo'' single procedure claims for CY 2010 that meet the criteria for payment of each composite APC.

Specifically, to calculate the proposed median costs for composite APCs 8002 and 8003, we selected single and ''pseudo'' single procedure claims that met each of the following criteria:

1. Did not contain a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service 1 day earlier than the date of service associated with HCPCS code G0378. (By selecting these claims from single and ''pseudo'' single claims, we had already assured that they would not contain a code for a service with status indicator ''T'' on the same date of service.);

2. Contained eight or more units of HCPCS code G0378; and

3. Contained one of the following codes:

- In the case of composite APC 8002, HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as HCPCS code G0378; or CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)); or CPT code 99215 (Office or other outpatient visit for the evaluation and management of an established patient (Level 5)) provided on the same date of service or one day before the date of service for HCPCS code G0378.
- In the case of composite APC 8003, CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0384 (Level 5 hospital emergency department visit provided in a Type B emergency department) provided on the same date of service or one day before the date of service for HCPCS code G0378. (As discussed in detail in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68684), we added HCPCS code G0384 to the eligibility criteria for composite APC 8003 for CY 2009.)

As discussed further in section VII. of this proposed rule, and consistent with our CY 2008, CY 2009, CY 2010, and CY 2011 final policies, when calculating the median costs for the clinic, Type A emergency department visit, Type B emergency department visit, and critical care APCs (0604 through 0617 and 0626 through 0630), we utilize our methodology that excludes those claims for visits that are eligible for payment through the two extended assessment and management composite APCs, that is APC 8002 or APC 8003. We believe that this approach results in the most accurate cost estimates for APCs 0604 through 0617 and 0626 through 0630 for CY 2012.

At its February 28–March 1, 2011 meeting, the APC Panel recommended that CMS consider expanding the extended assessment and management composite APCs for CY 2012. We are accepting this recommendation.

Consistent with our acceptance of the APC Panel's recommendation, we have examined various ways of potentially expanding the current extended assessment and management composite APCs to further limit the possibility that total beneficiary copayments would exceed the inpatient deductible during extended observation encounters. At this time, we have decided not to pursue for CY 2012 the expanded extended assessment and management composite APCs that we analyzed because, while the composites that we modeled would serve to further limit the number of beneficiaries with copayments that exceeded the inpatient deductible, the modeled composites also had the effect of possibly increasing copayments by a small amount for the majority of beneficiaries undergoing extended observation. In addition, expanded assessment and management composite APCs do not address certain concerns about extended observation services raised by stakeholders at CMS' observation listening session last year (that is, observation time not counting towards the 3-day prior hospitalization requirement for the skilled nursing facility benefit). We will continue our efforts to model other composite structures for a possible new extended assessment and management composite structure for CY 2013.

In summary, for CY 2012, we are proposing to continue to include composite APCs 8002 and 8003 in the OPPS. We are proposing to continue the extended assessment and management composite APC payment methodology and criteria that we finalized for CYs 2009, 2010, and 2011. We also are proposing to calculate the median costs for APCs 8002 and 8003 using the same methodology that we used to calculate the medians for composite APCs 8002 and 8003 for the CY 2008 OPPS (72 FR 66649). That is, we used all single and ''pseudo'' single procedure claims from CY 2010 that met the criteria for payment of each composite APC and applied the standard packaging and trimming rules to the claims before calculating the proposed CY 2012 median costs. The proposed CY 2012 median cost resulting from this methodology for composite APC 8002 is approximately $395, which was calculated from 16,770 single and ''pseudo'' single bills that met the required criteria. The proposed CY 2012 median cost for composite APC 8003 is approximately $735, which was calculated from 225,874 single and ''pseudo'' single bills that met the required criteria.

(2) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC (APC 8001)

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT

codes are used to report the composite treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex). Generally, the component services represented by both codes are provided in the same operative session in the same hospital on the same date of service to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66653), OPPS payment rates for CPT code 77778, in particular, had fluctuated over the years. We were frequently informed by the public that reliance on single procedure claims to set the median costs for these services resulted in use of mainly incorrectly coded claims for LDR prostate brachytherapy because a correctly coded claim should include, for the same date of service, CPT codes for both needle/catheter placement and application of radiation sources, as well as separately coded imaging and radiation therapy planning services (that is, a multiple procedure claim).

In order to base payment on claims for the most common clinical scenario, and to further our goal of providing payment under the OPPS for a larger bundle of component services provided in a single hospital encounter, beginning in CY 2008, we began providing a single payment for LDR prostate brachytherapy when the composite service, reported as CPT codes 55875 and 77778, is furnished in a single hospital encounter. We based the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the median cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes that are not on the bypass list. In uncommon occurrences in which the services are billed individually, hospitals have continued to receive separate payments for the individual services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66652 through 66655) for a full history of OPPS payment for LDR prostate brachytherapy and a detailed description of how we developed the LDR prostate brachytherapy composite APC.

For CY 2012, we are proposing to continue paying for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2011. That is, we are proposing to use CY 2010 claims on which both CPT codes 55875 and 77778 were billed on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2011 practice, we are proposing not to use the claims that meet these criteria in the calculation of the median costs for APCs 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures) and 0651 (Complex Interstitial Radiation Source Application), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. The median costs for APCs 0163 and 0651 would continue to be calculated using single and ''pseudo'' single procedure claims. We believe that this composite APC contributes to our goal of creating hospital incentives for efficiency and cost containment, while providing hospitals with the most flexibility to manage their resources. We also continue to believe that data from claims reporting both services required for LDR prostate brachytherapy provide the most accurate median cost upon which to base the composite APC payment rate.

Using partial year CY 2010 claims data available for this CY 2012 proposed rule, we were able to use 556 claims that contained both CPT codes 55875 and 77778 to calculate the median cost upon which the proposed CY 2012 payment for composite APC 8001 is based. The proposed median cost for composite APC 8001 for CY 2012 is approximately $3,364. This is an increase compared to the CY 2011 final median cost for this composite APC of approximately $3,195 based on 849 single bill claims from a full year of CY 2009 claims data. The proposed CY 2012 median cost for this composite APC is slightly less than $3,555, the sum of the proposed median costs for APCs 0163 and 0651 ($2,658 + $897), the APCs to which CPT codes 55875 and 77778 map if one service is billed on a claim without the other. We believe the proposed CY 2012 median cost for composite APC 8001 of approximately $3,364, calculated from claims we believe to be correctly coded, would result in a reasonable and appropriate payment rate for this service in CY 2012.

(3) Cardiac Electrophysiologic Evaluation and Ablation Composite APC (APC 8000)

Cardiac electrophysiologic evaluation and ablation services frequently are performed in varying combinations with one another during a single episode of care in the hospital outpatient setting. Therefore, correctly coded claims for these services often include multiple codes for component services that are reported with different CPT codes and that, prior to CY 2008, were always paid separately through different APCs (specifically, APC 0085 (Level II Electrophysiologic Evaluation), APC 0086 (Ablate Heart Dysrhythm Focus), and APC 0087 (Cardiac Electrophysiologic Recording/Mapping)). As a result, there would never be many single bills for cardiac electrophysiologic evaluation and ablation services, and those that are reported as single bills would often represent atypical cases or incorrectly coded claims. As described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66655 through 66659), the APC Panel and the public expressed persistent concerns regarding the limited and reportedly unrepresentative single bills available for use in calculating the median costs for these services according to our standard OPPS methodology.

Effective January 1, 2008, we established APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite) to pay for a composite service made up of at least one specified electrophysiologic evaluation service and one specified electrophysiologic ablation service. Calculating a composite APC for these services allowed us to utilize many more claims than were available to establish the individual APC median costs for these services, and we also saw this composite APC as an opportunity to advance our stated goal of promoting hospital efficiency through larger payment bundles. In order to calculate the median cost upon which the payment rate for composite APC 8000 is based, we used multiple procedure claims that contained at least one CPT code from group A for evaluation services and at least one CPT code from group B for ablation services reported on the same date of service on an individual claim. Table 9 in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66656) identified the CPT codes that are assigned to groups A and B. For a full discussion of how we identified the group A and group B procedures and established the payment rate for the cardiac electrophysiologic evaluation and ablation composite APC, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66655 through 66659). Where a service in group A is furnished on a date of service that is different from the date of service

for a code in group B for the same beneficiary, payments are made under the appropriate single procedure APCs and the composite APC does not apply.

For CY 2012, we are proposing to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology proposed and implemented for CY 2008 through CY 2011. Consistent with our CY 2008 through CY 2011 practice, we are proposing not to use the claims that meet the composite payment criteria in the calculation of the median costs for APC 0085 and APC 0086, to which the CPT codes in both groups A and B for composite APC 8000 are otherwise assigned. Median costs for APCs 0085 and 0086 would continue to be calculated using single procedure claims. We continue to believe that the composite APC methodology for cardiac electrophysiologic evaluation and ablation services is the most efficient and effective way to use the claims data for the majority of these services and best represents the hospital resources associated with performing the common combinations of these services that are clinically typical. Furthermore, this approach creates incentives for efficiency by providing a single payment for a larger bundle of major procedures when they are performed together, in contrast to continued separate payment for each of the individual procedures.

For CY 2012, using a partial year of CY 2010 claims data available for this proposed rule, we were able to use 11,156 claims containing a combination of group A and group B codes and calculate a proposed median cost of approximately $11,598 for composite APC 8000. This is an increase compared to the CY 2011 final median cost for this composite APC of approximately $10,673 based on a full year of CY 2009 claims data. We believe the proposed median cost of $11,598 calculated from a high volume of correctly coded multiple procedure claims would result in an accurate and appropriate proposed payment for cardiac electrophysiologic evaluation and ablation services when at least one evaluation service is furnished during the same clinical encounter as at least one ablation service.

Table 7 below list the groups of procedures upon which we based proposed composite APC 8000 for CY 2012.

TABLE 7—PROPOSED GROUPS OF CARDIAC ELECTROPHYSIOLOGIC EVALUATION AND ABLATION PROCEDURES UPON WHICH COMPOSITE APC 8000 IS BASED

Codes used in combinations: At least one in Group A and one in Group B	CY 2011 CPT Code	Proposed single code CY 2012 APC	Proposed CY 2012 SI (composite)
Group A:			
Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia.	93619	0085	Q3
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording.	93620	0085	Q3
Group B:			
Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement.	93650	0085	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connections or other atrial foci, singly or in combination.	93651	0086	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia.	93652	0086	Q3

(4) Mental Health Services Composite APC (APC 0034)

For CY 2012, we are proposing to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization, which we consider to be the most resource-intensive of all outpatient mental health treatment for CY 2012. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy. We continue to believe that the costs associated with administering a partial hospitalization program represent the most resource-intensive of all outpatient mental health treatment. Therefore, we do not believe that we should pay more for a day of individual mental health services under the OPPS than the partial hospitalization per diem payment.

As discussed in detail in section VIII. of this proposed rule, for CY 2012, we are proposing to continue using a provider-specific two tiered payment approach for partial hospitalization services that distinguishes payment made for services furnished in a CMHC from payment made for services furnished in a hospital. Specifically, we are proposing one APC for partial hospitalization program days with three services furnished in a CMHC (APC 0172, (Level I Partial Hospitalization (3 services) for CMHCs) and one APC for days with four or more services furnished in a CMHC (APC 0173, Level II Partial Hospitalization (4 or more services) for CMHCs). We are proposing that the payment rates for these two APCs be based upon the median per diem costs calculated using data only from CMHCs. Similarly, we are proposing one APC for partial hospitalization program days with three services furnished in a hospital (APC 0175, Level I Partial Hospitalization (3 services) for Hospital-Based PHPs), and one APC for days with four or more services furnished in a hospital (APC 0176, Level II Partial Hospitalization (4 or more services) for Hospital-Based PHPs). We are proposing that the payment rates for these two APCs be based on the median per diem costs calculated using data only from hospitals.

Because our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment rate for the most

resource-intensive of all outpatient mental health treatment, we are proposing to continue to set the CY 2012 payment rate for APC 0034 (Mental Health Services Composite) at the same rate as we are proposing for APC 0176, which is the maximum partial hospitalization per diem payment. We believe this APC payment rate would provide the most appropriate payment for composite APC 0034, taking into consideration the intensity of the mental health services and the differences in the HCPCS codes for mental health services that could be paid through this composite APC compared with the HCPCS codes that could be paid through partial hospitalization APC 0176. When the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on one date of service based on the payment rates associated with the APCs for the individual services exceeds the maximum per diem partial hospitalization payment, we are proposing that those specified mental health services would be assigned to APC 0034. We are proposing that APC 0034 would have the same payment rate as APC 0176 and that the hospital would continue to be paid one unit of APC 0034. The I/OCE currently determines, and we are proposing for CY 2012 that it would continue to determine, whether to pay these specified mental health services individually or to make a single payment at the same rate as the APC 0176 per diem rate for partial hospitalization for all of the specified mental health services furnished by the hospital on that single date of service.

(5) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Prior to CY 2009, hospitals received a full APC payment for each imaging service on a claim, regardless of how many procedures were performed during a single session using the same imaging modality. Based on extensive data analysis, we determined that this practice neither reflected nor promoted the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). As a result of our data analysis, and in response to ongoing recommendations from MedPAC to improve payment accuracy for imaging services under the OPPS, we expanded the composite APC model developed in CY 2008 to multiple imaging services. Effective January 1, 2009, we provide a single payment each time a hospital bills more than one imaging procedure within an imaging family on the same date of service. We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 13 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71859 through 71860).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement at section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included in the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment for APC 8008, the ''with contrast'' composite APC.

Hospitals continue to use the same HCPCS codes to report imaging procedures, and the I/OCE determines when combinations of imaging procedures qualify for composite APC payment or map to standard (sole service) APCs for payment. We make a single payment for those imaging procedures that qualify for composite APC payment, as well as any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

At its February 2010 meeting, the APC Panel recommended that CMS continue providing analysis on an ongoing basis of the impact on beneficiaries of the multiple imaging composite APCs as data become available. In the CY 2011 OPPS/ASC proposed rule, we indicated that we were accepting this recommendation and would provide the requested analysis to the APC Panel at a future meeting (75 FR 46212). At the February 28–March 1, 2011 APC Panel meeting, CMS staff provided an updated analysis of the multiple imaging composite APCs to the Panel, comparing partial year CY 2010 imaging composite cost and utilization data to comparable CY 2009 data in order to meet the APC Panel request that we provide analysis of the impact on beneficiaries of the multiple imaging composite APCs.

For CY 2012, we are proposing to continue paying for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite payment methodology. The proposed CY 2012 payment rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) are based on median costs calculated from the partial year CY 2010 claims available for this proposed rule that qualified for composite payment under the current policy (that is, those claims with more than one procedure within the same family on a single date of service). To calculate the proposed median costs, we used the same methodology that we used to calculate the final CY 2011 median costs for these composite APCs. That is, we removed any HCPCS codes in the OPPS imaging families that overlapped with codes on our bypass list (''overlap bypass codes'') to avoid splitting claims with multiple units or multiple occurrences of codes in an OPPS imaging family into new ''pseudo'' single claims. The imaging HCPCS codes that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC median costs appear in Table 9 of this proposed rule. (We note that, consistent with our proposal in section II.A.1.b. of this proposed rule to add CPT code 71550 (Magnetic resonance (e.g., proton) imaging, chest (e.g., for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s)) to the list of bypass codes for CY 2012, we also are proposing to add CPT code 71550 to the list of proposed OPPS imaging family services overlapping with HCPCS codes on the

proposed CY 2012 bypass list.) We integrated the identification of imaging composite ''single session'' claims, that is, claims with multiple imaging procedures within the same family on the same date of service, into the creation of ''pseudo'' single procedure claims to ensure that claims were split in the ''pseudo'' single process into accurate reflections of either a composite ''single session'' imaging service or a standard sole imaging service resource cost. Like all single bills, the new composite ''single session'' claims were for the same date of service and contained no other separately paid services in order to isolate the session imaging costs. Our last step after processing all claims through the ''pseudo'' single process was to reassess the remaining multiple procedure claims using the full bypass list and bypass process in order to determine if we could make other ''pseudo'' single bills. That is, we assessed whether a single separately paid service remained on the claim after removing line-items for the ''overlap bypass codes.''

As discussed in detail in section III.D.2. of this proposed rule, we are proposing to establish two APCs to which we would propose to assign the codes created for CY 2011 by the AMA's CPT Editorial Board for combined abdominal and pelvis CT services. Specifically, we are proposing to create new APC 0331 (Combined Abdominal and Pelvis CT Without Contrast), to which we are proposing to assign CPT code 74176 (Computed tomography, abdomen and pelvis; without contrast material); and we are proposing to create new APC 0334 (Combined Abdominal and Pelvis CT With Contrast), to which we are proposing to assign CPT codes 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)) and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions) for the CY 2012 OPPS. As noted and listed in section III.D.2. of this proposed rule, we selected claims of predecessor codes of new CPT codes 74176, 74177, and 74178 to calculate the costs of proposed new APCs 0331 and 0334, respectively. Therefore, we are proposing not to use those claims listed in Table 21 in section III.D.2. of this proposed rule in calculating the costs of APCs 8005 and 8006.

We were able to identify 1 million ''single session'' claims out of an estimated 2 million potential composite cases from our ratesetting claims data, or approximately half of all eligible claims, to calculate the proposed CY 2012 median costs for the multiple imaging composite APCs. We list in Table 8 below the HCPCS codes that would be subject to the proposed multiple imaging composite policy, the approximate proposed median costs for the imaging composite APCs, and their respective families for CY 2012. The HCPCS codes listed in Table 8 are assigned status indicated ''Q3''' in Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) to identify their status as potentially payable through a composite APC. Their proposed composite APC assignment is identified in Addendum M to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site). Table 9 below lists the OPPS imaging family services that overlap with HCPCS codes on the proposed CY 2012 bypass list.

TABLE 8—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1—Ultrasound

Proposed CY 2012 APC 8004 (Ultrasound Composite)	Proposed CY 2012 Approximate APC Median Cost = $197
76604	Us exam, chest.
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76775	Us exam abdo back wall, lim.
76776	Us exam k transpl w/ Doppler.
76831	Echo exam, uterus.
76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.

Family 2—CT and CTA With and Without Contrast

Proposed CY 2012 APC 8005 (CT and CTA Without Contrast Composite)*	Proposed CY 2012 Approximate APC Median Cost = $445
70450	Ct head/brain w/o dye.
70480	Ct orbit/ear/fossa w/o dye.
70486	Ct maxillofacial w/o dye.
70490	Ct soft tissue neck w/o dye.
71250	Ct thorax w/o dye.
72125	Ct neck spine w/o dye.
72128	Ct chest spine w/o dye.
72131	Ct lumbar spine w/o dye.
72192	Ct pelvis w/o dye.
73200	Ct upper extremity w/o dye.
73700	Ct lower extremity w/o dye.
74150	Ct abdomen w/o dye.
74261	Ct colonography, w/o dye.
74176	Ct angio abd & pelvis.

Proposed CY 2012 APC 8006 (CT and CTA With Contrast Composite)	Proposed CY 2012 Approximate APC Median Cost = $744
70487	Ct maxillofacial w/dye.
70460	Ct head/brain w/dye.
70470	Ct head/brain w/o & w/ dye.
70481	Ct orbit/ear/fossa w/dye.
70482	Ct orbit/ear/fossa w/o & w/dye.
70488	Ct maxillofacial w/o & w/ dye.
70491	Ct soft tissue neck w/ dye.
70492	Ct sft tsue nck w/o & w/ dye.
70496	Ct angiography, head.
70498	Ct angiography, neck.
71260	Ct thorax w/dye.
71270	Ct thorax w/o & w/dye.
71275	Ct angiography, chest.
72126	Ct neck spine w/dye.
72127	Ct neck spine w/o & w/ dye.
72129	Ct chest spine w/dye.
72130	Ct chest spine w/o & w/ dye.
72132	Ct lumbar spine w/dye.
72133	Ct lumbar spine w/o & w/ dye.
72191	Ct angiograph pelv w/o & w/dye.
72193	Ct pelvis w/dye.
72194	Ct pelvis w/o & w/dye.
73201	Ct upper extremity w/ dye.
73202	Ct uppr extremity w/o & w/dye.
73206	Ct angio upr extrm w/o & w/dye.
73701	Ct lower extremity w/dye.
73702	Ct lwr extremity w/o & w/ dye.
73706	Ct angio lwr extr w/o & w/dye.
74160	Ct abdomen w/dye.
74170	Ct abdomen w/o & w/ dye.
74175	Ct angio abdom w/o & w/ dye.
74262	Ct colonography, w/dye.
75635	Ct angio abdominal arteries.
74177	Ct angio abd & pelv w/ contrast.
74178	Ct angio abd & pelv 1+ regns.

* If a ''without contrast'' CT or CTA procedure is performed during the same session as a ''with contrast'' CT or CTA procedure, the I/OCE will assign APC 8006 rather than APC 8005.

Family 3—MRI and MRA With and Without Contrast

Proposed CY 2012 APC 8007 (MRI and MRA Without Contrast Composite)*	Proposed CY 2012 Approximate APC Median Cost = $718
70336	Magnetic image, jaw joint.

TABLE 8—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

70540	Mri orbit/face/neck w/o dye.
70544	Mr angiography head w/o dye.
70547	Mr angiography neck w/o dye.
70551	Mri brain w/o dye.
70554	Fmri brain by tech.
71550	Mri chest w/o dye.
72141	Mri neck spine w/o dye.
72146	Mri chest spine w/o dye.
72148	Mri lumbar spine w/o dye.
72195	Mri pelvis w/o dye.
73218	Mri upper extremity w/o dye.
73221	Mri joint upr extrem w/o dye.
73718	Mri lower extremity w/o dye.
73721	Mri jnt of lwr extre w/o dye.
74181	Mri abdomen w/o dye.
75557	Cardiac mri for morph.
75559	Cardiac mri w/stress img.
C8901	MRA w/o cont, abd.
C8904	MRI w/o cont, breast, uni.
C8907	MRI w/o cont, breast, bi.
C8910	MRA w/o cont, chest.
C8913	MRA w/o cont, lwr ext.
C8919	MRA w/o cont, pelvis.
C8932	MRA, w/o dye., spinal canal.
C8935	MRA, w/o dye., upper extr.
Proposed CY 2012 APC 8008 (MRI and MRA with Contrast Composite)	Proposed CY 2012 Approximate APC Median Cost = $1,032
70549	Mr angiograph neck w/o & w/dye.
70542	Mri orbit/face/neck w/dye.
70543	Mri orbt/fac/nck w/o & w/dye.
70545	Mr angiography head w/dye.
70546	Mr angiograph head w/o & w/dye.
70548	Mr angiography neck w/dye.
70552	Mri brain w/dye.
70553	Mri brain w/o & w/dye.
71551	Mri chest w/dye.
71552	Mri chest w/o & w/dye.
72142	Mri neck spine w/dye.
72147	Mri chest spine w/dye.
72149	Mri lumbar spine w/dye.
72156	Mri neck spine w/o & w/dye.
72157	Mri chest spine w/o & w/dye.
72158	Mri lumbar spine w/o & w/dye.
72196	Mri pelvis w/dye.
72197	Mri pelvis w/o & w/dye.
73219	Mri upper extremity w/dye.
73220	Mri uppr extremity w/o & w/dye.
73222	Mri joint upr extrem w/dye.
73223	Mri joint upr extr w/o & w/dye.
73719	Mri lower extremity w/dye.

TABLE 8—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

73720	Mri lwr extremity w/o & w/dye.
73722	Mri joint of lwr extr w/dye.
73723	Mri joint lwr extr w/o & w/dye.
74182	Mri abdomen w/dye.
74183	Mri abdomen w/o & w/dye.
75561	Cardiac mri for morph w/dye.
75563	Card mri w/stress img & dye.
C8900	MRA w/cont, abd.
C8902	MRA w/o fol w/cont, abd.
C8903	MRI w/cont, breast, uni.
C8905	MRI w/o fol w/cont, brst, un.
C8906	MRI w/cont, breast, bi.
C8908	MRI w/o fol w/cont, breast.
C8909	MRA w/cont, chest.
C8911	MRA w/o fol w/cont, chest.
C8912	MRA w/cont, lwr ext.
C8914	MRA w/o fol w/cont, lwr ext.
C8918	MRA w/cont, pelvis.
C8920	MRA w/o fol w/cont, pelvis.
C8931	MRA, w/dye., spinal canal.
C8933	MRA, w/o & w/dye., spinal canal.
C8934	MRA, w/dye., upper extremity.
C8936	MRA, w/o & w/dye., upper extr.

* If a ''without contrast'' MRI or MRA procedure is performed during the same session as a ''with contrast'' MRI or MRA procedure, the I/OCE will assign APC 8008 rather than 8007.

TABLE 9—PROPOSED OPPS IMAGING FAMILY SERVICES OVERLAPPING WITH HCPCS CODES ON THE PROPOSED CY 2012 BYPASS LIST

Family 1—Ultrasound	
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76775	Us exam abdo back wall, lim.
76776	Us exam k transpl w/Doppler.
76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.
Family 2—CT and CTA with and without contrast	
70450	Ct head/brain w/o dye.
70480	Ct orbit/ear/fossa w/o dye.
70486	Ct maxillofacial w/o dye.
70490	Ct soft tissue neck w/o dye.
71250	Ct thorax w/o dye.
72125	Ct neck spine w/o dye.
72128	Ct chest spine w/o dye.
72131	Ct lumbar spine w/o dye.
72192	Ct pelvis w/o dye.
73200	Ct upper extremity w/o dye.

TABLE 9—PROPOSED OPPS IMAGING FAMILY SERVICES OVERLAPPING WITH HCPCS CODES ON THE PROPOSED CY 2012 BYPASS LIST—Continued

73700	Ct lower extremity w/o dye.
74150	Ct abdomen w/o dye.
Family 3—MRI and MRA with and without contrast	
70336	Magnetic image, jaw joint.
70544	Mr angiography head w/o dye.
70551	Mri brain w/o dye.
71550	Mri chest w/o dye.
72141	Mri neck spine w/o dye.
72146	Mri chest spine w/o dye.
72148	Mri lumbar spine w/o dye.
73218	Mri upper extremity w/o dye.
73221	Mri joint upr extrem w/o dye.
73718	Mri lower extremity w/o dye.
73721	Mri jnt of lwr extre w/o dye.

(6) Cardiac Resynchronization Therapy Composite APC (APCs 0108, 0418, 0655, and 8009)

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD). CRT performed by the implantation of an ICD along with a pacing electrode is referred to as ''CRT–D.'' CRT performed by the implantation of a pacemaker along with a pacing electrode is referred to as ''CRT–P.''

CRT–D procedures are described by combinations of CPT codes for the insertion of pulse generators and the insertion of the leads associated with ICDs, along with the insertion of the pacing electrode. For the implantation of a pulse generator, hospitals may use CPT code 33240 (Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator), which is the only CPT code assigned to APC 0107 (Insertion of Cardioverter-Defibrillator) for CY 2011. For the implantation of a pulse generator and leads, hospitals may use CPT code 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator), which is the only CPT code assigned to APC 0108 (Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads) for CY 2011.

For CRT–P, hospitals may use CPT codes 33206 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial) and 33207 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); ventricular), which are

assigned to APC 0089 (Insertion/Replacement of Permanent Pacemaker and Electrodes) for CY 2011. Hospitals also may use CPT code 33208 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular), for the implantation of a pacemaker with leads, which is assigned to APC 0655 (Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker).

When CRT–P is provided, hospitals would report CPT code 33206, 33207, or 33208 codes for ICD or pacemaker insertion, along with CPT code 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system)), for implantation of the pacing electrode, which is assigned to APC 0418 (Insertion of Left Ventricular Pacing Electrode) for CY 2011.

A number of commenters who responded to prior OPPS proposed rules, as well as public presenters to the APC Panel, have recommended that CMS establish new composite APCs for CRT–D, citing significant fluctuations in the median cost for CPT code 33225 and the payment rate for APC 0418. The commenters and presenters have pointed out that, because the definition of CPT code 33225 specifies that the pacing electrode is inserted at the same time as an ICD or pacemaker, CMS would not have many valid single or pseudo single claims upon which to calculate an accurate median cost. These commenters and presenters also asserted that claims data for these services demonstrate that the percentage of single claims available for use in CRT ratesetting is very low compared to the total number of claims submitted for CRT–D or CRT–P services. The APC Panel at its February and August 2009 meetings recommended that CMS evaluate the implications of the creation of a new composite APC for CRT–D and recommended that CMS reconsider creating a composite APC or group of composite APCs for CRT–D and CRT–P. While we did not propose any new composite APCs for CY 2010 or CY 2011, we accepted both of these APC Panel recommendations (75 FR 71852).

In response to the APC Panel recommendations and the comments we have received, we have evaluated the implications of creating four composite APCs for CRT, which would include the ICD and pacemaker insertion procedures listed previously in this section (described by CPT codes 33240, 33249, 33206, 33207, and 33208) performed in combination with the insertion of a pacing electrode (described by CPT code 33225). Table 10 below outlines the four potential composite APCs that we modeled. Specifically, we provide a description of each potential composite APC, the combination of CPT codes that we used to define the potential composite APC, the frequency of claims that met the definition of the potential composite APC that could be used to calculate a median cost for the potential composite APC, and the median cost calculated for the potential composite APC. Table 10 below contains the results from our calculations for the four potential composite APCs using CY 2010 claims data available for this proposed rule, that is, those claims processed between January 1 and December 31, 2010.

TABLE 10—POTENTIAL COMPOSITE APCS

Potential composite APC	Description	Component APCs	CPT codes	CY 2010 frequency	CY 2012 payment estimate
A	Cardiac Resynchronization Therapy—ICD Pulse Generator and Leads	0418 0107	33225 33240	21	$35,623
B	Cardiac Resynchronization Therapy—ICD Pulse Generator	0418 0108	33225 33249	2,358	38,854
C	Cardiac Resynchronization Therapy—Pacemaker Pulse Generator, and Leads (Atrial or Ventricular).	0418 0089	33225 33206 33207	84	17,306
D	Cardiac Resynchronization Therapy—Pacemaker Pulse Generator, and Leads (Atrial and Ventricular).	0418 0655	33225 33208	314	18,705

For CY 2012, under the authority of section 1833(t)(1)(B) of the Act, we are proposing to create a new composite APC 8009 (Cardiac Resynchronization Therapy with Defibrillator Composite), listed as potential composite APC ''B'' in Table 10 above, for CRT–D services. This proposed composite APC is the only modeled composite in the study as shown above in Table 10, with significant claims volume, and would combine a procedure currently in APC 0418 with a procedure currently in APC 0108 (Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads) when performed on the same date of service. Specifically, we are proposing to create composite APC 8009, which would be used when CPT 33249 and CPT 33225 are performed on the same day, in order to recognize the inherent challenges in calculating accurate median costs for CPT code 33225 based on single procedure claims utilized in standard OPPS ratesetting methodology, and to address commenters' concerns regarding the fluctuations in median costs for APC 0418. We believe a composite payment methodology is appropriate for these services and would result in more accurate payment for these services because such a methodology is specifically designed to provide payment for two or more procedures when they are provided in the same encounter, thus enabling us to use more claims data and to use claims data that more accurately represents the full cost of the services when they are furnished in the same encounter. We also believe that there is sufficient claims volume for CPT 33249 and CPT 33225 provided in the same encounter to warrant creation of the composite APC. In addition, we believe that the claims volume for CPT 33249 and CPT 33225 is sufficient to demonstrate that these services are commonly performed together. While the other combinations of CRT procedures listed in Table 10 may also be performed together, we are not proposing to implement composite APCs for these services because of the low frequency with which CPT code 33225 is reported with other CPT codes for ICD and pacemaker insertion in the claims data. As we have stated previously (74 FR 60392), because of the complex claims processing and ratesetting logic involved, in the past, we have explored composite APCs only for combinations of services that are commonly performed together. Because

of the low frequency of the other combinations of CRT procedures listed in Table 10, we do not consider them to be commonly performed together.

Under the authority of section 1833(t)(2)(E) of the Act, we also are proposing to cap the payment rate for composite APC 8009 at the most comparable Medicare-severity diagnosis-related group (MS–DRG) payment rate established under the IPPS that would be provided to acute care hospitals for providing CRT–D services to hospital inpatients. Specifically, we are proposing to pay APC 8009 at the lesser of the APC 8009 median cost or the IPPS payment rate for MS–DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization without Major Complication or Comorbidity), as adopted in the FY 2012 IPPS/LTCH PPS final rule. We would establish the OPPS payment amount at the FY 2012 IPPS standardized payment amount for MS–DRG 227. In the FY 2012 IPPS/LTCH proposed rule, this amount is $26,364.93. We calculated the standardized payment rate for MS–DRG 227 ($26,364.93) by multiplying the normalized weight from Table 5 of the FY 2012 IPPS/LTCH PPS proposed rule (5.1370) by the sum of the nonlablor and labor-related shares of the proposed FY 2012 IPPS operating standardized amount (nonwage-adjusted) ($5,132.36) which were obtained from Table 1B. For further detail on the calculation of the IPPS proposed FY 2012 payments rates, we refer readers to the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26028 through 26029).

We consider the standardized payment rate for MS–DRG 227 to represent appropriate payment for a comparable package of services furnished to outpatients. We believe that, because this MS–DRG includes defibrillator implantation for those inpatients without major complications or comorbidities, it represents the payment made for hospital inpatients who are most similar to patients who would receive CRT–D on an outpatient basis, because hospital outpatients are generally less sick than hospital inpatients and because patients who had complications or comorbitities would be most likely to be admitted to inpatient status to receive CRT–D therapy. Similar to the proposed payment rate for composite APC 8009, the proposed payment rate for MS–DRG 227 includes the device costs associated with CRT–D along with the service costs associated with CPT codes 33249 and 33225, which are the procedures that are reported for implanting those devices. We believe that we should not pay more for these services under the proposed OPPS composite APC payment than under the IPPS because the OPPS payment would, by definition, include fewer items and services than the corresponding IPPS MS–DRG payment. For example, the IPPS MS–DRG payment includes payment for drugs and diagnostic tests that would be separately payable under the OPPS. A payment cap is necessary, therefore, to ensure that we do not create an inappropriate payment incentive to provide CRT–D services in one setting of care over another by paying more for CRT–D in the outpatient setting compared to the inpatient setting. We also believe that limiting payment for CRT–D services under the OPPS to the IPPS MS–DRG payment will ensure appropriate and equitable payment to hospitals because patients who receive these services in the hospital outpatient setting are not as sick as patients who have been admitted to receive this same service in the hospital inpatient setting. Therefore, we expect it would be less costly to provide care for these patients, who would also spend less time in the facility. For more detail and how this payment rate was calculated, we refer readers to section III. D. 6 of this proposed rule.

In order to ensure that hospitals correctly code for CRT services in the future, we are proposing to create claim processing edits that would return claims to providers unless CPT code 33225 is billed in conjunction with one of the following CPT codes, as specified by AMA in the CPT code book:

- 33206 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial);
- 33207 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); ventricular);
- 33208 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular);
- 33212 (Insertion or replacement of pacemaker pulse generator only; single chamber, atrial or ventricular);
- 33213 (Insertion or replacement of pacemaker pulse generator only; dual chamber, atrial or ventricular);
- 33214 (Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator));
- 33216 (Insertion of a single transvenous electrode, permanent pacemaker or cardioverter-defibrillator);
- 33217 (Insertion of 2 transvenous electrodes, permanent pacemaker or cardioverter-defibrillator);
- 33222 (Revision or relocation of skin pocket for pacemaker), 33233 (Removal of permanent pacemaker pulse generator);
- 33234 (Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular);
- 33235 (Removal of transvenous pacemaker electrode(s); dual lead system, atrial or ventricular);
- 33240 (Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator); or
- 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator).

Finally, in order to reduce the extent to which payment rates for the two services currently assigned to APC 0418, described by CPT codes 33224 and 33225, might continue to fluctuate, we also are proposing to move CPT 33225 from APC 0418 to APC 0108. We believe that moving these codes to APCs that have higher volumes of services to which they are more similar in clinical characteristics and median costs will increase the stability of the payments for these services from year to year. In general, a higher volume of services across multiple procedures within an APC results in more stable APC median costs and, therefore, in the payment rate from one year to the next. We also are proposing to change the name of APC 0108 from ''Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads'' to ''Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes.'' Similarly, we are proposing to move CPT 33224 from APC 0418 to APC 0655 and to change the name of APC 0655 from ''Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker'' to ''Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode.'' We believe that moving CPT code 33224 into APC 0655 will promote stability in payment for CPT code 33224 because CPT code 33224 would then be in an APC with similar median costs but with a higher volume of services and, therefore, will benefit from the stability in APC median cost and payment rate that generally results as the volume of services within an APC increases. Because these proposed actions would result in APC 0418 containing no CPT codes, we are proposing to delete APC 0418.

In summary, for CY 2012, we are proposing to create a composite for CRT–D services billed with CPT code 33225 and CPT code 33249 on the same date of service (Composite APC 8009

(Cardiac Resynchronization Therapy—ICD Pulse Generator and Leads)), for which we are proposing that payment would be capped at the IPPS payment rate for MS–DRG 227. In other words, we would pay APC 8009 at the lesser of the APC 8009 median cost or the IPPS standardized payment for MS–DRG 227. We also are proposing to implement claims processing edits that would return to providers incorrectly coded claims on which a pacing electrode insertion (CPT code 33225) is billed without an ICD or pacemaker insertion. Finally, we are proposing to delete APC 0418, and to redistribute its component CPT codes (33225 and 33224) to APCs 0108 and 0655. The proposed changes would all be made in a budget neutral manner, in the same way that payment for other composite APCs and the reassignment of codes to APCs are budget neutral within the OPPS. We refer readers to section II.A.4 of this proposed rule for a discussion of the scaling of payment weights for budget neutrality.

3. Proposed Changes to Packaged Services

a. Background

The OPPS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a service or bundle of services for a particular patient, but with the exception of outlier cases, the payment is adequate to ensure access to appropriate care. Packaging payment for multiple interrelated services into a single payment creates incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment. For example, where there are a variety of supplies that could be used to furnish a service, some of which are more expensive than others, packaging encourages hospitals to use the least expensive item that meets the patient's needs, rather than to routinely use a more expensive item. Packaging also encourages hospitals to negotiate carefully with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while carefully scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the stability of payment for services over time. Finally, packaging also may reduce the importance of refining service-specific payment because there is more opportunity for hospitals to average payment across higher cost cases requiring many ancillary services and lower cost cases requiring fewer ancillary services. For these reasons, packaging payment for services that are typically ancillary and supportive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000.

We assign status indicator ''N'' to those HCPCS codes that we believe are always integral to the performance of the primary modality; therefore, we always package their costs into the costs of the separately paid primary services with which they are billed. Services assigned status indicator ''N'' are unconditionally packaged.

We assign status indicator ''Q1'' (''STVX–Packaged Codes''), ''Q2'' (''T–Packaged Codes''), or ''Q3'' (Codes that may be paid through a composite APC) to each conditionally packaged HCPCS code. An ''STVX-packaged code'' describes a HCPCS code whose payment is packaged when one or more separately paid primary services with the status indicator of ''S,'' ''T,'' ''V,'' or ''X'' are furnished in the hospital outpatient encounter. A ''T-packaged code'' describes a code whose payment is packaged when one or more separately paid surgical procedures with the status indicator of ''T'' are provided during the hospital outpatient encounter. ''STVX-packaged codes'' and ''T-packaged codes'' are paid separately in those uncommon cases when they do not meet their respective criteria for packaged payment. ''STVX-packaged codes'' and ''T-packaged codes'' are conditionally packaged. We refer readers to section XI.A.1. of this proposed rule and Addenda D1 (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) with other Addenda, for a complete listing of proposed status indicators and the meaning of each.

We use the term ''dependent service'' to refer to the HCPCS codes that represent services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality. We use the term ''independent service'' to refer to the HCPCS codes that represent the primary therapeutic or diagnostic modality into which we package payment for the dependent service. In future years, as we consider the development of larger payment groups that more broadly reflect services provided in an encounter or episode-of-care, it is possible that we might propose to bundle payment for a service that we now refer to as ''independent.''

Hospitals include HCPCS codes and charges for packaged services on their claims, and the estimated costs associated with those packaged services are then added to the costs of separately payable procedures on the same claims in establishing payment rates for the separately payable services. We encourage hospitals to report all HCPCS codes that describe packaged services that were provided, unless the CPT Editorial Panel or CMS provide other guidance. The appropriateness of the OPPS payment rates depends on the quality and completeness of the claims data that hospitals submit for the services they furnish to our Medicare beneficiaries.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66610 through 66659), we adopted the packaging of payment for items and services in seven categories into the payment for the primary diagnostic or therapeutic modality to which we believe these items and services are typically ancillary and supportive. The seven categories are: (1) Guidance services; (2) image processing services; (3) intraoperative services; (4) imaging supervision and interpretation services; (5) diagnostic radiopharmaceuticals; (6) contrast media; and (7) observation services. We specifically chose these categories of HCPCS codes for packaging because we believe that the items and services described by the codes in these categories are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support.

In addition, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66650 through 66659), we finalized additional packaging for the CY 2008 OPPS, which included the establishment of new composite APCs for CY 2008, specifically APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite), APC 8001 (LDR Prostate Brachytherapy Composite), APC 8002 (Level I Extended Assessment & Management Composite), and APC 8003 (Level II Extended Assessment & Management Composite). In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569), we expanded the composite APC model to one new clinical area—multiple imaging services. We created five multiple imaging composite APCs for payment in CY 2009 that incorporate statutory requirements to differentiate between

imaging services provided with contrast and without contrast as required by section 1833(t)(2)(G) of the Act. The multiple imaging composite APCs are: (1) APC 8004 (Ultrasound Composite); (2) APC 8005 (CT and CTA without Contrast Composite); (3) APC 8006 (CT and CTA with Contrast Composite); (4) APC 8007 (MRI and MRA without Contrast Composite); and (5) APC 8008 (MRI and MRA with Contrast Composite). We discuss composite APCs in more detail in section II.A.2.e. of this proposed rule.

We recognize that decisions about packaging and bundling payment involve a balance between ensuring that payment is adequate to enable the hospital to provide quality care and establishing incentives for efficiency through larger units of payment. Therefore, we invite public comments regarding our packaging proposals for the CY 2012 OPPS.

b. Packaging Issues

(1) CMS Presentation of Findings Regarding Expanded Packaging at the February 28–March 1, 2011 APC Panel Meeting

In deciding whether to package a service or pay for a code separately, we have historically considered a variety of factors, including whether the service is normally provided separately or in conjunction with other services; how likely it is for the costs of the packaged code to be appropriately mapped to the separately payable codes with which it was performed; and whether the expected cost of the service is relatively low.

As discussed in section I.D. of this proposed rule, the APC Panel advises CMS on the clinical integrity of payment groups and their weights, and the APC Panel has had a Packaging Subcommittee that is now renamed the Subcommittee for APC Groups and Status Indicator (SI) Assignments to reflect that its function has expanded to include assisting CMS with assignment of HCPCS codes to APCs. As part of its function, the APC Panel studies and makes recommendations on issues pertaining to services that are not separately payable under the OPPS, but whose payments are bundled or packaged into APC payments. The APC Panel has considered packaging issues at several earlier meetings. For discussions of earlier APC Panel meetings and recommendations, we refer readers to previously published hospital OPPS/ASC proposed and final rules on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/HORD/list.asp.*

(2) Packaging Recommendations of the APC Panel at Its February 28–March 1, 2011 Meeting

During the February 28–March 1, 2011 APC Panel meeting, the APC Panel accepted the report of the Subcommittee for APC Groups and Status Indicator (SI) Assignment, heard several public presentations related to packaged services, discussed the deliberations of the subcommittee, and made five recommendations related to packaging and to the function of the subcommittee. The Report of the February 28–March 1, 2011 meeting of the APC Panel may be found at the Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.*

To summarize, the APC Panel made five recommendations regarding the packaging of payment under the CY 2012 OPPS. Below we present each of these five packaging recommendations and our responses to those recommendations. One recommendation that evolved from the discussions of the APC Groups and Status Indicator Subcommittee that is specific to HCPCS codes is discussed in section III.D. of this proposed rule.

APC Panel Recommendation 4: That HCPCS code 31627 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])) continue to be assigned a status indicator of ''N.'' The Panel further recommended that CMS continue to collect claims data for HCPCS code 31627.

CMS Response to Recommendation 4: HCPCS code 31627 was new for CY 2010, and we assigned a new interim status indicator of ''N'' in our CY 2010 OPPS/ASC final rule with comment period based on our policy of packaging guidance and intraoperative services that are ancillary and dependent upon an independent separately paid procedure. At the APC Panel's February 2010 meeting, the manufacturer of the electromagnetic navigation bronchoscopy (ENB) technology, one of several technologies that can be used to perform the service described by HCPCS code 31627, asserted that use of the ENB technology during a bronchoscopy procedure enables access to distal lesions that are otherwise not accessible without use of the ENB technology. The manufacturer also stated that without separate payment for the ENB technology, hospitals would likely not adopt the technology and the population that would likely benefit from the ENB technology would not have access to this technology. In response to the manufacturer's presentation at the February 2010 Panel meeting, the APC Panel asked CMS to consider whether HCPCS code 31627 should be packaged or paid separately; and if it should be paid separately, the APC Panel asked CMS to investigate the appropriate APC assignment. The report of the February 2010 APC Panel meeting is available at *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.*

We stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46223) that we considered and analyzed the information available to us for HCPCS code 31627 and believed that the code described a procedure that is supportive of and ancillary to the primary diagnostic or therapeutic modality. Therefore, we proposed to package payment for HCPCS code 31627. We stated that, by proposing to package payment for this procedure, we would be treating it in the same manner as similar computer-assisted, navigational diagnostic procedures that are supportive of and ancillary to a primary diagnostic or therapeutic modality.

At its August 23–24, 2010 meeting, the APC Panel listened to discussions regarding whether HCPCS code 31627 should remain packaged for CY 2011. After hearing presentations from the public, the APC Panel recommended that CMS continue to package payment for HCPCS code 31627 into payment for the major separately paid procedure with which it is performed and asked that CMS bring claims data on the cost of HCPCS code 31627 to the APC Panel's winter 2011 meeting for review. After consideration of all of the information provided by commenters on this issue, and hearing the discussion of the issue by the APC Panel at its August 23–24, 2010 meeting, we accepted the APC Panel's recommendation to continue to package payment for HCPCS code 31627 into the payment for the major separately paid procedure with which it is reported for CY 2011. In addition, we also accepted the APC Panel's recommendation that CMS bring claims data [for HCPCS code 31627 to the winter 2011 APC Panel meeting. The report of the August 2010 APC Panel meeting is available at *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.*

At its meeting on February 28–March 1, 2011, the APC Panel listened to a public presentation in which the manufacturer of the ENB technology requested that HCPCS code 31627 be paid separately on the basis that the cost

of the technology is substantially higher than the OPPS payment for APC 0076 (Level I Endoscopy Lower Airway), the APC to which most bronchoscopy codes are assigned and into which payment for HCPCS code 31627 is packaged. The manufacturer stated that if CMS does not pay HCPCS code 31627 separately, hospitals will not furnish the procedure to hospital outpatients.

In response to the request of the APC Panel at its August 2010 meeting, we presented the available data on HCPCS code 31627 that could be derived from the hospital outpatient claims that were paid under the OPPS for services on and after January 1, 2010 through and including September 30, 2010, as processed through the CMS common working file by December 31, 2010. Specifically, using the limited set of APC Panel data, CMS found that 119 hospitals billed for 573 units of HCPCS code 31627, and that HCPCS code 31627 had a median cost of approximately $329 per unit. We also found that HCPCS code 31627 is reported on 0 to 4 percent of the claims for bronchoscopy codes with which CPT guidance states that it is permissible to report HCPCS code 31627, with the exception of HCPCS code 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple). HCPCS code 31627 was reported on approximately 52% of claims for HCPCS code 31626 in the APC Panel data. The APC Panel considered this information in its formulation of Recommendation 4 that CMS continue to package payment for HCPCS code 31627 into the payment for the bronchoscopy code with which HCPCS code 31627 is reported. Subsequent to the APC Panel meeting, examination and analysis of the CY 2012 proposed rule data found that 149 hospitals reported 867 units of HCPCS code 31627, and that HCPCS code 31627 has a proposed rule median cost of approximately $344 per unit.

After considering the public presentation and the information presented by CMS staff, the APC Panel recommended that HCPCS code 31627 continue to be assigned a status indicator of ''N.'' The Panel further recommended that CMS continue to collect claims data for HCPCS code 31627. We are proposing to accept both of the APC Panel's recommendations for the CY 2012 OPPS. Specifically, we are proposing to assign HCPCS code 31627 to status indicator ''N'' for the CY 2012 OPPS and, therefore, are proposing to package payment for the procedure into payment for the bronchoscopy to which we believe that it is ancillary and supportive. As with all packaged items and services, the cost we calculate for CPT code 31627 will be added to the costs on the single bill for the bronchoscopy code with which the service reported by CPT code 31627 is furnished, and therefore, the cost of CPT code 31627 will be incorporated into the payment for the APC to which that bronchoscopy code is assigned. We continue to believe that HCPCS code 31627, for which there are several different technologies, describes a service that is supportive and ancillary to the primary bronchoscopy procedure with which it must be reported, as defined by CPT. HCPCS code 31627 describes a computer assisted image guided navigation service that is not furnished without a bronchoscopy. As defined by CPT, HCPCS code 31627 may only be furnished in addition to a bronchocsopy service and therefore we believe that it is ancillary and supportive to the bronchsocopy service with which it must be reported. We agree to provide further claims information on HCPCS code 31627 to the APC Panel when it becomes available.

APC Panel Recommendation 5: That CMS consider a more appropriate APC assignment for HCPCS code 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers), the most common code with which HCPCS code 31627 was billed in 2010.

CMS Response to Recommendation 5: We are accepting this recommendation, and therefore are proposing to reassign HCPCS code 31626 (which has a proposed CY 2012 APC median cost of approximately $2,708) from APC 0076 (which has a proposed CY 2012 APC median cost of approximately $751) to APC 0415 (Level II Endoscopy Lower Airway), which has a proposed CY 2012 APC median cost of approximately $2,007. We agree with the APC Panel that it appears that the proposed APC median cost of HCPCS code 31626 of $2,708 justifies placement in an APC that has a median cost that is more similar to the APC median cost for this code. We believe that APC 0415 is the most appropriate clinically similar APC because the proposed CY 2012 median cost for APC 0415 of $2,007 is more similar in clinical resource for HCPCS code 31626 than the proposed CY 2012 median cost for APC 0076 of $715.

APC Panel Recommendation 6: That Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., continue to chair the APC Groups and Status Indicator (SI) Assignments Subcommittee for 2011.

CMS Response to Recommendation 6: We are accepting the APC Panel's recommendation that Judith Kelly, R.H.I.T., R.H.I.A., C.C.S. continue to chair the APC Groups and Status Indicator Assignments Subcommittee for 2011.

APC Panel Recommendation 7: That CMS furnish the results of its investigation of claims that contain the following unconditionally packaged codes without separately paid procedures:

- HCPCS code G0177 (Training and educational services related to the care and treatment of patient's disabling mental health problems per session (45 minutes or more));
- HCPCS code G0378 (Hospital observation service, per hour);
- HCPCS code 75940 (Percutaneous placement of IVC filter, radiological supervision and interpretation);
- HCPCS code 76937 (Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure)).

CMS Response to Recommendation 7: We are accepting the APC Panel's recommendation that CMS furnish the results of its investigation of claims that contain the unconditionally packaged codes: HCPCS code G0177, HCPCS code G0378, HCPCS code 75940, and HCPCS code 76937 at a future APC Panel meeting.

APC Panel Recommendation 8: That the work of the APC Groups and Status Indicator (SI) Assignments Subcommittee continue.

CMS Response to Recommendation 8: We are accepting the APC Panel's recommendation that the work of the APC Groups and Status Indicator Assignments Subcommittee continue.

(3) Other Packaging Proposals for CY 2012

The HCPCS codes for which we are proposing that payment be packaged into payment for the separately paid procedures with which the codes are reported either unconditionally (for which we are proposing to continue to assign status indicator ''N''), or conditionally (for which we are proposing to continue to assign status indicators ''Q1'', ''Q2'', or ''Q3'') are displayed in Addendum B of this proposed rule (which is referenced in section XVIII. of this proposed rule and available via the Internet on the CMS Web site). The supporting documents

for this CY 2012 OPPS/ASC proposed rule, including but not limited to Addendum B, are available at *http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD*. To view the proposed status indicators by HCPCS code in Addendum B, select CMS 1525-P and then select the folder labeled ''2012 OPPS Proposed Rule Addenda'' from the list of supporting files. Open the zipped file and select Addendum B, which is available as both an Excel file and a text file.

The proposed continuation of our standard policy regarding packaging of drugs and biologicals, implantable biologicals, contrast agents and diagnostic radiopharmaceuticals is discussed in section V.B. of this proposed rule. We note that an implantable biological that is surgically inserted or implanted through a surgical incision or a natural orifice is commonly referred to throughout this proposed rule as an ''implantable biological.''

The proposed creation of a new composite APC for CY 2012 for payment of the insertion of cardiac resynchronization devices is discussed in section II.A.2.e.(6) of this proposed rule.

4. Proposed Calculation of OPPS Scaled Payment Weights

Using the APC median costs discussed in sections II.A.1. and II.A.2. of this proposed rule, we calculated the proposed relative payment weights for each APC for CY 2012 shown in Addenda A and B to this proposed rule (which are referenced in section XVIII. of this proposed rule and available via the Internet on the CMS Web site). In years prior to CY 2007, we standardized all the relative payment weights to APC 0601 (Mid Level Clinic Visit) because mid-level clinic visits were among the most frequently performed services in the hospital outpatient setting. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601 to derive the relative payment weight for each APC.

Beginning with the CY 2007 OPPS (71 FR 67990), we standardized all of the relative payment weights to APC 0606 (Level 3 Clinic Visits) because we deleted APC 0601 as part of the reconfiguration of the clinic visit APCs. We selected APC 0606 as the base because APC 0606 was the mid-level clinic visit APC (that is, Level 3 of five levels). Therefore, for CY 2012, to maintain consistency in using a median for calculating unscaled weights representing the median cost of some of the most frequently provided services, we are proposing to continue to use the median cost of the mid-level clinic visit APC (APC 0606) to calculate unscaled weights. Following our standard methodology, but using the proposed CY 2012 median cost for APC 0606, for CY 2012 we assigned APC 0606 a relative payment weight of 1.00 and divided the median cost of each APC by the proposed median cost for APC 0606 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to base the proposed relative weights for all other APCs does not affect the payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2012 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we are proposing to compare the estimated aggregate weight using the CY 2011 scaled relative weights to the estimated aggregate weight using the proposed CY 2012 unscaled relative weights. For CY 2011, we multiplied the CY 2011 scaled APC relative weight applicable to a service paid under the OPPS by the volume of that service from CY 2010 claims to calculate the total weight for each service. We then added together the total weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2012, we performed the same process using the proposed CY 2012 unscaled weights rather than scaled weights. We then calculated the weight scaler by dividing the CY 2011 estimated aggregate weight by the proposed CY 2012 estimated aggregate weight. The service-mix is the same in the current and prospective years because we use the same set of claims for service volume in calculating the aggregate weight for each year. For a detailed discussion of the weight scaler calculation, we refer readers to the OPPS claims accounting document available on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/*. We included payments to CMHCs in our comparison of estimated unscaled weight in CY 2012 to estimated total weight in CY 2011 using CY 2010 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we adjusted the unscaled relative weights for purposes of budget neutrality. The proposed CY 2012 unscaled relative payment weights were adjusted by multiplying them by a proposed weight scaler of 1.4647 to ensure that the proposed CY 2012 relative weights are budget neutral.

Section 1833(t)(14) of the Act provides the payment rates for certain ''specified covered outpatient drugs.'' That section states that ''Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting and other adjustment factors for 2004 and 2005 under paragraph (9) but shall be taken into account for subsequent years.'' Therefore, the cost of those specified covered outpatient drugs (as discussed in section V.B.3. of this proposed rule) was included in the proposed budget neutrality calculations for the CY 2012 OPPS.

The proposed scaled relative payment weights listed in Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) incorporate the proposed recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires us to update the conversion factor used to determine payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25949), consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2011 forecast of the FY 2012 market basket increase, we proposed that the FY 2012 IPPS market basket update would be 2.8 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(ii) of the Act, as added by section 3401(i) of the Pub. L. 111–148 and as amended by section 10319(g) of such law and further amended by section 1105(e) of Public Law 111–152, provide adjustments to the OPD fee schedule update for CY 2012.

Specifically, section 1833(t)(3)(F) requires that the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the adjustments described in section 1833(t)(3)(F) of the

Act. Specifically, section 1833(t)(3)(F)(i) of the Act requires that the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act for 2012 and subsequent years. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). We refer readers to the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25949 through 25951) for a discussion of the calculation of the MFP adjustment. The proposed MFP adjustment for FY 2012 is estimated to be 1.2 percentage points.

We are proposing to reduce the OPD fee schedule increase factor for CY 2012 by the proposed MFP adjustment of 1.2 percentage points for FY 2012. Since the OPD fee schedule increase factor is based on the IPPS hospital inpatient market basket percentage increase, we believe that it is appropriate to apply the same MFP adjustment that is used to reduce the IPPS market basket increase to the OPD fee schedule increase factor. Consistent with the FY 2012 IPPS/LTCH PPS proposed rule, we are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the FY 2012 market basket update and MFP adjustment in the CY 2012 final rule. We believe that it is appropriate to apply the MFP adjustment, which is calculated on a fiscal year basis, to the OPD fee schedule increase factor, which is used to update the OPPS payment rates on a calendar year basis, because we believe that it is appropriate for the numbers associated with both components of the calculation (the underlying OPD fee schedule increase factor and the productivity adjustment) to be aligned so that changes in market conditions are aligned.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the adjustment described in subparagraph (G) for each of 2010 through 2019. For CY 2012, section 1833(t)(3)(G)(ii) of the Act provides a 0.1 percentage point reduction to the OPD fee schedule increase factor under subparagraph (C)(iv). Therefore, we are proposing to apply a 0.1 percentage point reduction to the OPD fee schedule increase factor.

We note that section 1833(t)(F) of the Act provides that application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year. As described in further detail below, we are proposing an OPD fee schedule increase factor of 1.5 percent for the CY 2012 OPPS (2.8 percent, which is the proposed estimate of the hospital market basket increase, less the proposed 1.2 percentage points MFP adjustment, less the 0.1 percentage point additional adjustment).

We are proposing to revise 42 CFR 419.32 to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2012, we reduce the OPD fee schedule increase factor by the multifactor productivity adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(ii) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by 0.1 percentage point for CY 2012. We also are proposing to amend § 419.32 (iv)(A) to indicate that the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act is further reduced by the adjustments necessary to satisfy the requirements in sections 1833(t)(3)(F) and (t)(3)(G) of the Act.

Hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of additional 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates made for their services as required by section 1833(t)(17) of the Act. For a complete discussion of the Hospital OQR requirements and the payment reduction for hospitals that fail to meet those requirements, we refer readers to section XIV. of this proposed rule.

To set the OPPS conversion factor for CY 2012, we are proposing to increase the CY 2011 conversion factor of $68.876 by 1.5 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing to further adjust the conversion factor for CY 2012 to ensure that any revisions we make to the updates for a revised wage index and rural adjustment are made on a budget neutral basis. We calculated a proposed overall budget neutrality factor of 1.0003 for wage index changes by comparing total estimated payments from our simulation model using the FY 2012 IPPS proposed wage indices to those payments using the current (FY 2011) IPPS wage indices, as adopted on a calendar year basis for the OPPS. For CY 2012, we are not proposing to make a change to our rural adjustment policy. Therefore, the proposed budget neutrality factor for the rural adjustment would be 1.0000. For CY 2012, we are proposing a cancer hospital payment adjustment policy, as discussed in section II.F. of this proposed rule, and, therefore, we applied a proposed budget neutrality adjustment of 0.9927 to adjust the conversion factor for that proposed policy. We calculated the proposed cancer hospital budget neutrality factor of 0.9927 by comparing total estimated payments from our simulation model for CY 2012 including the proposed payment adjustment for cancer hospitals to total estimated payments from our simulation model for CY 2012 without the proposed payment adjustment for cancer hospitals.

For this proposed rule, we estimate that pass-through spending for both drugs and biologicals and devices for CY 2012 would equal approximately $64.5 million, which represents 0.15 percent of total projected CY 2012 OPPS spending. Therefore, the conversion factor would also be adjusted by the difference between the 0.15 percent estimate of pass-through spending for CY 2011 and the 0.15 percent estimate of CY 2012 pass-through spending. Finally, estimated payments for outliers remain at 1.0 percent of total OPPS payments for CY 2012.

The proposed OPD fee schedule increase factor of 1.5 percent for CY 2012 (that is, the estimate of the hospital market basket increase of 2.8 percent less the 1.2 percentage points MFP adjustment and less the 0.1 percentage point adjustment which are necessary in order to comply with the requirements of the Affordable Care Act), the required proposed wage index budget neutrality adjustment of approximately 1.0003, the proposed cancer hospital payment adjustment of 0.9927, and the proposed adjustment of 0.00 percent of projected OPPS spending for the difference in the pass-through spending result in a proposed conversion factor for CY 2012 of $69.420, which reflects the full OPD fee schedule increase, after including the adjustments necessary to comply with the requirements of the Affordable Care Act.

To calculate the proposed CY 2012 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the Hospital OQR Program for the full CY 2012 payment

update, we are proposing to make all other adjustments discussed above, but would use a proposed reduced OPD fee schedule update factor of −0.5 percent (that is, the proposed OPD fee schedule increase factor further reduced by 2.0 percentage points as required by section 1833(t)(17)(A)(i) of the Act for failure to comply with the Hospital OQR requirements). This resulted in a proposed reduced conversion factor for CY 2012 of $68.052 for those hospitals that fail to meet the Hospital OQR requirements (a difference of −$1.368 in the proposed conversion factor relative to those hospitals that met the Hospital OQR requirements).

In summary, for CY 2012, we are proposing to use a conversion factor of $69.420 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using median costs. We are proposing to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (*3*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2012 in order to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(ii) of the Act. We also are proposing to amend § 419.32(b)(1)(iv)(A) to indicate that the hospital inpatient market basket percentage increase is reduced by the adjustments described in § 419.32(b)(1)(iv)(B). We are proposing to use a reduced conversion factor of $68.052 in the calculation of payments for hospitals that fail to comply with the Hospital OQR requirements to reflect the reduction to the OPD fee schedule increase factor that is required by section 1833(t)(17) of the Act for these hospitals.

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust, for geographic wage differences, the portion of the OPPS payment rate, which includes the copayment standardized amount, that is attributable to labor and labor-related cost. This portion of the OPPS payment rate is called the OPPS labor-related share. This adjustment must be made in a budget neutral manner and budget neutrality is discussed in section II.B. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). Therefore, we are not proposing to revise this policy for the CY 2012 OPPS. We refer readers to section II.H. of this proposed rule for a description and example of how the proposed wage index for a particular hospital is used to determine the proposed payment for the hospital.

As discussed in section II.A.2.c. of this proposed rule, for estimating national median APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same proposed FY 2012 pre-reclassified wage index that the IPPS uses to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and the copayment amount.

As published in the original OPPS April 7, 2000 final rule with comment period (65 FR 18545), the OPPS has consistently adopted the final fiscal year IPPS wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Thus, the wage index that applies to a particular acute care short-stay hospital under the IPPS would also apply to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule, we believed that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contains provisions that affect the proposed FY 2012 IPPS wage index values, including revisions to the reclassification wage comparability criteria that were finalized in the FY 2009 IPPS final rule (73 FR 48568 through 48570), and the application of rural floor budget neutrality on a national, rather than State-specific, basis through a uniform, national adjustment to the area wage index (76 FR 26021). In addition, section 10324 of the Affordable Care Act requires CMS to establish an adjustment to create a wage index floor of 1.00 for hospitals located in States determined to be frontier States.

Section 10324 specifies that, for services furnished beginning CY 2011, the wage adjustment factor applicable to any hospital outpatient department that is located in a frontier State (as defined in section 1886(d)(3)(E)(iii)(II) of the Act) may not be less than 1.00. Further, section 10324 states that this adjustment to the wage index for these outpatient departments should not be made in a budget neutral manner. As such, for the CY 2012 OPPS, we are proposing to continue to adjust the FY 2012 IPPS wage index, as adopted on a calendar year basis for the OPPS, for all hospitals paid under the OPPS, including non-IPPS hospitals (providers that are not paid under the IPPS) located in a frontier State, to 1.00 in instances where the proposed FY 2012 wage index (that reflects Medicare Geographic Classification Review Board (MGCRB) reclassifications, the application of the rural floor, and the rural floor budget neutrality adjustment) for these hospitals is less than 1.00. Similar to our current policy for HOPDs that are affiliated with multicampus hospital systems, we fully expect that the HOPD would receive a wage index based on the geographic location of the specific inpatient hospital with which it is associated. Therefore, if the associated hospital is located in a frontier State, the wage index adjustment applicable for the hospital would also apply for the affiliated HOPD. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160) for a detailed discussion regarding this provision, including our methodology for identifying which areas meet the definition of frontier States as provided for in section 1886(d)(3)(E)(iii)(II)) of the Act.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2012 IPPS wage indices continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (out-migration adjustment). We refer readers to the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25880 through 25888) for a detailed discussion of all proposed changes to the FY 2012 IPPS wage indices. In addition, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65842 through 65844) and subsequent OPPS rules for a detailed discussion of the history of these wage index adjustments as applied under the OPPS.

Section 3137 of the Affordable Care Act extended, through FY 2010, section 508 reclassifications as well as certain special exceptions. The most recent extension of the provision was included in section 102 of the Medicare and Medicaid Extender Act, which extends,

through FY 2011, section 508 reclassifications as well as certain special exceptions. The latest extension of these provisions expires on September 30, 2011, and will no longer be applicable effective with FY 2012. As we did for CY 2010, we revised wage index values for certain special exception hospitals from January 1, 2011 through December 31, 2011, under the OPPS, in order to give these hospitals the special exception wage indices under the OPPS for the same time period as under the IPPS. In addition, because the OPPS pays on a calendar year basis, the effective date under OPPS for all other non-section 508 and non-special exception providers is July 1, 2011, instead of April 1, 2011, so that these providers may also receive a full 6 months of payment under the revised wage index comparable to IPPS.

For purposes of the OPPS, we are proposing to continue our policy in CY 2012 to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment. Table 4J listed in the FY 2012 IPPS/LTCH PPS proposed rule (and made available via the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp*) identifies counties eligible for the proposed out-migration adjustment and providers proposed to receive the adjustment for FY 2012. We note that, beginning with FY 2012, we proposed under the IPPS that an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the disproportionate share hospital (DSH) payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. We refer readers to the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25885) for more detailed discussion on the proposed Lugar redesignation waiver for the out-migration adjustment). As we have done in prior years, we are reprinting Table 4J as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2012 OPPS. Addendum L is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site.

As stated earlier in this section, our longstanding policy for OPPS has been to adopt the final wage index used in IPPS. Therefore, for calculating proposed OPPS payments in CY 2012, we use the proposed FY 2012 IPPS wage indices. However, section 1833(t)(2)(D) of the Act confers broad discretionary authority upon the Secretary in determining the wage adjustment factor used under the OPPS. Specifically, this provision provides that ''subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions. * * *'' In other prospective payment systems, we do not adopt the adjustments applied to the IPPS wage index, such as the outmigration adjustment, reclassifications, and the rural floor. For the OPPS, using the hospital IPPS wage index as the source of an adjustment factor for geographic wage differences has in the past been both reasonable and logical, given the inseparable, subordinate status of the outpatient department within the hospital overall.

However, in recent years, we have become concerned that hospitals converting status significantly inflates wage indexes across a State, in a manner that was not intended by the Congress. In the FY 2008 IPPS final rule (72 FR 47324 and 47325), we discussed a situation where a CAH may have converted back to IPPS status in order to increase the rural floor.

The FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26060) shows the impact of the CAH conversion. Hospitals in one State can expect an approximate 8-percent increase in IPPS payments due to the conversion and resulting increase of the rural floor. Our concern is that the manipulation of the rural floor is of sufficient magnitude that it requires all hospital wage indexes to be reduced approximately 0.62 percent as a result of nationwide budget neutrality for the rural floor (or more than a 0.4 percent total payment reduction to all IPPS hospitals).

In addition to the CAH conversion, we recently received two requests from urban hospitals to convert to rural hospital status under section 1886(d)(8)(E) of the Act, which would inflate other States' rural floors, through the conversion of what would otherwise be urban hospitals to rural status. While we recognize that conversions from urban-to-rural status are permitted under section 1886(d)(8)(E) of the Act, we do not believe Congress anticipated individual urban to rural conversion allowing payment redistributions of this magnitude.

We believe the above discussions demonstrate that, as a result of hospital actions not envisioned by Congress, the rural floor is resulting in significant disparities in wage index and, in some cases, resulting in situations where all hospitals in a State receive a wage index higher than that of the single highest wage index urban hospital in the State. As stated above, the statute does not require the Secretary to use the IPPS wage adjustment factor to wage adjust OPPS payments and copayments, nor to apply to OPPS payment and copayment calculation the same adjustment that the law requires be applied to the IPPS wage adjustment factor.

We are considering adopting a policy that would address situations where IPPS wage index adjustments, such as the rural floor, are resulting in significant fluctuations in the wage index. One option would be to not apply the rural floor wage index at all in the OPPS where the rural floor is set by a snall number of hospitals and results in a rural floor that benefits all hospitals in the State. Alternatively, we could apply within State rural budget neutrality to the OPPS wage index as we did for both the IPPS and OPPS wage index beginning in FY 2009. We are seeking public comment on whether to: (1) Adopt the IPPS wage index for the OPPS in its entirety including the rural floor, geographic reclassifications and all other wage index adjustments; (2) adopt the IPPS wage index for the OPPS in its entirety except when a small number of hospitals set the rural floor for the benefit of all other hospitals in the State; (3) adopt the IPPS wage index for the OPPS in its entirety except apply rural floor budget neutrality within each State instead of nationally; or (4) adopt another decision rule for when the rural floor should not be applied in the OPPS when we have concerns about disproportionate impact.

We also are requesting public comments on an option that we are considering adopting for both the IPPS and the OPPS, where we would determine the applicable rural wage index floor using only data from those hospitals geographically rural under OMB and the Census Bureau's MSA designations, and without including wage data associated with hospitals reclassified from urban to rural status under section 1886(d)(8)(E) of the Act. Such a policy would eliminate the incentive to reclassify from urban to rural status primarily to increase rural floors across a State, and would ensure

that the rural floor is based upon hospitals located in rural areas.

With the exception of the proposed out-migration wage adjustment table (Addendum L to this proposed rule, which is available via the Internet on the CMS Web site), which includes non-IPPS hospitals paid under the OPPS, we are not reprinting the proposed FY 2012 IPPS wage indices referenced in this discussion of the wage index. We refer readers to the CMS Web site for the OPPS at: *http://www.cms.gov/HospitalOutpatientPPS/.* At this link, readers will find a link to the proposed FY 2012 IPPS wage index tables.

D. Proposed Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. Medicare contractors cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned above until a hospital's Medicare contractor is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, hospitals that are new, have not accepted assignment of an existing hospital's provider agreement, and have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a biased CCR (that is, the CCR falls outside the predetermined ceiling threshold for a valid CCR) or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11). In this proposed rule, we are proposing to update the default ratios for CY 2012 using the most recent cost report data. We discuss our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009.

For CY 2012, we are proposing to continue to use our standard methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that we use to adjust charges to costs on claims data for setting the proposed CY 2012 OPPS relative weights. Table 11 below lists the proposed CY 2012 default urban and rural CCRs by State and compares them to last year's default CCRs. These proposed CCRs represent the ratio of total costs to total charges for those cost centers relevant to outpatient services from each hospital's most recently submitted cost report, weighted by Medicare Part B charges. We also are proposing to adjust ratios from submitted cost reports to reflect final settled status by applying the differential between settled to submitted overall CCRs for the cost centers relevant to outpatient services from the most recent pair of final settled and submitted cost reports. We then weight each hospital's CCR by the volume of separately paid line-items on hospital claims corresponding to the year of the majority of cost reports used to calculate the overall CCRs. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66680 through 66682) and prior OPPS rules for a more detailed discussion of our established methodology for calculating the statewide average default CCRs, including the hospitals used in our calculations and our trimming criteria.

For this CY 2012 OPPS/ASC proposed rule, approximately 87 percent of the submitted cost reports utilized in the default ratio calculations represented data for cost reporting periods ending in CY 2009 and 13 percent were for cost reporting periods ending in CY 2008. For Maryland, we used an overall weighted average CCR for all hospitals in the Nation as a substitute for Maryland CCRs. Few hospitals in Maryland are eligible to receive payment under the OPPS, which limits the data available to calculate an accurate and representative CCR. The weighted CCR is used for Maryland because it takes into account each hospital's volume, rather than treating each hospital equally. We refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65822) for further discussion and the rationale for our longstanding policy of using the national average CCR for Maryland. In general, observed changes in the statewide average default CCRs between CY 2011 and CY 2012 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 11 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2012.

TABLE 11—PROPOSED CY 2012 STATEWIDE AVERAGE CCRS

State	Urban/rural	Proposed CY 2012 default CCR	Previous default CCR (CY 2011 OPPS final rule)
ALASKA	RURAL	0.487	0.479
ALASKA	URBAN	0.321	0.315
ALABAMA	RURAL	0.213	0.212
ALABAMA	URBAN	0.191	0.193
ARKANSAS	RURAL	0.225	0.223
ARKANSAS	URBAN	0.274	0.282
ARIZONA	RURAL	0.236	0.231
ARIZONA	URBAN	0.193	0.202
CALIFORNIA	RURAL	0.189	0.195
CALIFORNIA	URBAN	0.202	0.205
COLORADO	RURAL	0.345	0.350
COLORADO	URBAN	0.225	0.233
CONNECTICUT	RURAL	0.356	0.356
CONNECTICUT	URBAN	0.292	0.291
DISTRICT OF COLUMBIA	URBAN	0.301	0.313
DELAWARE	RURAL	0.280	0.279
DELAWARE	URBAN	0.347	0.362

TABLE 11—PROPOSED CY 2012 STATEWIDE AVERAGE CCRS—Continued

State	Urban/rural	Proposed CY 2012 default CCR	Previous default CCR (CY 2011 OPPS final rule)
FLORIDA	RURAL	0.183	0.185
FLORIDA	URBAN	0.170	0.172
GEORGIA	RURAL	0.241	0.246
GEORGIA	URBAN	0.214	0.220
HAWAII	RURAL	0.320	0.356
HAWAII	URBAN	0.306	0.308
IOWA	RURAL	0.297	0.252
IOWA	URBAN	0.272	0.288
IDAHO	RURAL	0.416	0.419
IDAHO	URBAN	0.378	0.384
ILLINOIS	RURAL	0.245	0.251
ILLINOIS	URBAN	0.240	0.239
INDIANA	RURAL	0.298	0.302
INDIANA	URBAN	0.268	0.270
KANSAS	RURAL	0.282	0.286
KANSAS	URBAN	0.209	0.215
KENTUCKY	RURAL	0.223	0.220
KENTUCKY	URBAN	0.245	0.244
LOUISIANA	RURAL	0.256	0.256
LOUISIANA	URBAN	0.226	0.235
MARYLAND	RURAL	0.280	0.284
MARYLAND	URBAN	0.251	0.256
MASSACHUSETTS	URBAN	0.320	0.314
MAINE	RURAL	0.440	0.460
MAINE	URBAN	0.460	0.450
MICHIGAN	RURAL	0.313	0.312
MICHIGAN	URBAN	0.314	0.320
MINNESOTA	RURAL	0.482	0.483
MINNESOTA	URBAN	0.326	0.311
MISSOURI	RURAL	0.248	0.258
MISSOURI	URBAN	0.267	0.264
MISSISSIPPI	RURAL	0.226	0.229
MISSISSIPPI	URBAN	0.186	0.182
MONTANA	RURAL	0.434	0.444
MONTANA	URBAN	0.398	0.399
NORTH CAROLINA	RURAL	0.256	0.254
NORTH CAROLINA	URBAN	0.264	0.264
NORTH DAKOTA	RURAL	0.322	0.351
NORTH DAKOTA	URBAN	0.429	0.360
NEBRASKA	RURAL	0.323	0.328
NEBRASKA	URBAN	0.252	0.259
NEW HAMPSHIRE	RURAL	0.323	0.323
NEW HAMPSHIRE	URBAN	0.292	0.290
NEW JERSEY	URBAN	0.221	0.221
NEW MEXICO	RURAL	0.266	0.277
NEW MEXICO	URBAN	0.286	0.307
NEVADA	RURAL	0.242	0.269
NEVADA	URBAN	0.169	0.178
NEW YORK	RURAL	0.410	0.415
NEW YORK	URBAN	0.350	0.375
OHIO	RURAL	0.324	0.327
OHIO	URBAN	0.241	0.241
OKLAHOMA	RURAL	0.248	0.260
OKLAHOMA	URBAN	0.220	0.208
OREGON	RURAL	0.302	0.306
OREGON	URBAN	0.327	0.340
PENNSYLVANIA	RURAL	0.270	0.275
PENNSYLVANIA	URBAN	0.200	0.210
PUERTO RICO	URBAN	0.490	0.505
RHODE ISLAND	URBAN	0.287	0.284
SOUTH CAROLINA	RURAL	0.222	0.222
SOUTH CAROLINA	URBAN	0.217	0.227
SOUTH DAKOTA	RURAL	0.309	0.316
SOUTH DAKOTA	URBAN	0.253	0.251
TENNESSEE	RURAL	0.212	0.221
TENNESSEE	URBAN	0.201	0.204
TEXAS	RURAL	0.239	0.245
TEXAS	URBAN	0.210	0.216

TABLE 11—PROPOSED CY 2012 STATEWIDE AVERAGE CCRS—Continued

State	Urban/rural	Proposed CY 2012 default CCR	Previous default CCR (CY 2011 OPPS final rule)
UTAH	RURAL	0.385	0.386
UTAH	URBAN	0.359	0.362
VIRGINIA	RURAL	0.238	0.241
VIRGINIA	URBAN	0.257	0.263
VERMONT	RURAL	0.415	0.411
VERMONT	URBAN	0.365	0.365
WASHINGTON	RURAL	0.366	0.367
WASHINGTON	URBAN	0.317	0.327
WISCONSIN	RURAL	0.407	0.412
WISCONSIN	URBAN	0.327	0.334
WEST VIRGINIA	RURAL	0.283	0.291
WEST VIRGINIA	URBAN	0.335	0.337
WYOMING	RURAL	0.385	0.393
WYOMING	URBAN	0.302	0.296

E. Proposed OPPS Payments to Certain Rural and Other Hospitals

1. Hold Harmless Transitional Payment Changes Made by Pub. L. 110–275 (MIPPA)

When the OPPS was implemented, every provider was eligible to receive an additional payment adjustment (called either transitional corridor payments or transitional outpatient payments (TOPs)) if the payments it received for covered OPD services under the OPPS were less than the payments it would have received for the same services under the prior reasonable cost-based system (referred to as the pre-BBA amount). Section 1833(t)(7) of the Act provides that the transitional corridor payments are temporary payments for most providers and were intended to ease their transition from the prior reasonable cost-based payment system to the OPPS system. There are two exceptions to this provision, cancer hospitals and children's hospitals, and those hospitals receive the transitional corridor payments on a permanent basis. Section 1833(t)(7)(D)(i) of the Act originally provided for transitional corridor payments to rural hospitals with 100 or fewer beds for covered OPD services furnished before January 1, 2004. However, section 411 of Public Law 108–173 amended section 1833(t)(7)(D)(i) of the Act to extend these payments through December 31, 2005, for rural hospitals with 100 or fewer beds. Section 411 also extended the transitional corridor payments to sole community hospitals (SCHs) located in rural areas for services furnished during the period that began with the provider's first cost reporting period beginning on or after January 1, 2004, and ending on December 31, 2005. Accordingly, the authority for making transitional corridor payments under section 1833(t)(7)(D)(i) of the Act, as amended by section 411 of Public Law 108–173, for rural hospitals having 100 or fewer beds and SCHs located in rural areas expired on December 31, 2005.

Section 5105 of Public Law 109–171 reinstituted the TOPs for covered OPD services furnished on or after January 1, 2006, and before January 1, 2009, for rural hospitals having 100 or fewer beds that are not SCHs. When the OPPS payment was less than the provider's pre-BBA amount, the amount of payment was increased by 95 percent of the amount of the difference between the two amounts for CY 2006, by 90 percent of the amount of that difference for CY 2007, and by 85 percent of the amount of that difference for CY 2008.

For CY 2006, we implemented section 5105 of Public Law 109–171 through Transmittal 877, issued on February 24, 2006. In the Transmittal, we did not specifically address whether TOPs apply to essential access community hospitals (EACHs), which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Accordingly, under the statute, EACHs are treated as SCHs. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010), we stated that EACHs were not eligible for TOPs under Public Law 109–171. However, we stated they were eligible for the adjustment for rural SCHs. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68228), we updated § 419.70(d) of our regulations to reflect the requirements of Public Law 109–171.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41461), we stated that, effective for services provided on or after January 1, 2009, rural hospitals having 100 or fewer beds that are not SCHs would no longer be eligible for TOPs, in accordance with section 5105 of Public Law 109–171. However, subsequent to issuance of the CY 2009 OPPS/ASC proposed rule, section 147 of Public Law 110–275 amended section 1833(t)(7)(D)(i) of the Act by extending the period of TOPs to rural hospitals with 100 beds or fewer for 1 year, for services provided before January 1, 2010. Section 147 of Public Law 110–275 also extended TOPs to SCHs (including EACHs) with 100 or fewer beds for covered OPD services provided on or after January 1, 2009, and before January 1, 2010. In accordance with section 147 of Public Law 110–275, when the OPPS payment is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payment amounts for CY 2009.

For CY 2009, we revised our regulations at §§ 419.70(d)(2) and (d)(4) and added a new paragraph (d)(5) to incorporate the provisions of section 147 of Public Law 110–275. In addition, we made other technical changes to § 419.70(d)(2) to more precisely capture our existing policy and to correct an inaccurate cross-reference. We also made technical corrections to the cross-references in paragraphs (e), (g), and (i) of § 419.70.

For CY 2010, we made a technical correction to the heading of § 419.70(d)(5) to correctly identify the policy as described in the subsequent regulation text. The paragraph heading now indicates that the adjustment applies to small SCHs, rather than to rural SCHs.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60425), we

stated that, effective for services provided on or after January 1, 2010, rural hospitals and SCHs (including EACHs) having 100 or fewer beds would no longer be eligible for TOPs, in accordance with section 147 of Public Law 110–275. However, subsequent to issuance of the CY 2010 OPPS/ASC final rule with comment period, section 3121(a) of the Affordable Care Act amended section 1833(t)(7)(D)(i)(III) of the Act by extending the period of TOPs to rural hospitals that are not SCHs with 100 beds or fewer for 1 year, for services provided before January 1, 2011. Section 3121(a) of the Affordable Care Act amended section 1833(t)(7)(D)(i)(III) of the Act and extended the period of TOPs to SCHs (including EACHs) for 1 year, for services provided before January 1, 2011, with section 3121(b) of the Affordable Care Act removing the 100-bed limitation applicable to such SCHs for covered OPD services furnished on and after January 1, 2010, and before January 1, 2011. In accordance with section 3121 of the Affordable Care Act, when the OPPS payment is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payment amounts for CY 2010. Accordingly, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71882), we updated § 419.70(d) of the regulations to reflect the TOPs extensions and amendments described in section 3121 of the Affordable Care Act.

Section 108 of the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309) extended for one year the hold harmless provision for a rural hospital with 100 or fewer beds that is not an SCH (as defined in section 1886(d)(5)(D)(iii). Therefore, for such a hospital, for services furnished before January 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments. In addition, section 108 of the MMEA also extended for one year the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act (including EACHs) removing the 100-bed limit applicable to such SCHs for covered OPD services furnished on or after January 1, 2010 and before January 1, 2012. Therefore, for such hospitals, for services furnished before January 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments. We are proposing to revise our regulations at § 419.70(d) to conform the regulation text to the self-implementing provisions of section 108 of the MMEA described above.

2. Proposed Adjustment for Rural SCHs and EACHs Under Section 1833(t)(13)(B) of the Act

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of Public Law 108–173. Section 411 gave the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In CY 2007, we became aware that we did not specifically address whether the adjustment applies to EACHs, which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Thus, under the statute, EACHs are treated as SCHs. Therefore, in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) to clarify that EACHs are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, three hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outliers and copayment. As stated in the CY 2006 OPPS final rule with comment period (70 FR 68560), we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2011. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2012 OPPS, we are proposing to continue our policy of a budget neutral 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs (75 FR 46232). We intend to reassess the 7.1 percent adjustment in the near future by examining differences between urban and rural hospitals' costs using updated claims, cost reports, and provider information.

F. Proposed OPPS Payments to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA), Medicare has paid cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act (cancer hospitals) under the OPPS for covered outpatient hospital services. There are 11 cancer hospitals that meet the classification criteria in section 1886(d)(1)(B)(v) of the Act. These 11 cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999, Congress created section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to serve as a permanent payment floor by limiting cancer hospitals' potential losses under the OPPS. Through section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA'' amount. That is, cancer hospitals are permanently held harmless to their ''pre-BBA'' amount, and they receive Transitional Outpatient Payments (TOPs) to ensure that they do not receive a payment that is lower under the OPPS than the payment they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA'' payment amount is an amount equal to the product of the reasonable cost of the hospital for covered outpatient services for the portions of the hospital's cost

reporting period (or periods) occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital. The ''pre-BBA'' amount, including the determination of the base PCR, are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital and Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, as applicable) each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations. Almost all of the 11 cancer hospitals receive TOPs each year. The volume weighted average payment-to-cost ratio (PCR) for the cancer hospitals is 0.83, or outpatient payment with TOPs to cancer hospitals is 83 percent of reasonable cost.

Section 3138 of the Affordable Care Act instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to ambulatory payment classification (APC) groups exceed the costs incurred by other hospitals furnishing services under section 1833(t) of the Act as determined appropriate by the Secretary. In addition, section 3138 of the Affordable Care Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by such hospitals when studying cancer hospital costliness. Further, section 3138 of the Affordable Care Act provides that if the Secretary determines that cancer hospitals' costs with respect to APC groups are determined to be greater than the costs of other hospitals furnishing services under section 1833(t) of the Act, the Secretary shall provide an appropriate adjustment to reflect these higher costs. Cancer hospitals described in section 1886(d)(1)(B)(v) of the Act remain eligible for TOPs (which are not budget neutral) and outlier payments (which are budget neutral).

2. Study of Cancer Hospitals' Costs Relative to Other Hospitals

It has been our standard analytical approach to use a combination of explanatory and payment regression models to assess the costliness of a class of hospitals while controlling for other legitimate influences of costliness, such as ability to achieve economies of scale, to ensure that costliness is due to the type of hospital and to identify appropriate payment adjustments. We used this approach in our CY 2006 OPPS final rule with comment period to establish the 7.1 percent payment adjustment for rural SCHs (70 FR 68556 through 68561). In our discussion for the CY 2006 OPPS proposed rule, we stated that a simple comparison of unit costs would not be sufficient to assess the costliness of a class of hospitals because the costs faced by individual hospitals, whether urban or rural, are a function of many varying factors, including local labor supply and the complexity and volume of services provided (70 FR 42699).

In constructing our analysis of cancer hospitals' costs with respect to APC groups relative to other hospitals, we considered whether our standard analytical approach to use a combination of explanatory and payment regression models would lead to valid results for this particular study, or whether we should develop a different or modified analytic approach. We note that the analyses presented in the CY 2006 OPPS proposed and final rules were designed to establish an adjustment for a large class of rural hospitals. In contrast, section 3138 of the Affordable Care Act is specifically limited to identifying an adjustment for 11 cancer hospitals to the extent their costs with respect to APC groups exceeded those costs incurred by other hospitals furnishing services under section 1833(t) of the Act. With such a small sample size (11 out of approximately 4,000 hospitals paid under the OPPS), we were concerned that the standard explanatory and payment regression models used to establish the rural hospital adjustment would lead to imprecise estimates of payment adjustments for this small group of hospitals. Further, section 3138 of the Affordable Care Act specifies explicitly that cost comparisons between classes of hospitals must include the cost of drugs and biologicals. In our CY 2006 analysis of rural hospitals, we excluded the cost of drugs and biologicals in our model because the extreme units associated with proper billing for some drugs and biologicals can bias the calculation of a service mix index, or volume weighted average APC relative weight, for each hospital (70 FR 42698). Therefore, we chose not to pursue our standard combination of explanatory and payment regression modeling to determine a proposed cancer hospital adjustment.

As discussed in the CY 2011 OPPS/ASC proposed rule (75 FR 46235), while we chose not to use our standard models to calculate a proposed cancer hospital adjustment, we determined it still would be appropriate to construct our usual provider-level analytical dataset consisting of variables related to assessing costliness with respect to APC groups, including average cost per unit for a hospital and the hospital's average APC relative weight as an indicator of the hospital's resource intensity, as measured by the APC relative weights. We used these variables to calculate univariate statistics that describe the costliness with respect to APC groups and related aspects of cancer hospitals and other hospitals paid under the OPPS. While descriptive statistics cannot control for the myriad factors that contribute to observed costs, we believed that stark differences in cost between cancer hospitals and other hospitals paid under the OPPS that would be observable by examining descriptive univariate statistics would provide some indication of relative costliness. We began our analysis of the cancer hospitals by creating an analytical dataset of hospitals billing under the OPPS for CY 2009 (a total of 3,933) that were included in our claims dataset for establishing the CY 2011 OPPS proposed APC relative weights. This analytical dataset included the 3,933 OPPS hospitals' total estimated cost (including packaged cost), total lines, total discounted units as modeled for CY 2011 OPPS payment, and the average weight of their separately payable services (total APC weight divided by total units) as modeled for the CY 2011 OPPS. We then summarized estimated utilization and payment for each hospital (''hospital-level''). These files consist of hospital-level aggregate costs (including the cost of packaged items and services), total estimated discounted units under the modeled proposed CY 2011 OPPS, total estimated volume of number of occurrences of separately payable HCPCS codes under the modeled proposed CY 2011 OPPS, and total relative weight of separately payable services under the modeled proposed CY 2011 OPPS. After summarizing modeled payment to the hospital-level, we removed 48 hospitals in Puerto Rico from our dataset because we did not believe that their cost structure reflected the costs of most hospitals paid under the OPPS and because they could bias the calculation of hospital-weighted statistics. We then removed an additional 66 hospitals with a cost per unit of more than 3 standard deviations from the geometric mean (mean of the natural log) because including outliers in hospital-weighted descriptive statistics also could bias those statistics. This resulted in a dataset with 11 cancer hospitals and 3,808 other hospitals.

We included the following standard hospital-level variables that describe hospital costliness in our analysis file: outpatient cost per discounted unit

under the modeled CY 2011 OPPS (substituting a cost per administration, rather than a cost per unit, for drugs and biologicals); each hospital's proposed CY 2011 wage index as a measure of relative labor cost; the service mix index, or volume-weighted average proposed CY 2011 APC relative weight (including a simulated weight for drugs and biologicals created by dividing the CY 2010 April ASP-based payment amount at ASP+6 percent appearing in Addendum A and B of the proposed rule by the proposed conversion factor of $68.267); outpatient volume based on number of occurrences of HCPCS codes in the CY 2009 claims data; and number of beds. We used these variables because they are key indicators of costliness with respect to APC groups under the modeled OPPS system, and they allowed us to assess the relative costliness of classes of hospitals under the proposed CY 2011 OPPS. A hospital's service mix index is a measure of resource intensity of the services provided by the hospital as measured by the proposed CY 2011 OPPS relative weights, and standardizing the cost per discounted unit by the service mix index creates an adjusted cost per unit estimate that reflects the remaining relative costliness of a hospital remaining after receiving the estimated payments that we proposed to make under the CY 2011 OPPS. In short, if a class of hospitals demonstrates higher cost per unit after standardization by service mix, it is an early indication that the class of hospitals may be significantly more costly in the regression models. We used these data to calculate the descriptive univariate statistics for cancer hospitals appearing in Table 12 below. We note that because drugs and biologicals are such a significant portion of the services that the cancer hospitals provide, and because section 3138 of the Affordable Care Act explicitly requires us to consider the cost of drugs and biologicals, we included the cost of these items in our total cost calculation for each hospital, counting each occurrence of a drug in the modeled proposed CY 2011 data (based on units in CY 2009 claims data). That is, we sought to treat each administration of a drug or biological as one unit.

In reviewing these descriptive statistics, we observed that cancer hospitals had a standardized cost per discounted unit of $150.12 compared to a standardized cost per discounted unit of $94.14 for all other hospitals. That is, cancer hospitals' average cost per discounted unit remained high even after accounting for payment under the modeled proposed CY 2011 payment system, which is not true for all other hospitals. Observing such differences in standardized cost per discounted unit led us to conclude that cancer hospitals are more costly with respect to APC groups than other hospitals furnishing services under the OPPS, even without the inferential statistical models that we typically employ.

TABLE 12—MEANS AND STANDARD DEVIATIONS FOR KEY VARIABLES BY CANCER AND NON-CANCER OPPS HOSPITALS

Variable	Cancer hospitals		Non-cancer hospitals	
	Mean	Standard deviation	Mean	Standard deviation
Outpatient Cost per Unit *	$344.20	(64.68)	$264.11	(165.86)
Unit Cost Standardized by Service Mix Wage Indices	$150.12	(31.64)	$94.14	(81.19)
Wage Index	1.10	(0.13)	0.98	(0.16)
Service Mix Index *	2.19	(0.26)	3.18	(2.25)
Outpatient Volume	192,197	(186,063)	34,578	(43,094)
Beds	173	(162.33)	173	(171.46)
Number of Hospitals	11	.....	3,808	.....

* Includes drugs and biologicals based on per administration rather than per unit.

3. CY 2011 Proposed Payment Adjustment for Certain Cancer Hospitals

Having reviewed the cost data from the standard analytic database and determined that cancer hospitals are more costly with respect to APC groups than other hospitals furnishing services under the OPPS system, we decided to examine hospital cost report data from Worksheet E, Part B (where TOPs are calculated on the Hospital and Hospital Health Care Complex Cost Report each year) in order to determine whether our findings were further supported by cost report data and to determine an appropriate proposed payment adjustment methodology for CY 2011 based on cost report data. Analyses on our standard analytic database and descriptive statistics presented in Table 12 above did not consider TOPs in assessing costliness of cancer hospitals relative to other hospitals furnishing services under section 1833(t) of the Act. There were several reasons for this. One, TOPs have no associated relative weight that could be included in an assessment of APC-based payment. TOPs are paid at cost report settlement on an aggregate basis, not on a per service basis, and we would have no way to break these payments down into a relative weight to incorporate these retrospective aggregate payments in the form of a relative weight. In addition, section 3138 of the Affordable Care Act requires that any cancer adjustment be made within the budget neutral system, and TOPs are not part of the budget neutral payment system. The cost report data we selected for the analysis were limited to the OPPS-specific payment and cost data available on Worksheet E, Part B. These data include aggregate OPPS payments, including outlier payments and the cost of medical and other health services. These aggregate measures of cost and payment also include the cost and payment for drugs and biologicals and other adjustments that we typically include in our regression modeling, including wage index adjustment and rural adjustment, if applicable. While these cost report data cannot provide an estimate of cost per unit after controlling for other potential factors that could influence cost per unit, we used this aggregate cost and payment data to examine the cancer hospitals' OPPS PCR and OPPS PCR with TOPs, and compare these to the OPPS PCR for other hospitals. PCRs calculated from the most recent cost report data available at the time of the CY 2011 OPPS/ASC proposed rule also indicated that costs relative to payments at cancer hospitals were higher than those at other hospitals paid under the OPPS (that is, cancer hospitals have lower PCRs). In order to calculate PCRs for hospitals paid under the OPPS (including cancer hospitals), we used the same extract of cost report data from the Hospital Cost Report Information System (HCRIS) that we used to calculate the CCRs that were used to estimate median costs for the CY 2011

OPPS. We limited the dataset to the hospitals with CY 2009 claims data that we used to model the CY 2011 proposed APC relative weights.

We estimated that, on average, the OPPS payments to the 11 cancer hospitals, not including TOPs, were approximately 62 percent of reasonable cost (that is, we calculated a PCR of 0.615 for the cancer hospitals), whereas we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 87 percent of reasonable cost (resulting in a PCR of 0.868). When TOPS were included in the calculation of the PCR, cancer hospitals, as a group, received payments that were approximately 83 percent of reasonable cost, which was still lower than the average PCR of other OPPS hospitals of approximately 87 percent of reasonable cost.

Based on our findings that cancer hospitals, as a class, have a significantly lower volume weighted average PCR than the volume weighted PCR of other hospitals furnishing services under the OPPS and our findings that the cancer hospitals cost per discounted unit standardized for service mix remains much higher than the standardized cost per discounted unit of all other hospitals, we proposed an adjustment for cancer hospitals to reflect these higher costs, effective January 1, 2011. For purposes of calculating a proposed adjustment, we chose to rely on this straightforward assessment of payments and costs from the cost report data because of the concerns outlined above with respect to the small number of hospitals, and because of the challenges associated with accurately including drug and biological costs in our standard regression models. We believed that an appropriate adjustment would redistribute enough payments from other hospitals furnishing services under the OPPS to the cancer hospitals to give cancer hospitals a PCR that was comparable to the average PCR for other hospitals furnishing services under the OPPS. Therefore, we proposed a hospital-specific payment adjustment determined as the percentage of additional payment needed to raise each cancer hospital's PCR to the weighted average PCR for other hospitals furnishing services under the OPPS (0.868) in the CY 2011 dataset. This would be accomplished by adjusting each cancer hospital's OPPS payment by the percentage difference between the hospital's individual PCR (without TOPs) and the weighted average PCR of the other hospitals furnishing services under the OPPS. This cancer hospital payment adjustment proposed for CY 2011 would have resulted in an estimated aggregate increase in OPPS payments to cancer hospitals of 41.2 percent and a net increase in total payments, including TOPs, of 5 percent for CY 2011.

4. Proposed CY 2011 Cancer Hospital Payment Adjustment That Was Not Finalized

The public comments associated with the cancer hospital adjustment that we proposed for CY 2011 are detailed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71886 through 71887). Many commenters urged CMS to consider TOPs when calculating the cancer hospital payment adjustment stating that the proposed methodology results, largely, in a change in the form of outpatient payments to cancer hospitals by shifting payment from hold harmless payment under the TOPs provision to APC payments. Noting that the majority of cancer care provided in the country is provided by the non-cancer hospitals that would experience a payment reduction under the CY 2011 proposal, commenters also suggested that the associated budget neutral payment reduction of 0.7 percent was not appropriate or equitable to other OPPS hospitals. Commenters also expressed concern that the proposed payment adjustment would increase beneficiary copayments. That is, they believed that the proposed cancer hospital adjustment would increase APC payments and, because beneficiary copayment is a percentage of the APC payment, Medicare beneficiaries seeking services at the 11 designated cancer hospitals would experience higher copayments due to the proposed methodology. These commenters strongly encouraged CMS to implement the adjustment in a way that does not increase beneficiary copayments. These commenters also indicated that CMS should have taken into account the concentration of outpatient services at the designated cancer hospitals, as compared to other OPPS hospitals, and adjust the PCR benchmark higher. The commenters argued that other PPS hospitals have the ability to improve their Medicare margins through other payment systems, but that cancer hospitals receive the majority of their Medicare payments through the OPPS. One commenter suggested that the CMS analysis was inadequate to conclude that costs are higher in cancer hospitals and that an adjustment is warranted. As indicated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71887), because the many public comments we received identified a broad range of very important issues and concerns associated with the proposed cancer hospital payment adjustment, we determined that further study and deliberation was necessary and, therefore, we did not finalize the CY 2011 proposed payment adjustment for certain cancer hospitals.

5. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2012

During our deliberations that occurred subsequent to the CY 2011 OPPS/ASC final rule, we reconfirmed that TOPs could not be included when establishing the PCR target given the current statutory language in section 1833(t)(18) of the Act that was to capture costliness with respect to APC groups. Specifically, section 1833(t)(18)(A) of the Act requires the Secretary to determine if, under the OPPS, costs incurred by cancer hospitals with respect to APC groups exceed those costs incurred by other hospitals furnishing services under the OPPS. As discussed in the CY 2011 OPPS/ASC proposed rule and final rule with comment period, TOPs payments are not paid on a service specific basis, and we have no way to break these payments down into a relative weight that could be included in an assessment of an APC-based payment. Because section 1833(t)(18)(A) of the Act ties the assessment of the costs incurred by the 11 cancer hospitals to APC groups, we cannot include TOPs, which are not tied to APC groups, in such assessment. In addition, section 1833(t)(7)(D)(ii) of the Act (the hold harmless provision for cancer hospitals) provides that this adjustment is applied for covered OPD services for which the ''PPS amount'' is less than the ''pre-BBA'' amount. The ''PPS amount'' means, with respect to covered OPD services, ''the amount payable under this title [Title 18] for such services (determined without regard to this paragraph) * * *'' (See section 1833(t)(7)(E) of the Act). Under this provision, the cancer adjustment must be included in the calculation of the ''PPS amount'' because it is an integral component of ''the amount payable under this title.'' Further, we note that the Affordable Care Act requires that any cancer hospital payment adjustment be made within the budget neutral system. We note that TOPs are not part of the budget neutral payment system.

In addition, we have revisited the issue of whether payments associated with the cancer hospital payment adjustment can be excluded from the amount of payment on which the copayment amount is determined. We continue to believe that the statute requires such payment to be included in

the amount of payment upon which the copayment amount is determined. Specifically, section 1833(t)(8) of the Act sets forth the methodology for calculating the copayment amount under section 1833(t). Section 1833(t)(8)(A) of the Act states the following: ''Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).'' We note that the amount in paragraph (4)(B) incorporates the amount calculated under subparagraph (A) of section 1833(t)(4) of the Act which provides that the ''Medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).'' The reference to ''factors computed under paragraphs* * * (2)(E)'' includes a cancer hospital payment adjustment because it is required to be provided under paragraph (2)(E). Therefore, the statute is clear that the cancer hospital payment adjustment is a component of the payment amount upon which the beneficiary copayment is determined.

Finally, though commenters suggested that CMS take into account the cancer hospitals' significant Medicare outpatient concentration relative to that of other OPPS hospitals when establishing an appropriate PCR benchmark, we believe it is inappropriate to incorporate the payments associated with other Medicare payment systems when determining a payment adjustment under the OPPS.

After a thorough review and deliberation of the issues associated with the cancer hospital payment adjustment proposed for CY 2011, we continue to believe a straightforward and appropriate method to adjust payments of cancer hospitals described in section 1886(d)(1)(B)(v) of the Act in order to reflect their higher costs with respect to APC groups is to propose to redistribute enough payments from other hospitals furnishing services under the OPPS to the cancer hospitals to give each cancer hospital a PCR that is comparable to the weighted average PCR for other hospitals furnishing services under section 1833(t) of the Act. Therefore, as explained in more detail below, for services furnished on and after January 1, 2012, we are proposing that, for a cancer hospital with an individual PCR (as determined by the Secretary) below the weighted average PCR for other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary) (Target PCR), we would make a hospital-specific payment adjustment by adjusting the wage-adjusted OPPS payment for covered OPD services (except for devices receiving pass-through status as defined in 42 CFR 419.66) by the percent difference between the hospital's individual PCR and the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act in the CY 2012 dataset. With respect to such hospitals, for devices receiving pass-through status as defined in 42 CFR 419.66 which are furnished on and after January 1, 2012, we are proposing a zero percent adjustment. For a cancer hospital with an individual PCR (as determined by the Secretary) above the weighted average PCR for other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary), we are proposing a zero percent adjustment for covered hospital outpatient services furnished on and after January 1, 2012.

In order to calculate PCRs for hospitals furnishing services under the OPPS (including cancer hospitals) for the proposed CY 2012 cancer hospital payment adjustment, we used the same extract of cost report data from HCRIS, as discussed in section II.A of this proposed rule, used to estimate median costs for the proposed CY 2012 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled. We then limited the data set to the hospitals with CY 2010 claims data that we use to model the impact of the CY 2012 proposed APC relative weights (4,009 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled proposed CY 2012 OPPS. The cancer hospitals in this dataset largely had cost report data from cost reporting periods ending in FY 2009 and FY 2010. The cost report data for the other hospitals were from cost report periods with fiscal year ends ranging from 2008 to 2010. We then removed the cost report data for 47 hospitals from Puerto Rico from our data set because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and therefore their inclusion may bias the calculation of hospital-weighted statistics. We also removed 206 hospitals with cost report data that were not complete (missing OPPS payments, including outliers, missing aggregate cost data, or both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a final analytic file of 3,756 hospitals with cost report data. We believe that the costs and PPS payments reported on Worksheet E, Part B, for the hospitals included in our CY 2012 modeling should be sufficiently accurate for assessing the hospital's relative costliness because all of the key elements that we believe are necessary for the analysis (payment and cost) are contained on this worksheet.

Using this smaller dataset of cost report data, we estimate that, on average, the OPPS payments to the 11 cancer hospitals, not including TOPs, are approximately 65 percent of reasonable cost (that is, we calculated a PCR of 0.647 for the cancer hospitals), whereas, we estimate that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 90 percent of reasonable cost (resulting in a PCR of 0.901). Individual cancer hospitals' OPPS PCRs range from approximately 0.56 to approximately 0.82.

As indicated above, we are proposing that, for a cancer hospital with an individual PCR below the weighted average PCR for other hospitals furnishing services under the OPPS in the CY 2012 dataset, we would make a hospital-specific payment adjustment by adjusting the wage-adjusted OPPS payment for covered OPD services (except devices receiving pass-through status because these items and services are always paid at the estimated full cost and, therefore, no payment adjustment is necessary) furnished on and after January 1, 2012, by the percent difference between the hospital's individual PCR and the weighted average PCR of other hospitals furnishing services under the OPPS in the CY 2012 dataset. This proposed methodology would result in the proposed percentage payment adjustments for the 11 cancer hospitals appearing in Table 13 below. In addition, we note that we are proposing to amend 42 CFR 419.43 by adding a new paragraph (i). Proposed new paragraph (i)(1) would specify that CMS provides for a payment adjustment for covered hospital outpatient services furnished on or after January 1, 2012, by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act. Proposed new paragraph (i)(2) would specify how the amount of the payment adjustment to cancer hospitals is established. Proposed new paragraph (i)(3) would specify that this payment adjustment would be budget neutral, consistent

with section 1833(t)(18)(B) of the Act. Proposed new paragraph (i)(4) would specify the services or groups that are excluded from qualifying for the cancer hospital payment adjustment. In the event that a cancer hospital has a PCR that is higher than the weighted average PCR for other OPPS hospitals furnishing services under the OPPS, we are proposing that the specific hospital would receive a zero percent adjustment. We believe that this would indicate that the cancer hospital's costs do not exceed the costs incurred by other hospitals furnishing services under the OPPS and, therefore, a payment adjustment above zero percent would not be necessary.

We note that the proposed payment adjustment for all cancer hospitals would result in an estimated aggregate increase in OPPS payments to cancer hospitals of 39 percent for CY 2012 and an estimated net increase in total payments, including TOPs, of 9 percent, based on cost report data. The dataset of hospital cost report data that we used to model this proposed payment adjustment for cancer hospitals is available under supporting documentation for this proposed rule on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/HORD/*.

TABLE 13—PROPOSED CY 2012 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS WITHOUT REGARD TO TOPS AND OUTLIER PAYMENTS

Provider number	Hospital name	Percent increase without TOPs or outlier payment
050146 ...	City of Hope Helford Clinical Research Hospital	10.1
050660 ...	USC Kenneth Norris Jr. Cancer Hospital	15.7
100079 ...	University of Miami Hospital & Clinic	27.6
100271 ...	H. Lee Moffitt Cancer Center & Research Institute	21.6
220162 ...	Dana-Farber Cancer Institute	54.4
330154 ...	Memorial Hospital for Cancer and Allied Diseases	39.4
330354 ...	Roswell Park Cancer Institute	24.3
360242 ...	James Cancer Hospital & Solove Research Institute	30.1
390196 ...	Hospital of the Fox Chase Cancer Center	15.3
450076 ...	University of Texas M. D. Anderson Cancer Center	61.8
500138 ...	Seattle Cancer Care Alliance	43.7
Proposed Aggregate Payment Adjustment		39.3

Because section 7101 of the Affordable Care Act expanded the 340B drug program to include certain cancer hospitals, we believe that the PCRs and any cancer hospital payment adjustment should be recalculated annually. The 340B drug program allows certain hospitals to purchase certain outpatient drugs at reduced prices. The Affordable Care Act provision was effective for drugs purchased on or after January 1, 2010. Inclusion of cancer hospitals in the 340B drug program should lower drug costs at these cancer hospitals going forward and, therefore, may cause significant changes in each cancer hospital's PCR compared to the previous year's calculation. Therefore, we are proposing to recalculate the PCR of each cancer hospital and the weighted average PCR of the other hospitals furnishing services under 1833(t) on an annual basis in order to determine an appropriate hospital specific payment adjustment to cancer hospitals each year.

We note that the changes made by section 3138 of the Affordable Care Act do not affect the existing statutory provisions that provide for outlier payment for all hospitals paid under the OPPS, including cancer hospitals and TOPs for cancer hospitals. Because outlier payments are made within budget neutrality, outlier payments are assessed after all budget neutral payments for an individual service have been made, including the cancer hospital payment adjustment. The TOPs are assessed after all payments have been made for a cost reporting period. Further, both outlier payments and TOPs serve as a safety net for hospitals, although outliers are budget neutral and TOPs are not, and TOPs are limited to certain hospitals. Outliers and TOPs are assessed after final payments have been made. If this proposed payment adjustment is finalized, we estimate that there would be no cancer hospitals that would continue to receive TOPs. We are proposing to update the hospital-specific cancer hospital payment adjustments in Table 13 using the more recent cost reports that will become available for the CY 2012 OPPS/ASC final rule with comment period.

G. Proposed Hospital Outpatient Outlier Payments

1. Background

Currently, the OPPS pays outlier payments on a service-by-service basis. For CY 2011, the outlier threshold is met when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,025 fixed-dollar threshold. We introduced a fixed-dollar threshold in CY 2005, in addition to the traditional multiple threshold, in order to better target outliers to those high cost and complex procedures where a very costly service could present a hospital with significant financial loss. If the cost of a service meets both of these conditions, the multiple threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate. Before CY 2009, this outlier payment had historically been considered a final payment by longstanding OPPS policy. We implemented a reconciliation process similar to the IPPS outlier reconciliation process for cost reports with cost reporting periods beginning on or after January 1, 2009 (73 FR 68594 through 68599).

It has been our policy for the past several years to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the proposed OPPS. Our current estimate of total outlier payments as a percent of total CY 2010 OPPS payment, using available CY 2010 claims and the revised OPPS expenditure estimate for the Presidential Budget for FY 2012, is

approximately 1.11 percent of the total aggregated OPPS payments. Therefore, for CY 2010, we estimate that we paid at 0.11 percent above the CY 2010 outlier target of 1.0 percent of total aggregated OPPS payments.

As explained in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71887 through 71889), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for CY 2011. The outlier thresholds were set so that estimated CY 2011 aggregate outlier payments would equal 1.0 percent of the total estimated aggregate payments under the OPPS. Using CY 2010 claims data and CY 2011 payment rates, we currently estimate that the aggregate outlier payments for CY 2011 would be approximately 1.06 percent of the total CY 2011 OPPS payments. The difference between 1.0 percent and 1.06 percent is reflected in the regulatory impact analysis in section XX. of this proposed rule. We note that we provide estimated CY 2012 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital-Specific Impacts—Provider-Specific Data file on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/*.

2. Proposed Outlier Calculation

We are proposing for CY 2012 to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. We are proposing that a portion of that 1.0 percent, specifically 0.14 percent, would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated outlier payments. As discussed in section VIII.C. of this proposed rule, for CMHCs, we are proposing to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) or APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), exceeds 3.40 times the payment for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this proposed rule.

To ensure that the estimated CY 2012 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing that the hospital outlier threshold be set so that outlier payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,100 fixed-dollar threshold. This proposed threshold reflects the methodology discussed below in this section, as well as the proposed APC recalibration for CY 2012.

We calculated the proposed fixed-dollar threshold for this proposed rule using largely the same methodology as we did in CY 2011 (75 FR 71887 through 71889). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2011 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCR, which are maintained by the Medicare contractors and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years. For this proposed rule, we used CY 2010 claims to model the CY 2012 OPPS. In order to estimate the proposed CY 2012 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2010 claims using the same inflation factor of 1.0908 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26024). We used an inflation factor of 1.0444 to estimate CY 2011 charges from the CY 2010 charges reported on CY 2010 claims. The methodology for determining this charge inflation factor is discussed in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26024). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we are proposing to apply the same CCR inflation adjustment factor that we are proposing to apply for the FY 2012 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2012 OPPS outlier payments that determine the fixed-dollar threshold. Specifically, for CY 2012, we are proposing to apply an adjustment of 0.9850 to the CCRs that were in the April 2011 OPSF to trend them forward from CY 2011 to CY 2012. The methodology for calculating this proposed adjustment is discussed in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26024 through 26025).

Therefore, to model hospital outlier payments for this CY 2012 OPPS/ASC proposed rule, we applied the overall CCRs from the April 2011 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9850 to approximate CY 2012 CCRs) to charges on CY 2010 claims that were adjusted (using the proposed charge inflation factor of 1.0908 to approximate CY 2012 charges). We simulated aggregated CY 2012 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2012 OPPS payments. We estimate that a proposed fixed-dollar threshold of $2,100, combined with the proposed multiple threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. We are proposing to continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the proposed fixed-dollar threshold of $2,100 are met. For CMHCs, we are proposing that, if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in

reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR requirements. For hospitals that fail to meet the Hospital OQR requirements, we are proposing to continue our policy that we implemented in CY 2010 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIV. of this proposed rule.

3. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 CFR 68599), we adopted as final policy a process to reconcile hospital or CMHC outlier payments at cost report settlement for services furnished during cost reporting periods beginning in CY 2009. OPPS outlier reconciliation more fully ensures accurate outlier payments for those facilities that have CCRs that fluctuate significantly relative to the CCRs of other facilities, and that receive a significant amount of outlier payments (73 FR 68598). As under the IPPS, we do not adjust the fixed-dollar threshold or the amount of total OPPS payments set aside for outlier payments for reconciliation activity because such action would be contrary to the prospective nature of the system. Our proposed outlier threshold calculation assumes that overall ancillary CCRs accurately estimate hospital costs based on the information available to us at the time we set the prospective fixed-dollar outlier threshold. For these reasons, as we have previously discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68596), we are not proposing to incorporate any assumptions about the effects of reconciliation into our calculation of the OPPS fixed-dollar outlier threshold.

H. Proposed Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR Part 419, subparts C and D. For this proposed rule, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the proposed conversion factor calculated in accordance with section II.B. of this proposed rule and the proposed relative weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) was calculated by multiplying the proposed CY 2012 scaled weight for the APC by the proposed CY 2012 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XVI.D. of this proposed rule.

We demonstrate in the steps below how to determine the APC payments that will be made in a calendar year under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' ''V,'' or ''X'' (as defined in Addendum D1 to this proposed rule), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the proposed national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the full CY 2012 OPPS fee schedule increase factor of 1.50 percent.

Step 1. Calculate 60 percent (the labor-related portion) of the proposed national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. We confirmed that this labor-related share for hospital outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553).

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 * (\text{national unadjusted payment rate})$

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards)

to which hospitals are assigned for FY 2012 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Public Law 98–21. We note that the reclassifications of hospitals under section 508 of Public Law 108–173, as extended by sections 3137 and 10317 of the Affordable Care Act, expired on September 30, 2010. Section 102 of the Medicare and Medicaid Extenders Act of 2010 extends Section 508 and certain additional special exception hospital reclassifications from October 1, 2010 through September 30, 2011. Therefore, these reclassifications will not apply to the CY 2012 OPPS. (For further discussion of the changes to the FY 2012 IPPS wage indices, as applied to the CY 2012 OPPS, we refer readers to section II.C. of this proposed rule.) We are proposing to continue applying a wage index floor of 1.00 to frontier states, in accordance with section 10324 of the Affordable Care Act.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) contains the qualifying counties and the associated proposed wage index increase developed for the FY 2012 IPPS and listed as Table 4J in the FY 2012 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp.* This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national payment rate for the specific service by the wage index.

X_a *is the labor-related portion of the national unadjusted payment rate (wage adjusted).*

X_a = .60 * (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = .40 * (national unadjusted payment rate)

Adjusted Medicare Payment = $Y + X_a$

Step 6. If a provider is a SCH, set forth in the regulations at § 412.92, or an EACH, which is considered to be a SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the proposed total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071

We have provided examples below of the calculation of both the proposed full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we use a provider that is located in Brooklyn, New York that is assigned to CBSA 35644. This provider bills one service that is assigned to APC 0019 (Level I Excision/Biopsy). The proposed CY 2012 full national unadjusted payment rate for APC 0019 is $338.51. The proposed reduced national unadjusted payment rate for a hospital that fails to meet the Hospital OQR Program requirements is $331.74. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 0019.

The proposed FY 2012 wage index for a provider located in CBSA 35644 in New York is 1.3190. The proposed labor-related portion of the full national unadjusted payment is $267.90 (.60 * $338.51 *1.3190). The proposed labor-related portion of the reduced national unadjusted payment is $262.54 (.60 * $331.74 * 1.3190). The proposed nonlabor-related portion of the full national unadjusted payment is $135.40 (.40 * $338.51). The proposed nonlabor-related portion of the reduced national unadjusted payment is $132.70 (.40 * $331.74). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is $403.30 ($267.90 + $135.40). The sum of the reduced national adjusted payment is $395.24 ($262.54 + $132.70).

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, for all services paid under the OPPS in CY 2010, and in calendar years thereafter, the percentage is 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected to the amount of the inpatient deductible. Section 4104 of the Affordable Care Act eliminated the Part B coinsurance for preventive services furnished on and after January 1, 2011 that meet certain requirements, including flexible sigmoidoscopies and screening colonscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011 may be found in section XII.B. of the CY 2011 OPPS final rule (75 FR 72013).

2. Proposed OPPS Copayment Policy

For CY 2012, we are proposing to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In

addition, we are proposing to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2012, are shown in Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site). As discussed in section XIV.E. of this proposed rule, for CY 2012, the proposed Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 0019, $67.71 is 20 percent of the full national unadjusted payment rate of $338.51. For APCs with only a minimum unadjusted copayment in Addenda A and B of this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this proposed rule. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary percentage to the adjusted payment rate for a service calculated under section II.H. of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.980.

The proposed unadjusted copayments for services payable under the OPPS that would be effective January 1, 2012, are shown in Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed full CY 2012 OPD fee schedule increase factor discussed in section XIV.E. of this proposed rule.

Also as noted above, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected to the amount of the inpatient deductible.

III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims: (1) Category I CPT codes, which describe medical services and procedures; (2) Category III CPT codes, which describe new and emerging technologies, services, and procedures; and (3) Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes. CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and/or provides payment or more accurate payment for these items or services in a timelier manner than if CMS waited for the annual rulemaking process. We solicit comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process. In Table 14 below, we summarize our proposed process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing their treatment under the OPPS. We note that because of the timing of the publication of this proposed rule, the codes that will be implemented through the July 2011 OPPS quarterly update are not included in Addendum B of this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site), while those codes based upon the April 2011 OPPS quarterly update are included in Addendum B.

TABLE 14—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April I, 2011	Level II HCPCS Codes	April 1, 2011	CY 2012 OPPS/ASC proposed rule.	CY 2012 OPPS/ASC final rule with comment period.
July 1, 2011	Level II HCPCS Codes	July 1, 2011	CY 2012 OPPS/ASC proposed rule.	CY 2012 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2011	CY 2012 OPPS/ASC proposed rule.	CY 2012 OPPS/ASC final rule with comment period.
October 1, 2011	Level II HCPCS Codes	October 1, 2011	CY 2012 OPPS/ASC final rule with comment period.	CY 2013 OPPS/ASC final rule with comment period.
January 1, 2012	Level II HCPCS Codes	January 1, 2012	CY 2012 OPPS/ASC final rule with comment period.	CY 2013 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2012	CY 2012 OPPS/ASC final rule with comment period.	CY 2013 OPPS/ASC final rule with comment period.

This process is discussed in detail below. We have separated our discussion into two sections based on whether we are proposing to solicit public comments in this CY 2012 OPPS/ASC proposed rule or whether we will be soliciting public comments in the CY 2012 OPPS/ASC final rule with comment period. We note that we sought public comment in the CY 2011 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2011. We also sought public comments in the CY 2011 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2010. These new codes, with an effective date of October 1, 2010, or January 1, 2011, were flagged with comment indicator ''NI'' (New code, interim APC assignment; comments will be accepted on the interim APC assignment for the new code) in Addendum B to the CY 2011 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and an APC and payment rate, if applicable, which were subject to public comment following publication of the CY 2011 OPPS/ASC final rule with comment period. We will respond to public comments and finalize our proposed OPPS treatment of these codes in the CY 2012 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New Level II HCPCS Codes and Category I CPT Vaccine Codes and Category III CPT Codes for Which We Are Soliciting Public Comments in This CY 2012 Proposed Rule

Through the April 2011 OPPS quarterly update CR (Transmittal 2174, Change Request 7342, dated March 18, 2011) and the July 2011 OPPS quarterly update CR (Transmittal 2234, Change Request 7443, dated May 27, 2011), we recognized several new HCPCS codes for separate payment under the OPPS. Effective April 1 and July 1 of CY 2011, we made effective a total of 22 new Level II HCPCS codes and 14 Category III CPT codes. Specifically, 5 new Level II HCPCS codes were effective for the April 2011 update and another 17 new Level II HCPCS codes were effective for the July 2011 update for a total of 22. Fourteen new Category III CPT codes were effective for the July 2011 update. Of the 22 new Level II HCPCS codes, we recognized for separate payment 16 of these codes, and of the 14 new Category III CPT codes, we recognized for separate payment 12 of these codes, for a total of 28 new HCPCS codes that are recognized for separate payment for CY 2012.

Through the April 2011 OPPS quarterly update CR, we allowed separate payment for each of the five new Level II HCPCS codes. Specifically, as displayed in Table 15 below, we provided separate payment for the following HCPCS codes:

- HCPCS code C9280 (Injection, eribulin mesylate, 1 mg)
- HCPCS code C9281 (Injection, pegloticase, 1 mg)
- HCPCS code C9282 (Injection, ceftaroline fosamil, 10 mg)
- HCPCS code Q2040 (Injection, incobotulinumtoxin A, 1 unit)
- HCPCS code C9729 (Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with ligamentous resection, discectomy, facetectomy and/or foraminotomy, when performed) any method under indirect image guidance, with the use of an endoscope when performed, single or multiple levels, unilateral or bilateral; lumbar)

We note that HCPCS code Q2040 replaced HCPCS code C9278 (Injection, incobotulinumtoxin A, 1 unit) beginning April 1, 2010. HCPCS code C9278 was effective January 1, 2011, and deleted March 30, 2011, because it was replaced with HCPCS code Q2040. HCPCS code C9278 was assigned to pass-through status beginning January 1, 2011, when the code was implemented. Because HCPCS code Q2040 describes the same drug as HCPCS code C9278, we are continuing its pass-through status and assigning the HCPCS Q-code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 15 below. Specifically, HCPCS code Q2040 is assigned to APC 9278 and status indicator ''G.''

We are proposing to assign the Level II HCPCS codes listed in Table 15 to the specific proposed APCs and status indicators set forth in this proposed rule.

TABLE 15—LEVEL II HCPCS CODES WITH A CHANGE IN OPPS STATUS INDICATOR OR NEWLY IMPLEMENTED IN APRIL 2011

CY 2011 HCPCS code	CY 2011 long descriptor	Proposed CY 2012 status indicator	Proposed CY 2012 APC
C9280	Injection, eribulin mesylate, 1 mg	G	9280

TABLE 15—LEVEL II HCPCS CODES WITH A CHANGE IN OPPS STATUS INDICATOR OR NEWLY IMPLEMENTED IN APRIL 2011—Continued

CY 2011 HCPCS code	CY 2011 long descriptor	Proposed CY 2012 status indicator	Proposed CY 2012 APC
C9281	Injection, pegloticase, 1 mg	G	9281
C9282	Injection, ceftaroline fosamil, 10 mg	G	9282
C9729	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with ligamentous resection, discectomy, facetectomy and/or foraminotomy, when performed) any method under indirect image guidance, with the use of an endoscope when performed, single or multiple levels, unilateral or bilateral; lumbar.	T	0208
Q2040* ...	Injection, incobotulinumtoxin A, 1 unit	G	9278

*Level II HCPCS code C9278 was deleted March 31, 2011, and replaced with HCPCS code Q2040 effective April 1, 2011.

Through the July 2011 OPPS quarterly update CR, which included HCPCS codes that were made effective July 1, 2011, we allowed separate payment for 11 of the 17 new Level II HCPCS codes. Specifically, as displayed in Table 16 of this proposed rule, we provided separate payment for the following HCPCS codes:

- HCPCS code C9283 (Injection, acetaminophen, 10 mg)
- HCPCS code C9284 (Injection, ipilimumab, 10 mg)
- HCPCS code C9285 (Lidocaine 70 mg/tetracaine 70 mg, per patch)
- HCPCS code C9365 (Oasis Ultra Tri-Layer matrix, per square centimeter)
- HCPCS code C9406 (Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries)
- HCPCS code C9730 (Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 1 lobe)
- HCPCS code C9731 (Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 2 or more lobes)
- HCPCS code Q2041 (Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco)
- HCPCS code Q2042 (Injection, hydroxyprogesterone caproate, 1 mg)
- HCPCS code Q2043 (Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion)
- HCPCS code Q2044 (Injection, belimumab, 10 mg)

We note that two of the Level II HCPCS Q-codes that were made effective July 1, 2011, were previously described by a HCPCS J-code and a C-code that were assigned to pass-through status under the hospital OPPS. Specifically, HCPCS code Q2041 replaced HCPCS code J7184 (Injection, von willebrand factor complex (human), Wilate, per 100 iu vwf:rco) beginning July 1, 2011. HCPCS code J7184 was assigned to pass-through status when it was made effective January 1, 2011; however, the code is ''Not Payable by Medicare'' because HCPCS code J7184 is replaced with HCPCS code Q2041 effective July 1, 2011. Therefore, HCPCS code J7184 was reassigned to status indicator ''E'' effective July 1, 2011. Because HCPCS code J7184 describes the same drug as HCPCS code Q2041, we continued its pass-through status and assigned HCPCS code Q2041 to status indicator ''G'' effective July 1, 2011. However, because the dosage descriptor for HCPCS code Q2041 is not the same as HCPCS code J7184, we reassigned HCPCS code Q2041 to a new APC to maintain data consistency for future rulemaking. Specifically, HCPCS code Q2041 was assigned to APC 1352 effective July 1, 2011. In addition, HCPCS code Q2043 replaced HCPCS code C9273 (Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion) beginning July 1, 2011. HCPCS code C9273 was assigned to pass-through status when it was made effective October 1, 2010. Because HCPCS code Q2043 describes the same product as HCPCS code C9273, we continued its pass-through status and assigned HCPCS code Q2043 to status indicator ''G'' as well as assigned it to the same APC, specifically APC 9273, effective July 1, 2011.

Of the 17 HCPCS codes that were made effective July 1, 2011, we did not recognize for separate payment 6 HCPCS codes that describe durable medical equipment (DME) because DME is paid under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule and not the OPPS. These codes are listed in Table 16 below, and are assigned to either status indicator ''Y'' or ''A'' effective July 1, 2011.

Table 16 below includes a complete list of the Level II HCPCS codes that were made effective July 1, 2011, with their proposed status indicators, APC assignments, and payment rates for CY 2012.

TABLE 16—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2011

CY 2011 HCPCS code	CY 2011 long descriptor	Proposed CY 2012 status indicator	Proposed CY 2012 APC	Proposed CY 2012 payment rate
C9283	Injection, acetaminophen, 10 mg	G	9283	$0.11
C9284	Injection, ipilimumab, 1 mg	G	9284	127.20
C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285	13.57
C9365	Oasis Ultra Tri-Layer matrix, per square centimeter	G	9365	10.60
C9406	Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406	1,908.00
C9730	Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 1 lobe.	T	0415	1,971.77
C9731	Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 2 or more lobes.	T	0415	1,971.77

TABLE 16—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2011—Continued

CY 2011 HCPCS code	CY 2011 long descriptor	Proposed CY 2012 status indicator	Proposed CY 2012 APC	Proposed CY 2012 payment rate
K0741	Portable gaseous oxygen system, rental, includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing, for cluster headaches.	Y	NA	NA
K0742	Portable oxygen contents, gaseous, 1 month's supply = 1 unit, for cluster headaches, for initial months supply or to replace used contents.	Y	NA	NA
K0743	Suction pump, home model, portable, for use on wounds	Y	NA	NA
K0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 square inches or less.	A	NA	NA
K0745	Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 square inches but less than or equal to 48 square inches.	A	NA	NA
K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 square inches.	A	NA	NA
Q2041	Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco	G	1352	0.88
Q2042	Injection, hydroxyprogesterone caproate, 1 mg	K	1354	2.90
Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion.	G	9273	32,860.00
Q2044	Injection, belimumab, 10 mg	G	1353	39.15

For CY 2012, we are proposing to continue our established policy of recognizing Category I CPT vaccine codes for which FDA approval is imminent and Category III CPT codes that the AMA releases in January of each year for implementation in July through the OPPS quarterly update process. Under the OPPS, Category I vaccine codes and Category III CPT codes that are released on the AMA Web site in January are made effective in July of the same year through the July quarterly update CR, consistent with the AMA's implementation date for the codes. Through the July 2011 OPPS quarterly update CR, we allow separate payment for 12 of the 14 new Category III CPT codes effective July 1, 2011. Specifically, as displayed in Table 17 of this proposed rule, we allow separate payment for the following CPT codes:

- CPT code 0263T (Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest)
- CPT code 0264T (Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest)
- CPT code 0265T (Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy)
- CPT code 0267T (Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0269T (Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0270T (Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0271T (Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0272T (Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day))
- CPT code 0273T (Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming)
- CPT 0274T (Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic)
- CPT 0275T (Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar) (As published in the July 2011 OPPS quarterly update CR, CPT code 0275T replaced Level II HCPCS code C9729 effective July 1, 2011.)

We note that Category III CPT codes 0262T (Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach) and 0266T (Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement,

intra-operative interrogation, programming, and repositioning, when performed)) are assigned to status indicator ''C'' (Inpatient Procedures) under the hospital OPPS beginning July 1, 2011. We believe these procedures should only be paid when provided in the inpatient setting because of the clinical circumstances under which these procedures are performed. There are no new Category I Vaccine CPT codes for the July 2011 update.

Table 17 below lists the Category III CPT codes that were implemented in July 2011 for which we are proposing to allow separate payment, along with their proposed status indicators, proposed APC assignments, and proposed payment rates for CY 2012.

TABLE 17—CATEGORY III CPT CODES IMPLEMENTED IN JULY 2011

CY 2011 CPT code	CY 2011 long descriptor	Proposed CY 2012 status indicator	Proposed CY 2012 APC	Proposed CY 2012 payment rate
0262T	Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach.	C	NA	NA
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest.	S	0112	$2,166.33
0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest.	S	0112	2,166.33
0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy.	S	0112	2,166.33
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed).	C	NA	NA
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed).	T	0687	1,496.15
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed).	S	0039	14,743.58
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed).	T	0221	2,567.33
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed).	T	0687	1,496.15
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed).	T	0688	2,003.33
0272T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day).	S	0218	80.78
0273T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming.	S	0218	80.78
0274T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic.	T	0208	3,535.92
0275T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar.	T	0208	3,535.92

We are soliciting public comments on the CY 2012 proposed status indicators and the proposed APC assignments and payment rates, if applicable, for the Level II HCPCS codes and the Category III CPT codes that are newly recognized in April or July 2011 through the respective OPPS quarterly update CRs. These codes are listed in Tables 15, 16, and 17 of this proposed rule. We are proposing to finalize their status indicators and their APC assignments and payment rates, if applicable, in the CY 2012 OPPS/ASC final rule with comment period. Because the July 2011 OPPS quarterly update CR is issued close to the publication of this proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2011 OPPS quarterly update CR could not be included in Addendum B to this proposed rule, but these codes are listed in Tables 16 and 17, respectively. We are proposing to incorporate these codes into Addendum B to the CY 2012 OPPS/ASC final rule with comment period, which is consistent with our annual OPPS update policy. The Level II HCPCS codes implemented or modified through the April 2011 OPPS update CR and displayed in Table 15 are included in Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site), where their proposed CY 2012 payment rates also are shown.

2. Proposed Process for New Level II HCPCS Codes and Category I and Category III CPT Codes for Which We Will Be Soliciting Public Comments on the CY 2012 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the OPPS for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January OPPS quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period updating the OPPS for the following calendar year. All of these codes are flagged with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. Specifically, the status indicator and the APC assignment and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the final rule with comment period, and we respond to these comments in the OPPS/ASC final rule with comment period for the next calendar year's OPPS/ASC update. We are proposing to continue this process for CY 2012. Specifically, for CY 2012, we are proposing to include in Addendum B (which is available via the Internet on the CMS Web site) to the CY 2012 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2012 (including the Category III CPT codes that were released by the AMA in July 2011) that would be incorporated in the January 2012 OPPS quarterly update CR and the new Level II HCPCS codes, effective October 1, 2011, or January 1, 2012, that would be released by CMS in its October 2011 and January 2012 OPPS quarterly update CRs. These codes would be flagged with comment indicator ''NI'' in Addendum B to the CY 2012 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim OPPS payment status for CY 2012. Their status indicators and their APC assignments and payment rates, if applicable, would be open to public comment in the CY 2012 OPPS/ASC final rule with comment period and would be finalized in the CY 2013 OPPS/ASC final rule with comment period. We note that the Category III CPT codes that were released by the AMA in July 2011 that are subject to comment in this CY 2012 OPPS/ASC proposed rule, and are listed in Table 17, will not be assigned to comment indicator ''NI'' in Addendum B because comments about these codes will be addressed in the CY 2012 OPPS/ASC final rule with comment period.

B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in § 419.31 of the regulations. We use Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices.

We have packaged into payment for each procedure or service within an APC group the costs associated with those items or services that are directly related to, and supportive of, performing the main independent procedures or furnishing the services. Therefore, we do not make separate payment for these packaged items or services. For example, packaged items and services include: (1) use of an operating, treatment, or procedure room; (2) use of a recovery room; (3) observation services; (4) anesthesia; (5) medical/surgical supplies; (6) pharmaceuticals (other than those for which separate payment may be allowed under the provisions discussed in section V. of this proposed rule); (7) incidental services such as venipuncture; and (8) guidance services, image processing services, intraoperative services, imaging supervision and interpretation services, diagnostic radiopharmaceuticals, and contrast media. Further discussion of packaged services is included in section II.A.3. of this proposed rule.

In CY 2008, we implemented composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service (72 FR 66650 through 66652). Under CY 2011 OPPS policy, we provide composite APC payment for certain extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, and multiple imaging services. Further discussion of composite APCs is included in section II.A.2.e. of this proposed rule.

Under the OPPS, we generally pay for hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. Each APC weight represents the hospital median cost of the services included in that APC, relative to the

hospital median cost of the services included in APC 0606 (Level 3 Hospital Clinic Visits). The APC weights are scaled to APC 0606 because it is the middle level hospital clinic visit APC (the Level 3 hospital clinic visit CPT code out of five levels), and because middle level hospital clinic visits are among the most frequently furnished services in the hospital outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review, on a recurring basis occurring no less than annually and revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors; the Act further requires us to repeat this process on a basis that is not less often than annually. Section 1833(t)(9)(A) of the Act also requires the Secretary, beginning in CY 2001, to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights (the APC Panel recommendations for specific services for the CY 2012 OPPS and our responses to them are discussed in the relevant specific sections throughout this proposed rule).

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost as elected by the Secretary) for an item or service in the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the same group (referred to as the ''2 times rule''). We use the median cost of the item or service in implementing this provision. The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act).

2. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the median cost of the highest cost item or service within an APC group is more than 2 times greater than the median of the lowest cost item or service within that same group. In making this determination, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant HCPCS for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC median cost to be significant (75 FR 71832). This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing median costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC median. In this proposed rule, we are proposing to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as low volume items and services for CY 2012.

During the APC Panel's February 2011 meeting, we presented median cost and utilization data for services furnished during the period of January 1, 2010, through September 30, 2010, about which we had concerns or about which the public had raised concerns regarding their APC assignments, status indicator assignments, or payment rates. The discussions of most service-specific issues, the APC Panel recommendations, if any, and our proposals for CY 2012 are contained mainly in sections III.C. and III.D. of this proposed rule.

In addition to the assignment of specific services to APCs that we discussed with the APC Panel, we also identified APCs with 2 times violations that were not specifically discussed with the APC Panel but for which we are proposing changes to their HCPCS codes' APC assignments in Addendum B (available via the Internet) to this proposed rule. In these cases, to eliminate a 2 times violation or to improve clinical and resource homogeneity, we are proposing to reassign the codes to APCs that contain services that are similar with regard to both their clinical and resource characteristics. We also are proposing to rename existing APCs or create new clinical APCs to complement proposed HCPCS code reassignments. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2012 included in this proposed rule are related to changes in median costs of services that are observed in the CY 2010 claims data newly available for CY 2012 ratesetting. We also are proposing changes to the status indicators for some codes that are not specifically and separately discussed in this proposed rule. In these cases, we are proposing to change the status indicators for some codes because we believe that another status indicator would more accurately describe their payment status from an OPPS perspective based on the policies that we are proposing for CY 2012.

Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) identifies with comment indicator ''CH'' those HCPCS codes for which we are proposing a change to the APC assignment or status indicator that were initially assigned in the April 2011 Addendum B update (via Transmittal 2174, Change Request 7342, dated March 18, 2011).

3. Proposed Exceptions to the 2 Times Rule

As discussed earlier, we may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases such as low-volume items and services. Taking into account the APC changes that we are proposing for CY 2012 based on the APC Panel recommendations that are discussed mainly in sections III.C. and III.D. of this proposed rule, the other proposed changes to status indicators and APC assignments as identified in Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site), and the use of CY 2010 claims data to calculate the median costs of procedures classified in the APCs, we reviewed all the APCs to determine which APCs would not satisfy the 2 times rule. We used the following criteria to decide whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18457 and 18458).

Table 18 of this proposed rule lists 17 APCs that we are proposing to exempt from the 2 times rule for CY 2012 based on the criteria cited above and based on claims data processed from January 1, 2010, through September 30, 2010. For the final rule with comment period, we plan to use claims data for dates of service between January 1, 2010, and December 31, 2010, that were processed on or before June 30, 2011, and updated CCRs, if available. Based on our analysis of CY 2010 claims data in preparation for this proposed rule, we found 17 APCs with 2 times rule violations. We applied the criteria as described earlier to identify the APCs that we are proposing as exceptions to the 2 times rule for CY 2012, and identified 17 APCs that meet the criteria for exception to the 2 times rule for this proposed rule. These proposed APC exceptions are listed in Table 18 below. For cases in which a recommendation by the APC Panel appeared to result in or allow a violation of the 2 times rule, we generally accepted the APC Panel's recommendation because those recommendations were based on explicit consideration of resource use, clinical homogeneity, hospital specialization, and the quality of the CY 2010 claims data used to determine the APC payment rates that we are proposing for CY 2012. The proposed median costs for hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp.*

TABLE 18—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2012

Proposed CY 2012 APC	Proposed CY 2012 APC title
0016	Level IV Debridement & Destruction.
0057	Bunion Procedures.
0058	Level I Strapping and Cast Application.
0060	Manipulation Therapy.
0080	Diagnostic Cardiac Catheterization.
0105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices.
0235	Level I Posterior Segment Eye Procedures.
0245	Level I Cataract Procedures without IOL Insert.
0263	Level I Miscellaneous Radiology Procedures.
0340	Minor Ancillary Procedures.
0347	Level III Transfusion Laboratory Procedures.
0367	Level I Pulmonary Test.
0369	Level III Pulmonary Tests.
0432	Health and Behavior Services.
0604	Level 1 Hospital Clinic Visits.
0660	Level II Otorhinolaryngologic Function Tests.
0667	Level II Proton Beam Radiation Therapy.

C. Proposed New Technology APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we finalized changes to the time period a service was eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We note that the cost bands for New Technology APCs range from $0 to $50 in increments of $10, from $50 to $100 in increments of $50, from $100 to $2,000 in increments of $100, and from $2,000 to $10,000 in increments of $500. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level VII ($500—$600)) is made at $550. Currently, there are 82 New Technology APCs, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level IA ($0–$10)) through the highest cost band assigned to APC 1574 (New Technology—Level XXXVII ($9,500–$10,000). In CY 2004 (68 FR 63416), we last restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of ''S''' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

Every year we receive many requests for higher payment amounts under our New Technology APCs for specific procedures under the OPPS because they require the use of expensive equipment. We are taking this opportunity to reiterate our response in general to the issue of hospitals' capital expenditures as they relate to the OPPS and Medicare.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital inpatient market basket increase. We believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries in cost-efficient settings, and we believe that our rates are adequate to ensure access to services.

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under our New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on Medicare beneficiary projected utilization and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies.

We note that, in a budget neutral environment, payments may not fully cover hospitals' costs in a particular

circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

2. Proposed Movement of Procedures From New Technology APCs to Clinical APCs

As we explained in the November 30, 2001 final rule (66 FR 59902), we generally keep a procedure in the New Technology APC to which it is initially assigned until we have collected sufficient data to enable us to move the procedure to a clinically appropriate APC. However, in cases where we find that our original New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that most appropriately reflects its cost.

Consistent with our current policy, we are proposing for CY 2012 to retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to a clinically appropriate APC. The flexibility associated with this policy allows us to move a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been collected. Table 19 below lists the HCPCS codes and associated status indicators that we are proposing to reassign from a New Technology APC to a clinically appropriate APC or to a different New Technology APC for CY 2012.

Currently, in CY 2011, there are three procedures described by a HCPCS G-code receiving payment through a New Technology APC. Specifically, HCPCS code G0417 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21–40 specimens) is assigned to New Technology APC 1506 (New Technology—Level VI ($400–$500)); HCPCS code G0418 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41–60 specimens) is assigned to New Technology APC 1511 (New Technology—Level XI ($900–$1,000)); and HCPCS code G0419 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens) is assigned to New Technology APC 1513 (New Technology—Level XIII ($1,100–$1,200)).

Analysis of our hospital outpatient data for claims submitted for CY 2010 indicates that prostate saturation biopsy procedures are rarely performed on Medicare patients. For OPPS claims submitted from CY 2009 through CY 2010, our claims data show that there were only five claims submitted for HCPCS code G0417 in CY 2009 and only one in CY 2010 with a proposed median cost of approximately $532. Our claims data did not show any hospital outpatient claims for HCPCS codes G0418 and G0419 from either CY 2009 or CY 2010.

While we believe that these procedures will always be low volume, given the number of specimens being collected, we believe that we should continue their New Technology payments for another year for HCPCS codes G0417, G0418, and G0419 to see if more claims data become available. For CY 2012, we are proposing to revise the APC assignments for these procedures and continue the New Technology APC payments for HCPCS G-codes G0417, G0418, and G0419. Specifically, we are proposing to reassign HCPCS code G0417 from APC 1506 to APC 1505 (New Technology–Level V ($300–$400)), HCPCS code G0418 from APC 1511 to APC 1506 (New Technology—Level VI ($400–$500)), and HCPCS G0419 code from APC 1513 to APC 1508 (New Technology—Level VIII ($600–$700)). We believe that the proposed revised APC assignments would more appropriately reflect the procedures described by these three HCPCS G-codes, based on clinical and resource considerations. These procedures and their proposed APC assignments are displayed in Table 19.

TABLE 19—PROPOSED REASSIGNMENT OF PROCEDURES ASSIGNED TO NEW TECHNOLOGY APCS FOR CY 2012

CY 2011 HCPCS code	CY 2011 short descriptor	CY 2011 SI	CY 2011 APC	Proposed CY 2012 SI	Proposed CY 2012 APC
G0417	Sat biopsy prostate 21–40	S	1506	S	1505
G0418	Sat biopsy prostate 41–60	S	1511	S	1506
G0419	Sat biopsy prostate: >60	S	1513	S	1508

D. Proposed OPPS APC-Specific Policies

1. Revision/Removal of Neurostimulator Electrodes (APC 0687)

For CY 2011, we continued to assign CPT codes 63661 (Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed), 63662 (Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed), 63663 (Revision, including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed), and 63664 (Revision, including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed) to APC 0687 (Revision/Removal of Neurostimulator Electrodes), which had a CY 2011 final rule median cost of approximately $1,480. These codes were created effective for services performed

on or after January 1, 2010, when the AMA CPT Editorial Board deleted CPT code 63660 (Revision or removal of spinal neurostimulator electrode percutaneous array(s) or plate/paddle(s)) and created new CPT codes 63661, 63662, 63663, and 63664 to differentiate between revision and removal procedures, and to also differentiate between percutaneous leads (arrays) and surgical leads (plates/paddles).

As discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71913), we have received several comments objecting to the placement of CPT codes 63663 and 63664 in APC 0687 because, the commenter stated, these codes are used to report both revision and replacement of neurostimulator electrodes. The commenters believed that the use of hospital resources is substantially greater when neurostimulator electrodes are being replaced rather than revised. We responded to these comments by stating that we did not have CY 2009 claims data on the cost of these codes upon which to make an assessment of whether there is a meaningful difference between the cost of revising the electrodes or replacing them, and that we were not convinced by the commenters stating that the use of the CPT codes for these services and the assignment of the codes for revision/replacement of neurostimulator electrodes to APC 0687 was inappropriate. We further stated that the OPPS is a payment system of averages in which the payment for a service is based on the estimated relative cost of the service, including a range of supply and other input costs, as well as other services in the same APC that are comparable in resource cost and clinical homogeneity. We noted that we expect that hospital charges for a service, which are derived from the cost of a service, can vary across individual patients. Therefore, we expect variability in the estimated cost of a service, across cases in a hospital and among hospitals, to be reflected at some level in the final APC relative payment weight. We indicated that we would examine estimated costs for these CPT codes in the CY 2010 claims data that we would use to model the CY 2012 proposed rule when these data became available.

At its February 28–March 1, 2011 meeting, the APC Panel recommended that CMS provide more data on CPT codes 63663, 63664, and 64569 (Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator) to determine whether they represent primarily device replacements or device revisions. We are accepting this recommendation and have examined the CY 2010 claims data available for this proposed rule to compare the frequency of claims containing CPT codes 63663 or 63664 that were billed with HCPCS C1778 (Lead, neurostimulator (implantable)) or C1897 (Lead, neurostimulator test kit (implantable)) to the frequency of claims with CPT codes 63663 or 63664 billed without HCPCS codes C1778 and C1897, in order to determine whether they represent primarily device replacements or device revisions. We found that 61 percent of claims containing CPT codes 63663 or 63664 did not contain HCPCS code C1778 or C1897, while 39 percent of claims with CPT codes 63663 or 63664 did contain HCPCS code C1778 or C1897. Because the majority of the claims did not contain HCPCS code C1778 or C1897, these findings suggest that these CPT codes are used to describe mainly device revision procedures, although there are a significant number of cases of device replacement procedures in the claims data. We will present the requested data for CPT code 64569 at a future meeting of the APC Panel.

We also have completed an examination of the estimated costs for CPT codes 63661, 63662, 63663, and 63664 now that claims data for these CPT codes are available for the first time since they became effective on January 1, 2010. Based on the partial year claims data available for this proposed rule, the proposed median costs for CPT codes 63661 and 63662 are approximately $1,167 and $2,190, respectively. The claims data show a median cost of approximately $4,316 for CPT code 63663 and a median cost of approximately $4,883 for CPT code 63664, which constitute a 2 times rule violation within APC 0687.

In order to resolve the 2 times rule violation in APC 0687, we are proposing to move CPT codes 63663 and 63664 from APC 0687 to APC 0040 (Percutaneous Implantation of Neurostimulator Electrodes), which has a CY 2012 proposed median cost of approximately $4,516 that is more consistent with the median costs for CPT codes 63663 and 63664. We also are proposing to change the title of APC 0040 to ''Level I Implantation/Revision/Replacement of Neurostimulator Electrodes'' to reflect that the APC would include revision and replacement procedures beginning in CY 2012, and to change the title of APC 0061 from ''Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes'' to ''Level II Implantation/Revision/Replacement of Neurostimulator Electrodes'' to be consistent with the APC 0040 title change. We believe that CPT codes 63661 and 63662 continue to be placed appropriately in APC 0687 because their CY 2012 proposed CPT median costs of approximately $1,167 and $2,190, respectively, are consistent with the overall proposed APC 0687 median cost of approximately $1,492 and because they describe only device removal procedures.

2. Computed Tomography of Abdomen and Pelvis (APCs 0331 and 0334)

The AMA CPT Editorial Panel created three new codes for computed tomography (CT) of abdominal and pelvis that were effective January 1, 2011: CPT code 74176 (Computed tomography, abdomen and pelvis; without contrast material); CPT code 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)); and CPT code 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions). As with all new CPT codes for CY 2011, these new codes were announced through the publication of the CY 2011 CPT in November 2010, effective on January 1, 2011.

In accordance with our longstanding policy, we made an interim APC assignment for each new code for CY 2011 based on our understanding of the resources required to furnish the service as the service was defined in the new code (75 FR 71898). Specifically, for CY 2011, we assigned new CPT code 74176 to APC 0332 (Computed Tomography Without Contrast), which has a CY 2011 payment rate of approximately $194; we assigned CPT code 74177 to APC 0283 (Computed Tomography With Contrast), which has a CY 2011 payment rate of $300; and we assigned CPT code 74178 to CPT code 0333 (Computed Tomography Without Contrast Followed by With Contrast), which has a CY 2011 payment rate of $334. For CY 2011, we also made these codes eligible for composite payment under the multiple imaging composite APC methodology when they are furnished with other CT procedures to the same patient on the same day.

As is our standard practice each year, our clinicians review each of the many CPT code changes that will be effective in the forthcoming year and make a decision regarding status indicator and/or APC assignment based on their understanding of the nature of the services furnished. We are unable to

include a proposed status indicator and/or APC assignment in the proposed rule for codes that are not announced by the AMA CPT Editorial Board prior to the proposed rule. Therefore, in accordance with our longstanding policy, we include, in the final rule with comment period, an interim status indicator and/or APC assignment for all new CPT codes that are announced by the AMA CPT Editorial Board subsequent to the OPPS/ASC proposed rule to enable payment to be made for new services as soon as the code is effective. In accordance with our longstanding practice, we identified the new codes for abdominal/pelvis CT for CY 2011 in Addendum B of the CY 2011 OPPS/ASC final rule with comment period as having new interim APC assignments by showing a comment indicator of ''NI,'' and we provided a public comment period. As we do with all new CPT codes, we will respond to the public comments in the OPPS/ASC final rule with comment period for CY 2012. This longstanding process enables us to pay for new services as soon as the new CPT codes for them go into effect, despite the fact that they first become publicly available at the same time the final rule with comment period for the upcoming year is made public.

At its February 28–March 1, 2011 meeting, the APC Panel heard public presentations on this issue and recommended that CMS provide more data on the new CPT codes for combined abdomen and pelvis CT as soon as these data are available. We are accepting this recommendation, and we will provide claims data as soon as the data are available. We note that because these codes were effective January 1, 2011, the first available claims data for these codes will be the APC Panel claims data for the CY 2013 OPPS rulemaking. These data will be for dates of service January 1, 2011 through and including September 30, 2011, as processed through the Common Working File on or before September 30, 2011.

In general, stakeholders who provided comments on the interim assignment of these codes for CY 2011 stated that the most appropriate approach to establishing payment for these new codes is to assign these procedures to APCs that recognize that each of the new codes reflects the reporting under a single code of two services that were previously reported under two separate codes and that, therefore, payments would be more accurate and better reflective of the relative cost of the services under the OPPS if we were to establish payment rates for the codes for CY 2012 using claim data that reflect the combined cost of the two predecessor codes. They noted that when these services were reported in CY 2010 using two CPT codes, rather than a single code, the services that are being reported under CPT code 74176 were assigned to imaging composite APC 8005 (CT and CTA without Contrast) for which the CY 2010 payment was $419.45. Similarly, the services being reported under CPT code 74177 or CPT code 74178 were assigned to composite APC 8006 (CT and CTA with Contrast) for which the CY 2010 payment was $628.49. They indicated that they believed that simulating the median cost for CPT codes 74176, 74177, and 74178 using historic claims data from the predecessor codes in a manner similar to that used to create the composite APC medians would result in the best estimates of costs for these codes and, therefore, the most accurate payment rate for these codes.

After considering the presentations at the APC Panel meeting, the views of stakeholders who met with us to discuss this issue, and the comments in response to the CY 2011 final rule with public comment period, and after examining our claims data for the predecessor codes, we believe that establishment of payment rates for these services based on historic claims data for the combinations of predecessor codes that are now reported by CPT codes 74176, 74177, and 74178 would result in a more accurate and appropriate payment for these services for CY 2012 because it would take into account the full cost of both services that are now reported by a single CPT code. We believe that the best way to secure the most appropriate payments for CY 2012 is to use the claims data from the predecessor codes under which the new codes were reported for CY 2010 to simulate median costs for the new codes and to create APCs that are appropriate to the services. To do so should reflect both the full cost of the service as reported by the new code and should also reflect the efficiencies of reporting the service represented by the single new code. Therefore, we are proposing to establish two APCs to which we would propose to assign the combined abdominal and pelvis CT services. Specifically, we are proposing to create new APC 0331 (Combined Abdominal and Pelvis CT Without Contrast), to which we are proposing to assign CPT code 74176 and for which we are proposing to base the CY 2012 OPPS payment rate on a median cost of approximately $417. We also are proposing to create new APC 0334 (Combined Abdominal and Pelvis CT With Contrast), to which we are proposing to assign CPT codes 74177 and 74178 for the CY 2012 OPPS and for which we are proposing to base the CY 2012 OPPS payment rate on a median cost of approximately $592. We are proposing to create two new APCs to which to assign these codes, rather than one, because CPT code 74176 is furnished without contrast, while CPT codes 74177 and 74178 are furnished with contrast. Section 1833(t)(2)(G) of the Act requires that services with contrast may not be assigned to APCs that contain services without contrast, and therefore, we could not assign CPT code 74176, which does not require contrast, to the same APC as CPT codes 74177 and 74178, which require contrast.

We are proposing to create new APC 0331 to which we would assign CPT code 74176 and to create new APC 0334 to which we would assign CPT codes 74177 and 74178 because the proposed methodology for simulating the median costs for CPT codes 74176, 74177, and 74178, which uses claims data for the predecessor codes is unique to these CPT codes. Therefore, we believe that it is appropriate to create APCs comprised only of services for which we calculated medians using claims data for the predecessor codes. To the extent this policy is finalized, we would reassess whether it continues to be appropriate to pay these codes under APCs 0331 and 0334 once the median costs for the proposed CY 2013 OPPS are calculated using our standard methodology, based on hospitals' CY 2011 charges for CPT codes 74176, 74177, and 74178.

To calculate the median costs for proposed APCs 0331 and 0334 for CY 2012, we selected claims that contained one unit of both of the predecessor CPT codes that appear in the CY 2011 CPT for CPT codes 74676, 74677, and 74678. The predecessor codes are limited to the codes in Table 20 below.

TABLE 20—CPT CODES THAT WERE COMBINED TO CREATE NEW ABDOMINAL AND PELVIS CPT CODES FOR CY 2011

CPT Code	Descriptor
72192 ..	Computed tomography, pelvis; without contrast material.
72193 ..	Computed tomography, pelvis; with contrast material(s).
72194 ..	Computed tomography, pelvis; without contrast material, followed by contrast material(s) and further sections.
74150 ..	Computed tomography, abdomen; without contrast material.

TABLE 20—CPT CODES THAT WERE COMBINED TO CREATE NEW ABDOMINAL AND PELVIS CPT CODES FOR CY 2011—Continued

CPT Code	Descriptor
74160 ..	Computed tomography, abdomen; with contrast material(s).
74170 ..	Computed tomography, abdomen; without contrast material, followed by contrast material(s) and further sections.

For purposes of selecting claims to be used to calculate simulated median costs, we selected only claims that contained one (and only one) unit of each of the predecessor codes in the allowed combinations identified in Table 21 below. We used only claims that contained one and only one unit of each of the code combinations because we believe that it represents the best simulation of the definition of the new codes. Where more than one unit of either or both codes were reported, the claim would be paid under an imaging composite APC, not under APC 0331 or 0334. For median calculation, claims that contained more than one unit of either or both codes were assigned to the applicable imaging composite APC. We refer readers to section II.A.2.e.5 of this proposed rule for discussion of the imaging composite APCs.

TABLE 21—COMBINATIONS OF PREDECESSOR CPT CODES USED TO SIMULATE MEDIAN COSTS FOR THE COMBINED ABDOMINAL AND PELVIS CT CODES THAT ARE NEW FOR CY 2011

Combined abdominal and pelvis CT code	Predecessor CT abdomen without contrast	Predecessor CT pelvis without contrast	Predecessor CT abdomen with contrast	Predecessor CT pelvis with contrast
74176	74150	72192	.....	.....
74177	.....	.....	74160	72193
74178	74150	.....	.....	72193
74178	74150	.....	.....	72194
74178	.....	72192	74160	.....
74178	.....	.....	74160	72194
74178	.....	72192	74170	.....
74178	.....	.....	74170	72193
74178	.....	.....	74170	72194

After we selected the claims that contained one and only one unit of each code in each combination, we deleted claims that contained other separately paid HCPCS codes if those codes did not appear on the bypass list (we refer readers to section II.A.1.b. of this proposed rule and to Addendum N, which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site). We bypassed the costs for codes that appeared on the bypass list to create simulated single procedure claims for CPT codes 74178, 74177, and 74178. Using the remaining simulated single procedure claims for the combined abdominal and pelvis CT services, we applied our standard trimming, packaging, and wage standardization methodology to calculate the median cost for each combined abdominal and pelvis CT code for the two proposed APCs. We refer readers to section II.A.2.c. of this proposed rule for discussion of our standard trimming, packaging, and wage standardization methodology.

We found that using this proposed methodology resulted in a simulated median cost for CPT code 74176 of approximately $417, and that, because we are proposing that CPT code 74176 would be the only HCPCS code assigned to APC 0331, the simulated median cost for APC 0331 also would be approximately $417. We found that using this proposed methodology, the simulated median cost for CPT code 74177 was approximately $570 and the simulated median cost for CPT code 74178 was approximately $638, and that the simulated median cost for proposed APC 0334 was approximately $592. We are proposing to use this simulation methodology to establish proposed median costs for proposed APCs 0331 and 0334 for the CY 2012 OPPS.

We also are proposing that, in cases where CPT code 74176 is reported with CT codes that describe CT services for other regions of the body other than the abdomen and pelvis in which contrast is not used, it would be assigned to imaging composite APC 8005 (CT and CTA Without Contrast), for which we are proposing a median cost of approximately $445 for the CY 2012 OPPS. In cases where CPT code 74177 or 74178 is reported with CT codes that describe CT services for regions of the body other than abdomen and pelvis in which contrast is used, we are proposing that the code would be assigned to APC 8006 (CT and CTA With Contrast), for which we are proposing a median cost of approximately $744 for the CY 2012 OPPS. We are proposing to assign CPT codes 74176 to imaging composite APC 8005 and to assign CPT codes 74177 and 74178 to imaging composite APC 8006 because the predecessor codes for CPT codes 74176, 74177 and 74178 (identified in Table 20), continue to be reported when either abdominal CT or pelvis CT (but not both) is furnished, and we are proposing to continue to assign them to imaging composite APCs 8005 and 8006. We believe that it would be inconsistent with our proposed imaging composite policy if we did not propose to assign CPT codes 74176, 74177, and 74178 to the applicable imaging composite APC for CY 2012. We refer readers to section II.A.2.e.(5) of this proposed rule for the discussion of the calculation of our proposed median costs for APCs 8005 and 8006 for CY 2012.

In summary, we are proposing to establish new APCs 0331 and 0334 to which we would assign the abdominal and pelvis CT codes that were created by the AMA CPT Editorial Panel for CY 2011 and to use the simulation methodology we describe above to establish simulated median costs on which we would base the CY 2012 payment rates because we believe that to do so would result in relative payment weights for these new services that will more accurately reflect the resources required to furnish these services as defined by CPT than would be true of continued assignment of the codes to the single service APCs to which we made interim assignments for

CY 2011. We note that claims and cost data for these services will be available for the CY 2013 OPPS rulemaking, and we will reassess the payment policy for these codes based on the cost data that are used to establish the CY 2013 OPPS median cost and payment rates.

3. Placement of Amniotic Membrane (APCs 0233 and 0244)

For the CY 2011 update, the AMA CPT Editorial Panel revised the long descriptor for CPT code 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers) to include the words ''multiple layers'' to further clarify the code descriptor. In addition, the AMA CPT Editorial Panel created two new CPT codes that describe the placement of amniotic membrane on the ocular surface without reconstruction; one describing the placement of a self-retaining (non-sutured/non-glued) device on the surface of the eye, and the other describing a single layer of amniotic membrane sutured to the surface of the eye. Specifically, the AMA CPT Editorial Panel created CPT codes 65778 (Placement of amniotic membrane on the ocular surface for wound healing; self-retaining) and 65779 (Placement of amniotic membrane on the ocular surface for wound healing; single layer, sutured), effective January 1, 2011.

As has been our practice since the implementation of the OPPS in 2000, we carefully review all new procedures before assigning them to an APC. In determining the APC assignments for CPT codes 65778 and 65779, we took into consideration the clinical and resource characteristics involved with placement of amniotic membrane products on the eye for wound healing via a self-retaining device and a sutured, single-layer technique. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72402), we assigned CPT code 65780 to APC 0244 (Corneal and Amniotic Membrane Transplant) with a CY 2011 payment rate of approximately $2,681. We assigned CPT code 65778 to APC 0239 (Level II Repair and Plastic Eye Procedures) with a payment rate of approximately $559, and CPT code 65779 to APC 0255 (Level II Anterior Segment Eye Procedures) with a payment rate of approximately $519. In addition, we assigned both CPT codes 65778 and 65779 to comment indicator ''NI'' in Addendum B of the CY 2011 OPPS/ASC final rule with comment period to indicate that both codes were new codes for CY 2011 with an interim APC assignment subject to public comment. We will address any public comments on issues regarding these new codes in the CY 2012 OPPS/ASC final rule with comment period.

At the APC Panel at the February 28–March 1, 2011 meeting, a presenter requested the reassignment of both new CPT codes 65778 and 65779 to APC 0244, which is the same APC to which CPT code 65780 is assigned. The presenter indicated that prior to CY 2011, the procedures described by CPT codes 65578 and 65779 were previously reported under the original version of CPT code 65780, which did not specify ''multiple layers,'' and as such these new codes should continue to be assigned to APC 0244. Further, the presenter stated that the costs of the new procedures described by CPT codes 65778 and 65779 are very similar to the procedure described by CPT code 65780.

The APC Panel recommended that CMS reassign both CPT codes 65778 and 65779 to APC 0233 (Level III Anterior Segment Eye Procedures), citing clinical similarity to procedures already in APC 0233. Based on clinical as well as resource similarity to the other procedures currently assigned to APC 0233, we are proposing to accept the APC Panel's recommendations to reassign CPT code 65778 from APC 0239 to APC 0233 and to reassign CPT code 65779 from APC 0255 to APC 0233. However, based upon our further review and analysis of the clinical characteristics of the procedure described by CPT code 65778, we also are proposing to conditionally package CPT code 65778. The service described by CPT code 65778 would rarely be provided as a separate, stand-alone service in the HOPD; it would almost exclusively be provided in addition to another procedure or service. Our medical advisors indicate that the procedure described by CPT code 65778 is not significantly different than placing a bandage contact lens on the surface of the eye to cover a corneal epithelial defect. CPT code 65778 describes the simple placement of a special type of bandage (a self-retaining amniotic membrane device) on the surface of the eye, which would most commonly be used in the HOPD to cover the surface of the eye after a procedure that results in a corneal epithelial defect. Given the characteristics of this procedure and its likely use in the HOPD, we are proposing to conditionally package CPT code 65778 for CY 2012 and reassign its status indicator from ''T'' to ''Q2'' to indicate that the procedure is packaged when it is billed on the same date with another procedure or service that is also assigned to status indicator ''T.'' Otherwise, separate payment would be made for the procedure.

In summary, for CY 2012, we are proposing to reassign CPT code 65778 from APC 0239 to APC 0233 with a conditionally packaged status, to reassign CPT code 65779 from APC 0255 to APC 0233, which has a proposed median cost of approximately $1,214, and to continue to assign CPT code 65780 to APC 0244, which has a proposed median cost of approximately $2,767.

As has been our practice since the implementation of the OPPS, we annually review all the items and services within an APC group to determine, with respect to comparability of the use of resources, for any 2 times violations. In making this determination, we review our claims data and determine whether we need to make changes to the current APC assignments for the following year. Because CPT codes 65778 and 65779 are new for CY 2011, and we have no claims data for the CY 2012 update, we will again reevaluate the status indicator and APC assignments for CPT codes 65778, 65779, and 65780 in CY 2012 for the CY 2013 OPPS rulemaking cycle. The amniotic membrane procedures and their CY 2012 proposed APC assignments are displayed in Table 22 below.

TABLE 22—PROPOSED APC ASSIGNMENT FOR THE AMNIOTIC MEMBRANE PROCEDURES FOR CY 2012

CY 2011 HCPCS code	CY 2011 short descriptor	CY 2011 SI	CY 2011 APC	Proposed CY 2012 SI	Proposed CY 2012 APC
65778	Cover eye w/membrane	T	0239	Q2	0233
65779	Cover eye w/membrane suture	T	0255	T	0233
65780	Ocular reconst transplant	T	0244	T	0244

4. Upper Gastrointestinal Services (APCs 0141, 0419, and 0422)

For CY 2011, there are two upper gastrointestinal (GI) procedure APCs, APC 0141 (Level I Upper GI Procedures), which has a CY 2011 national unadjusted payment rate of $611.73, and APC 0422 (Level II Upper GI Procedures), which has a CY 2011 national unadjusted payment rate of $1,148.75. In the CY 2011 OPPS/ASC proposed rule, we proposed to reconfigure APCs 0141 (Level I Upper GI Procedures) and APC 0442 (Level II Upper GI Procedures) by moving several CPT codes from APC 0141 to APC 0422. We received public comments on the proposed rule objecting to our proposal on the basis that the reconfiguration would reduce the median cost and, therefore, the payment for services to which APC 0422 was assigned and would not maintain the clinical homogeneity of these services. Instead commenters, including the applicable medical specialty societies, asked that we reconfigure APCs 0141 and 0422 to create three APCs by adding a new APC for upper GI procedures. They also recommended a HCPCS configuration that they believed would provide payment rates that would more accurately reflect the median costs of the services in APCs 0141 and 0422. We finalized our proposed changes to APCs 0141 and 0422 for CY 2011 without establishing a third APC for upper GI procedures for the reasons discussed in the CY 2011 OPPS/ASC final rule with public comment period (75 FR 71907).

However, when we developed the median costs for APCs 0141 and 0422 using CY 2010 claims data for discussion at the APC Panel meeting of February 28–March 1, 2011, we observed that there was a 2 times violation for APC 0141 that had not existed for CY 2010 OPPS. For the APC Panel meeting, we simulated the HCPCS and APC median costs that would result from the reconfiguration that was recommended by the stakeholders in their comments on the CY 2011 OPPS/ASC final rule with comment period, and we discussed the results with the APC Panel. The APC Panel recommended that CMS create an intermediate level upper GI procedures APC (APC Panel Recommendation 13). The APC Panel recommendations and report may be found at the APC Panel Web site, located at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.*

For the reasons we discuss below, we are accepting the APC Panel recommendation to propose to establish three levels of upper GI procedure APCs and to propose to adopt the reconfiguration recommended by stakeholders because we believe that the proposed reconfiguration will provide payments that are more closely aligned with the median costs of the services. Creating an intermediate APC for upper GI procedures provides APC median costs that are more closely aligned with the median costs for the many CPT codes for upper GI procedures, and therefore, the APC median costs better reflect the resources required to provide these services as defined by the CPT codes for them. Moreover, the proposed reconfiguration resolves the 2 times rule violation that would result in APC 0141 if we were to apply the CY 2011 APC configuration to the CY 2012 proposed rule data. Therefore, we believe that we would need to propose to reassign HCPCS codes regardless of whether we created the intermediate APC for CY 2012. We believe that the proposed reconfiguration to create the intermediate APC is the most appropriate means of avoiding a 2 times violation that would otherwise exist for CY 2012 and that the resulting median costs will provide payments that are more reflective of the relative costs of the services being furnished.

Therefore, for CY 2012, we are proposing to create new APC 0419 (Level II Upper GI Procedures), as recommended by the stakeholders, and we are proposing to reassign HCPCS codes previously assigned to APCs 0141 and 0422 to the three APC configuration. Table 23 below contains the proposed HCPCS reassignments for CY 2012 using the proposed three APC reconfiguration. We believe that this proposed reconfiguration classifies upper GI CPT codes in groups that demonstrate the best clinical and resource homogeneity. For APC 0141, we calculated a proposed rule median cost for CY 2012 of approximately $603. For proposed new APC 0419, we calculated a proposed rule median cost of approximately $904. For APC 0422, we calculated a proposed rule median cost of approximately $1,833.

TABLE 23—PROPOSED RECONFIGURATION OF UPPER GI PROCEDURE CODES FOR CY 2012

APC	HCPCS	SI	Description	Median	Single bill frequency	Percent single bills	Total frequency
0141			Level I Upper GI Procedures	$602.59			
	43831	T	Place gastrostomy tube	0.00	0		0
	43510	T	Surgical opening of stomach	186.33	1		1
	43999	T	Stomach surgery procedure	238.68	1,732		2,128
	43204	T	Esoph scope w/sclerosis inj	361.50	2		6
	43761	T	Reposition gastrostomy tube	496.12	361		602
	43235	T	Uppr gi endoscopy diagnosis	538.38	70,885	20	124,837
	43200	T	Esophagus endoscopy	592.17	1,016		5,513
	43239	T	Upper gi endoscopy biopsy	618.39	260,422	73	516,015
	43202	T	Esophagus endoscopy biopsy	619.63	461		1,244
	43248	T	Uppr gi endoscopy/guide wire	621.09	16,548	5	37,741
	43234	T	Upper gi endoscopy exam	644.39	510		872
	43247	T	Operative upper GI endoscopy	656.88	5,028	1	16,489
	43236	T	Uppr gi scope w/submuc inj	660.41	3,369	1	8,141
	43600	T	Biopsy of stomach	666.46	5		14
	43243	T	Upper gi endoscopy & inject	748.56	161		326
	43241	T	Upper GI endoscopy with tube	782.08	164		462
	43499	T	Esophagus surgery procedure	2,158.45	528		1,375
0419			Level II Upper GI Procedures	903.97			
	91111	T	Esophageal capsule endoscopy	730.21	69		79
	43250	T	Upper GI endoscopy/tumor	730.67	949	1	3,083
	43201	T	Esoph scope w/submucous inj	760.79	99		256
	43251	T	Operative upper GI endoscopy	793.29	2,976	3	10,936
	43237	T	Endoscopic us exam esoph	796.01	369		696

TABLE 23—PROPOSED RECONFIGURATION OF UPPER GI PROCEDURE CODES FOR CY 2012—Continued

APC	HCPCS	SI	Description	Median	Single bill frequency	Percent single bills	Total frequency
	43259	T	Endoscopic ultrasound exam	811.70	13,234	15	21,312
	43246	T	Place gastrostomy tube	814.37	15,205	17	20,923
	43231	T	Esoph endoscopy w/us exam	822.22	346		455
	43244	T	Upper GI endoscopy/ligation	875.56	5,100	6	6,916
	43215	T	Esophagus endoscopy	881.45	220		858
	43255	T	Operative upper GI endoscopy	882.09	3,810	4	7,517
	43458	T	Dilate esophagus	890.28	145		1,305
	43217	T	Esophagus endoscopy	890.36	24		104
	49446	T	Change g-tube to g-j perc	891.78	389		681
	43205	T	Esophagus endoscopy/ligation	894.22	121		142
	43249	T	Esoph endoscopy dilation	897.83	19,351	22	50,173
	49440	T	Place gastrostomy tube perc	899.69	1,770	2	2,823
	43245	T	Uppr gi scope dilate strictr	919.77	2,489	3	5,401
	43226	T	Esoph endoscopy dilation	925.45	741	1	1,138
	43240	T	Esoph endoscope w/drain cyst	953.86	32		85
	49441	T	Place duod/jej tube perc	976.70	136		232
	43220	T	Esoph endoscopy dilation	1,011.56	593	1	908
	43232	T	Esoph endoscopy w/us fn bx	1,017.09	351		425
	44100	T	Biopsy of bowel	1,028.66	5		22
	43238	T	Uppr gi endoscopy w/us fn bx	1,115.06	383		539
	43242	T	Uppr gi endoscopy w/us fn bx	1,125.47	12,260	14	16,443
	43258	T	Operative upper GI endoscopy	1,138.38	5,654	6	10,278
	43227	T	Esoph endoscopy repair	1,405.46	25		39
	43830	T	Place gastrostomy tube	1,721.16	150		288
0422			Level III Upper GI Procedures	1,833.15			
	43216	T	Esophagus endoscopy/lesion	1,416.11	12		31
	43870	T	Repair stomach opening	1,651.04	95	4	153
	43257	T	Uppr gi scope w/thrml txmnt	1,724.95	46	2	62
	43228	T	Esoph endoscopy ablation	1,829.56	2,518	93	3,022
	C9724	T	EPS gast cardia plic	5,957.92	38	1	69

5. Pulmonary Rehabilitation (APC 0102)

Section 144(a)(1) of Public Law 110–275 (MIPPA) added section 1861(fff) to the Act to provide Medicare Part B coverage and payment for a comprehensive program of pulmonary rehabilitation services furnished to beneficiaries with chronic obstructive pulmonary disease, effective January 1, 2010. Accordingly, in the CY 2010 OPPS/ASC final rule with comment period, we established a policy to pay for pulmonary rehabilitation services furnished as a part of the comprehensive pulmonary rehabilitation program benefit (74 FR 60567). There was and continues to be no single CPT code that fully and accurately describes the comprehensive pulmonary rehabilitation benefit provided in section 1861(fff) of the Act. Moreover, there were no alphanumeric HCPCS codes that described the comprehensive pulmonary rehabilitation benefit in effect for CY 2008 (on which the CY 2010 OPPS was based) or CY 2009 (on which the CY 2011 OPPS was based). Therefore, for CY 2010, we created new HCPCS code G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day) and assigned the code to APC 0102 (Level II Pulmonary Treatment), which we also created for CY 2010 OPPS. Because none of the pulmonary treatment codes for which there were charges for CY 2008 or CY 2009 accurately described the comprehensive pulmonary rehabilitation service for which MIPPA provided coverage, we did not assume that the charge reported on any one of the previously existing HCPCS codes under which pulmonary treatments were reported would represent the full charge for the comprehensive pulmonary rehabilitation service.

Instead, for the CY 2010 OPPS, which was based on claims for services in CY 2008, we calculated a median ''per session'' cost that we simulated from historical hospital claims data for pulmonary therapy services that were billed in combination with one another, much like we create composite APC median costs by summing the costs of multiple procedures that are typically provided on the same date. Our methodology for calculating the ''per session'' median cost that we used as the basis for the CY 2010 OPPS payment rate for HCPCS code G0424 and APC 0102 is discussed in detail in the CY 2010 OPPS final rule with comment period (74 FR 60567 through 60570).

Specifically, to simulate the ''per session'' median cost of new HCPCS code G0424 from claims data for existing services, we used only claims that contained at least one unit of HCPCS code G0239 (Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring), the group code that is without limitation on time duration, and one unit of HCPCS code G0237 (Therapeutic procedures to increase strength or endurance of respiratory muscles, one on one, face to face, per 15 minutes (includes monitoring) or HCPCS code G0238 (Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, one on one, face to face, per 15 minutes (includes monitoring), the individual, face-to-face codes that report 15 minutes of service, on the same date of service. We reasoned that patients in a pulmonary rehabilitation program would typically receive individual and group services in each session of approximately 1 hour in duration. This was consistent with public comments that suggested that pulmonary rehabilitation is often provided in group sessions in the HOPD, although patients commonly require additional one-on-one care in order to fully participate in

the program. We note that our use of ''per session'' claims reporting one unit of HCPCS code G0237 or G0238 and one unit of HCPCS code G0239 in this simulation methodology was also consistent with our overall finding of approximately 2.4 service units of the HCPCS G-codes per day on a single date of service, usually consisting of both individual and group services, for patients receiving pulmonary therapy services in the HOPD based upon CY 2008 claims. We concluded that the typical session of pulmonary rehabilitation would be 1 hour based on public comments that indicated that a session of pulmonary rehabilitation is typically 1 hour and based on our findings that the most commonly reported HCPCS code for pulmonary treatment is HCPCS code G0239, which has no time definition for this group service.

We included all costs of the related tests and assessment services (CPT codes 94620 (Pulmonary stress testing; simple (e.g., 6-minute walk test, prolonged exercise test for bronchospasm with pre- and post-spirometry and oximetry)); 94664 (Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB device); and 94667 (Manipulation chest wall, such as cupping, percussion and vibration to facilitate lung function; initial demonstration and/or evaluation), and all CPT codes for established patient clinic visits, on the same date of service as the HCPCS G-codes in the claims we used to simulate the median cost for HCPCS code G0424. After identifying these ''per session'' claims, which we believe to represent 1 hour of care, we summed the costs on them and calculated the median cost for the set of selected claims. In light of the cost and clinical similarities of pulmonary rehabilitation and the existing services described by HCPCS codes G0237, G0238, and G0239 and the CPT codes for related assessments and tests, and the significant number of ''per session'' hospital claims we found, we believed that the simulated median cost for HCPCS code G0424, constructed to include the costs of these services where furnished, was our best estimate of the expected hospital cost of a pulmonary rehabilitation session, given that we did not have hospital charges for the comprehensive pulmonary rehabilitation service provided by MIPPA for which we created HCPCS code G0424.

We used the resulting simulated median ''per session'' cost of approximately $50 as the basis for the payment for pulmonary rehabilitation service for CY 2010, the first year in which the comprehensive pulmonary rehabilitation benefit was covered. For CY 2011, which was based on claims for services furnished in CY 2009, we continued to assign HCPCS code G0424 to APC 0102 and to apply the simulation methodology that we used in CY 2010 to claims for services in CY 2009 to calculate a median ''per session'' cost simulated from historical hospital claims data for similar pulmonary therapy services for the CY 2011 OPPS. The CY 2011 OPPS final rule median cost of approximately $62 resulted in a national unadjusted payment rate for CY 2011 of approximately $63.

For the CY 2012 OPPS, however, we have a very robust set of claims for HCPCS code G0424 on which hospitals reported the charges for the comprehensive pulmonary rehabilitation service for which MIPPA provided the pulmonary rehabilitation benefit beginning on January 1, 2010. Specifically, the CY 2012 OPPS proposed rule data, based on CY 2010 claims, contained a total frequency of 393,056 lines of HCPCS code G0424, of which we were able to use 391,901 single procedure bills or almost 100 percent of the claims submitted for HCPCS code G0424. This is an extremely robust volume of single procedure bills containing charges for HCPCS code G0424 on which to base a median cost. In general, we have found that higher volumes of single bills both in absolute numbers and as a percentage of total frequency provide very stable estimates of hospital costs.

Therefore, we are proposing that the payment rate for HCPCS code G0424 and, therefore, for APC 102, would be based on the median cost for the service as derived from claims for services furnished in CY 2010 and the most current available cost report information, using our longstanding process for estimating the median cost of a service described by a HCPCS code. We refer readers to section II. of this proposed rule for a description of our longstanding standard process for calculating the median costs on which the OPPS payment rates are based. Using our standard median calculation process for HCPCS code G0424 results in a proposed median cost of approximately $38 for HCPCS code G0424 and, therefore, for APC 0102. Given that the volume of claims in the CY 2012 OPPS proposed rule data is so robust for HCPCS code G0424, we believe that the proposed median cost we calculated for HCPCS code G0424 is a valid reflection of the relative cost of the comprehensive pulmonary rehabilitation service described by HCPCS code G0424 and that the proposed median cost for HCPCS code G0424 is an appropriate basis on which to establish the proposed national unadjusted payment rate for APC 0102.

We recognize that there is a significant difference between our simulated median cost for CY 2011 and the CY 2012 proposed rule median cost of approximately $38 that is derived from application of our standard median calculation process to hospital claims data for CY 2010. We believe that this difference arises because the median simulation methodology we used for CY 2010 and CY 2011 selected claims that contained multiple procedures and packaged the costs of numerous services into the ''per session'' cost for the simulated code where numerous services appeared on the same date of service. Our simulation methodology assumed that hospitals would include the charges for these additional services in their CY 2010 charges for HCPCS code G0424 because the services are included in the definition of comprehensive pulmonary rehabilitation.

In response to the CY 2012 OPPS proposed median of approximately $38 for HCPCS code G0424, we looked at our claims data in more depth. We found that 1,048 hospitals, approximately 25 percent of hospitals paid under the OPPS, reported HCPCS code G0424 and that the median line item median cost (exclusive of packaging) was approximately $38, virtually no different from the median cost per unit that we derived from the single bills. We also examined the charges that were submitted for HCPCS code G0424 in CY 2010 and the CCRs that were applied to the charges for HCPCS code G0424 to calculate the estimated median cost for the code for this CY 2012 proposed rule. We also looked at the revenue codes under which charges for HCPCS code G0424 were reported and the percentage of cost that was associated with packaged costs, such as oxygen, drugs, and medical supplies. We found that the median line item charge for HCPCS code G0424 in the CY 2012 proposed rule data was approximately $150 and that the median CCR was 0.29. We also found that the most frequently reported revenue code for HCPCS code G0424 was revenue code 410 (Respiratory therapy), approximately 108,000 single bills, and with revenue code 948 (Pulmonary Rehabilitation), approximately 81,000 single bills, being the second most commonly reported revenue code for HCPCS code G0424. We found that only

0.02 percent of the cost of HCPCS code G0424 was packaged cost (for example, oxygen, drugs, and supplies). In general, our detailed examination of total and line item charges for pulmonary rehabilitation, the CCRs used to reduce the charges to estimated costs on the single bills, the revenue codes reported, and the absence of packaging on the single bills supports the proposed median cost of $38 per unit as a valid estimate of the relative cost of one unit of HCPCS code G0424.

In summary, our examination of the claims and cost data for HCPCS code G0424 causes us to believe that the proposed median cost that we calculated from claims data for HCPCS code G0424 was calculated correctly according to our longstanding standard median cost calculation methodology. Therefore, we are proposing to base the CY 2012 OPPS payment rate for HCPCS code G0424 and APC 0102 on the median cost that we derive from applying our standard median calculation methodology to the CY 2010 charges and cost data for HCPCS code G0424.

6. Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes (APC 0108)

For CY 2011, only HCPCS code 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator) is assigned to APC 0108 (Insertion/Replacement/Repair of Cardioverter Defibrillator Leads). HCPCS code 33249, and therefore APC 0108, has a CY 2011 OPPS median cost of $26,543.91 on which the CY 2011 national unadjusted payment rate is based. For CY 2011, there are two HCPCS codes assigned to APC 0418: CPT code 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system) (List separately in addition to code for primary procedure)), and CPT code 33224 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of generator)). APC 0418 is titled ''Insertion of left ventricular pacing electrode'' for CY 2011. APC 0418 has a CY 2011 median cost of $10,516.97 on which the CY 2011 payment rate for HCPCS codes 33225 and 33224 are based. Both APCs 0108 and 0418 are device-dependent APCs for which the criteria and process used for calculating the median costs are discussed in section II.A.2.d.1. of this proposed rule.

In the CY 2010 claims data used for this CY 2012 proposed rule, HCPCS code 33249 has a median cost of approximately $27,020 based on 6,139 single bills; HCPCS code 33225 has a median cost of approximately $34,018 based on 458 single bills, and HCPCS code 33224 has a median cost of approximately $12,418 based on 201 single bills. We are proposing to retain HCPCS code 33249 in APC 0108 but to reassign HCPCS code 33225 to APC 0108 on the basis that these codes are similar in clinical characteristics and median cost. We are proposing to revise the title of APC 0108 to read ''Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes'' for CY 2012. Under our standard methodology, using CY 2010 claims data, we calculated a median cost of approximately $27,361 for APC 0108.

We also are proposing to assign HCPCS code 33224 to APC 0655 because it is similar in clinical characteristics and median costs to the other services in APC 0655, and to revise the title of APC 0655 to read ''Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode.'' We are proposing a CY 2012 OPPS median cost for APC 0655 of approximately $9,785 upon which we are proposing to base the CY 2012 OPPS payment rate. We are proposing the changes to the titles of APCs 0108 and 0655 to better describe the proposed content of the APCs. Because the reassignment of HCPCS code 33225 to APC 0108 and HCPCS 33244 to APC 0655 would result in APC 0418 containing no HCPCS codes, we are proposing to delete APC 0418.

As we discuss in detail in section III.D. of this proposed rule, we are proposing that HCPCS codes 33249 and 33225 would be paid under APC 0108 only if they are not reported on the same date of service. We are proposing that, when HCPCS codes 33249 and 33225 are reported on the same date of service, they would be paid through proposed new composite APC 8009 (Cardiac Resynchronization Therapy with Defibrillator Composite) and that the payment rate for proposed composite APC 8009 would be limited to the proposed IPPS standardized payment amount for MS–DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization and without Medical Complications and Comorbidities), which is currently estimated to be $26,364.93. In other words, we are proposing to pay APC 8009 at the lesser of the APC 8009 median cost or the IPPS standardized payment rate for MS–DRG 227. We calculated the standardized payment rate for MS–DRG 227 ($26,364.93) by multiplying the normalized weight from Table 5 of the FY 2012 IPPS/LTCH PPS proposed rule (5.1370) by the sum of the nonlabor and labor-related shares of the proposed FY 2012 IPPS operating standardized amount (nonwage-adjusted) labor-related share $3,182.06 + nonlabor-related share $1,950.30 = $5,132.36) which were obtained from Table1B. For further detail on the calculation of the IPPS proposed FY 2012 payment rates, we refer readers to the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26028 through 26029).

In addition, under the authority of section 1833(t)(2)(E) of the Act, which gives the Secretary the authority to make adjustments to ensure equitable payments, we are proposing to limit the payment for services that are assigned to APC 0108, to the proposed IPPS standardized payment amount for MS–DRG 227. In other words, we are proposing to pay APC 0108 at the lesser of the APC 0108 median cost or the IPPS standardized payment rate for MS–DRG 227. We believe that MS–DRG 227 is the most comparable DRG to APC 0108 because, like APC 0108, MS–DRG 227 includes implantation of a defibrillator in patients who do not have medical complication or comorbidities. If we were to base payment for APC 0108 on our calculated median cost of approximately $27,361, it would result in a payment under the CY 2012 OPPS that would exceed our proposed standardized payment under the IPPS for MS–DRG 227 of $26,364.93. We do not believe that it would be equitable to pay more for the implantation of a cardioverter defibrillator or implantation of a left ventricular pacing electrode for an outpatient encounter, which, by definition, includes fewer items and services than an inpatient stay during which the patient has the same procedure. In contrast, the amount Medicare would pay for an inpatient stay includes continuous skilled nursing care, room and board, all medications, and all diagnostic tests for an average of 3 days.

We believe that limiting OPPS payment for the services described by HCPCS codes 33249 and 33225 to the IPPS MS–DRG payment will ensure sufficient, appropriate, and equitable payment to hospitals because patients who receive these services in the hospital outpatient setting are not as sick as patients who have been admitted to receive this same service in the hospital inpatient setting. Therefore, we

expect it would be less costly to care for these patients as outpatients, who would also spend less time in the facility and receive fewer services. In addition, we believe that a payment cap is necessary to ensure that we do not create an inappropriate payment incentive to implant ICDs and left ventricular leads in one setting of care over another by paying more in the outpatient setting compared to the inpatient setting.

We are proposing to continue all other standard policies that apply to device-dependent procedures, including the procedure-to-device edits that were established beginning in the CY 2005 OPPS for claims processing and median calculation; and calculation of and application of device offset amounts when pass-through devices are used and when an ''FB'' or ''FC'' modifier is attached to the line for either CPT code 33249 or 33225. However, for CY 2012, we are proposing that if the APC 0108 median cost that we will calculate for the CY 2012 OPPS/ASC final rule exceeds the FY 2012 IPPS standardized payment rate for MS–DRG 227, as adopted in the FY 2012 IPPS/LTCH PPS final rule, we would establish the OPPS payment amount at the IPPS standardized payment rate for MS–DRG 227 for FY 2012. In the FY 2012 IPPS/LTCH PPS proposed rule, this amount is $26,364.93. If the median cost for APC 0108 as calculated using the CY 2012 OPPS/ASC final rule data is less than the FY 2012 IPPS standardized payment rate for MS–DRG 227, we would base the payment for APC 0108 on the CY 2012 OPPS/ASC final rule median cost for APC 0108. These proposed changes would be made in a budget neutral manner, in the same way that payment for other APCs is budget neutral within the OPPS.

IV. Proposed OPPS Payment for Devices

A. Proposed Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

a. Background

Section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3, years. This pass-through payment eligibility period begins with the first date on which transitional pass-through payments may be made for any medical device that is described by the category. We may establish a new device category for pass-through payment in any quarter. Under our established policy, we base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category. The date on which a pass-through category is in effect is the first date on which pass-through payment may be made for any medical device that is described by such category. We propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update.

We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763). Brachytherapy sources, which are now separately paid in accordance with section 1833(t)(2)(H) of the Act, are an exception to this established policy.

There currently is one new device category eligible for pass-through payment, described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable), which we announced in the October 2010 OPPS Update (Transmittal 2050, Change Request 7117, dated September 17, 2010). There are no categories for which we proposed expiration of pass-through status in CY 2011. If we create new device categories for pass-through payment status during the remainder of CY 2011, we will propose future expiration dates in accordance with the statutory requirement that they be eligible for pass-through payments for at least 2, but not more than 3, years from the date on which pass-through payment for any medical device described by the category may first be made.

b. Proposed CY 2012 Policy

As stated above, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. Device pass-through category C1749 was established for pass-through payments on October 1, 2010, and will have been eligible for pass-through payments for more than 2 years but less than 3 years as of the end of CY 2012. Therefore, we are proposing an expiration date for pass-through payment for device category C1749 of December 31, 2012. Therefore, under our proposal, beginning January 1, 2013, device category C1749 will no longer be eligible for pass-through payments.

2. Proposed Provisions for Reducing Transitional Pass-Through Payments to Offset Costs Packaged into APC Groups

a. Background

We have an established policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments (66 FR 59904). We deduct from the pass-through payments for identified device categories eligible for pass-through payments an amount that reflects the portion of the APC payment amount that we determine is associated with the cost of the device, defined as the device APC offset amount, as required by section 1833(t)(6)(D)(ii) of the Act. We have consistently employed an established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC rates (72 FR 66751 through 66752). We establish and update the applicable device APC offset amounts for eligible pass-through device categories through the transmittals that implement the quarterly OPPS updates.

We currently have published a list of all procedural APCs with the CY 2011 portions (both percentages and dollar amounts) of the APC payment amounts that we determine are associated with the cost of devices, on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp*. The dollar amounts are used as the device APC offset amounts. In addition, in accordance with our established practice, the device APC offset amounts in a related APC are used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices, as specified in our regulations at § 419.66(d).

As of CY 2009, the costs of implantable biologicals without pass-through status are packaged into the payment for the procedures in which they are inserted or implanted because implantable biologicals without pass-through status are not separately paid (73 FR 68633 through 68636). For CY 2010, we finalized a new policy to specify that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice; also referred to as ''implantable

biologicals'') and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only. As a result, for CY 2010, we included implantable biologicals in our calculation of the device APC offset amounts (74 FR 60476). We calculated and set the device APC offset amount for a newly established device pass-through category, which could include a newly eligible implantable biological, beginning in CY 2010 using the same methodology we have historically used to calculate and set device APC offset amounts for device categories eligible for pass-through payment (72 FR 66751 through 66752), with one modification. Because implantable biologicals are considered devices rather than drugs for purposes of pass-through evaluation and payment under our established policy, the device APC offset amounts include the costs of implantable biologicals. For CY 2010, we also finalized a policy to utilize the revised device APC offset amounts to evaluate whether the cost of an implantable biological in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices. Further, for CY 2010, we no longer used the ''policy-packaged'' drug APC offset amounts for evaluating the cost significance of implantable biological pass-through applications under review and for setting the APC offset amounts that would apply to pass-through payment for those implantable biologicals, effective for new pass-through status determinations beginning in CY 2010 (74 FR 60463).

For CY 2011, we continued our policy that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only.

b. Proposed CY 2012 Policy

We are proposing to continue our policy, for CY 2012, that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only. The rationale for this policy is provided in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477). We also are proposing to continue our established policies for calculating and setting the device APC offset amounts for each device category eligible for pass-through payment. In addition, we are proposing to continue to review each new device category on a case-by-case basis to determine whether device costs associated with the new category are already packaged into the existing APC structure. If device costs packaged into the existing APC structure are associated with the new category, we would deduct the device APC offset amount from the pass-through payment for the device category. As stated earlier, these device APC offset amounts also would be used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices (§ 419.66(d)).

For CY 2012, we also are proposing to continue our policy established in CY 2010 to include implantable biologicals in our calculation of the device APC offset amounts. In addition, we are proposing to continue to calculate and set any device APC offset amount for a new device pass-through category that includes a newly eligible implantable biological beginning in CY 2012 using the same methodology we have historically used to calculate and set device APC offset amounts for device categories eligible for pass-through payment, and to include the costs of implantable biologicals in the calculation of the device APC offset amounts, as we first finalized and implemented for CY 2010.

In addition, we are proposing to update, on the CMS Web site at *http://www.cms.gov/HospitalOutpatientPPS,* the list of all procedural APCs with the final CY 2012 portions of the APC payment amounts that we determine are associated with the cost of devices so that this information is available for use by the public in developing potential CY 2012 device pass-through payment applications and by CMS in reviewing those applications.

In summary, for CY 2012, consistent with the policy established for CY 2010, we are proposing to continue the following policies related to pass-through payment for devices: (1) treating implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status on or after January 1, 2010, as devices for purposes of the OPPS pass-through evaluation process and payment methodology; (2) including implantable biologicals in calculating the device APC offset amounts; (3) using the device APC offset amounts to evaluate whether the cost of a device (defined to include implantable biologicals) in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices; and (4) reducing device pass-through payments based on device costs already included in the associated procedural APCs, when we determine that device costs associated with the new category are already packaged into the existing APC structure.

B. Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

1. Background

In recent years, there have been several field actions on and recalls of medical devices as a result of implantable device failures. In many of these cases, the manufacturers have offered devices without cost to the hospital or with credit for the device being replaced if the patient required a more expensive device. In order to ensure that payment rates for procedures involving devices reflect only the full costs of those devices, our standard ratesetting methodology for device-dependent APCs uses only claims that contain the correct device code for the procedure, do not contain token charges, do not contain the ''FB'' modifier signifying that the device was furnished without cost or with a full credit, and do not contain the ''FC'' modifier signifying that the device was furnished with partial credit. As discussed in section II.A.2.d.(1) of this proposed rule, we are proposing to continue to use our standard ratesetting methodology for device-dependent APCs for CY 2012.

To ensure equitable payment when the hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals are instructed to report no cost/full credit cases using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without

cost or with full credit, the hospital is instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, the hospital is instructed to report as the device charge the difference between its usual charge for the device being implanted and its usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals are instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device.

We reduce the OPPS payment for the implantation procedure by 100 percent of the device offset for no cost/full credit cases when both a specified device code is present on the claim and the procedure code maps to a specified APC. Payment for the implantation procedure is reduced by 50 percent of the device offset for partial credit cases when both a specified device code is present on the claim and the procedure code maps to a specified APC. Beneficiary copayment is based on the reduced payment amount when either the ''FB'' or the ''FC'' modifier is billed and the procedure and device codes appear on the lists of procedures and devices to which this policy applies. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' payment adjustment policies (72 FR 66743 through 66749).

2. Proposed APCs and Devices Subject to the Adjustment Policy

For CY 2012, we are proposing to continue the existing policy of reducing OPPS payment for specified APCs by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. Because the APC payments for the related services are specifically constructed to ensure that the full cost of the device is included in the payment, we continue to believe it is appropriate to reduce the APC payment in cases in which the hospital receives a device without cost, with full credit, or with partial credit, in order to provide equitable payment in these cases. (We refer readers to section II.A.2.d.(1) of this proposed rule for a description of our standard ratesetting methodology for device-dependent APCs.) Moreover, the payment for these devices comprises a large part of the APC payment on which the beneficiary copayment is based, and we continue to believe it is equitable that the beneficiary cost sharing reflects the reduced costs in these cases.

For CY 2012, we also are proposing to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which this policy applies (71 FR 68072 through 68077). Specifically: (1) all procedures assigned to the selected APCs must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and (3) the device offset amount must be significant, which, for purposes of this policy, is defined as exceeding 40 percent of the APC cost. We also are proposing to continue to restrict the devices to which the APC payment adjustment would apply to a specific set of costly devices to ensure that the adjustment would not be triggered by the implantation of an inexpensive device whose cost would not constitute a significant proportion of the total payment rate for an APC. As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71925), we continue to believe these criteria are appropriate because free devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost.

We examined the offset amounts calculated from the CY 2012 proposed rule data and the clinical characteristics of APCs to determine whether the APCs to which the no cost/full credit and partial credit device adjustment policy applied in CY 2011 continue to meet the criteria for CY 2012, and to determine whether other APCs to which the policy did not apply in CY 2011 would meet the criteria for CY 2012. Based on the CY 2010 claims data available for this proposed rule, we are not proposing any changes to the APCs and devices to which this policy applies. However, as discussed in section II.A.2.e.(6) of this proposed rule, we are proposing to delete APC 0418 (Insertion of Left Ventricular Pacing Electrode) for CY 2012 and, therefore, are proposing to remove this APC from the list of APCs to which the no cost/full credit and partial credit device adjustment policy would apply in CY 2012.

Table 24 below lists the proposed APCs to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2012 and displays the proposed payment adjustment percentages for both no cost/full credit and partial credit circumstances. We are proposing that the no cost/full credit adjustment for each APC to which this policy would continue to apply would be the device offset percentage for the APC (the estimated percentage of the APC cost that is attributable to the device costs that are packaged into the APC). We also are proposing that the partial credit device adjustment for each APC would continue to be 50 percent of the no cost/full credit adjustment for the APC.

Table 25 below lists the proposed devices to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2012. In the CY 2012 OPPS/ASC final rule with comment period, we will update the lists of APCs and devices to which the no cost/full credit and partial credit device adjustment policy would apply for CY 2012, consistent with the three selection criteria discussed earlier in this section, based on the final CY 2010 claims data available for the final rule with comment period.

We are proposing, for CY 2012, that OPPS payments for implantation procedures to which the ''FB'' modifier is appended be reduced by 100 percent of the device offset for no cost/full credit cases when both a device code listed in Table 25 below, is present on the claim and the procedure code maps to an APC listed in Table 24 below. We are also proposing that OPPS payments for implantation procedures to which the ''FC'' modifier is appended are reduced by 50 percent of the device offset when both a device code listed in Table 25 is present on the claim and the procedure code maps to an APC listed in Table 24. Beneficiary copayment is based on the reduced amount when either the ''FB'' modifier or the ''FC'' modifier is billed and the procedure and device codes appear on the lists of procedures and devices to which this policy applies.

TABLE 24—PROPOSED APCS TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY IN CY 2012

Proposed CY 2012 APC	Proposed CY 2012 APC title	Proposed CY 2012 device offset percentage for no cost/full credit case	Proposed CY 2012 device offset percentage for partial credit case
0039	Level I Implantation of Neurostimulator Generator	85%	43%
0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	54%	27%
0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	64%	32%
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	71%	35%
0090	Insertion/Replacement of Pacemaker Pulse Generator	73%	37%
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes	43%	21%
0107	Insertion of Cardioverter-Defibrillator	88%	44%
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	87%	43%
0227	Implantation of Drug Infusion Device	81%	40%
0259	Level VII ENT Procedures	83%	41%
0315	Level II Implantation of Neurostimulator Generator	88%	44%
0318	Implantation of Cranial Neurostimulator Pulse Generator and Electrode	86%	43%
0385	Level I Prosthetic Urological Procedures	61%	30%
0386	Level II Prosthetic Urological Procedures	70%	35%
0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
0648	Level IV Breast Surgery	44%	22%
0654	Insertion/Replacement of a permanent dual chamber pacemaker	74%	37%
0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	73%	37%
0680	Insertion of Patient Activated Event Recorders	72%	36%

TABLE 25—PROPOSED DEVICES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY IN CY 2012

CY 2012 Device HCPCS code	CY 2012 Short descriptor
C1721	AICD, dual chamber.
C1722	AICD, single chamber.
C1728	Cath, brachytx seed adm.
C1764	Event recorder, cardiac.
C1767	Generator, neurostim, imp.
C1771	Rep dev, urinary, w/sling.
C1772	Infusion pump, programmable.
C1776	Joint device (implantable).
C1777	Lead, AICD, endo single coil.
C1778	Lead, neurostimulator.
C1779	Lead, pmkr, transvenous VDD.
C1785	Pmkr, dual, rate-resp.
C1786	Pmkr, single, rate-resp.
C1789	Prosthesis, breast, imp.
C1813	Prosthesis, penile, inflatab.
C1815	Pros, urinary sph, imp.
C1820	Generator, neuro rechg bat sys.
C1881	Dialysis access system.
C1882	AICD, other than sing/dual.
C1891	Infusion pump, non-prog, perm.
C1895	Lead, AICD, endo dual coil.
C1896	Lead, AICD, non sing/dual.
C1897	Lead, neurostim, test kit.
C1898	Lead, pmkr, other than trans.
C1899	Lead, pmkr/AICD combination.
C1900	Lead coronary venous.
C2619	Pmkr, dual, non rate-resp.
C2620	Pmkr, single, non rate-resp.
C2621	Pmkr, other than sing/dual.
C2622	Prosthesis, penile, non-inf.
C2626	Infusion pump, non-prog, temp.
C2631	Rep dev, urinary, w/o sling.
L8600	Implant breast silicone/eq.
L8614	Cochlear device/system.
L8680	Implt neurostim elctr each.
L8685	Implt nrostm pls gen sng rec.
L8686	Implt nrostm pls gen sng non.
L8687	Implt nrostm pls gen dua rec.
L8688	Implt nrostm pls gen dua non
L8690	Aud osseo dev, int/ext comp.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals (also referred to as biologics). As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106–113), this provision requires the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107–186); current drugs and biologicals and brachytherapy sources used for the treatment of cancer; and current radiopharmaceutical drugs and biologicals. For those drugs and biologicals referred to as ''current,'' the transitional pass-through payment began on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' Under the statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the product's first payment as a hospital outpatient service under Medicare Part B. Proposed CY 2012 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this proposed rule, which are referenced in section XVII. of this proposed rule and available via the Internet.

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee

schedule that the Secretary determines is associated with the drug or biological. If the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, the pass-through payment amount is determined by the Secretary to be equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary. As we noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68633), the Part B drug CAP program was postponed beginning in CY 2009 (Medicare Learning Network (MLN) Matters Special Edition 0833, available via the Web site: *http://www.cms.gov*). As of publication of this proposed rule, the postponement of the Part B drug CAP program remains in effect, and there is no effective CAP program rate for pass-through drugs and biologicals as of January 1, 2009. Consistent with what we indicated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71928), if the program is reinstituted during CY 2012 and Part B drug CAP rates become available, we would again use the Part B drug CAP rate for pass-through drugs and biologicals if they are a part of the Part B drug CAP program. Otherwise, we would continue to use the rate that would be paid in the physician's office setting for all drugs and biologicals with pass-through status.

This methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64, which specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological. Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this proposed rule, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS Web site at: *http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice*.

For CYs 2005, 2006, and 2007, we estimated the OPPS pass-through payment amount for drugs and biologicals to be zero based on our interpretation that the ''otherwise applicable Medicare OPD fee schedule'' amount was equivalent to the amount to be paid for pass-through drugs and biologicals under section 1842(o) of the Act (or section 1847B of the Act, if the drug or biological is covered under a competitive acquisition contract). We concluded for those years that the resulting difference between these two rates would be zero. For CYs 2008 and 2009, we estimated the OPPS pass-through payment amount for drugs and biologicals to be $6.6 million and $23.3 million, respectively. For CY 2010, we estimated the OPPS pass-through payment estimate for drugs and biologicals to be $35.5 million. For CY 2011, we estimated the OPPS pass-through payment for drugs and biologicals to be $15.5 million. Our proposed OPPS pass-through payment estimate for drugs and biologicals in CY 2012 is $19 million, which is discussed in section VI.B. of this proposed rule.

The pass-through application and review process for drugs and biologicals is explained on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp*.

2. Proposed Drugs and Biologicals With Expiring Pass-Through Status in CY 2012

We are proposing that the pass-through status of 19 drugs and biologicals would expire on December 31, 2011, as listed in Table 26 below. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2011. These drugs and biologicals were approved for pass-through status on or before January 1, 2010. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through status, specifically diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals, our standard methodology for providing payment for drugs and biologicals with expiring pass-through status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed at $80 for CY 2012), as discussed further in section V.B.2. of this proposed rule. If the drug's or biological's estimated per day cost is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we would provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+4 percent for CY 2012, as discussed further in section V.B.3. of this proposed rule). Section V.B.2.d. of this proposed rule discusses the packaging of all nonpass-through contrast agents, diagnostic radiopharmaceuticals, and implantable biologicals.

TABLE 26—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2011

Proposed CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2012 SI	Proposed CY 2012 APC
A9582	Iodine I-123 iobenguane, diagnostic, per study dose, up to 15 millicuries	N	N/A
A9583	Injection, gadofosveset trisodium, 1 ml	N	N/A
C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2 ml	K	9250
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters.	K	9360
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length	N	N/A
C9362	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc.	N	N/A
C9363	Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter	K	9363
C9364	Porcine implant, Permacol, per square centimeter	N	N/A
J0598	Injection, C–1 esterase inhibitor (human), Cinryze, 10 units	K	9251
J0641	Injection, levoleucovorin calcium, 0.5 mg	K	1236

TABLE 26—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2011—Continued

Proposed CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2012 SI	Proposed CY 2012 APC
J0718	Injection, certolizumab pegol, 1 mg	K	9249
J1680	Injection, human fibrinogen concentrate, 100 mg	K	1290
J2426	Injection, paliperidone palmitate, 1 mg	K	9255
J2562	Injection, plerixafor, 1 mg	K	9252
J7312	Injection, dexamethasone intravitreal implant, 0.1 mg	K	9256
J8705	Topotecan, oral, 0.25 mg	K	1238
J9155	Injection, degarelix, 1 mg	K	1296
J9328	Injection, temozolomide, 1 mg	K	9253
Q0138	Injection, Ferumoxytol, for treatment of iron deficiency anemia, 1 mg	K	1297

3. Proposed Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Status in CY 2012

We are proposing to continue pass-through status in CY 2012 for 33 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2011. These drugs and biologicals, which were approved for pass-through status between April 1, 2010 and July 1, 2011, are listed in Table 27 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through April 1, 2011, are assigned status indicator ''G'' in Addenda A and B, which are referenced in section XVIII of this proposed rule and available via the Internet.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a CAP under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary) and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at the physician's office payment rate of ASP+6 percent. We believe it is consistent with the statute to propose to continue to provide payment for drugs and biologicals with pass-through status at a rate of ASP+6 percent in CY 2012, the amount that drugs and biologicals receive under section 1842(o) of the Act. Thus, for CY 2012, we are proposing to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2012. Therefore, the difference between ASP+4 percent that we are proposing to pay for nonpass-through separately payable drugs under the CY 2012 OPPS and ASP+6 percent would be the CY 2012 pass-through payment amount for these drugs and biologicals. In the case of pass-through contrast agents and diagnostic radiopharmaceuticals, their pass-through payment amount would be equal to ASP+6 percent because, if not on pass-through status, payment for these products would be packaged into the associated procedures. We note that we are proposing to expire pass-through status for the remaining three implantable biologicals approved on or before January 1, 2010, under pass-through status as a drug or biological. Therefore, as described in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60476) and as proposed in this proposed rule, implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) would be evaluated under the device pass-through process and paid according to the device payment methodology. Payment for nonpass-through implantable biologicals would continue to be packaged into the payment for the associated procedure as described in section V.B.2.d. of this proposed rule.

In addition, we are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2012 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 42722 and 42723). If the Part B drug CAP is reinstated during CY 2012, and a drug or biological that has been granted pass-through status for CY 2012 becomes covered under the Part B drug CAP, we are proposing to provide pass-through payment at the Part B drug CAP rate and to make the adjustments to the payment rates for these drugs and biologicals on a quarterly basis, as appropriate. As is our standard methodology, we annually review new permanent HCPCS codes and delete temporary HCPCS C-codes if an alternate permanent HCPCS code is available for purposes of OPPS billing and payment.

In CY 2012, as is consistent with our CY 2011 policy for diagnostic and therapeutic radiopharmaceuticals, we are proposing to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through status based on the ASP methodology. As stated above, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through status during CY 2012, we are proposing to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we are proposing to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information is also not available, we are proposing to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

As discussed in more detail in section V.B.2.d. of this proposed rule, over the last 4 years, we implemented a policy whereby payment for all nonpass-through diagnostic

radiopharmaceuticals, contrast agents, and implantable biologicals is packaged into payment for the associated procedure. We are proposing to continue the packaging of these items, regardless of their per day cost, in CY 2012. As stated earlier, pass-through payment is the difference between the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a CAP under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary) and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Because payment for a drug that is either a diagnostic radiopharmaceutical or a contrast agent (identified as a ''policy-packaged'' drug, first described in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68639)) would otherwise be packaged if the product did not have pass-through status, we believe the otherwise applicable OPPS payment amount would be equal to the ''policy-packaged'' drug APC offset amount for the associated clinical APC in which the drug or biological is utilized. The calculation of the ''policy-packaged'' drug APC offset amounts are described in more detail in section IV.A.2. of this proposed rule. It follows that the copayment for the nonpass-through payment portion (the otherwise applicable fee schedule amount that we would also offset from payment for the drug or biological if a payment offset applies) of the total OPPS payment for those drugs and biologicals would, therefore, be accounted for in the copayment for the associated clinical APC in which the drug or biological is used.

According to section 1833(t)(8)(E) of the Act, the amount of copayment associated with pass-through items is equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied. Therefore, as we did in CY 2011, we are proposing to continue to set the associated copayment amount for pass-through diagnostic radiopharmaceuticals and contrast agents that would otherwise be packaged if the item did not have pass-through status to zero for CY 2012. The separate OPPS payment to a hospital for the pass-through diagnostic radiopharmaceutical or contrast agent, after taking into account any applicable payment offset for the item due to the device or ''policy-packaged'' APC offset policy, is the item's pass-through payment, which is not subject to a copayment according to the statute. Therefore, we are proposing to not publish a copayment amount for these items in Addenda A and B to the proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

The 33 drugs and biologicals that we are proposing to continue on pass-through status for CY 2012 or that have been granted pass-through status as of July 2011 are displayed in Table 27. We note that, for CY 2010 and the first two quarters of CY 2011, HCPCS code J1572 (Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg) was assigned a status indicator of ''K,'' meaning that this product was paid separately as a nonpass-through separate payable drug. Beginning on July 1, 2011, HCPCS code J1572 is assigned a status indicator of ''G'' and will be given pass-through status for at least 2, but not more than 3, years. The payment rate reflecting a pass-through payment amount of ASP+6 percent is not included in Addenda A and B of this proposed rule because these Addenda solely reflect codes and prices effective as of the second quarter of CY 2011, or April 2011.

TABLE 27—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2012

Proposed CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2012 SI	Proposed CY 2012 APC
C9270	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg	G	9270
C9272	Injection, denosumab, 1 mg	G	9272
C9274	Crotalidae polyvalent immune fab (ovine), 1 vial	G	9274
C9275	Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose	G	9275
C9276	Injection, cabazitaxel, 1 mg	G	9276
C9277	Injection, alglucosidase alfa (Lumizyme), 1 mg	G	9277
C9279	Injection, ibuprofen, 100 mg	G	9279
C9280	Injection, eribulin mesylate, 1 mg	G	9280
C9281	Injection, pegloticase, 1 mg	G	9281
C9282	Injection, ceftaroline fosamil, 10 mg	G	9282
C9283**	Injection, acetaminophen, 10 mg	G	9283
C9284**	Injection, ipilimumab, 1 mg	G	9284
C9285**	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285
C9365**	Oasis Ultra Tri-Layer Matrix, per square centimeter	G	9365
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	G	9367
C9406**	Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406
J0597	Injection, C–1 Esterase inhibitor (human), Berinert, 10 units	G	9269
J0775	Injection, collagenase clostridium histolyticum, 0.01 mg	G	1340
J1290	Injection, ecallantide, 1 mg	G	9263
J1572***	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg.	G	0947
J3095	Injection, telavancin, 10 mg	G	9258
J3262	Injection, tocilizumab, 1 mg	G	9624
J3357	Injection, ustekinumab, 1 mg	G	9261
J3385	Injection, velaglucerase alfa, 100 units	G	9271
J7335	Capsaicin 8% patch, per 10 square centimeters	G	9268
J8562	Fludarabine phosphate, oral, 10 mg	G	1339
J9302	Injection, ofatumumab, 10 mg	G	9260
J9307	Injection, pralatrexate, 1 mg	G	9259
J9315	Injection, romidepsin, 1 mg	G	9625

TABLE 27—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2012—Continued

Proposed CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2012 SI	Proposed CY 2012 APC
Q2040	Injection, incobotulinumtoxin A, 1 unit	G	9278
Q2041 ** ...	Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco	G	1352
Q2043 *	Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP–GM–CSF, including leukapheresis and all other preparatory procedures, per infusion.	G	9273
Q2044 ** ...	Injection, belimumab, 10 mg	G	1353

* HCPCS code C9273 was deleted June 30, 2011, and replaced with HCPCS code Q2043 effective July 1, 2011.
** These HCPCS codes are effective July 1, 2011, and are not included in the Addenda to this proposed rule.
*** HCPCS code J1572 has a status indicator of ''G,'' effective July 1, 2011.

4. Proposed Provisions for Reducing Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals and Contrast Agents To Offset Costs Packaged into APC Groups

a. Background

Prior to CY 2008, diagnostic radiopharmaceuticals and contrast agents were paid separately under the OPPS if their mean per day costs were greater than the applicable year's drug packaging threshold. In CY 2008 (72 FR 66768), we began a policy of packaging payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents as ancillary and supportive items and services into their associated nuclear medicine procedures. Therefore, beginning in CY 2008, nonpass-through diagnostic radiopharmaceuticals and contrast agents were not subject to the annual OPPS drug packaging threshold to determine their packaged or separately payable payment status, and instead all nonpass-through diagnostic radiopharmaceuticals and contrast agents were packaged as a matter of policy. For CY 2012, we are proposing to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, as discussed in section V.B.2.d. of this proposed rule.

b. Proposed Payment Offset Policy for Diagnostic Radiopharmaceuticals

As previously noted, radiopharmaceuticals are considered to be drugs for OPPS pass-through payment purposes. As described above, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act (or the Part B drug CAP rate) and the otherwise applicable OPD fee schedule amount. There is currently one radiopharmaceutical with pass-through status under the OPPS, HCPCS code C9406 (Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries). HCPCS code C9406 was granted pass-through status beginning July 1, 2011, and is proposed to continue receiving pass-through status in CY 2012. We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for this product. As described earlier in section V.A.3. of this proposed rule, we are proposing that new pass-through diagnostic radiopharmaceuticals would be paid at ASP+6 percent, while those without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor radiopharmaceuticals in order to ensure no duplicate radiopharmaceutical payment is made. In CY 2009, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals when considering a new diagnostic radiopharmaceutical for pass-through payment (73 FR 68638 through 68641). Specifically, we utilize the ''policy-packaged'' drug offset fraction for APCs containing nuclear medicine procedures, calculated as 1 minus (the cost from single procedure claims in the APC after removing the cost for ''policy-packaged'' drugs divided by the cost from single procedure claims in the APC). In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60480 through 60484), we finalized a policy to redefine ''policy-packaged'' drugs as only nonpass-through diagnostic radiopharmaceuticals and contrast agents, as a result of the policy discussed in sections V.A.4. and V.B.2.d. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477 and 60495 through 60499, respectively) that treats nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) with newly approved pass-through status beginning in CY 2010 or later as devices, rather than drugs. To determine the actual APC offset amount for pass-through diagnostic radiopharmaceuticals that takes into consideration the otherwise applicable OPPS payment amount, we multiply the ''policy-packaged'' drug offset fraction by the APC payment amount for the nuclear medicine procedure with which the pass-through diagnostic radiopharmaceutical is used and, accordingly, reduce the separate OPPS payment for the pass-through diagnostic radiopharmaceutical by this amount.

Beginning in CY 2011 and as discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71934 through 71936), we finalized a policy to require hospitals to append modifier ''FB'' to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit. These instructions are contained within the I/OCE CMS specifications on the CMS Web site at *http://www.cms.gov/OutpatientCodeEdit/02_OCEQtrReleaseSpecs.asp#TopOfPage.* For CY 2012 and future years, we are proposing to continue to require hospitals to append modifier ''FB'' to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit. In addition, we are proposing to continue to require that when a hospital bills with an ''FB'' modifier with the nuclear medicine scan, the payment amount for procedures in the APCs listed in Table

28 of this proposed rule would be reduced by the full ''policy-packaged'' offset amount appropriate for diagnostic radiopharmaceuticals. Finally, we also are proposing to continue to require hospitals to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is furnished without cost or with full credit.

For CY 2011, we finalized a policy to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described above. For CY 2012, we are proposing to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals. Table 28 displays the proposed APCs to which nuclear medicine procedures would be assigned in CY 2012 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 28—PROPOSED APCS TO WHICH NUCLEAR MEDICINE PROCEDURES WOULD BE ASSIGNED FOR CY 2012

Proposed CY 2012 APC	CY 2012 APC title
0307	Myocardial Positron Emission Tomography (PET) imaging.
0308	Non-Myocardial Positron Emission Tomography (PET) imaging.
0377	Level II Cardiac Imaging.
0378	Level II Pulmonary Imaging.
0389	Level I Non-imaging Nuclear Medicine.
0390	Level I Endocrine Imaging.
0391	Level II Endocrine Imaging.
0392	Level II Non-imaging Nuclear Medicine.
0393	Hematologic Processing & Studies.
0394	Hepatobiliary Imaging.
0395	GI Tract Imaging.
0396	Bone Imaging.
0397	Vascular Imaging.
0398	Level I Cardiac Imaging.
0400	Hematopoietic Imaging.
0401	Level I Pulmonary Imaging.
0402	Level II Nervous System Imaging.
0403	Level I Nervous System Imaging.
0404	Renal and Genitourinary Studies.
0406	Level I Tumor/Infection Imaging.
0408	Level II Tumor/Infection Imaging.
0414	Level II Tumor/Infection Imaging.

c. Proposed Payment Offset Policy for Contrast Agents

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act (or the Part B drug CAP rate) and the otherwise applicable OPD fee schedule amount. There is currently one contrast agent with pass-through status under the OPPS: HCPCS code C9275 (Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose). HCPCS code C9275 was granted pass-through status beginning January 1, 2011, and is proposed to continue with pass-through status in CY 2012. As described earlier in section V.A.3. of this proposed rule, new pass-through contrast agents would be paid at ASP+6 percent, while those without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

We believe that a payment offset is necessary in order to provide an appropriate transitional pass-through payment for contrast agents, because all of these items are packaged when they do not have pass-through status. In accordance with our standard offset methodology, we are proposing for CY 2012 to deduct from the payment for pass-through contrast agents an amount that reflects the portion of the APC payment associated with predecessor contrast agents, in order to ensure no duplicate contrast agent payment is made.

In CY 2010, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor contrast agents when considering new contrast agents for pass-through payment (74 FR 60482 through 60484). For CY 2012, as we did in CY 2011, we are proposing to continue to apply this same policy to contrast agents. Specifically, we are proposing to utilize the ''policy-packaged'' drug offset fraction for clinical APCs calculated as 1 minus (the cost from single procedure claims in the APC after removing the cost for ''policy-packaged'' drugs divided by the cost from single procedure claims in the APC). In CY 2010, we finalized a policy to redefine ''policy-packaged'' drugs as only nonpass-through diagnostic radiopharmaceuticals and contrast agents (74 FR 60495 through 60499). To determine the actual APC offset amount for pass-through contrast agents that takes into consideration the otherwise applicable OPPS payment amount, we are proposing to multiply the ''policy-packaged'' drug offset fraction by the APC payment amount for the procedure with which the pass-through contrast agent is used and, accordingly, reduce the separate OPPS payment for the pass-through contrast agent by this amount. We are proposing to continue to apply this methodology for CY 2012 to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 29, a specific offset based on the procedural APC would be applied to payments for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

We are proposing to continue to post annually on the CMS Web site at *http://www.cms.gov/HospitalOutpatientPPS* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost

significance for candidate pass-through device categories and drugs and biologicals, including contrast agents, and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide, for every OPPS clinical APC, the amounts and percentages of APC payment associated with packaged implantable devices, ''policy-packaged'' drugs, and ''threshold-packaged'' drugs and biologicals.

Proposed procedural APCs for which we expect a contrast offset could be applicable in the case of a pass-through contrast agent have been identified as any procedural APC with a ''policy-packaged'' drug amount greater than $20 that is not a nuclear medicine APC identified in Table 28 above and these APCs are displayed in Table 29 below. The methodology used to determine a proposed threshold cost for application of a contrast agent offset policy is described in detail in the CY 2010 OPPS/ASC final rule with comment period (70 FR 60483 through 60484). For CY 2012, we are proposing to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 29, a specific offset based on the procedural APC would be applied to payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

TABLE 29—PROPOSED APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2012

Proposed CY 2012 APC	Proposed CY 2012 APC title
0080	Diagnostic Cardiac Catheterization.
0082	Coronary or Non-Coronary Atherectomy.
0083	Coronary or Non-Coronary Angioplasty and Percutaneous Valvulopasty.
0093	Vascular Reconstruction/Fistula Repair without Device.
0104	Transcathether Placement of Intracoronary Stents.
0128	Echocardiogram with Contrast.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0229	Transcathether Placement of Intravascular Shunts.
0278	Diagnostic Urography.
0279	Level II Angiography and Venography.
0280	Level III Angiography and Venography.
0283	Computed Tomography with Contrast.
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast.
0333	Computed Tomography without Contrast followed by Contrast.
0334	Combined Abdomen and Pelvis CT with Contrast
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast.
0375	Ancillary Outpatient Services When Patient Expires.
0383	Cardiac Computed Tomographic Imaging.
0388	Discography.
0418	Insertion of Left Ventricular Pacing Elect.
0442	Dosimetric Drug Administration.
0653	Vascular Reconstruction/Fistula Repair with Device.
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0662	CT Angiography.
0668	Level I Angiography and Venography.
8006	CT and CTA with Contrast Composite.
8008	MRI and MRA with Contrast Composite.

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

1. Background

Under the CY 2011 OPPS, we currently pay for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status in one of two ways: as a packaged payment included in the payment for the associated service; or as a separate payment (individual APCs). We explained in the April 7, 2000 OPPS final rule with comment period (65 FR 18450) that we generally package the cost of drugs and radiopharmaceuticals into the APC payment rate for the procedure or treatment with which the products are usually furnished. Hospitals do not receive separate payment for packaged items and supplies, and hospitals may not bill beneficiaries separately for any packaged items and supplies whose costs are recognized and paid within the national OPPS payment rate for the associated procedure or service. (Transmittal A–01–133, issued on November 20, 2001, explains in greater detail the rules regarding separate payment for packaged services.)

Packaging costs into a single aggregate payment for a service, procedure, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility.

Section 1833(t)(16)(B) of the Act set the threshold for establishing separate APCs for drugs and biologicals at $50 per administration for CYs 2005 and 2006. Therefore, for CYs 2005 and 2006, we paid separately for drugs, biologicals, and radiopharmaceuticals whose per day cost exceeded $50 and packaged the costs of drugs, biologicals, and radiopharmaceuticals whose per day cost was equal to or less than $50 into the procedures with which they were billed. For CY 2007, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $55. For CYs 2008 and 2009, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $60. For CY 2010, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $65. For CY 2011, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $70. The methodology used to establish the $55

threshold for CY 2007, the $60 threshold for CYs 2008 and 2009, the $65 threshold for CY 2010, the $70 threshold for CY 2011, and our proposed approach for CY 2012 are discussed in more detail in section V.B.2.b. of this proposed rule.

2. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Background

As indicated in section V.B.1. of this proposed rule, in accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $60 for CYs 2008 and 2009. For CY 2010, we set the packaging threshold at $65; and for CY 2011, we set the packaging threshold at $70.

Following the CY 2007 methodology, for CY 2012, we used updated four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2012 and again rounded the resulting dollar amount ($77.63) to the nearest $5 increment, which yielded a figure of $80. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from CMS' Office of the Actuary (OACT). We note that we are not proposing a change to the PPI that is used to calculate the threshold for CY 2012; however, this change in terminology reflects a change to the BLS naming convention for this series. We refer to this series generally as the PPI for Prescription Drugs below. We chose this PPI as it reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. In addition, we chose this price series because it is publicly available and regularly published, improving public access and transparency. Forecasts of the PPI for Prescription Drugs are developed by IHS Global Insight, Inc., a nationally recognized economic and financial forecasting firm. As actual inflation for past quarters replaced forecasted amounts, the PPI estimates for prior quarters have been revised (compared with those used in the CY 2007 OPPS/ASC final rule with comment period) and have been incorporated into our calculation. Based on the calculations described above, we are proposing a packaging threshold for CY 2012 of $80. (For a more detailed discussion of the OPPS drug packaging threshold and the use of the PPI for Prescription Drugs, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086).)

b. Proposed Cost Threshold for Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Nonimplantable Biologicals, and Therapeutic Radiopharmaceuticals (''Threshold-Packaged Drugs'')

To determine their proposed CY 2012 packaging status for this proposed rule, we calculated on a HCPCS code-specific basis (with the exception of those drugs and biologicals with multiple HCPCS codes that include different dosages as described in section V.B.2.c. of this proposed rule and excluding diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals that we are proposing to continue to package in CY 2012, as discussed in section V.B.2.d. of this proposed rule) the per day cost of all drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2010 and were paid (via packaged or separate payment) under the OPPS, using CY 2010 claims data processed before January 1, 2011. In order to calculate the per day costs for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2012, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 70 FR 68638).

To calculate the CY 2012 proposed rule per day costs, we used an estimated payment rate for each drug and nonimplantable biological HCPCS code of ASP+4 percent (which is the payment rate we are proposing for separately payable drugs and nonimplantable biologicals for CY 2012, as discussed in more detail in section V.B.3.b. of this proposed rule). We used the manufacturer submitted ASP data from the fourth quarter of CY 2010 (data that were used for payment purposes in the physician's office setting, effective April 1, 2011) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2012, we are proposing to use payment rates based on the ASP data from the fourth quarter of CY 2010 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet) because these are the most recent data available for use at the time of development of this proposed rule. These data were also the basis for drug payments in the physician's office setting, effective April 1, 2011. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2010 hospital claims data to determine their per day cost. We are proposing to package items with a per day cost less than or equal to $80 and identified items with a per day cost greater than $80 as separately payable. Consistent with our past practice, we crosswalked historical OPPS claims data from the CY 2010 HCPCS codes that were reported to the CY 2011 HCPCS codes that we display in Addendum B of this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet) for payment in CY 2012.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals for the final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period will be subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and nonimplantable biologicals in the CY 2012 OPPS/ASC final rule with comment period, we are proposing to use ASP data from the first quarter of CY 2011, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2011, along with

updated hospital claims data from CY 2010. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for the CY 2012 OPPS/ASC final rule with comment period. Payment rates for HCPCS codes for separately payable drugs and nonimplantable biologicals included in Addenda A and B to the final rule with comment period will be based on ASP data from the second quarter of CY 2011, which will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2011. These rates would then be updated in the January 2012 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2012. For items that do not currently have an ASP-based payment rate, we are proposing to recalculate their mean unit cost from all of the CY 2010 claims data and updated cost report information available for the CY 2012 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in this CY 2012 OPPS/ASC proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the final rule with comment period. Under such circumstances, we are proposing to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose median cost fluctuates relative to the proposed CY 2012 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2011. Specifically, for CY 2012, we are proposing to apply the following policies to these HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals whose relationship to the proposed $80 drug packaging threshold changes:

- HCPCS codes for drugs and nonimplantable biologicals that were paid separately in CY 2011 and that are proposed for separate payment in CY 2012, and that then have per day costs equal to or less than $80, based on the ASPs and hospital claims data used for this CY 2012 proposed rule, would continue to receive separate payment in CY 2012.
- HCPCS codes for drugs and nonimplantable biologicals that were packaged in CY 2011 and that are proposed for separate payment in CY 2012, and that then have per day costs equal to or less than $80, based on the ASPs and hospital claims data used for this CY 2012 proposed rule, would remain packaged in CY 2012.
- HCPCS codes for drugs and nonimplantable biologicals for which we are proposing packaged payment in CY 2012 but then have per day costs greater than $80, based on the ASPs and hospital claims data used for this CY 2012 proposed rule, would receive separate payment in CY 2012.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60485 through 60489), we implemented a policy to treat oral and injectable forms of 5–HT3 antiemetics comparably to all other threshold packaged drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals under our standard packaging methodology of packaging drugs with a per day cost less than $65. We are proposing for CY 2012 to continue our policy of not exempting these 5–HT3 antiemetic products from our standard packaging methodology. For CY 2012, we are proposing to package payment for all of the 5–HT3 antiemetics except palonosetron hydrochloride, which for CY 2012 has a estimated per day cost, from the CY 2010 claims data, above the proposed CY 2012 drug packaging threshold. Our rationale for this policy is outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60487 through 60488).

c. Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66776), we began recognizing, for OPPS payment purposes, multiple HCPCS codes reporting different dosages for the same covered Part B drugs or biologicals in order to reduce hospitals' administrative burden by permitting them to report all HCPCS codes for drugs and biologicals. In general, prior to CY 2008, the OPPS recognized for payment only the HCPCS code that described the lowest dosage of a drug or biological. We extended this recognition to multiple HCPCS codes for several other drugs under the CY 2009 OPPS (73 FR 68665). During CYs 2008 and 2009, we applied a policy that assigned the status indicator of the previously recognized HCPCS code to the associated newly recognized code(s), reflecting the packaged or separately payable status of the new code(s). In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66775), we explained that once claims data were available for these previously unrecognized HCPCS codes, we would determine the packaging status and resulting status indicator for each HCPCS code according to the general, established HCPCS code-specific methodology for determining a code's packaging status for a given update year. However, we also stated that we planned to closely follow our claims data to ensure that our annual packaging determinations for the different HCPCS codes describing the same drug or biological did not create inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages. We analyzed CY 2008 claims data for the HCPCS codes describing different dosages of the same drug or biological that were newly recognized in CY 2008 and found that our claims data would result in several different packaging determinations for different codes describing the same drug or biological. Furthermore, we found that our claims data would include few units and days for a number of newly recognized HCPCS codes, resulting in our concern that these data reflected claims from only a small number of hospitals, even though the drug or biological itself may be reported by many other hospitals under the most common HCPCS code. Based on these findings from our first available claims data for the newly recognized HCPCS codes, we believed that adopting our standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes instead of others, particularly because we do not currently require hospitals to report all drug and biological HCPCS codes under the OPPS in consideration of our previous policy that generally recognized only the lowest dosage HCPCS code for a drug or biological for OPPS payment. For CY 2012, we continue to believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes for drugs instead of others. Making packaging determinations on a drug-specific basis eliminates these incentives and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we are proposing to continue our policy to make packaging determinations on a

drug-specific basis, rather than an HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2012.

For CY 2012, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2010 claims data and our pricing information at ASP+4 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. All HCPCS codes listed in Table 30 below had ASP pricing information available for this CY 2012 OPPS/ASC proposed rule. Therefore, we multiplied the weighted average ASP+4 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to $80 (whereupon all HCPCS codes for the same drug or biological would be packaged) or greater than $80 (whereupon all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply is displayed in Table 30 below.

TABLE 30.—PROPOSED HCPCS CODES TO WHICH THE CY 2012 DRUG—SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

Proposed CY 2012 HCPCS code	Proposed CY 2012 long descriptor	Proposed CY 2012 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1070	Injection, testosterone cypionate, up to 100 mg	N
J1080	Injection, testosterone cypionate, 1 cc, 200 mg	N
J1440	Injection, filgrastim (g-csf), 300 mcg	K
J1441	Injection, filgrastim (g-csf), 480 mcg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J2270	Injection, morphine sulfate, up to 10 mg	N
J2271	Injection, morphine sulfate, 100mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	K
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	K
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3120	Injection, testosterone enanthate, up to 100 mg	N
J3130	Injection, testosterone enanthate, up to 200 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7050	Infusion, normal saline solution , 250 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7030	Infusion, normal saline solution , 1000 cc	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	K
J8521	Capecitabine, oral, 500 mg	K
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N
Q0164	Prochlorperazine maleate, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour doseage regimen.	N
Q0165	Prochlorperazine maleate, 10 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour doseage regimen.	N
Q0167	Dronabinol, 2.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0168	Dronabinol, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0169	Promethazine hydrochloride, 12.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0170	Promethazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N

TABLE 30.—PROPOSED HCPCS CODES TO WHICH THE CY 2012 DRUG—SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY—Continued

Proposed CY 2012 HCPCS code	Proposed CY 2012 long descriptor	Proposed CY 2012 SI
Q0171	Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0172	Chlorpromazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotheapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0175	Perphenazine, 4 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0176	Perphenazine, 8 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0177	Hydroxyzine pamoate, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0178	Hydroxyzine pamoate, 50 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N

d. Proposed Packaging of Payment for Diagnostic Radiopharmaceuticals, Contrast Agents, and Implantable Biologicals (''Policy-Packaged'' Drugs and Devices)

Prior to CY 2008, the methodology of calculating a product's estimated per day cost and comparing it to the annual OPPS drug packaging threshold was used to determine the packaging status of drugs, biologicals, and radiopharmaceuticals under the OPPS (except for our CYs 2005 through 2009 exemption for 5-HT3 antiemetics). However, as established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66766 through 66768), we began packaging payment for all diagnostic radiopharmaceuticals and contrast agents into the payment for the associated procedure, regardless of their per day costs. In addition, in CY 2009 we adopted a policy that packaged the payment for nonpass-through implantable biologicals into payment for the associated surgical procedure on the claim (73 FR 68633 through 68636). We refer to diagnostic radiopharmaceuticals and contrast agents collectively as ''policy-packaged'' drugs and implantable biologicals as devices because, in CY 2010, we began to treat implantable biologicals as devices for all OPPS payment purposes.

According to our regulations at § 419.2(b), as a prospective payment system, the OPPS establishes a national payment rate that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis including, but not limited to, implantable prosthetics, implantable durable medical equipment, and medical and surgical supplies. Packaging costs into a single aggregate payment for a service, encounter, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility.

Prior to CY 2008, we noted that the proportion of drugs, biologicals, and radiopharmaceuticals that were separately paid under the OPPS had increased in recent years, a pattern that we also observed for procedural services under the OPPS. Our final CY 2008 policy that packaged payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, regardless of their per day costs, contributed significantly to expanding the size of the OPPS payment bundles and is consistent with the principles of a prospective payment system.

As discussed in more detail in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645 through 68649), we presented several reasons supporting our initial policy to package payment of diagnostic radiopharmaceuticals and contrast agents into their associated procedures on a claim. Specifically, we stated that we believed packaging was appropriate because: (1) the statutorily required OPPS drug packaging threshold has expired; (2) we believe that diagnostic radiopharmaceuticals and contrast agents function effectively as supplies that enable the provision of an independent service; and (3) section 1833(t)(14)(A)(iii) of the Act requires that payment for specified covered outpatient drugs (SCODs) be set prospectively based on a measure of average hospital acquisition cost. For these reasons, we believe it is appropriate to continue to treat diagnostic radiopharmaceuticals and contrast agents differently from other SCODs for CY 2012. Therefore, we are proposing to continue packaging payment for all contrast agents and diagnostic radiopharmaceuticals, collectively referred to as ''policy-packaged'' drugs, regardless of their per day costs, for CY 2012. We also are proposing to continue to package the payment for diagnostic radiopharmaceuticals into the payment for the associated nuclear medicine procedure and to package the payment for contrast agents into the payment of the associated echocardiography imaging procedure, regardless of whether the agent met the OPPS drug packaging threshold. We refer readers to the CY 2010 OPPS/ASC final rule with comment period for a detailed discussion of nuclear medicine and echocardiography services (74 FR 35269 through 35277).

In CY 2009, we adopted a final policy to package payment for all nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) like our longstanding policy that packaged payment for all implantable nonbiological devices without pass-

through status. We finalized a policy in CY 2010 to package payment for nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body, considering them to be devices. For CY 2012, we are proposing to continue to package payment for nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body, considering them to be devices. Three of the products with expiring pass-through status for CY 2012 are biologicals that, according to their FDA-approved indications, are only surgically implanted. These products are described by HCPCS codes C9361 (Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length), C9362 (Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc), and C9364 (Porcine implant, Permacol, per square centimeter). Like the two implantable biologicals with expiring pass-through status in CY 2011 that were discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71948 through 71950), we believe that the three biologicals specified above with expiring pass-through status for CY 2012 differ from other biologicals paid under the OPPS in that they specifically function as surgically implanted devices. As a result of our proposed packaged payment methodology for nonpass-through implantable biologicals, we are proposing to package payment for HCPCS codes C9361, C9362, and C9364 and assign them status indicator ''N'' for CY 2012. In addition, any new biologicals without pass-through status that are surgically inserted or implanted (through a surgical incision or a natural orifice) would be packaged in CY 2012. Moreover, for nonpass-through biologicals that may sometimes be used as implantable devices, we continue to instruct hospitals to not bill separately for the HCPCS codes for the products when used as implantable devices. This reporting ensures that the costs of these products that may be, but are not always, used as implanted biologicals are appropriately packaged into payment for the associated implantation procedures.

3. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' is a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of ''specified covered outpatient drugs,'' known as SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. Most physician Part B drugs are paid at ASP+6 percent pursuant to section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E) of the Act provides for an adjustment in OPPS payment rates for overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.

In the CY 2006 OPPS proposed rule (70 FR 42728 through 42731), we discussed the June 2005 report by MedPAC regarding pharmacy overhead costs in HOPDs and summarized the findings of that study:

- Handling costs for drugs, biologicals, and radiopharmaceuticals administered in the HOPD are not insignificant;
- Little information is available about the magnitude of pharmacy overhead costs;
- Hospitals set charges for drugs, biologicals, and radiopharmaceuticals at levels that reflect their respective handling costs; and
- Hospitals vary considerably in their likelihood of providing services that utilize drugs, biologicals, or radiopharmaceuticals with different handling costs.

As a result of these findings, MedPAC developed seven drug categories for pharmacy and nuclear medicine handling costs based on the estimated level of hospital resources used to prepare the products (70 FR 42729). Associated with these categories were two recommendations for accurate payment of pharmacy overhead under the OPPS.

1. CMS should establish separate, budget neutral payments to cover the costs hospitals incur for handling separately payable drugs, biologicals, and radiopharmaceuticals.

2. CMS should define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs; CMS should instruct hospitals to submit charges for these APCs and base payment rates for the handling fee APCs on submitted charges reduced to costs.

In response to the MedPAC findings, in the CY 2006 OPPS proposed rule (70 FR 42729), we discussed our belief that, because of the varied handling resources required to prepare different forms of drugs, it would be impossible to exclusively and appropriately assign a drug to a certain overhead category that would apply to all hospital outpatient uses of the drug. Therefore, our CY 2006 OPPS proposal included a proposal to establish three distinct Level II HCPCS

C-codes and three corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals (70 FR 42730). We also proposed: (1) to combine several overhead categories recommended by MedPAC; (2) to establish three drug handling categories, as we believed that larger groups would minimize the number of drugs that may fit into more than one category and would lessen any undesirable payment policy incentives to utilize particular forms of drugs or specific preparation methods; (3) to collect hospital charges for these HCPCS C-codes for 2 years; and (4) to ultimately base payment for the corresponding drug handling APCs on CY 2006 claims data available for the CY 2008 OPPS.

In the CY 2006 OPPS final rule with comment period (70 FR 68659 through 68665), we discussed the public comments we received on our proposal regarding pharmacy overhead. The overwhelming majority of commenters did not support our proposal regarding pharmacy overhead and urged us not to finalize this policy, as it would be administratively burdensome for hospitals to establish charges for HCPCS codes for pharmacy overhead and to report them. Therefore, we did not finalize this proposal for CY 2006. Instead, we established payment for separately payable drugs and biologicals at ASP+6 percent, which we calculated by comparing the estimated aggregate cost of separately payable drugs and biologicals in our claims data to the estimated aggregate ASP dollars for separately payable drugs and biologicals, using the ASP as a proxy for average acquisition cost (70 FR 68642). Hereinafter, we refer to this methodology as our standard drug payment methodology. We concluded that payment for drugs and biologicals and pharmacy overhead at a combined ASP+6 percent rate would serve as an acceptable proxy for the combined acquisition and overhead costs of each of these products.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68091), we finalized our proposed policy to provide a single payment of ASP+6 percent for the hospital's acquisition cost for the drug or biological and all associated pharmacy overhead and handling costs. The ASP+6 percent rate that we finalized was higher than the equivalent average ASP-based amount calculated from claims of ASP+4 percent according to our standard drug payment methodology, but we adopted payment at ASP+6 percent for stability while we continued to examine the issue of the costs of pharmacy overhead in the HOPD and awaited the accumulation of CY 2006 data as discussed in the prior year's rule.

In the CY 2008 OPPS/ASC proposed rule (72 FR 42735), in response to ongoing discussions with interested parties, we proposed to continue our methodology of providing a combined payment rate for drug and biological acquisition and pharmacy overhead costs while continuing our efforts to improve the available data. We also proposed to instruct hospitals to remove the pharmacy overhead charge for both packaged and separately payable drugs and biologicals from the charge for the drug or biological and report the pharmacy overhead charge on an uncoded revenue code line on the claim. We believed that this would provide us with an avenue for collecting pharmacy handling cost data specific to drugs in order to package the overhead costs of these items into the associated procedures, most likely drug administration services. Similar to the public response to our CY 2006 pharmacy overhead proposal, the overwhelming majority of commenters did not support our CY 2008 proposal and urged us to not finalize this policy (72 FR 66761). At its September 2007 meeting, the APC Panel recommended that hospitals not be required to separately report charges for pharmacy overhead and handling and that payment for overhead be included as part of drug payment. The APC Panel also recommended that CMS continue to evaluate alternative methods to standardize the capture of pharmacy overhead costs in a manner that is simple to implement at the organizational level (72 FR 66761). Because of concerns expressed by the APC Panel and public commenters, we did not finalize the proposal to instruct hospitals to separately report pharmacy overhead charges for CY 2008. Instead, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66763), we finalized a policy of providing payment for separately payable drugs and biologicals and their pharmacy overhead at ASP+5 percent as a transition from their CY 2007 payment of ASP+6 percent to payment based on the equivalent average ASP-based payment rate calculated from hospital claims according to our standard drug payment methodology, which was ASP+3 percent for the CY 2008 OPPS/ASC final rule with comment period. Hospitals continued to include charges for pharmacy overhead costs in the line-item charges for the associated drugs reported on claims.

For CY 2009, we proposed to pay separately payable drugs and biologicals at ASP+4 percent, including both SCODs and other drugs without CY 2009 OPPS pass-through status, based on our standard drug payment methodology. We also continued to explore mechanisms to improve the available data. We proposed to split the ''Drugs Charged to Patients'' cost center into two cost centers: One for drugs with high pharmacy overhead costs and one for drugs with low pharmacy overhead costs (73 FR 41492). We noted that we expected that CCRs from the proposed new cost centers would be available in 2 to 3 years to refine OPPS drug cost estimates by accounting for differential hospital markup practices for drugs with high and low overhead costs. After consideration of the public comments received and the APC Panel recommendations, we finalized a CY 2009 policy (73 FR 68659) to provide payment for separately payable nonpass-through drugs and biologicals based on costs calculated from hospital claims at a 1-year transitional rate of ASP+4 percent, in the context of an equivalent average ASP-based payment rate of ASP+2 percent calculated according to our standard drug payment methodology from the final rule claims data and cost report data. We did not finalize our proposal to split the single standard ''Drugs Charged to Patients'' cost center into two cost centers largely due to concerns raised by hospitals about the associated administrative burden. Instead, we indicated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68659) that we would continue to explore other potential approaches to improve our drug cost estimation methodology, thereby increasing payment accuracy for separately payable drugs and biologicals.

In response to the CMS proposals for the CY 2008 and CY 2009 OPPS, a group of pharmacy stakeholders (hereinafter referred to as the pharmacy stakeholders), including some cancer hospitals, some pharmaceutical manufacturers, and some hospital and professional associations, commented that CMS should pay an acquisition cost of ASP+6 percent for separately payable drugs, should substitute ASP+6 percent for the packaged cost of all packaged drugs and biologicals on procedure claims, and should redistribute the difference between the aggregate estimated packaged drug cost in claims and payment for all drugs, including packaged drugs at ASP+6 percent, as separate pharmacy overhead payments for separately payable drugs. They indicated that this approach would preserve the aggregate drug cost observed in the claims data, while

significantly increasing payment accuracy for individual drugs and procedures by redistributing drug cost from packaged drugs. Their suggested approach would provide a separate overhead payment for each separately payable drug or biological at one of three different levels, depending on the pharmacy stakeholders' assessment of the complexity of pharmacy handling associated with each specific drug or biological (73 FR 68651 through 68652). Each separately payable drug or biological HCPCS code would be assigned to one of the three overhead categories, and the separate pharmacy overhead payment applicable to the category would be made when each of the separately payable drugs or biologicals was paid.

In the CY 2010 OPPS/ASC proposed rule (74 FR 35332), we acknowledged the limitations of our data and our availability to find a method to improve that data in a way that did not impose unacceptable administrative burdens on providers. Accepting that charge compression was a reasonable but unverifiable supposition, we proposed to redistribute between one-third and one-half of the estimated overhead cost associated with coded packaged drugs and biologicals with an ASP, which resulted in our proposal to pay for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that did not have pass-through payment status at ASP+4 percent. We calculated estimated overhead cost for coded packaged drugs and biologicals by determining the difference between the aggregate claims cost for coded packaged drugs and biologicals with an ASP and the ASP dollars (ASP multiplied by the drug's or biological's units in the claims data) for those same coded drugs and biologicals; this difference was our estimated overhead cost for coded packaged drugs and biologicals. In our rationale described in the CY 2010 OPPS/ASC proposed rule (74 FR 35326 through 35333), we stated that we believed that approximately $150 million of the estimated $395 million total in pharmacy overhead cost, specifically between one-third and one-half of that cost, included in our claims data for coded packaged drugs and biologicals with reported ASP data should be attributed to separately payable drugs and biologicals and that the $150 million serves as the adjustment for the pharmacy overhead costs of separately payable drugs and biologicals. As a result, we also proposed to reduce the costs of coded drugs and biologicals that are packaged into payment for procedural APCs to offset the $150 million adjustment to payment for separately payable drugs and biologicals. In addition, we proposed that any redistribution of pharmacy overhead cost that may arise from the CY 2010 final rule data would occur only from some drugs and biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals that we calculate based on the charges and costs reported by hospitals on claims and cost reports. As a result of this approach, no redistribution of cost would occur from other services to drugs and biologicals or vice versa.

Using our CY 2010 proposed rule data, and applying our longstanding methodology for calculating the total cost of separately payable drugs and biologicals in our claims compared to the ASP dollars for the same drugs and biologicals, without applying the proposed overhead cost redistribution, we determined that the estimated aggregate cost of separately payable drugs and biologicals (status indicators ''K'' and ''G''), including acquisition and pharmacy overhead costs, was equivalent to ASP–2 percent. Therefore, under the standard methodology for establishing payment for separately payable drugs and biologicals, we would have paid for those drugs and biologicals at ASP–2 percent for CY 2010, their equivalent average ASP-based payment rate. We also determined that the estimated aggregate cost of coded packaged drugs and biologicals with an ASP (status indicator ''N''), including acquisition and pharmacy overhead costs, was equivalent to ASP+247 percent.

While we had no way of assessing whether this current distribution of overhead cost to coded packaged drugs and biologicals with an ASP was appropriate, we acknowledged that the established method of converting billed charges to costs had the potential to ''compress'' the calculated costs to some degree. Further, we recognized that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. Changes to the packaging threshold may result in changes to payment for the overhead cost of drugs and biologicals that do not reflect actual changes in hospital pharmacy overhead cost for those products. For these reasons, we stated that we believed some portion, but not all, of the total overhead cost that is associated with coded packaged drugs and biologicals (the difference between aggregate cost for those drugs and biologicals on the claims and ASP dollars for the same drugs and biologicals), based on our standard drug payment methodology, should, at least for CY 2010, be attributed to separately payable drugs and biologicals.

We acknowledged that the observed combined payment for acquisition and pharmacy overhead costs of ASP–2 percent for separately payable drugs and biologicals may be too low and ASP+247 percent for coded packaged drugs and biologicals with reported ASP data in the CY 2010 claims data may be too high (74 FR 35327 and 35328). In addition, we stated that we believed that the pharmacy stakeholders' recommendation to set packaged drug and biological dollars to ASP+6 percent was inappropriate, given our understanding that an equal allocation of indirect overhead costs among packaged and separately payable drugs and biologicals would lead to a higher observed ASP+X percent than ASP+6 percent for packaged drugs and biologicals. Further, we indicated that indirect overhead costs that are common to all drugs and biologicals have no relationship to the cost of an individual drug or biological or to the complexity of the handling, preparation, or storage of that individual drug or biological. Therefore, we indicated that we believed that indirect overhead cost alone for an inexpensive drug or biological which would be packaged could be far in excess of the ASP for that inexpensive product. We also explained that layered on these indirect costs are direct costs of staff, supplies, and equipment that are directly attributable only to the storage, handling, preparation, and distribution of drugs and biologicals and which do vary, sometimes considerably, depending upon the drug being furnished.

Therefore, we stated that a middle ground would represent the most accurate redistribution of pharmacy overhead cost. Our assumption was that approximately one-third to one-half of the total pharmacy overhead cost currently associated with coded packaged drugs and biologicals in the CY 2008 claims data offered a more appropriate allocation of drug and biological cost to separately payable drugs and biologicals. One third of the $395 million of pharmacy overhead cost associated with packaged drugs and biologicals was $132 million, whereas one-half was $198 million.

Within the one-third to one-half parameters, we proposed that

reallocating $150 million in drug and biological cost observed in the claims data from coded packaged drugs and biologicals with an ASP to separately payable drugs and biologicals for CY 2010 would more appropriately distribute pharmacy overhead cost among packaged and separately payable drugs and biologicals. Based on this redistribution, we proposed a CY 2010 payment rate for separately payable drugs and biologicals of ASP+4 percent. Redistributing $150 million represented a reduction in cost of coded packaged drugs and biologicals with reported ASP data in the CY 2010 proposed rule claims data of 27 percent.

We also proposed that any redistribution of pharmacy overhead cost that may arise from CY 2010 final rule data would occur only from some drugs and biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals in our claims data (no redistribution of cost would occur from other services to drugs and biologicals or vice versa). We further proposed that the claims data for 340B hospitals be included in the calculation of payment for drugs and biologicals under the CY 2010 OPPS, and that hospitals that participate in the 340B program would be paid the same amounts for separately payable drugs and biologicals as hospitals that do not participate in the 340B program (74 FR 35332 through 35333). Finally, we proposed that, in accordance with our standard drug payment methodology, the estimated payments for separately payable drugs and biologicals would be taken into account in the calculation of the weight scaler that would apply to the relative weights for all procedural services (but would not apply to separately payable drugs and biologicals) paid under the OPPS, as required by section 1833(t)(14)(H) of the Act (74 FR 35333).

In the CY 2010 OPPS final rule with comment period, we adopted a transitional payment rate of ASP+4 percent based on a pharmacy overhead adjustment methodology for CY 2010 that redistributed $200 million from packaged drug and biological cost to separately payable drug cost. This $200 million included the proposed $150 million redistribution from the pharmacy overhead cost of coded packaged drugs and biologicals for which an ASP is reported and an additional $50 million dollars from the total uncoded drug and biological cost to separately payable drugs and biologicals as a conservative estimate of the pharmacy overhead cost of uncoded packaged drugs and biologicals that should be appropriately associated with the cost of separately payable drugs and biologicals (74 FR 60517). We believed that our proposal to reallocate $150 million of costs from coded packaged drugs and biologicals, or one-third of the pharmacy overhead costs of these products, based upon the claims data available for the CY 2010 final rule, to separately payable drugs and biologicals was appropriate (74 FR 60511). We also acknowledged that, to some unknown extent, there are pharmacy overhead costs being attributed to the items and services reported under the pharmacy revenue code without HCPCS codes that are likely pharmacy overhead for separately payable drugs. Therefore, we reallocated $50 million or 8 percent of the total cost of uncoded packaged drug and biological cost in order to represent the pharmacy overhead cost of uncoded packaged drugs and biologicals that should be appropriately associated with the cost of separately payable drugs and biologicals. This was an intentionally conservative estimate as we could not identify definitive evidence that uncoded packaged drug and biological cost included a pharmacy overhead amount comparable to that of coded packaged drugs and biologicals with an ASP. We stated that we could not know the amount of overhead associated with these drugs without making significant assumptions about the amount of pharmacy overhead cost associated with the drug and biologicals captured by these uncoded packaged drug costs (74 FR 60511 through 60513).

We noted that our final CY 2010 payment policy for separately payable drugs and biologicals at ASP+4 percent fell within the range of ASP–3 percent (that would have resulted from no pharmacy overhead cost redistribution from packaged to separately payable drugs and biologicals), to ASP+7 percent (that would have resulted from redistribution of pharmacy overhead cost based on expansive assumptions about the nature of uncoded packaged drug and biological cost). We finalized a policy of redistributing pharmacy overhead cost from some drugs and biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals in our claims data (no redistribution of cost would occur from other services to drugs and biologicals or vice versa). We also reiterated our commitment to continue in our efforts to refine our analyses.

For CY 2011, we continued the CY 2010 pharmacy overhead adjustment methodology (74 FR 60500 through 60512). We determined the total cost of separately payable drugs using CY 2009 claims data and compared these costs to the ASP dollars (April 2010 ASP quarterly payment rates multiplied by units for the separately payable drugs and biologicals in the claims data) for the same drugs and biologicals. We determined that the total estimated payment for separately payable drugs and biologicals (status indicators ''K'' and ''G''), including acquisition and pharmacy overhead costs, was ASP–1 percent, which also would be the ASP-based payment rate under the standard methodology that we established in CY 2006 (75 FR 46275). Additionally, we determined that the total estimated aggregate cost for packaged drugs and biologicals with a HCPCS code for which manufacturers report ASP data (status indicator ''N''), including acquisition and pharmacy overhead costs, was equivalent to ASP+296 percent. Finally, we determined that the total estimated cost for both packaged drugs and biologicals with a HCPCS code and separately payable drugs and biologicals (status indicators ''N,'' ''K,'' and ''G'') for which we also have ASP data, including acquisition and pharmacy overhead costs, was ASP+13 percent. Consistent with our supposition that the combined payment for average acquisition and pharmacy overhead costs under our standard methodology may understate the cost of separately payable drugs and biologicals and related pharmacy overhead for those drugs and biologicals, we redistributed $150 million from the pharmacy overhead cost of coded packaged drugs and biologicals with an ASP and redistributed $50 million from the cost of uncoded packaged drugs and biologicals, for a total redistribution of $200 million from costs for coded and uncoded packaged drugs to separately payable drugs and biologicals, with the result that we pay separately paid drugs and biologicals at ASP+5 percent for CY 2011. The redistribution amount of $150 million in overhead cost from coded packaged drugs and biologicals with an ASP and $50 million in costs from uncoded packaged drugs and biologicals without an ASP were within the parameters established in the CY 2010 OPPS/ASC final rule. In addition, as in prior years, we described some of our work to improve our analyses during the preceding year, and reiterated our commitment to continue to refine our drug pricing methodology.

b. Proposed Payment Policy

Section 1833(t)(14)(A)(iii) of the Act, as described above, continues to be applicable to determining payments for SCODs for CY 2012. This provision requires that payment for SCODs be equal to the average acquisition cost for

the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the GAO in CYs 2004 and 2005 and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, section 1833(t)(14)(A)(iii)(II) of the Act requires that payment be equal to payment rates established under the methodology described in section 1842(o) of the Act, section 1847A of the Act (ASP+6 percent as paid for physician Part B drugs), or section 1847B of the Act (CAP), as the case may be, as calculated and adjusted by the Secretary as necessary. In accordance with sections 1842(o) and 1847A of the Act, payments for most Medicare non-OPPS Part B drugs furnished on or after January 1, 2005, are paid based on the ASP methodology. Medicare Part B drugs generally fall into three categories: physician-administered drugs (drugs furnished incident to a physician's service), drugs delivered through DME (drugs furnished under the durable medical equipment benefit), and drugs specifically covered by a statutory provision (certain oral anti-cancer and immunosuppressive drugs). Section 1833(t)(14)(E)(ii) of the Act authorizes, but does not require, the Secretary to adjust APC weights to take into account the 2005 MedPAC report relating to overhead and related expenses, such as pharmacy services and handling costs. As discussed in V.B.3.a. of this proposed rule, since CY 2006, we have used ASP data and costs estimated from charges on hospital claims data as a proxy for the sum of the average hospital acquisition cost that the statute requires for payment of SCODs and the associated pharmacy overhead cost in order to establish a combined payment rate for acquisition cost and pharmacy overhead. Prior to CY 2010, we applied this methodology to payment for all separately payable drugs and biologicals without pass-through status, including both SCODs and other drugs and biologicals that do not meet the statutory definition of SCODs.

For the CY 2010 OPPS, as part of our ongoing efforts to improve the validity of our payments, we revised the standard methodology to include an adjustment for pharmacy overhead. As explained previously, we have acknowledged, and continue to believe, that the established method of converting billed charges to costs had the potential to ''compress'' the calculated costs to some degree. We recognized that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. To some unknown extent, we believe that some pharmacy overhead costs attributed to packaged drugs and biologicals may include pharmacy overhead costs for separately payable drugs.

For this CY 2012 OPPS/ASC proposed rule, we are proposing to continue to use our standard methodology for determining the total cost of separately payable drugs and biologicals in our CY 2010 claims data and comparing these costs to the ASP dollars (April 2011 ASP quarterly payment rates multiplied by units for the separately payable drugs and biologicals in the claims data) for the same drugs and biologicals. We determined that the total estimated payment for separately payable drugs and biologicals (status indicators ''K'' and ''G''), including acquisition and pharmacy overhead costs, is ASP–2 percent, which also would be the ASP-based payment rate under the standard methodology that we established in CY 2006 (75 FR 46275). Additionally, we determined that the total estimated aggregate cost for packaged drugs and biologicals with a HCPCS code for which manufacturers report ASP data (status indicator ''N''), including acquisition and pharmacy overhead costs, is equivalent to ASP+188 percent. Finally, we determined that the total estimated cost for both packaged drugs and biologicals with a HCPCS code and separately payable drugs and biologicals (status indicators ''N,'' ''K,'' and ''G'') for which we also have ASP data, including acquisition and pharmacy overhead costs, is ASP+11 percent. Table 31 below displays our findings with regard to the percentage of ASP in comparison to the cost for packaged coded drugs and biologicals and for separately payable coded drugs and biologicals before application of the proposed overhead adjustment methodology.

TABLE 31—CY 2012 PROPOSED RULE DATA: ASP+X CALCULATION UNDER STANDARD METHODOLOGY

	Total ASP dollars for drugs and biologicals in claims data (in millions)*	Total cost of drugs and biologicals in claims data (in millions)**	Ratio of cost to ASP (column 3/column 2)	ASP+X percent
Uncoded Packaged Pharmaceutical Revenue Code Costs	Unknown	* * *$502	Unknown	Unknown
Coded Packaged Drugs and Biologicals with a reported ASP	$244	705	2.88	ASP+188
Separately Payable Drugs and Biologicals with a reported ASP	3,536	3,476	0.98	ASP–2
All Coded Drugs and Biologicals with a reported ASP	3,780	4,181	1.11	ASP+11

*Total April 2011 ASP dollars (ASP multiplied by drug or biologicals units in CY 2010 claims) for drugs and biologicals with a HCPCS code and ASP information.
**Total cost in the CY 2010 claims data for drugs and biologicals.
***Pharmacy revenue code costs without HCPCS codes.

We acknowledge that the combined payment for average acquisition and pharmacy overhead costs under our standard methodology may understate the cost of separately payable drugs and biologicals and related pharmacy overhead for those drugs and biologicals. Specifically, we recognize that payment at ASP–2 percent for such costs may not be sufficient. We also acknowledge that ASP +188 percent may overstate the combined acquisition and pharmacy overhead cost of packaged drugs and biologicals. Therefore, given this issue, for CY 2012, we are proposing to continue the CY 2010 and CY 2011 overhead adjustment methodology, which redistributes $200 million in cost from packaged drugs with an ASP and uncoded packaged drugs, as first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60501 through 60517).

For CY 2012, because we are proposing to continue to make an overhead adjustment for another year,

we believe it is appropriate to account for inflation that has occurred since the overhead redistribution amount of $200 million was applied in CY 2011. Therefore, we are proposing to apply an inflation allowance to account for inflation and changes in the prices of pharmaceuticals in the overall economy. We are proposing to adjust the overhead redistribution amount of $200 million using the PPI for Pharmaceuticals for Human Use. The PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003), provided through CMS' Office of the Actuary (OACT) is a price series that reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. We refer to this series generally as the PPI for Prescription Drugs. We believe that this price series is appropriate to use to update the overhead redistribution amount because the PPI for Prescription Drugs is publicly available and regularly published and because we have successfully utilized the PPI for Prescription Drugs for the past 5 years to update the drug packaging threshold as described in section V.B.2.a. of this proposed rule.

In order to apply the inflation allowance to the overhead redistribution amount for CY 2012, we used the most recent forecast of yearly index levels provided in the PPI for Prescription Drugs to calculate an updated overhead redistribution amount. After adjusting the $200 million overhead redistribution amount for inflation using the PPI for Prescription Drugs, we determined that $161 million would need to be redistributed from coded packaged drugs and biologicals with reported ASP data and $54 million would need to be redistributed from the cost of uncoded packaged drugs and biologicals without an ASP to separately payable drugs and biologicals. The proposed redistribution amount of $161 million in overhead cost from coded packaged drugs and biologicals is within the redistribution parameters established in the CY 2010 OPPS/ASC final rule with comment period of roughly one-third to one-half of overhead cost in coded packaged drugs and biologicals. The total proposed redistribution amount from both coded and uncoded packaged drugs and biologicals to separately paid drugs and biologicals would therefore be $215 million. Having determined to redistribute overhead, we also continue to believe that the methodology to redistribute a portion of drug overhead cost from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals while keeping the total cost of drugs and biologicals in the claims data constant continues to be appropriate for the reasons set forth in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60501 through 60517). Therefore, for CY 2012, we are proposing to redistribute a total overhead redistribution amount, adjusted for inflation, of $215 million from coded and uncoded packaged drugs and biologicals to separately payable drugs and biologicals.

In the CY 2010 OPPS/ASC final rule with comment period, we reallocated $150 million in overhead cost from coded packaged drugs and biologicals with an ASP to separately payable drugs and biologicals with an ASP, or one-third of the pharmacy overhead cost of these products based upon the claims data available for the CY 2010 final rule. In addition, we noted that some of the cost associated with uncoded packaged drugs and biologicals was appropriate to redistribute to separately payable drugs and biologicals. Therefore, we made a conservative estimate, as compared with the case of coded packaged drugs and biologicals with an ASP for which we had a specific pharmacy overhead cost estimate in relationship to their known ASPs, and reallocated $50 million, or 8 percent of the total cost of uncoded packaged drugs and biologicals with no ASP. We made the assumption that whatever pharmacy overhead cost inappropriately associated with uncoded packaged drugs and biologicals would not be less than 8 percent of total uncoded drugs and biologicals cost.

For this CY 2012 OPPS/ASC proposed rule, we note that continuing to redistribute $200 million (or $215 million with the adjustment for inflation) falls within the parameters originally established in the CY 2010 OPPS/ASC final rule with comment period. A redistribution amount of $161 million in overhead cost from coded packaged drugs and biologicals with an ASP or approximately 35 percent falls within one-third to one-half of the estimated pharmacy overhead cost. In addition, we note that a redistribution amount of $54 million in overhead cost from uncoded packaged drugs and biologicals, or approximately 11 percent, is not less than 8 percent of the total cost of uncoded packaged drugs and biologicals. Therefore, our proposal to redistribute $215 million is consistent with the overhead adjustment methodology first implemented in CY 2010. We continue to believe that a middle ground of approximately one-third to one-half of the total pharmacy overhead cost currently associated with coded packaged drugs and biologicals in the CY 2010 claims data represents the most accurate redistribution of pharmacy overhead cost.

We estimate the overhead cost for coded packaged drugs to be $544 million ($705 million in total cost for coded packaged drugs and biologicals with a reported ASP, less $161 million in total ASP dollars for coded packaged drugs and biologicals with a reported ASP). As we did in CY 2010 and CY 2011, we are proposing for CY 2012 that any redistribution of pharmacy overhead cost would occur only among drugs and biologicals in our claims data, that no redistribution of cost would occur from other services to drugs and biologicals or vice versa. We believe that redistributing $215 million from packaged to separately payable drugs and biologicals, which includes an adjustment for inflation, is an appropriate redistribution of pharmacy overhead costs to address any charge compression in the standard methodology. This would result in a proposed CY 2012 payment rate for separately payable drugs and biologicals of ASP+4 percent. We note that, in past years, the proposed ASP+X amount decreased by at least 1 percentage point when we updated the ASP data, claims data, and cost report data between the proposed rule and the final rule with comment period. Therefore, it is possible that the proposed methodology would result in an ASP+X amount that is different from ASP+4.

As indicated in Table 31 above, if we were to propose to establish payment for separately payable drugs and biologicals under the standard methodology established in CY 2006 without applying a pharmacy overhead adjustment, we would have to propose to pay for separately payable drugs and biologicals at ASP-2 percent. However, because we are concerned about the possibility of underpaying for separately payable drugs and biologicals, we believe that a pharmacy overhead adjustment using a redistribution methodology for determining the amount of payment for drugs and biologicals, as we did for CY 2011, is appropriate for CY 2012. We acknowledge that the observed ASP-2 percent may reflect some amount of charge compression and variability attributable to the choice of a packaging threshold.

TABLE 32—CY 2012 PROPOSED PHARMACY OVERHEAD ADJUSTMENT PAYMENT METHODOLOGY: ASP+X CALCULATION

	Total ASP dollars for drugs and biologicals in claims Data (in millions) *	Total cost of drugs and biologicals in claims data *after adjustment* (in millions) * *	Ratio of cost to ASP (column 3/column 2)	ASP+X percent
Uncoded Packaged Pharmaceutical Revenue Code Costs	Unknown	* * * $448	Unknown	Unknown
Coded Packaged Drugs and Biologicals with a reported ASP	244	544	2.23	ASP+123
Separately Payable Drugs and Biologicals with a reported ASP	3,536	3,691	1.04	ASP+4
All Coded Drugs and Biologicals with a reported ASP	3,780	4,181	1.11	ASP+11

* Total April 2011 ASP dollars (ASP multiplied by drug or biological units in CY 2010 claims) for drugs and biologicals with a HCPCS code and ASP information.
** Total cost in the CY 2010 claims data for drugs and biologicals.
*** Pharmacy revenue code costs without HCPCS codes.

We note that although it is CMS' longstanding policy under the OPPS to refrain from instructing hospitals on the appropriate revenue code to use to charge for specific services, we continue to encourage hospitals to bill all drugs and biologicals with HCPCS codes, regardless of whether they are separately payable or packaged, and to ensure that drug costs are completely reported, using appropriate revenue codes. We note that we make packaging determinations for drugs and biologicals annually based on cost information reported under HCPCS codes, and the OPPS ratesetting is best served when hospitals report charges for all items and services with HCPCS codes when they are available, whether or not Medicare makes separate payment for the items and services.

In summary, for the reasons set forth above and considering the data limitations we have previously discussed, we are proposing to continue our prior CY 2010 and CY 2011 acquisition cost proxy methodology and pharmacy overhead redistribution methodology. In addition, we are proposing to adjust the $200 million redistribution amount finalized in CY 2011 for inflation. Therefore, we are proposing to redistribute $161 million in overhead costs from coded packaged drugs and biologicals and $54 million in overhead costs from uncoded packaged drugs and biologicals to result in $215 million in costs redistributed from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals for CY 2012. The proposed redistribution amount of $161 million in overhead cost from coded packaged drugs and biologicals is within the redistribution parameters established in the CY 2010 OPPS/ASC final rule with comment period of roughly one-third to one-half of overhead cost in coded packaged drugs and biologicals. Approximately 11 percent of drug cost in uncoded packaged drugs and biologicals would be redistributed to separately payable drugs for CY 2012, and therefore, this amount continues to be no less than 8 percent of the total uncoded drug and biological cost. The result of this proposed methodology when applied using April 2011 ASPs, data for claims for services furnished during CY 2010 and processed through the Common Working File before January 1, 2010, and the most current submitted cost reports as of January 1, 2011, is a proposed ASP+4 percent amount for CY 2012.

Further, we are proposing to continue to include the claims data for 340B hospitals in the calculation of payment for drugs and biologicals under the CY 2012 OPPS because we believe excluding data from hospitals that participate in the 340B program from our ASP+X calculation, but paying those hospitals at that derived payment amount, would effectively redistribute payment to drugs or biologicals from payment for other services under the OPPS. Furthermore, we do not believe it would be appropriate to exclude claims from this subset of hospitals in the context of a proposed CY 2012 drug and biological payment policy that pays all hospitals the same rate for separately payable drugs and biologicals (74 FR 60517). In addition, we are proposing that 340B hospitals continue to be paid the same amounts for separately payable drugs and biologicals as hospitals that do not participate in the 340B program for CY 2012 because commenters have generally opposed differential payment for hospitals based on their 340B participation status. In addition, we are proposing to include claims from 340B hospitals in our assessment of average acquisition cost under section 1833(t)(14)(A)(iii) of the Act. We are proposing that the estimated payments for separately payable drugs and biologicals be taken into account in the calculation of the weight scaler that would apply to the relative weights for all procedural services (but would not apply to separately payable drugs and biologicals) paid under the OPPS, as required by section 1833(t)(14)(H) of the Act.

We note that we continue to pursue the most appropriate methodology for establishing payment for drugs and biologicals under the OPPS. Because we are always trying to improve the integrity of our data, we have previously proposed multiple mechanisms to improve the cost data available to us, but have not implemented those proposals due to hospital concerns about the administrative burden. We continue to be interested in developing mechanisms that improve the cost data available to us while minimizing to the extent possible the administrative burden on hospitals. For the past 3 years, we have proposed an internal adjustment to redistribute an amount from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals, because the results of our standard drug payment methodology are unlikely to accurately reflect the full cost of acquisition and pharmacy overhead for separately payable and packaged drugs and biologicals due to hospital charging practices and our use of an annual drug packaging threshold. As we continue to work to refine our payment systems, a goal to which we have been consistently committed over the past several years, we encourage public input on determining alternative cost-based methodologies to aid in our ongoing evaluation of alternative cost-based methodologies that could improve upon the current methodology.

c. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in the CY 2005 OPPS final rule with comment period, we

exempted radiopharmaceutical manufacturers from reporting ASP data for all radiopharmaceuticals for payment purposes under the OPPS. (For more information, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811) and the CY 2006 OPPS final rule with comment period (70 FR 68655).) Consequently, we did not have ASP data for radiopharmaceuticals for consideration for OPPS ratesetting until we began collecting ASP for nonpass-through separately paid therapeutic radiopharmaceuticals for CY 2010. In accordance with section 1833(t)(14)(B)(i)(I) of the Act, we have classified radiopharmaceuticals under the OPPS as SCODs. As such, we have paid for radiopharmaceuticals at average acquisition cost as determined by the Secretary and subject to any adjustment for overhead costs. For CYs 2006 and 2007, we used mean unit cost data from hospital claims to determine each radiopharmaceutical's packaging status and implemented a temporary policy to pay for separately payable radiopharmaceuticals based on the hospital's charge for each radiopharmaceutical adjusted to cost using the hospital's overall CCR. The methodology of providing separate radiopharmaceutical payment based on charges adjusted to cost through application of an individual hospital's overall CCR for CYs 2006 and 2007 was finalized as an interim proxy for average acquisition cost.

In CY 2008, we packaged payment for all diagnostic radiopharmaceuticals and we proposed and finalized a methodology to provide prospective payment for therapeutic radiopharmaceuticals (defined as those Level II HCPCS codes that include the term ''therapeutic'' along with a radiopharmaceutical in their long code descriptors) using mean costs derived from the CY 2006 claims data, where the costs were determined using our standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges, defaulting to hospital-specific overall CCRs only if appropriate departmental CCRs were unavailable (72 FR 66772). Following issuance of the CY 2009 OPPS/ASC proposed rule, section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) amended section 1833(t)(16)(C) of the Act, as amended by section 106(a) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173), to further extend the payment period for therapeutic radiopharmaceuticals based on hospitals' charges adjusted to cost through December 31, 2009. Therefore, for CY 2009, we finalized a policy to continue to pay hospitals for therapeutic radiopharmaceuticals at charges adjusted to cost through the end of CY 2009.

For CY 2010, we proposed and finalized a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. We allowed manufacturers to submit the ASP data in a patient-specific dose or patient-ready form in order to properly calculate the ASP amount for a given HCPCS code. This resulted in payment for nonpass-through separately paid therapeutic radiopharmaceuticals at ASP+4 percent for CY 2010 for products for which the manufacturer submitted ASP. We also finalized a policy to base therapeutic radiopharmaceutical payment on CY 2008 mean unit cost data derived from hospital claims if ASP information was unavailable. For CY 2011, we continued to pay for nonpass-through separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals, resulting in a payment rate for nonpass-through separately paid therapeutic radiopharmaceuticals of ASP+5 percent. We also continued to base therapeutic radiopharmaceutical payment on CY 2009 mean unit cost data derived from hospital claims if ASP information was unavailable.

We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through separately payable therapeutic radiopharmaceuticals in CY 2012. Therefore, we are proposing to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals under the ASP+X payment level established using the proposed pharmacy overhead adjustment based on a redistribution methodology to set payment for separately payable drugs and biologicals (proposed at ASP+4 percent, as discussed in section V.B.3.b. of this proposed rule) based on ASP information, if available, for a ''patient ready'' dose and updated on a quarterly basis for products for which manufacturers report ASP data. For a full discussion of how a ''patient ready'' dose is defined, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also are proposing to rely on CY 2010 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals, according to our usual process for updating the payment rates for separately payable drugs and biologicals, on a quarterly basis if updated ASP information is available.

The proposed CY 2012 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet).

4. Proposed Payment for Blood Clotting Factors

For CY 2011, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee. That is, for CY 2011, we provided payment for blood clotting factors under the OPPS at ASP+5 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2011 updated furnishing fee is $0.176 per unit.

For CY 2012, we are proposing to pay for blood clotting factors at ASP+4 percent, consistent with our proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our rationale for this proposed policy was first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and then later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we would announce the actual figure for the percent change in the applicable CPI

and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/.*

5. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes, but without OPPS Hospital Claims Data

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) does not address the OPPS payment in CY 2005 and after for drugs, biologicals, and radiopharmaceuticals that have assigned HCPCS codes, but that do not have a reference AWP or approval for payment as pass-through drugs or biologicals. Because there is no statutory provision that dictated payment for such drugs, biologicals, and radiopharmaceuticals in CY 2005, and because we had no hospital claims data to use in establishing a payment rate for them, we investigated several payment options for CY 2005 and discussed them in detail in the CY 2005 OPPS final rule with comment period (69 FR 65797 through 65799).

For CYs 2005 to 2007, we implemented a policy to provide separate payment for new drugs, biologicals, and radiopharmaceuticals with HCPCS codes (specifically those new drug, biological, and radiopharmaceutical HCPCS codes in each of those calendar years that did not crosswalk to predecessor HCPCS codes) but which did not have pass-through status, at a rate that was equivalent to the payment they received in the physician's office setting, established in accordance with the ASP methodology for drugs and biologicals, and based on charges adjusted to cost for radiopharmaceuticals. For CYs 2008 and 2009, we finalized a policy to provide payment for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals) and biologicals (excluding implantable biologicals for CY 2009) with HCPCS codes, but which did not have pass-through status and were without OPPS hospital claims data, at ASP+5 percent and ASP+4 percent, respectively, consistent with the final OPPS payment methodology for other separately payable drugs and biologicals. New therapeutic radiopharmaceuticals were paid at charges adjusted to cost based on the statutory requirement for CY 2008 and CY 2009 and payment for new diagnostic radiopharmaceuticals was packaged in both years. For CY 2010, we continued to provide payment for new drugs (excluding contrast agents), and nonimplantable biologicals with HCPCS codes that do not have pass-through status and are without OPPS hospital claims data, at ASP+4 percent, consistent with the CY 2010 payment methodology for other separately payable nonpass-through drugs, and nonimplantable biologicals. We also finalized a policy to extend the CY 2009 payment methodology to new therapeutic radiopharmaceutical HCPCS codes, consistent with our final policy in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60581 through 60526), providing separate payment for therapeutic radiopharmaceuticals that do not crosswalk to CY 2009 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data, at ASP+4 percent. This policy was continued in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71970 through 71973), paying for new drugs, nonimplantable biologicals and radiopharmaceuticals that do not crosswalk to CY 2010 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data at ASP+5 percent.

For CY 2012, we are proposing to continue our payment policies for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals that have HCPCS codes that do not crosswalk to CY 2011 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data. We are proposing to provide payment for new CY 2012 drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals, at ASP+4 percent, consistent with the proposed CY 2012 payment methodology for other separately payable nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals. We believe this proposed policy would ensure that new nonpass-through drugs, nonimplantable biologicals and therapeutic radiopharmaceuticals would be treated like other drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals under the OPPS, unless they are granted pass-through status. Only if they are pass-through drugs, nonimplantable biologicals, or therapeutic radiopharmaceuticals would they receive a different payment for CY 2012, generally equivalent to the payment these drugs and biologicals would receive in the physician's office setting, consistent with the requirements of the statute.

We also are proposing to continue our CY 2011 policy of packaging payment for all new nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals with HCPCS codes but without claims data (those new CY 2012 diagnostic radiopharmaceuticals, contrast agents, and implantable biological HCPCS codes that do not crosswalk to predecessor HCPCS codes), consistent with the proposed packaging of all existing nonpass-through diagnostic radiopharmaceuticals, contrast agents and implantable biologicals, as discussed in more detail in section V.B.2.d. and IV.A.2. of this proposed rule.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2012, we are proposing to continue the policy we implemented beginning in CY 2005 of using the WAC for the product to establish the initial payment rate for new nonpass-through drugs and biologicals with HCPCS codes, but which are without OPPS claims data. However, we note that if the WAC is also unavailable, we would make payment at 95 percent of the product's most recent AWP. We also are proposing to assign status indicator ''K'' (separately paid nonpass-through drugs and nonimplantable biologicals, including therapeutic radiopharmaceuticals) to HCPCS codes for new drugs and nonimplantable biologicals without OPPS claims data and for which we have not granted pass-through status. With respect to new, nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals, for which we do not have ASP data, we are proposing that once their ASP data become available in later quarterly submissions, their payment rates under the OPPS would be adjusted so that the rates would be based on the ASP methodology and set to the finalized ASP-based amount (proposed for CY 2012 at ASP+4 percent) for items that have not been granted pass-through status. This proposed policy, which is consistent with prior years' policies for these items, would ensure that new nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals under the OPPS, unless they are granted pass-through status. Only if they are pass-through drugs, nonimplantable biologicals, or therapeutic radiopharmaceuticals would they receive a different payment for CY

2012, generally equivalent to the payment these drugs and biologicals would receive in the physician's office setting, consistent with the requirements of the statute.

Similarly, we are proposing to continue our CY 2011 policy to base the initial payment for new therapeutic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals are not available. If the WACs are also unavailable, we are proposing to make payment for new therapeutic radiopharmaceutical at 95 percent of the products' most recent AWP because we would not have mean costs from hospital claims data upon which to base payment. As we are proposing with new drugs and biologicals, we are proposing to continue our policy of assigning status indicator ''K'' to HCPCS codes for new therapeutic radiopharmaceuticals without OPPS claims data for which we have not granted pass-through status.

Consistent with other ASP-based payment, for CY 2012 we are proposing to announce any changes to the payment amounts for new drugs and biologicals in the CY 2012 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2012 if later quarter ASP submissions (or more recent WACs or AWPs) indicate that changes to the payment rates for these drugs and biologicals are necessary. The payment rates for new therapeutic radiopharmaceuticals would also be changed accordingly, based on later quarter ASP submissions. We note that the new CY 2012 HCPCS codes for drugs, biologicals and therapeutic radiopharmaceuticals are not available at the time of development of this proposed rule. However, these agents will be included in Addendum B to the CY 2012 OPPS/ASC final rule with comment period where they will be assigned comment indicator ''NI'' (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) to reflect that their interim final OPPS treatment is open to public comment on the CY 2012 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2010 and/or CY 2011 for which we do not have CY 2010 hospital claims data available for this proposed rule and for which there are no other HCPCS codes that describe different doses of the same drug, but which have pricing information available for the ASP methodology. We note that there are currently no therapeutic radiopharmaceuticals in this category. In order to determine the packaging status of these products for CY 2012, we calculated an estimate of the per day cost of each of these items by multiplying the payment rate of each product based on ASP+4 percent, similar to other nonpass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting. This rationale was first adopted in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68666 and 68667). We are proposing to package items for which we estimated the per day administration cost to be less than or equal to $80, which is the general packaging threshold that we are proposing for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in CY 2012. We are proposing to pay separately for items with an estimated per day cost greater than $80 (with the exception of diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals, which we are proposing to continue to package regardless of cost as discussed in more detail in section V.B.2.d. of this proposed rule) in CY 2012. We are proposing that the CY 2012 payment for separately payable items without CY 2010 claims data would be ASP+4 percent, similar to payment for other separately payable nonpass-through drugs and biologicals under the OPPS. In accordance with the ASP methodology paid in the physician's office setting, in the absence of ASP data we are proposing to use the WAC for the product to establish the initial payment rate. However, we note that if the WAC is also unavailable, we would make payment at 95 percent of the most recent AWP available.

The proposed estimated units per day and status indicators for these items are displayed in Table 33 below.

TABLE 33—DRUGS AND BIOLOGICALS WITHOUT CY 2010 CLAIMS DATA

CY 2012 HCPCS Code	CY 2012 Long descriptor	Estimated average number of units per day	Proposed CY 2012 SI	Proposed CY 2012 APC
J0205	Injection, alglucerase, per 10 units	420	K	0900
J0364	Injection, apomorphine hydrochloride, 1 mg	12	N	N/A
J0630	Injection, calcitonin salmon, up to 400 units	1.5	N	N/A
J1680	Injection, human fibrinogen concentrate, 100 mg	49	K	1290
J2513	Injection, pentastarch, 10% solution, 100 ml	4	K	1222
J2724	Injection, protein c concentrate, intravenous, human, 10 iu	1540	K	1139
J3355	Injection, urofollitropin, 75 IU	2	K	1741
J9216	Injection, interferon, gamma 1-b, 3 million units	1	K	0838
Q0515	Injection, sermorelin acetate, 1 microgram	70	K	3050

Finally, there were five drugs and biologicals, shown in Table 34 below, that were payable in CY 2010, but for which we lacked CY 2010 claims data and any other pricing information for the ASP methodology for the CY 2012 OPPS/ASC proposed rule. In CY 2009, for similar items without CY 2007 claims data and without pricing information for the ASP methodology, we previously stated that we were unable to determine their per day cost and we packaged these items for the year, assigning these items status indicator ''N.''

For CY 2010, we finalized a policy to change the status indicator for drugs and biologicals previously assigned a payable status indicator to status indicator ''E'' (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) whenever we lacked claims data and pricing information and were unable to determine the per day cost. In addition, we noted that we would provide separate payment for these drugs and biologicals if pricing information reflecting recent sales becomes available mid-year in CY 2010 for the ASP

methodology. If pricing information became available, we would assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2010. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71973), for CY 2011, we continued our CY 2010 policy to assign status indicator ''E'' to drugs and biologicals that lacked CY 2009 claims data and pricing information for the ASP methodology. We also continued our policy to change the status indicator for these products to ''K'' if pricing information became available and pay for them separately for the remainder of CY 2011.

For CY 2012, we are proposing to continue our CY 2011 policy to assign status indicator ''E'' to drugs and biologicals that lack CY 2010 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2010 hospital claims data and data based on the ASP methodology that are assigned status indicator ''E'' on this basis at the time of this proposed rule for CY 2012 are displayed in Table 34 below. If pricing information becomes available, we are proposing to assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2012.

TABLE 34—DRUGS AND BIOLOGICALS WITHOUT CY 2010 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2012 SI
J2940	Injection, somatrem, 1 mg	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
J8650	Nabilone, oral, 1 mg	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
J9213	Injection, interferon, alfa-2a, recombinant, 3 million units	E

VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage'' (currently 2.0 percent, as stated below) of total program payments estimated to be made for all covered services under the hospital OPPS furnished for that year. For a year (or portion of a year) before CY 2004, the applicable percentage was 2.5 percent; for CY 2004 and subsequent years, the applicable percentage is a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We make an estimate of pass-through spending to determine not only whether payments exceed the applicable percentage, but also to determine the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year in order to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1883(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2012 entails estimating spending for two groups of items. The first group of items consists of device categories that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2012. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group contains items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2011 or beginning in CY 2012. Beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice; also referred to herein as ''implantable biologicals'') is the device pass-through process and payment methodology only (74 FR 60476). For CY 2012, we are proposing that the estimate of pass-through spending for implantable biologicals newly eligible for pass-through payment beginning in CY 2012 be included in the pass-through spending estimate for this second group of device categories. The sum of the CY 2012 pass-through estimates for these two groups of device categories would equal the total CY 2012 pass-through spending estimate for device categories with pass-through status.

For devices eligible for pass-through payment, section 1833(t)(6)(D)(ii) of the Act establishes the pass-through payment amount as the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable OPPS fee schedule payment that the Secretary determines is associated with the device. As discussed in section IV.A.2. of this proposed rule, we deduct from the pass-through payment for an identified device category eligible for pass-through payment an amount that reflects the portion of the APC payment amount that we determine is associated with the cost of the device, defined as the device APC offset amount, when we believe that the predecessor device costs for the device category newly approved for pass-through payment are already packaged into the existing APC structure. For each device category that becomes newly eligible for device pass-through payment, including implantable biologicals from CY 2010 forward, we estimate pass-through spending to be the difference between payment for the device category and the device APC offset amount, if applicable, for the procedures that would use the device. If we determine that the predecessor device costs for the new device category are not already included in the existing APC structure, the pass-through spending estimate for the device category is the full payment at charges adjusted to cost.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the

amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Because we are proposing to pay for most nonpass-through separately payable drugs and nonimplantable biologicals under the CY 2012 OPPS at ASP+4 percent, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and biologicals, and because we are proposing to pay for CY 2012 pass-through drugs and nonimplantable biologicals at ASP+6 percent or the Part B drug CAP rate, if applicable, our estimate of drug and nonimplantable biological pass-through payment for CY 2012 would not be zero, as discussed below. Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals without pass-through status, will always be packaged into payment for the associated procedures because these products will never be separately paid. However, all pass-through diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2012 would be paid at ASP+6 percent or the Part B drug CAP rate, if applicable, like other pass-through drugs and biologicals. Therefore, our estimate of pass-through payment for all diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2012 is also not zero. We note that there are no implantable biologicals proposed to continue on pass-through status for CY 2012 and, therefore, we are not proposing to include implantable biologicals in our estimate of pass-through payment. Payment for nonpass-through implantable biologicals will continue to be packaged into the payment for the associated procedure as described in section V.B.2.d of this proposed rule.

In section V.A.4. of this proposed rule, we discuss our proposed policy to determine if the cost of certain ''policy-packaged'' drugs, including diagnostic radiopharmaceuticals and contrast agents, are already packaged into the existing APC structure. If we determine that a ''policy-packaged'' drug approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that would be associated with the drug receiving pass-through payment, we are proposing to offset the amount of pass-through payment for diagnostic radiopharmaceuticals and contrast agents. For these drugs, the APC offset amount would be the portion of the APC payment for the specific procedure performed with the pass-through diagnostic radiopharmaceutical or contrast agent that is attributable to diagnostic radiopharmaceuticals or contrast agents, which we refer to as the ''policy-packaged'' drug APC offset amount. If we determine that an offset is appropriate for a specific diagnostic radiopharmaceutical or contrast agent receiving pass-through payment, we would reduce our estimate of pass-through payment for these drugs by this amount.

We note that the Part B drug CAP program has been postponed beginning January 1, 2009. We refer readers to the Medicare Learning Network (MLN) Matters Special Edition article SE0833 for more information, available via the CMS Web site at: *http://www.cms.gov/MLNMattersArticles/downloads/SE0833.pdf*. As of the publication of this proposed rule, the postponement of the Part B drug CAP program is still in effect. As in past years, for this proposed rule, we do not have an effective Part B drug CAP rate for pass-through drugs and biologicals.

Similar to pass-through estimates for devices, the first group of drugs and nonimplantable biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2012. The second group contains drugs and nonimplantable biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2011 or beginning in CY 2012. The sum of the CY 2012 pass-through estimates for these two groups of drugs and biologicals would equal the total CY 2012 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Proposed Estimate of Pass-Through Spending

We are proposing to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2012, consistent with our OPPS policy from CY 2004 through CY 2011 (75 FR 71975).

For the first group of devices for pass-through payment estimate purposes, there currently is one device category, C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable)) that became effective October 1, 2010, has been paid as a pass-through device for CY 2011, and will continue to be eligible for CY 2012. We estimate that CY 2012 pass-through expenditures related to C1749 will be approximately $35 million.

In estimating our proposed CY 2012 pass-through spending for device categories in the second group, which also includes any estimate for implantable biologicals that are eligible for pass-through payment, we include: Device categories that we know at the time of the development of this proposed rule would be newly eligible for pass-through payment in CY 2012 (of which there are none); additional device categories (including categories that describe implantable biologicals) that we estimate could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2012; and contingent projections for new device categories (including categories that describe implantable biologicals) established in the second through fourth quarters of CY 2012. We are proposing to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, the estimate of CY 2012 pass-through spending for this second group of device categories is $10 million. Using our established methodology, the total estimated pass-through spending for device categories for CY 2012 (spending for the first group of device categories ($35 million) plus spending for the second group of device categories ($10 million)) equals $45 million.

To estimate CY 2012 proposed pass-through spending for drugs and nonimplantable biologicals in the first group, specifically those drugs (including radiopharmaceuticals and contrast agents) and nonimplantable biologicals recently made eligible for pass-through payment and continuing on pass-through status for CY 2012, we are proposing to utilize the most recent Medicare physician's office data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or nonimplantable

biologicals, to project the CY 2012 OPPS utilization of the products.

For the known drugs and nonimplantable biologicals (excluding diagnostic radiopharmaceuticals and contrast agents) that would be continuing on pass-through status in CY 2012, we estimate the proposed pass-through payment amount as the difference between ASP+6 percent or the Part B drug CAP rate, as applicable, and the proposed payment rate for nonpass-through drugs and nonimplantable biologicals that would be separately paid at ASP+4 percent, aggregated across the projected CY 2012 OPPS utilization of these products. Because payment for a diagnostic radiopharmaceutical or contrast agent would be packaged if the product were not paid separately due to its pass-through status, we are proposing to include in the proposed CY 2012 pass-through estimate the difference between payment for the drug or nonimplantable biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the ''policy-packaged'' drug APC offset amount, if we have determined that the diagnostic radiopharmaceutical or contrast agent approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that would be associated with the drug receiving pass-through payment. For this proposed rule, we are proposing to continue to use the methodology used in CY 2011 to calculate a proposed spending estimate for this first group of drugs and biologicals to be approximately $5.7 million.

To estimate CY 2012 pass-through spending for drugs and nonimplantable biologicals in the second group (that is, drugs and nonimplantable biologicals that we know at the time of development of this proposed rule would be newly eligible for pass-through payment in CY 2012, additional drugs and nonimplantable biologicals that we estimate could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2012, and projections for new drugs and nonimplantable biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2012), we are proposing to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2012 proposed pass-through payment estimate. We are also considering the most recent OPPS experience in approving new pass-through drugs and nonimplantable biologicals. Using our proposed methodology for estimating CY 2012 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and nonimplantable biologicals to be approximately $13.8 million.

As discussed in section V.A. of this proposed rule, radiopharmaceuticals are considered drugs for pass-through purposes. Therefore, we include radiopharmaceuticals in our proposed CY 2012 pass-through spending estimate for drugs and biologicals. Our proposed CY 2012 estimate for total pass-through spending for drugs and biologicals (spending for the first group of drugs and nonimplantable biologicals ($5.7 million) plus spending for the second group of drugs and nonimplantable biologicals ($13.8 million)) equals $19.5 million.

In summary, in accordance with the methodology described above in this section, for this proposed rule, we estimate that total pass-through spending for the device categories and the drugs and nonimplantable biologicals that are continuing to receive pass-through payment in CY 2012 and those device categories, drugs, and nonimplantable biologicals that first become eligible for pass-through payment during CY 2012 would be approximately $64.5 million (approximately $45 million for device categories and approximately $19.5 million for drugs and non-implantable biologicals), which represents 0.15 percent of total OPPS projected total payments for CY 2012. We estimate that pass-through spending in CY 2012 would not amount to 2.0 percent of total projected OPPS CY 2012 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits

A. Background

Currently, hospitals report visit HCPCS codes to describe three types of OPPS services: Clinic visits; emergency department visits; and critical care services. For OPPS purposes, we recognize clinic visit codes as those codes defined in the CPT code book to report evaluation and management (E/M) services provided in the physician's office or in an outpatient or other ambulatory facility. We recognize emergency department visit codes as those codes used to report E/M services provided in the emergency department. Emergency department visit codes consist of five CPT codes that apply to Type A emergency departments and five Level II HCPCS codes that apply to Type B emergency departments. For OPPS purposes, we recognize critical care codes as those CPT codes used by hospitals to report critical care services that involve the ''direct delivery by a physician(s) of medical care for a critically ill or critically injured patient,'' as defined by the CPT code book. In Transmittal 1139, Change Request 5438, dated December 22, 2006, we stated that, under the OPPS, the time that can be reported as critical care is the time spent by a physician and/or hospital staff engaged in active face-to-face critical care of a critically ill or critically injured patient. Under the OPPS, we also recognize HCPCS code G0390 (Trauma response team associated with hospital critical care service) for the reporting of a trauma response in association with critical care services.

We are proposing to continue to recognize these CPT and HCPCS codes describing clinic visits, Type A and Type B emergency department visits, critical care services, and trauma team activation provided in association with critical care services for CY 2012. These codes are listed below in Table 35.

TABLE 35—PROPOSED HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES

CY 2012 HCPCS Code	CY 2012 Descriptor
Clinic Visit HCPCS Codes	
99201	Office or other outpatient visit for the evaluation and management of a new patient (Level 1).
99202	Office or other outpatient visit for the evaluation and management of a new patient (Level 2).
99203	Office or other outpatient visit for the evaluation and management of a new patient (Level 3).
99204	Office or other outpatient visit for the evaluation and management of a new patient (Level 4).
99205	Office or other outpatient visit for the evaluation and management of a new patient (Level 5).
99211	Office or other outpatient visit for the evaluation and management of an established patient (Level 1).

TABLE 35—PROPOSED HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES—Continued

CY 2012 HCPCS Code	CY 2012 Descriptor
99212	Office or other outpatient visit for the evaluation and management of an established patient (Level 2).
99213	Office or other outpatient visit for the evaluation and management of an established patient (Level 3).
99214	Office or other outpatient visit for the evaluation and management of an established patient (Level 4).
99215	Office or other outpatient visit for the evaluation and management of an established patient (Level 5).
Emergency Department Visit HCPCS Codes	
99281	Emergency department visit for the evaluation and management of a patient (Level 1).
99282	Emergency department visit for the evaluation and management of a patient (Level 2).
99283	Emergency department visit for the evaluation and management of a patient (Level 3).
99284	Emergency department visit for the evaluation and management of a patient (Level 4).
99285	Emergency department visit for the evaluation and management of a patient (Level 5).
G0380	Type B emergency department visit (Level 1).
G0381	Type B emergency department visit (Level 2).
G0382	Type B emergency department visit (Level 3).
G0383	Type B emergency department visit (Level 4).
G0384	Type B emergency department visit (Level 5).
Critical Care Services HCPCS Codes	
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes.
99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes.

TABLE 35—PROPOSED HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES—Continued

CY 2012 HCPCS Code	CY 2012 Descriptor
G0390	Trauma response associated with hospital critical care service.

During the February 28–March 1 2011 APC Panel meeting, the APC Panel recommended that CMS continue to report claims data for clinic and emergency department visits and observation, and, if CMS identifies changes in patterns of utilization or cost, it bring those issues before the Visits and Observation Subcommittee for future consideration. The APC Panel also recommended that the work of the Visits and Observation Subcommittee continue. We are accepting these recommendations and will present the available requested data at an upcoming meeting of the APC Panel.

B. Proposed Policies for Hospital Outpatient Visits

1. Clinic Visits: New and Established Patient Visits

As reflected in Table 35 hospitals use different CPT codes for clinic visits based on whether the patient being treated is a new patient or an established patient. Beginning in CY 2009, we refined the definitions of a new patient and an established patient to reflect whether or not the patient has been registered as an inpatient or outpatient of the hospital within the past 3 years. A patient who has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit would be considered to be an established patient for that visit, while a patient who has not been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit would be considered to be a new patient for that visit. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68677 through 68680) for a full discussion of the refined definitions.

We continue to believe that defining new or established patient status based on whether the patient has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit will reduce hospitals' administrative burden associated with reporting appropriate clinic visit CPT codes, as we stated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68677 through 68680). For CY 2012, we are proposing to continue to recognize the refined definitions of a new patient and an established patient, and applying our policy of calculating median costs for clinic visits under the OPPS using historical hospital claims data. As discussed in section II.A.2.e.(1) of the this proposed rule and consistent with our CY 2011 policy, when calculating the median costs for the clinic visit APCs (0604 through 0608), we are proposing to continue to utilize our methodology that excludes those claims for visits that are eligible for payment through the extended assessment and management composite APC 8002 (Level I Extended Assessment and Management Composite). We continue to believe that this approach results in the most accurate cost estimates for APCs 0604 through 0608 for CY 2012.

2. Emergency Department Visits

Since CY 2007, we have recognized two different types of emergency departments for payment purposes under the OPPS—Type A emergency departments and Type B emergency departments. As described in greater detail below, by providing payment for two types of emergency departments, we recognize, for OPPS payment purposes, both the CPT definition of an emergency department, which requires the facility to be available 24 hours, and the requirements for emergency departments specified in the provisions of the Emergency Medical Treatment and Labor Act (EMTALA) (Pub. L. 99–272), which do not stipulate 24-hour availability but do specify other obligations for hospitals that offer emergency services. For more detailed information on the EMTALA provisions, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68680).

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68132), we finalized the definition of a Type A emergency department to distinguish it from a Type B emergency department. A Type A emergency department must be available to provide services 24 hours a day, 7 days a week, and meet one or both of the following requirements related to the EMTALA definition of a dedicated emergency department specified at 42 CFR 489.24(b), specifically: (1) It is licensed by the State in which it is located under the applicable State law as an emergency room or emergency department; or (2) it is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an

urgent basis without requiring a previously scheduled appointment. For CY 2007 (71 FR 68140), we assigned the five CPT E/M emergency department visit codes for services provided in Type A emergency departments to five Emergency Visit APCs, specifically APC 0609 (Level 1 Emergency Visits), APC 0613 (Level 2 Emergency Visits), APC 0614 (Level 3 Emergency Visits), APC 0615 (Level 4 Emergency Visits), and APC 0616 (Level 5 Emergency Visits). We defined a Type B emergency department as any dedicated emergency department that incurred EMTALA obligations but did not meet the CPT definition of an emergency department. For example, a hospital department that may be characterized as a Type B emergency department would meet the definition of a dedicated emergency department but may not be available 24 hours a day, 7 days a week. Hospitals with such dedicated emergency departments incur EMTALA obligations with respect to an individual who presents to the department and requests, or has a request made on his or her behalf, examination or treatment for a medical condition.

To determine whether visits to Type B emergency departments have different resource costs than visits to either clinics or Type A emergency departments, in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68132), we finalized a set of five HCPCS G-codes for use by hospitals to report visits to all entities that meet the definition of a dedicated emergency department under the EMTALA regulations but that are not Type A emergency departments. These codes are called ''Type B emergency department visit codes.'' In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68132), we explained that these new HCPCS G-codes would serve as a vehicle to capture median cost and resource differences among visits provided by Type A emergency departments, Type B emergency departments, and clinics. We stated that the reporting of specific HCPCS G-codes for emergency department visits provided in Type B emergency departments would permit us to specifically collect and analyze the hospital resource costs of visits to these facilities in order to determine if, in the future, a proposal for an alternative payment policy might be warranted. We expected hospitals to adjust their charges appropriately to reflect differences in Type A and Type B emergency department visit costs.

As we noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68681), the CY 2007 claims data used for that rulemaking were from the first year of claims data available for analysis that included hospitals' cost data for these new Type B emergency department HCPCS visit codes. Based on our analysis of the CY 2007 claims data, we confirmed that the median costs of Type B emergency department visits were less than the median costs of Type A emergency department visits for all but the level 5 visit. In other words, the median costs from the CY 2007 hospital claims represented real differences in the hospital resource costs for the same level of visits in a Type A or Type B emergency department. Therefore, for CY 2009, we adopted the August 2008 APC Panel recommendation to assign Levels 1 through 4 Type B emergency department visits to their own APCs and to assign the Level 5 Type B emergency department visit to the same APC as the Level 5 Type A emergency department visit.

As discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60548 through 60551), analyses of CY 2008 hospitals' cost data from claims data used for CY 2010 ratesetting for the emergency department HCPCS G-codes demonstrated that the pattern of relative cost differences between Type A and Type B emergency department visits was largely consistent with the distributions we observed in the CY 2007 data, with the exception that, in the CY 2008 data, we observed a relatively lower HCPCS code-specific median cost associated with Level 5 Type B emergency department visits compared to the HCPCS code-specific median cost of Level 5 Type A emergency department visits. As a result, for CY 2010, we finalized a policy to continue to pay Levels 1 through 4 Type B emergency department visits through four levels of APCs, and to pay for Level 5 Type B emergency department visits through new APC 0630 (Level 5 Type B Emergency Department Visit), to which the Level 5 Type B emergency department visit HCPCS code is the only service assigned.

As we noted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71987), the pattern of relative cost differences between Type A and Type B emergency department visits is consistent with the distributions we observed in the CY 2008 claims data. Therefore, we finalized our proposal to continue to pay for Type B emergency department visits in CY 2011 based on their median costs through five levels of APCs: APC 0626 (Level 1 Type B Emergency Department Visit), APC 0627 (Level 2 Type B Emergency Department Visit), APC 0628 (Level 3 Type B Emergency Department Visit), APC 0629 (Level 4 Type B Emergency Department Visit), and APC 0630.

For CY 2012, we continue to believe that this configuration pays appropriately for each level of Type B emergency department visits based on estimated resource costs from the most recent CY 2010 claims data. Therefore, we are proposing to continue to pay for Type B emergency department visits in CY 2012 based on their median costs through the five levels of Type B emergency department APCs (APCs 0626 through 0630). We also note that, as discussed in section II.A.2.e.(1) of this proposed rule and consistent with our CY 2011 policy, when calculating the proposed median costs for the emergency department visit and critical care APCs (0609 through 0617 and 0626 through 0630), we are proposing to utilize our methodology that excludes those claims for visits that are eligible for payment through the extended assessment and management composite APC 8002. We believe that this approach would result in the most accurate cost estimates for APCs 0604 through 0608 for CY 2012.

Table 36 below displays the proposed median costs for each level of Type B emergency department visit APCs under the proposed CY 2012 configuration, compared to the proposed CY 2012 median costs for each level of clinic visit APCs and each level of Type A emergency department visit APCs.

TABLE 36—COMPARISON OF PROPOSED MEDIAN COSTS FOR CLINIC VISIT APCS, TYPE B EMERGENCY DEPARTMENT VISIT APCS, AND TYPE A EMERGENCY DEPARTMENT VISIT APCS

Visit level	Proposed CY 2012 clinic visit approximate APC median cost	Proposed CY 2012 Type B emergency department approximate APC median cost	Proposed CY 2012 Type A emergency visit approximate APC median cost
Level 1	$50	$41	$52
Level 2	75	59	89
Level 3	105	94	142
Level 4	138	141	229
Level 5	178	271	340

For CY 2010 and in prior years, the AMA CPT Editorial Panel defined critical care CPT codes 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and 99292 (Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)) to include a wide range of ancillary services such as electrocardiograms, chest X-rays and pulse oximetry. As we have stated in manual instruction, we expect hospitals to report in accordance with CPT guidance unless we instruct otherwise. For critical care in particular, we instructed hospitals that any services that the CPT Editorial Panel indicates are included in the reporting of CPT code 99291 (including those services that would otherwise be reported by and paid to hospitals using any of the CPT codes specified by the CPT Editorial Panel) should not be billed separately. Instead, hospitals were instructed to report charges for any services provided as part of the critical care services. In establishing payment rates for critical care services, and other services, CMS packages the costs of certain items and services separately reported by HCPCS codes into payment for critical care services and other services, according to the standard OPPS methodology for packaging costs (Medicare Claims Processing Manual, Pub. 100–04, Chapter 4, Section 160.1).

For CY 2011, the AMA CPT Editorial Panel revised its guidance for the critical care codes to specifically state that, for hospital reporting purposes, critical care codes do not include the specified ancillary services. Beginning in CY 2011, hospitals that report in accordance with the CPT guidelines should report all of the ancillary services and their associated charges separately when they are provided in conjunction with critical care. Because the CY 2011 payment rate for critical care services is based on hospital claims data from CY 2009, during which time hospitals would have reported charges for any ancillary services provided as part of the critical care services, we stated in the CY 2011 OPPS/ASC final rule with comment period that we believe it is inappropriate to pay separately in CY 2011 for the ancillary services that hospitals may now report in addition to critical care services (75 FR 71988). Therefore, for CY 2011, we continued to recognize the existing CPT codes for critical care services and established a payment rate based on our historical data, into which the cost of the ancillary services is intrinsically packaged, and implemented claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment. We noted in the CY 2011 OPPS/ASC final rule with comment period that the payment status of the ancillary services will not change when they are not provided in conjunction with critical care services. We assigned status indicator ''Q3'' (Codes That May Be Paid Through a Composite APC) to the ancillary services to indicate that payment for them is packaged into a single payment for specific combinations of services and made through a separate APC payment or packaged in all other circumstances, in accordance with the OPPS payment status indicated for status indicator ''Q3'' in Addendum D1 to the CY 2011 OPPS/ASC final rule with comment period. The ancillary services that were included in the definition of critical care prior to CY 2011 and that will be conditionally packaged into the payment for critical care services when provided on the same date of service as critical care services for CY 2011 were listed in Addendum M to that final rule with comment period.

Because the proposed CY 2012 median costs for critical care services are based upon CY 2010 claims data, which reflect the CPT billing guidance that was in effect prior to CY 2011, we are proposing to continue the methodology established in the CY 2011 OPPS/ASC final rule with comment period of calculating a payment rate for critical care services based on our historical data, into which the cost of the ancillary services is intrinsically packaged. We are proposing to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

3. Visit Reporting Guidelines

Since April 7, 2000, we have instructed hospitals to report facility resources for clinic and emergency department hospital outpatient visits using the CPT E/M codes and to develop internal hospital guidelines for reporting the appropriate visit level. Because a national set of hospital-specific codes and guidelines do not currently exist, we have advised hospitals that each hospital's internal guidelines that determine the levels of clinic and emergency department visits to be reported should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.

As noted in detail in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66802 through 66805), we observed a normal and stable distribution of clinic and emergency department visit levels in hospital claims over the past several years. The data indicated that hospitals, on average, were billing all five levels of visit codes with varying frequency, in a consistent pattern over time. Overall, both the clinic and emergency department visit distributions indicated that hospitals were billing consistently

over time and in a manner that distinguished between visit levels, resulting in relatively normal distributions nationally for the OPPS, as well as for specific classes of hospitals. The results of these analyses were generally consistent with our understanding of the clinical and resource characteristics of different levels of hospital outpatient clinic and emergency department visits. In the CY 2008 OPPS/ASC proposed rule (72 FR 42764 through 42765), we specifically invited public comment as to whether a pressing need for national guidelines continued at this point in the maturation of the OPPS, or if the current system where hospitals create and apply their own internal guidelines to report visits was currently more practical and appropriately flexible for hospitals. We explained that, although we have reiterated our goal since CY 2000 of creating national guidelines, this complex undertaking for these important and common hospital services was proving more challenging than we initially anticipated as we received new and expanded information from the public on current hospital reporting practices that led to appropriate payment for the hospital resources associated with clinic and emergency department visits. We stated our belief that many hospitals had worked diligently and carefully to develop and implement their own internal guidelines that reflected the scope and types of services they provided throughout the hospital outpatient system. Based on public comments, as well as our own knowledge of how clinics operate, it seemed unlikely that one set of straightforward national guidelines could apply to the reporting of visits in all hospitals and specialty clinics. In addition, the stable distribution of clinic and emergency department visits reported under the OPPS over the past several years indicated that hospitals, both nationally in the aggregate and grouped by specific hospital classes, were generally billing in an appropriate and consistent manner as we would expect in a system that accurately distinguished among different levels of service based on the associated hospital resources.

Therefore, we did not propose to implement national visit guidelines for clinic or emergency department visits for CY 2008. As we have done since publication of the CY 2008 OPPS/ASC final rule with comment period, we again examined the distribution of clinic and Type A emergency department visit levels based upon updated CY 2010 claims data available for the CY 2012 proposed rule. Analysis of this data confirmed that we continue to observe a normal and relatively stable distribution of clinic and emergency department visit levels in hospital claims compared to CY 2009 data. We note that we have observed a slight shift over time toward higher numbers of level 4 and level 5 visits relative to the lower level visits, when comparing the distributions of Type A emergency department visit levels from CY 2005 claims data to those from CY 2010. We also note that, in aggregate, hospitals' charges for these higher level emergency department visits seem to be trending upward year over year. We welcome comment on whether this is consistent with individual hospitals' experiences in developing, implementing, and refining their own guidelines over the last several years. We continue to believe that generally, hospitals are billing in an appropriate and consistent manner that distinguishes among different levels of visits based on their required hospital resources. We are encouraging hospitals to continue to report visits during CY 2012 according to their own internal hospital guidelines. As originally noted in detail in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66648), we continue to expect that hospitals will not purposely change their visit guidelines or otherwise upcode clinic and emergency department visits for purposes of extended assessment and management composite APC payment.

In addition, we note our continued expectation that hospitals' internal guidelines will comport with the principles listed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66805). We encourage hospitals with more specific questions related to the creation of internal guidelines to contact their servicing fiscal intermediary or MAC.

VIII. Proposed Payment for Partial Hospitalization Services

A. Background

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. Sections 1861(ff)(1) and (ff)(2) of the Act specify the items and services that are defined as partial hospitalization services and some conditions under which Medicare payment for the items and services will be made. Section 1861(ff)(3) of the Act specifies that a partial hospitalization program (PHP) is one that is furnished by a hospital or community mental health center (CMHC) that meets the requirements specified under that subsection of the Act.

In CY 2011, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that the program must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care ''other than in an individual's home or in an inpatient or residential setting.'' In addition, in accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the definition set forth at section 1861(ff)(3)(B) of the Act. We discussed our finalized policies for these two provisions of HCERA 2010 under section X.C. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71990). Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the OPD services to be covered under the OPPS. The existing Medicare regulations that implement this provision specify, at 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as those services furnished by hospitals to their outpatients. Section 1833(t)(2)(C) of the Act, in pertinent part, requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs'' using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, subparagraph (B) provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, CMS developed the APCs. Section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.'' Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we

established a per diem payment methodology for the PHP APCs, effective for services furnished on or after August 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs are used to calculate the relative payment weights for PHP APCs.

From CY 2003 through CY 2006, the median per diem cost for CMHCs fluctuated significantly from year to year, while the median per diem cost for hospital-based PHPs remained relatively constant. We were concerned that CMHCs may have increased and decreased their charges in response to Medicare payment policies. Therefore, we began efforts to strengthen the PHP benefit through extensive data analysis and policy and payment changes in the CY 2008 update (72 FR 66670 through 66676). We made two refinements to the methodology for computing the PHP median: the first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem costs by computing a separate per diem cost for each day rather than for each bill. A complete discussion of these refinements can be found in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66671 through 66676).

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tiered payment approach for PHP services under which we pay one amount for days with 3 services (APC 0172 (Level I Partial Hospitalization)) and a higher amount for days with 4 or more services (APC 0173 (Level II Partial Hospitalization)). We refer readers to section X.C.2. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68693) for a full discussion of the two-tiered payment system. In addition, for CY 2009, we finalized our policy to deny payment for any PHP claims for days when fewer than 3 units of therapeutic services are provided.

Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements at 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). We believe these changes have helped to strengthen the PHP benefit. We also revised the partial hospitalization benefit to include several coding updates. We refer readers to section X.C.2. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68695 through 68697) for a full discussion of these requirements.

For CY 2010, we retained the two-tiered payment approach for PHP services and used only hospital-based PHP data in computing the per diem payment rates. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we established four separate PHP APC per diem payment rates, two for CMHC PHPs (for Level I and Level II services for CMHCs) and two for hospital-based PHPs (Level I and Level II services for hospital-based PHPs). We proposed that CMHC PHP APC rates would be based only on CMHC data and hospital-based PHP APC rates would be based only on hospital-based PHP data (75 FR 46300). As stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46300) and final rule with comment period (75 FR 71991), for CY 2011, using CY 2009 cost data, CMHC costs had significantly decreased again. We attributed the decrease to the lower cost structure of CMHCs compared to hospitals, and not the impact of CY 2009 policies. CMHCs had a lower cost structure than hospital-based PHP providers, in part because the data showed that CMHCs provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. Therefore, it would be inappropriate to continue to treat CMHCs and hospital-based providers in the same manner regarding payment, particularly in light of such disparate differences in costs. We were concerned that paying hospital-based PHP programs at a lower rate than their cost structure reflects could lead to closures and possible access problems for hospital-based programs for Medicare beneficiaries. Creating the four payment rates (two for CMHC PHPs and two for hospital-based PHPs) supported continued access to the PHP benefit, including a more intensive level of care, while also providing appropriate payment based on the unique cost structures of CMHC PHPs and hospital-based PHPs. In addition, separation of cost data by provider type was supported by several hospital-based PHP commenters who responded to the CY 2011 OPPS/ASC proposed rule (75 FR 71992).

For CY 2011, we instituted a 2-year transition period for CMHC providers to CMHC rates based solely on CMHC data for the two CMHC PHP APC per diem payments. For the transition period, we calculated the CMHC PHP APC Level I and Level II rates by taking 50 percent of the difference between the CY 2010 final hospital-based medians and the CY 2011 final CMHC medians and then adding that number to the CY 2011 final CMHC medians. A 2-year transition under this methodology would move us in the direction of our goal, which is to pay appropriately for PHP services based on each provider type's cost data, while at the same time allow providers time to adjust their business operations and protect access to care for beneficiaries. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion of these four payment rates.

After publication of the CY 2011 OPPS/ASC final rule with comment period, in the case of *Paladin Community Mental Health Center* v. *Sebelius* (No. 1:10–CV–00949–LY (W.D. Tex.)), a CMHC and one of its outpatients challenged the OPPS rates for PHP services provided by CMHCs in CY 2011 as adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71995). Specifically, the plaintiffs in the case challenged the use of cost data derived from both hospitals and CMHCs in determining the relative payment weights for the OPPS rates for PHP services furnished by CMHCs. The plaintiffs alleged that section 1833(t)(2)(C) of the Act requires that such relative payment weights be based on cost data derived solely from hospitals. The Secretary has filed a motion to dismiss in this case, which is pending before the district court.

In addition to raising various jurisdictional defenses in the *Paladin* case, the Secretary argued that the agency had permissibly interpreted the statute in determining the relative payment weights for the OPPS rates for PHP services for CMHCs in CY 2011 on the basis of cost data derived from both hospitals and CMHCs. As discussed above, section 1833(t)(2)(C) of the Act requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services * * *) * * * based on * * * hospital costs.'' Numerous courts have held that ''based on'' does not mean ''based exclusively on.'' Thus, it was reasonable to interpret the statute to permit the use of cost data from CMHCs as well as from hospitals.

For CY 2012, as discussed in section VII.B. of this proposed rule, we are

proposing to determine the relative payment weights for PHP services by CMHCs based on cost data derived solely from CMHCs and the relative payment weights for hospital-based PHP services based exclusively on hospital cost data. We believe that, for purposes of this proposed rule for CY 2012, the statute is reasonably interpreted to allow the relative payment weights for the OPPS rates for PHP services provided by CMHCs to be based solely on CMHC cost data, whereas the corresponding relative payment weights for hospital-provided PHP services would be based exclusively on hospital cost data. Section 1833(t)(2)(C) of the Act requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on * * * hospital costs.'' In pertinent part, subparagraph (B) provides that ''the Secretary may establish groups of covered OPD services * * * so that services classified within each group are comparable clinically and with respect to the use of resources.'' In accordance with subparagraph (B), CMS developed the APCs, as set forth in § 419.31 of the regulations (65 FR 18446 and 18447; 63 FR 47559 and 47560). As discussed in section X.B. of this proposed rule, PHP services are grouped into APCs.

Based on section 1833(t)(2)(C) of the Act, we believe that the word ''establish'' can be interpreted as applying to APCs at the inception of the OPPS in 2000 or whenever a new APC is added to the OPPS. In creating the original APC for PHP services (APC 0033), we did ''establish'' the initial relative payment weight for PHP services, provided in hospital-based and CMHC-based settings, on the basis of only hospital data. Subsequently, from CY 2003 through CY 2008, the relative payment weights for PHP services were based on a combination of hospital and CMHC data. Similarly, we subsequently established new APCs for PHP services based exclusively on hospital costs. For CY 2009, we adopted a two-tiered APC methodology (in lieu of the original APC 0033) under which CMS paid one rate for days with 3 services (APC 0172) and a different payment rate for days with 4 or more services (APC 0173). These two new APCs were established using only hospital data. For CY 2011, we added two new APCs (APCs 0175 and 0176) for PHP services provided by hospitals and based the relative payment weights for these APCs solely on hospital data. APCs 0172 and 0173 were designated for PHP services provided by CMHCs and were based on a mixture of hospital and CMHC data. As the Secretary argued in the Paladin case, the courts have consistently held that the phrase ''based on'' does not mean ''based solely on.'' Thus, the relative payment weights for the two APCs for CMHC-provided PHP services in CY 2011 were ''based on'' hospital data, no less than the relative payment weights for the two APCs for hospital-provided PHP services.

Although we used only hospital data to establish the original relative payment weights for APC 0033 and later used hospital data to establish four new relative payment weights for PHP services, we believe that we have the authority to discontinue the use of hospital data after the original establishment of the relative payment weights for a given APC. Other parts of section 1833(t)(2)(C) of the Act make plain that the data source for the relative payment weights is subject to change from one period to another. Section 1833(t)(2)(C) of the Act provides that, in establishing the relative payment weights, ''the Secretary shall [ ] us[e] data on claims from 1996 and us[e] data from the most recent available cost reports.'' However, we used 1996 data (plus 1997 data) in determining only the original relative payment weights for 2000; in the ensuing calendar year updates, we continually used more recent cost report data.

Moreover, section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.'' For purposes of the CY 2012 update, we exercised our authority under section 1833(t)(9)(A) of the Act to change the data source for the relative payment weights for PHP services by CMHCs based on ''new cost data, and other relevant information and factors.''

B. Proposed PHP APC Update for CY 2012

To develop the proposed payment rates for the PHP APCs for CY 2012, we used CY 2010 claims data and computed median per diem costs in the following categories: (1) days with 3 services; and (2) days with 4 or more services. These proposed median per diem costs were computed separately for CMHC PHPs and hospital-based PHPs, as shown in Table 37 below.

TABLE 37—PROPOSED PHP MEDIAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHPS, BY CATEGORY, BASED ON CY 2010 CLAIMS DATA

Category	CMHC PHPs	Hospital-based PHPs
Days with 3 services	$97.78	$162.34
Days with 4 or more services	113.62	189.87

Using CY 2010 claims data and the refined methodology for computing PHP per diem costs adopted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66671 through 66676), we computed proposed median per diem costs for CY 2012 for each provider type using its own claims data. The data results indicate that, although both CMHCs and hospital-based PHPs have decreased costs for Level I and Level II services from CY 2011 to CY 2012, the median per diem costs for CMHC PHPs continue to be substantially lower than the median per diem costs for hospital-based PHPs, given the same units of service. The approximate median per diem costs for 3 services are $98 for CMHC PHPs compared to $162 for hospital-based PHPs. Furthermore, the approximate median per diem costs for 4 or more services are $114 for CMHC PHPs compared to $190 for hospital-based PHPs. The difference in costs between CMHC PHPs and hospital-based PHPs underscores the need to pay each provider type based on use of its own data.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991), we noted that CMHCs' costs decreased from $139 in CY 2009 (using CY 2007 data) to $118 for CY 2011 (using CY 2009 claims data) for Level I services (3 services); and from $172 for CY 2009 to $123 for CY 2011 for Level II services (4 or more services). For this CY 2012 proposed rule, our analysis of claims data (using CY 2010 claims data) shows

that CMHCs' approximate median per diem costs continue to decrease from $118 for CY 2011 (using CY 2009 claims data) to $98 for CY 2012 for Level I services (3 services), and from $123 for CY 2011 (using CY 2009 claims data) to $114 for CY 2012 for Level II services (4 or more services). We can reasonably attribute some of the decrease in costs to targeted fraud and abuse efforts implemented by the Department's Center for Program Integrity and the Office of Inspector General, and by the U.S. Department of Justice, collectively.

We note that hospital-based PHPs also show a decrease in costs for CY 2012 (using CY 2010 claims data). Although hospital-based PHPs have historically been consistent in their median costs since the inception of the OPPS, the CY 2010 claims data indicated a decrease in their median per diem costs since last year. Hospital-based PHPs' approximate median per diem costs decreased from $184 for CY 2011 (using CY 2009 claims data) to $162 for CY 2012 (using CY 2010 claims data) for Level I services (3 services), and from $236 for CY 2011 (using CY 2009 claims data) to $190 for CY 2012 (using CY 2010 claims data) for Level II services (4 or more services). We can attribute this decrease in costs to one provider whose costs inflated the CY 2011 hospital-based cost data and increased the CY 2011 hospital-based PHP median for Level II services by approximately $30. We included this provider in the CY 2011 ratesetting because this provider had paid claims in CY 2009. Subsequently, this provider did not bill for PHP services during CY 2010 and, therefore, was not included in the proposed CY 2012 ratesetting.

Based on the results of our analysis of the CY 2010 claims data, for CY 2012, we are proposing to calculate the proposed CMHC PHP APC per diem payment rates for Level I and Level II services using only CMHC data and calculating the proposed hospital-based PHPs APC per diem payment rates for Level I and Level II services using only hospital-based PHP data. Basing payment rates specific to each type of provider's own data would continue to support access to the PHP benefit, including a more intensive level of care, while also providing appropriate payment commensurate with the cost structures of CMHC PHPs and hospital-based PHPs. We invite public comments on our proposal to calculate the CMHC PHP APC per diem payment rates using only CMHC claims data and the hospital-based PHP APC per diem rates using only hospital data.

We are proposing the following APC median per diem costs for PHP services for CY 2012:

TABLE 38—PROPOSED CY 2012 MEDIAN PER DIEM COSTS FOR CMHC PHP SERVICES

Proposed APC	Group title	Proposed median per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$97.78
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	113.62

TABLE 39—PROPOSED CY 2012 MEDIAN PER DIEM COSTS FOR HOSPITAL–BASED PHP SERVICES

Proposed APC	Group title	Proposed median per diem costs
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	$162.34
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	189.87

C. Proposed Separate Threshold for Outlier Payments to CMHCs

In the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we indicated that, given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Prior to that time, there was a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. In addition, further analysis indicated that using the same OPPS outlier threshold for both hospitals and CMHCs did not limit outlier payments to high-cost cases and resulted in excessive outlier payments to CMHCs. Therefore, beginning in CY 2004, we established a separate outlier threshold for CMHCs. The separate outlier threshold for CMHCs has resulted in more commensurate outlier payments.

The separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004 and $0.5 million in outlier payments to CMHCs in CY 2005. In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments. We believe this difference in outlier payments indicates that the separate outlier threshold for CMHCs has been successful in keeping outlier payments to CMHCs in line with the percentage of OPPS payments made to CMHCs.

We are proposing to continue our policy of identifying 1.0 percent of the aggregate total payments under the OPPS for outlier payments for CY 2012. We are proposing that a portion of that 1.0 percent, an amount equal to 0.14 percent of outlier payments (or 0.0014 percent of total OPPS payments), would be allocated to CMHCs for PHP outlier payments. In section II.G. of this proposed rule, we are proposing to set a dollar threshold in addition to an APC multiplier threshold for OPPS outlier payments. However, because the PHP APCs are the only APCs for which CMHCs may receive payment under the OPPS, we would not expect to redirect outlier payments by imposing a dollar threshold. Therefore, we are not proposing to set a dollar threshold for CMHC outlier payments. We are proposing to set the outlier threshold for CMHCs for CY 2012 at 3.40 times the APC payment amount and the CY 2012 outlier payment percentage applicable to costs in excess of the threshold at 50 percent. Specifically, we are proposing to establish that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

IX. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

A. Background

Section 1833(t)(1)(B)(i) of the Act gives the Secretary broad authority to determine the services to be covered and paid for under the OPPS. Before implementation of the OPPS in August 2000, Medicare paid reasonable costs for services provided in the HOPD. The claims submitted were subject to medical review by the fiscal intermediaries to determine the appropriateness of providing certain services in the outpatient setting. We did not specify in our regulations those services that were appropriate to provide only in the inpatient setting and that, therefore, should be payable only when provided in that setting.

In the April 7, 2000 final rule with comment period (65 FR 18455), we identified procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the OPPS. These procedures comprise what is referred to as the ''inpatient list.'' The inpatient list specifies those services for which the hospital will be paid only when provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. As we discussed in that rule and in the November 30, 2001 final rule with comment period (66 FR 59884), we may use any of a number of criteria we have specified when reviewing procedures to determine whether or not they should be removed from the inpatient list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. Those criteria include the following:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be performed in most outpatient departments.
- The procedure is related to codes that we have already removed from the inpatient list.

In the November 1, 2002 final rule with comment period (67 FR 66741), we added the following criteria for use in reviewing procedures to determine whether they should be removed from the inpatient list and assigned to an APC group for payment under the OPPS:

- A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis; or
- A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

The list of codes that we are proposing to be paid by Medicare in CY 2012 only as inpatient procedures is included as Addendum E to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

B. Proposed Changes to the Inpatient List

For the CY 2012 OPPS, we are proposing to use the same methodology described in the November 15, 2004 final rule with comment period (69 FR 65835) to identify a subset of procedures currently on the inpatient list that are being performed a significant amount of the time on an outpatient basis. Using this methodology, we identified two procedures that met the criteria for potential removal from the inpatient list for CY 2012. We then clinically reviewed these two potential procedures for possible removal from the inpatient list and found them to be appropriate candidates for removal from the inpatient list. During the February 28–March 1, 2011 meeting of the APC Panel, we solicited the APC Panel's input on the appropriateness of removing these two procedures from the CY 2012 inpatient list: CPT codes 21346 (Open treatment of nasomaxillary complex fracture (Lefort II type); with wiring and/or local fixation) and 54411 (Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue).

As we indicated in the CY 2011 final rule with comment period (75 FR 71996), we solicited the APC Panel's input on the appropriateness of removing the procedures described by CPT codes 35045 (Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery) and 54650 (Orchiopexy, abdominal approach, for intra-abdominal testis (eg, Fowler-Stephens)), from the CY 2012 inpatient list. We also solicited the APC Panel's input on the appropriateness of removing the following procedures identified in a comment letter addressed to the APC Panel: CPT codes 61154 (Burr hole(s) with evacuation and/or drainage of hematoma, extradural or subdural); 61156 (Burr hole(s); with aspiration of hematoma or cyst, intracerebral); and 61210 (Burr hole(s); for implanting ventricular catheter, reservoir, eeg electrode(s), pressure recording device, or other cerebral monitoring device (separate procedure)). Following the discussion at its February 28–March 1, 2011 meeting, the APC Panel recommended that CMS remove from the CY 2012 inpatient list CPT codes 21346, 54411, 35045, 54650, and 61210. The APC Panel made no recommendation regarding CPT codes 61154 and 61156.

Additionally, during the February 28–March 1, 2011 meeting of the APC Panel, an APC Panel member requested removal of the following CPT codes from the CY 2012 inpatient list: 22551 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2); 22552 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)); 22554 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2); 22585 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2, each additional interspace (List separately in addition to code for primary procedure)); 61107 (Twist drill hole(s) for subdural, intracerebral, or ventricular puncture; for implanting ventricular catheter, pressure recording device, or other intracerebral monitoring device); and 63267 (Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar). Following the discussion at its February 28–March 1, 2011 meeting, the APC Panel recommended that CMS remove from the CY 2012 inpatient list CPT codes 22551, 22552, 22554, 22585, 61107, and 63267.

For CY 2012, we are proposing to accept the APC Panel's recommendations to remove the procedures described by CPT codes 21346, 35045, and 54650 from the inpatient list because we agree with the APC Panel that the procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the

evaluation criteria mentioned above. We also are proposing to not accept the APC Panel's recommendations to remove the procedures described by CPT codes 22551, 22552, 22554, 22585, 54411, 61107, 61210, and 63267, because upon further clinical review subsequent to the February 28–March 1, 2011 APC Panel meeting, we do not believe that these procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the evaluation criteria mentioned above, due to the clinical intensity of services provided. Furthermore, according to our utilization data, the procedures described by CPT codes 22551, 22552, 22554, 22585, 54411, 61107, 61210, and 63267 have very low volume in the outpatient hospital setting. We note that despite its low overall volume, CPT code 54411 is performed a significant percentage of the time in the outpatient hospital setting; however, we do not believe that the outpatient procedures being performed are truly reflective of the intensity of services requisite when performing the procedure as described by the CPT code's long descriptor. We invite public comment on the inclusion of CPT code 54411 on the CY 2012 inpatient list. The three procedures we are proposing to remove from the inpatient list for CY 2012 and their CPT codes, long descriptors, proposed APC assignments, and proposed status indictors are displayed in Table 40 below.

TABLE 40—PROCEDURES PROPOSED FOR REMOVAL FROM THE INPATIENT LIST AND THEIR PROPOSED APC ASSIGNMENTS FOR CY 2012

HCPCS code	Long descriptor	Proposed CY 2012 APC assignment	Proposed CY 2012 status indicator
21346	Open treatment of nasomaxillary complex fracture (Lefort II type); with wiring and/or local fixation.	0254	T
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery.	0093	T
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (e.g., Fowler-Stephens).	0154	T

X. Proposed Policies for the Supervision of Outpatient Services in Hospitals and CAHs

A. Background

In the CY 2000 OPPS final rule with comment period, CMS established the hospital OPPS and indicated that direct supervision is the standard for all hospital outpatient therapeutic services covered and paid by Medicare in hospitals and in provider-based departments (PBDs) of hospitals (65 FR 18524 through 18526). Currently, as discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72008), this standard requires the supervisory practitioner to be immediately available to furnish assistance and direction throughout the performance of a hospital outpatient therapeutic service or procedure. In the CY 2000 OPPS final rule with comment period, we established in regulation at § 410.28(e) that outpatient diagnostic services furnished in PBDs of hospitals must be supervised at the level indicated in the Medicare Physician Fee Schedule (MPFS) for each service, that is, general, direct or personal supervision. Since that time, we have clarified and refined these rules in several ways. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71998 through 72001), we provided a comprehensive review of the history of the supervision policies for both outpatient therapeutic and diagnostic services from the inception of the OPPS through CY 2010. In this section, we provide a more condensed overview of our supervision policy during that time period, and present background on issues that have arisen during the CY 2011 payment year.

By way of overview, we have defined supervision in the hospital outpatient setting by drawing on the three levels of supervision that CMS defined for the physician office setting at § 410.32(b) prior to establishment of the OPPS: General, direct, and personal supervision. Over time, we have tailored these definitions as needed to apply them in the hospital outpatient setting, so the definitions or applications in the OPPS may differ slightly from those in the physician office setting. This is the case in defining direct supervision, where the MPFS requires presence ''in the office suite,'' and the OPPS currently does not require presence within any specific physical boundary (in the past, the OPPS rules for direct supervision required presence on the hospital campus or in the PBD) (75 FR 72008, 72012).

To date, for purposes of the hospital outpatient setting, we have only defined direct and general supervision, and we have only defined general supervision insofar as it applies to the provision of nonsurgical extended duration therapeutic services (extended duration services) for which we require direct supervision during an initiation period, followed by a minimum standard of general supervision for the duration of the service (75 FR 72012). Under the OPPS, general supervision means that the service is furnished under the overall direction and control of the physician or appropriate nonphysician practitioner, but his or her physical presence is not required during the performance of the service. Direct supervision means that the physician or appropriate nonphysician practitioner is immediately available to furnish assistance and direction throughout the performance of a therapeutic service or procedure; however, he or she does not have to be present in the room where the service or procedure is being performed.

In the CY 2000 OPPS final rule with comment period (65 FR 18524 through 18526), we adopted physician supervision policies as a condition of payment under the OPPS to ensure that Medicare pays for high quality hospital outpatient services that are furnished in a safe and effective manner and consistent with Medicare requirements. The agency has long divided hospital outpatient services into the two categories of ''diagnostic'' services and other ''therapeutic'' services that aid the physician in the treatment of patients (Section 3112 of the Medicare Part A Intermediary Manual (July 1987)). Thus, we considered all nondiagnostic services to be ''therapeutic services'' which would include, but not be limited to, the services listed under section 1861(s)(2)(B) of the Act as incident to the services of physicians. As early as

1985, the agency defined therapeutic services as those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment of patients (Section 3112.4 of the Medicare Part A Intermediary Manual (May 1985)). In recognition of this historic classification of services, we established a direct supervision standard for outpatient therapeutic services under our regulation at § 410.27, which establishes the conditions for payment for outpatient hospital services provided ''incident to'' physicians' services. In the text of § 410.27, we also established standards requiring that these services be furnished either by or under arrangements made by the participating hospital (§ 410.27(a)(1)(i)), either in the hospital or in a location that the agency designates as a department of a provider under § 413.65 of the regulations (§ 410.27(a)(1)(iii)). Since 2000, we have maintained the classification of services as either diagnostic or therapeutic in our manual guidance that establishes the conditions of payment for hospital outpatient services under the OPPS (Sections 20.4 and 20.5, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100–02)). In the requirements for therapeutic services, in addition to the direct supervision standard, we applied the requirements of §§ 410.27(a)(1)(i) and (a)(1)(iii) regarding under arrangement and provider-based site of service to all outpatient therapeutic services that are paid under the OPPS (Section 20.5, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100–02)).

In the CY 2000 OPPS final rule with comment period, we amended our regulation at § 410.27 to specify that direct supervision is required for outpatient hospital services and supplies furnished incident to a physician's service in a location we designate as a department of a provider under § 413.65 of our regulations. We specified further in the regulation that direct supervision means the physician must be present on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the service or procedure. The requirement to be ''immediately available'' was included in the regulation, although at that time we did not define the term. Although the regulation required the physician to be present on the premises of the location where services were being furnished, it specified that the physician did not have to be present in the room when the procedure was performed. In the CY 2000 OPPS final rule with comment period (65 FR 18525), we emphasized the importance of establishing a supervision standard for services furnished in departments of the hospital that are not located on campus, indicating that our amendment applies to services furnished at an entity that is located off the campus of a hospital that we designate as having provider-based status in accordance with the provisions of § 413.65. In response to a commenter, we stated that, in accordance with Section 3112.4(A) of the Intermediary Manual, we assume the direct supervision standard is met when outpatient therapeutic services are provided incident to a physician's service in an on-campus department of a hospital.

In the CY 2000 OPPS final rule with comment period, we also defined the supervision standards for outpatient hospital diagnostic services furnished in PBDs of hospitals in § 410.28(e) of our regulations. The regulation at § 410.28(e) provided that diagnostic services furnished at facilities having provider-based status must be performed under the level of supervision indicated for the diagnostic test under the MPFS in accordance with the definitions in §§ 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii). In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60588 through 60591, and 60680), we revised § 410.28(e) to extend the supervision standards we had established for outpatient diagnostic tests furnished in PBDs to also apply to services furnished in the hospital setting or any other location where diagnostic services may be provided under arrangement. The supervision rules for diagnostic services under the regulation at § 410.28(e) explicitly apply to hospitals that are paid in accordance with section 1833(t) of the Act, which is the statutory authority for the OPPS. As noted in the CY 2010 OPPS/ASC final rule with comment period, Medicare makes payments to CAHs in accordance with section 1834(g) of the Act. Accordingly, CAHs are not subject to the supervision requirements for outpatient diagnostic services at this time. The supervision requirements for outpatient diagnostic services were also set forth in Section 20.4, Chapter 6, of the Medicare Benefit Policy Manual.

In the years following establishment of the initial OPPS regulations, we began to receive inquiries from providers about the supervision requirements. Many of these inquiries led us to believe that some hospitals may have misunderstood our statement to the effect that we assume physician supervision requirements are met for services furnished on the hospital premises, and were providing either general supervision or no supervision for therapeutic services furnished incident to physicians' services in the outpatient setting and for which we had established a requirement of direct supervision. Therefore, in the CY 2009 OPPS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, respectively), we clarified and restated the various supervision requirements for outpatient hospital therapeutic and diagnostic services. We clarified that therapeutic services furnished in the hospital and in all PBDs of the hospital, specifically both on-campus and off-campus PBDs, must be provided under the direct supervision of physicians. We also reiterated that all diagnostic services furnished in PBDs, whether on or off the hospital's main campus, should be supervised according to the levels assigned for the individual tests under the MPFS. We received very few public comments regarding this clarification and restatement during the comment period.

In response to concerns about our policy restatement articulated by stakeholders after publication of the CY 2009 OPPS/ASC final rule with comment period, we further refined our supervision policies in the CY 2010 OPPS/ASC proposed rule and final rule with comment period (74 FR 35365 and 74 FR 60679 through 60680, respectively). We established rules for diagnostic services furnished in locations other than PBDs (that is, in the hospital and under arrangement in nonhospital facilities). Accordingly, we expanded and refined the regulatory language regarding direct supervision of diagnostic services in those locations to refer to presence of the supervisory practitioner in the hospital or PBD (for services furnished in those locations) or in the office suite (for services furnished under arrangement in nonhospital space). For therapeutic services, we increased hospitals' flexibility regarding the direct supervision requirement by allowing all nonphysician practitioners whose services are those the practitioner is legally authorized to perform under State law that ''would otherwise be covered if furnished by a physician or as an incident to a physician's service'' (''would be physicians' services'') to supervise outpatient therapeutic services that are within their scope of practice under State law and their hospital-granted or CAH-granted privileges (sections 1861(s)(2)(K) through (N) of the Act; §§ 410.71 through 410.77 of the regulations). However, in implementing the new

benefits for pulmonary rehabilitation (PR), cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) services, we required that direct supervision of those services furnished in the hospital outpatient setting must be provided by a doctor of medicine or a doctor of osteopathy because, as we discussed in the CY 2010 and CY 2011 OPPS/ASC final rules with comment period (74 FR 60573 and 60582 and 75 FR 72009, respectively), the statute specifies that these services are physician-supervised (section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110–275). In addition, in the CY 2011 OPPS/ASC final rule with comment period, we revised our regulations at § 410.27 to remove the physical boundary requirements for direct supervision, and instead to allow the supervisory practitioner simply to be ''immediately available,'' meaning physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure, but without reference to any particular physical boundary.

In the CY 2010 OPPS/ASC final rule with comment period, we finalized a technical correction to the regulation at § 410.27 to clarify that the direct supervision requirement under that section applies to services furnished in CAHs as well as hospitals. Specifically, we added the phrase ''or CAH'' in the title and throughout the regulation text wherever the text referred only to ''hospital,'' to clarify that the requirements for payment of hospital outpatient therapeutic services in that section apply to CAHs as well as other types of hospitals. As we discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72000), we viewed this as a technical correction because the Act applies the same regulations to hospitals and CAHs when appropriate (CAHs are included if ''the context otherwise requires'' under section 1861(e) of the Act).

In response to our clarification that CAHs are subject to the direct supervision standard for payment of outpatient therapeutic services, CAHs and the hospital community at large suggested that CAHs should be exempt from this requirement because the requirement is at odds with longstanding and prevailing practices of many CAHs. For example, commenters noted that, due to low volume of services, a practitioner retained on the campus of a small rural hospital or CAH to meet supervision requirements may not have other concurrent responsibilities or patient care, which could lead to inefficiencies. In their correspondence and discussion in public forums, CAHs and small rural hospitals explicitly raised concerns about services that extend after regular operating hours, especially observation services. They asserted that direct supervision is not clinically necessary for some services that have a significant monitoring component that is typically performed by nursing or other auxiliary staff, including IV hydration, blood transfusions, and chemotherapy. They stated that their facilities have protocols to safely deliver all of these services, relying on nursing or other hospital staff to provide the service and having a physician or nonphysician practitioner available by phone to furnish assistance and direction throughout the duration of the therapeutic service.

We provided guidance regarding the flexibility that we believe exists within our requirement for direct supervision for an emergency physician or nonphysician practitioner, who would be the most likely practitioners staffing a small rural hospital or CAH, to provide the supervision, on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/05_OPPSGuidance.asp#TopOfPage*. However, these hospitals continued to express difficulty in meeting the standard. Small rural hospitals and CAHs indicated that, regulations notwithstanding, many of them did not have appropriate staff arrangements to provide the required supervision of some services, particularly services being provided after hours or consisting of a significant monitoring component that last for an extended period of time. In addition, the broader hospital community began requesting that we modify our policy to permit a lower level of supervision for therapeutic services for all hospitals.

After consideration of these requests, on March 15, 2010, we issued a **Federal Register** notice of nonenforcement of the requirement for direct supervision of outpatient therapeutic services in CAHs (which is available on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/Downloads/CMS_1504FC_OPPS_2011_FR_Physician_Supervision_Nonenf_Notice.pdf*). While CAHs remained subject to the direct supervision standard, we instructed our contractors not to evaluate or enforce the standard in CY 2010 until the agency could revisit the supervision policy during the CY 2011 rulemaking cycle.

As indicated above, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71998 through 72013), we further adjusted the direct supervision standard to increase flexibility for hospitals while maintaining an appropriate level of quality and safety and consistent with the incident to statutory provision. Specifically, we redefined direct supervision to remove all requirements that the supervisory practitioner remain present within a particular physical boundary, although we continued to require immediate availability. We also established a new category of services, ''nonsurgical extended duration therapeutic services'' (extended duration services), which have a substantial monitoring component. We specified that direct supervision is required for these services during an initiation period, but once the supervising physician or nonphysician practitioner has determined the patient is stable, the service can continue under general supervision.

In addition, in response to concerns expressed by the industry about appropriate levels of supervision for certain services furnished in various settings (for example, chemotherapy administration, and post-operative recovery services), we stated our intent to create through the CY 2012 rulemaking cycle an independent advisory review process for consideration of stakeholder requests for assignment of supervision levels other than direct supervision for specific outpatient hospital therapeutic services. We stated that the review entity would evaluate services for assignment of both higher (personal) and lower (general) levels of supervision because, in the course of evaluating a given service, the review entity may find that personal supervision is the most appropriate level (75 FR 72006). We also indicated that, as an interim measure while we are in the process of establishing an advisory review body, we would extend the nonenforcement policy for direct supervision of outpatient therapeutic services provided in CAHs for a second year through CY 2011 (which is available at the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/Downloads/CMS_1504FC_OPPS_2011_FR_Physician_Supervision_Nonenf_Notice.pdf*). In addition, we expanded the nonenforcement notice to include small and rural hospitals that have 100 or fewer beds, as defined by TOPs criteria, because we believe that these hospitals experience resource constraints that are similar to CAHs.

We indicated that we would consider the Federal Advisory Ambulatory Payment Classification (APC) Panel as a potential candidate to serve as the independent review entity to consider requests for alternative service-specific

supervision standards, and we requested public comment both on that idea and on other aspects of the review process, such as evaluation criteria and the potential structure of the process. We suggested the APC Panel could serve as the review entity because it is already funded and established by law under the Federal Advisory Committee Act (FACA, Pub. L. 92–463) to make independent recommendations to CMS. The APC Panel membership is geographically diverse, and it includes members with clinical as well as administrative, hospital billing, and coding expertise. In response to our discussion in the CY 2011 OPPS/ASC final rule with comment period, we received public comments and other considerable input on these topics from the hospital and CAH community and from rural stakeholders. In this proposed rule, we discuss these comments and our proposals for the independent review process in CY 2012, taking into account the comments received in response to the CY 2011 OPPS/ASC final rule with comment period.

With respect to outpatient hospital diagnostic services, following our revisions to the regulation at § 410.28(e) in the CY 2010 OPPS/ASC final rule with comment period described above, we have received very few comments from stakeholders regarding our revised policy. Therefore, we are not proposing any changes to those requirements in this proposed rule.

B. Issues Regarding the Supervision of Hospital Outpatient Therapeutic Services Raised by Hospitals and Other Stakeholders

1. Independent Review Process

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72012), we stated our intent to develop an independent technical review process through our CY 2012 rulemaking. Public comments that we received on this statement of intent focused on three primary topics: the potential nature of the review entity; the potential nature and structure of the review process; and potential means of evaluating services.

Commenters were generally favorable towards the establishment of an independent review entity, including use of the APC Panel as that entity, provided that CMS expand the APC Panel charter and its membership to include representatives of CAHs. They also were concerned that CMS ensure an adequate representation of clinicians on the Panel to provide the appropriate clinical review of supervision levels. Some commenters supported creation by law of a new committee comprised solely of clinicians (at least 15 multi-specialty physicians and mid-levels). Citing the potentially significant impact of the supervision rules on rural and CAH providers, these commenters also recommended that at least 50 percent of committee members be comprised of representatives of CAHs and other providers from rural States, with recommendations for supervision levels decided by majority vote. Other commenters preferred use of an existing body (for example, the APC Panel or the Relative Value Scale Update Committee (RUC)) and emphasized inclusion of nonclinical professionals with expertise in hospital/facility resource consumption in order to balance the panel's expertise. Some commenters sought to assure that if the APC Panel were selected, it would remain appropriately balanced and qualified to carry out its current role in APC deliberations under section 1833(t)(9)(A) of the Act. Commenters also were supportive of CMS using its authority to convene a Technical Expert Panel (TEP) as the review entity, but noted potential lack of available funding.

In considering these issues, we believe that the best course of action is to obtain independent advice with the transparency, formality and process associated with a Federal advisory committee. Stakeholders may view the recommendations of a FACA Committee as having greater legitimacy and, thus, its recommendations could be more useful to CMS than the recommendations that would be offered by other types of groups such as the American Medical Association's Relative Value Update Committee or a TEP. A TEP might be more conducive to in-depth research and data analysis, but unless the TEP complies with the Federal Advisory Committee Act, the TEP as a group cannot provide advice to CMS.

At this time, funding is not available to CMS to convene a new entity; therefore, we believe the most realistic and appropriate option is to use an existing body for reviewing supervision levels. We agree with commenters that the review body should be representative of all types of facilities that are subject to the supervision rules for payment, but we disagree that it should be 50 percent representative of a specific class of hospitals, particularly if those hospitals represent a minority of hospital outpatient service volume and payments. In addition, while we agree with commenters that clinical expertise is critical to this review process, we believe that additional perspectives should be represented, including those of hospital administrators and coding representatives. Under the FACA, committees and their subcommittees must have balanced membership with respect to points of view represented and the topics that are under their consideration; therefore, a Federal advisory review entity would be required to have a balanced representation of geographic interests, including those of CAHs and rural hospitals. It also would be required to have a balanced representation of clinical as well as any other relevant expertise.

With respect to structure of the actual review process, most commenters requested that we subject the recommendations of the review entity and CMS' decisions to notice and comment rulemaking. However, most commenters also requested a ''real-time'' process that would be more flexible than annual rulemaking and allow for continuous evaluation of services. Commenters further requested that there be a mechanism for reconsideration of CMS' decisions. In addition, they requested that CMS not allow any information presented to the review entity in the course of the review process to be used for enforcement purposes.

We believe that employing a subregulatory process to establish CMS' final decisions may best serve the interests of beneficiaries and also meet the needs of other stakeholders. While rulemaking would arguably provide some additional procedural protections to stakeholders in terms of an opportunity for notice and comment, due to the time involved in rulemaking, stakeholders would only be able to request changes in supervision levels once a year. Similarly, if confined to annual rulemaking, CMS would not be able to make swift changes to address any problems associated with supervision levels, for example access to care. Historically, CMS has used subregulatory processes rather than rulemaking to issue changes in certain administrative specifications at the level of individual CPT codes due to a need for agility in making such changes. For example, CMS has used a subregulatory process to set supervision levels for individual diagnostic services under the MPFS, which are adopted for provision of those services in the hospital outpatient setting. Given the strong stakeholder interest in policy changes in supervision levels for outpatient hospital therapeutic services, we believe we should provide an opportunity for public comment on our proposed decisions (which would be based upon

the review entity's recommendations) prior to finalizing them.

We agree with commenters that there should be a means of requesting reevaluation of CMS' decisions. However, because there is a potential for significant administrative burden in reconsidering requests for reevaluation, we believe that stakeholders should be required to provide significant justification to support consideration of a request for a change in supervision levels that has previously been considered, such as new clinical evidence, new technology, or new techniques in how patient care is furnished. In addition, we believe that new consideration of previously considered requests should receive the same independent evaluation as the initial request. Therefore, once we decide to consider a decision, we would request a new review by the independent review entity and follow the same process as a new request. The review entity would then deliberate and make a new recommendation to CMS, and CMS would then make another determination based on the new recommendation.

We received substantial comment on how we might structure the evaluation process. First, stakeholders continued to request that we establish a default supervision standard of general supervision for all therapeutic services, and assign direct supervision only as indicated through the review process. Commenters believed it was important that the review entity and CMS not consider services for assignment of personal supervision because many services that might qualify for personal supervision are already personally performed by a physician or nonphysician practitioner. Commenters also noted that certain services are not furnished personally by these practitioners and instead are furnished personally by auxiliary personnel such as technicians or registered nurses (RNs). However, commenters maintained that hospitals currently furnish adequate supervision of those services by higher-level practitioners. Further, they requested that any evaluation for personal supervision be based on clinical evidence and evidence of a current deficiency in the quality of care.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72006), we expressed our belief that direct supervision is the most appropriate level of supervision for most hospital outpatient therapeutic services due to the ''incident to'' nature of most hospital outpatient therapeutic services. We discussed how our historic requirements for physician (or nonphysician practitioner) orders and direct physician involvement in patient care stem from our interpretation of the nature of incident to services under the law. We reviewed our regulations and other guidance over the years which reflect these beliefs and interpretations (75 FR 71999 and 72005).

We continue to believe that, while the statute does not explicitly mandate direct supervision, direct supervision is the most appropriate level of supervision for most hospital outpatient services that are authorized for payment as ''incident to'' physicians' services unless personal supervision is appropriate. We also believe that the ''incident to'' nature of hospital outpatient therapeutic services under the law permits us to recognize specific circumstances in which general supervision is appropriate, as we have for extended duration services, and that CMS has authority to accept a recommendation by the review entity of general supervision for a given service. However, we continue to believe that direct supervision is the most appropriate level of supervision for the great majority of hospital outpatient therapeutic services and, as such, it is the proper choice for a default supervision standard.

In the course of evaluating a stakeholder request for review of the supervision level required for a given service, the independent review entity may recommend that personal supervision is the most appropriate level of supervision for the service. It may also be appropriate to assign personal supervision to certain services to ensure that auxiliary personnel or personnel in training (such as medical students) are adequately supervised. As we indicated in last year's final rule with comment period, our supervision policy is designed to preserve both the quality and safety of purchased hospital outpatient services for Medicare beneficiaries. Accordingly, we believe that the review entity should have authority to recommend personal supervision for a service if, in the course of its evaluation, it believes that personal supervision is most appropriate and safe.

We believe that the review entity should base its recommendations on any clinical evidence that is available. It should also take into consideration any known impacts of supervision on the quality of care. As we have previously noted (75 FR 72005), while literature or clinical opinions may exist on the risk of adverse outcomes and susceptibility to medical error associated with the provision of specific hospital outpatient procedures when a physician is not present, we do not know of any analyses that have directly examined levels of supervision and patient outcomes in the hospital outpatient setting. This may be an area for future study.

With respect to an initial agenda of services for the review entity, commenters recommended that CMS begin evaluating services with work Relative Value Units (RVUs) < 1.0 (approximately 160 services), which they believe would include many extended duration services. They also requested that CMS evaluate surgical procedures (especially minor surgical procedures) and portions of the surgical recovery period for general supervision. We continue to support direct supervision as the default supervision level for all hospital outpatient therapeutic services. We believe it would be appropriate to solicit services for evaluation from stakeholders, in a process similar to that currently used to solicit agenda items for the APC Panel meetings. Also, it will be important for CMS to be able to place services on the Panel agenda as issues arise, similar to the way the agency brings inpatient only procedures before the APC Panel for consideration of removal from the inpatient only list. If we received an unmanageable number of requests during a particular period, we propose to prioritize requests according to service volume, total expenditures for the service, frequency of requests, and the repetition of requests from prior public comments. In addition, we propose to require the submitter of a request to furnish a justification for the request, supported to the extent possible with clinical evidence. We would use the justifications to assist in prioritizing agenda items.

Commenters suggested that evaluation criteria include the general categories of risk, complexity, the type of professional and scope of practice of the professional furnishing the service, and whether the service is furnished in a CAH or rural facility, taking into consideration the workforce typically available to those hospitals. We agree with the suggested general parameters of risk and complexity, and we offer several similar potential measures below for the public's consideration. In recommending a level of supervision that would apply for a particular service described by a CPT code, we also believe that the review entity could take into consideration the varied environments in which the service described by that code may be delivered. We anticipate that representatives of different types of facilities on the Panel will facilitate an

understanding of any potential variation in conditions at different types of facilities.

Under the conditions of participation for hospitals at § 482.11(a), hospitals must comply with applicable Federal law related to the health and safety of patients. Under § 482.11(c), hospitals must also assure that personnel are licensed or meet other applicable standards of State or local law. Registered nurses (RNs) are not authorized to independently furnish services that would be physicians' services if furnished by a physician as described in section 1861(s)(2)(K) of the Act. In addition, under their State scope of practice, RNs are not licensed to independently furnish these services. Under the condition of participation regulation at § 482.11, hospitals must comply with these Federal and State rules. Because under the law RNs are not permitted to furnish ''would be'' physicians' services, we do not believe RNs should be permitted to supervise those services. Therefore, under the regulations at §§ 410.27 and 482.11, RNs cannot supervise ''would be'' physicians' services that they may not independently furnish (though they may furnish some of them under the supervision of an appropriately higher level practitioner), even in a CAH or rural facility that may be experiencing difficulty obtaining a higher level practitioner to supervise or furnish those services. In this case, the statute and the regulations determine at the service level which nonphysician professionals can and cannot supervise therapeutic services.

Furthermore, we note that we anticipate extending the notice of nonenforcement for direct supervision of outpatient therapeutic services in both CAHs and small rural hospitals another year through CY 2012, which we discuss in section X.C.2. of this proposed rule.

2. Conditions of Payment and Hospital Outpatient Therapeutic Services Described by Different Benefit Categories

Another issue that has been raised to us is the applicability of the payment conditions for hospital outpatient therapeutic services in § 410.27 to services described in paragraphs or subparagraphs of section 1861(s) of the Act other than section 1861(s)(2)(B) of the Act, which describes outpatient hospital services incident to physicians' services. Over the years, and particularly in recent months, we have received inquiries asking that we explain or clarify our application of the payment conditions under our regulation at § 410.27, which explicitly applies to ''hospital services and supplies furnished incident to a physician service to outpatients,'' to outpatient therapeutic services other than those specified under section 1861(s)(2)(B) of the Act. For example, we have received inquiries as to whether it is permissible for hospitals to furnish radiation therapy (described under section 1861(s)(4) of the Act) or ambulatory surgical center services (described under section 1832(a)(2)(F)(i) of the Act) under arrangement in locations that are not provider-based. Some have suggested that the language in § 410.27 is not applicable to services described by benefit categories in section 1861(s) of the Act other than section 1861(s)(2)(B) of the Act because § 410.27 only refers to ''incident to'' services.

Although we acknowledge the language of § 410.27 could be read as limited to services and supplies described under section 1861(s)(2)(B) of the Act, hospital services incident to physicians' services furnished to outpatients, we have not interpreted the regulation so narrowly. For instance, in the CY 2010 OPPS/ASC final rule with comment period, we noted that, long before the OPPS, we required that hospital services and supplies furnished to outpatients incident to a physician's service must be furnished ''on a physician's order by hospital personnel and under a physician's supervision'' (section 3112.4 of the Medicare Intermediary Manual). We also clearly treated all nondiagnostic services that are furnished to hospital outpatients as ''incident to services'' (sections 3112 and 3112.4 of the Medicare Intermediary Manual; Section 20.5, Chapter 6, of the Medicare Benefit Policy Manual (Pub. 100–02)). While we have not delineated this position as clearly in the regulations, and while the regulation text of § 410.27 only explicitly refers to ''incident to'' services, we note that our policy is longstanding and, in fact, predates the OPPS. In longstanding manual guidance, we have expressed our view that direct supervision is required for hospital outpatient therapeutic services, and suggested that this requirement stems from the ''incident to'' nature of those services. In the CY 2010 OPPS/ASC final rule with comment period, we stated, ''Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians and practitioners in the treatment of patients'' (74 FR 60584 through 60585). We indicated that outpatient therapeutic services and supplies must be furnished under the order of a physician or other appropriate nonphysician practitioner, and by hospital personnel under the direct supervision of a physician or appropriate nonphysician practitioner.

Thus, we have long maintained that all hospital outpatient therapeutic services are, in some sense, furnished ''incident to'' a physician's service even when described by benefit categories other than the specific ''incident to'' provision in section 1861(s)(2)(B) of the Act. Because hospital outpatient therapeutic services are furnished ''incident to'' a physician's professional service, we believe the conditions for payment, including the direct supervision standard, should apply to all of these services. As discussed above, because the statute includes specific requirements for physician supervision of PR, CR, and ICR, we believe that those statutory specifications take precedence over the agency's general requirements.

C. Proposed Policies on Supervision Standards for Outpatient Therapeutic Services in Hospitals and CAHs

In this proposed rule, we are proposing policies for the independent review process, grouped under three key topics: selection of a review body; structure of the review process; and evaluation criteria.

1. Selection of Review Entity

We are proposing that the existing APC Panel serve as the independent review entity. However, we would make some modifications to the APC Panel scope and composition in order to create a body that is prepared to address supervision standards and reflects the full range of parties subject to the standards. Specifically, we would use the discretionary authority in the Panel charter to expand its scope to include the topic of supervision standards. We are proposing to add several (2 to 4) representatives of CAHs as Panel members so that all hospitals subject to the supervision rules for payment would be represented. However, CAHs would not participate in deliberations about APC assignments under the OPPS, as these assignments do not affect CAHs. According to customary practice for the APC Panel, we are proposing to create a supervision subcommittee on the Panel, with balanced representation, that is charged to evaluate appropriate supervision standards for individual services and present its deliberations to the full Panel. Each member of the full

Panel would then vote to decide on the Panel's recommendation to CMS.

We are proposing to use the APC Panel for many reasons. As we discussed above, funding is not available to CMS at this time to convene a new entity. Also, it is not clear that the entire resources of a new body are necessary to accomplish the consideration of service-specific supervision standards, especially once initial determinations are made regarding key services. We are also proposing to use the APC Panel because we believe it is important to obtain advice that carries the weight of a Federal advisory recommendation, which may have greater legitimacy both with stakeholders and with CMS compared to the opinions of other types of groups.

In addition to being already established and funded, the APC Panel would necessarily be inclusive and well-balanced because it is subject to the FACA rules. Consistent with stakeholders' requests that the review entity have balanced representation from all hospitals that are subject to the supervision rules, the Federal Advisory APC Panel would be required by the FACA to have balanced membership on committees and their subcommittees with respect to the topics—in this case, supervision—that are under their consideration. In addition, the Panel incorporates clinical as well as facility, administrative, and coding perspectives. Commenters have been generally favorable towards selection of the APC Panel, provided we make the changes to the APC Panel that we are proposing in this proposed rule.

2. Review Process

We are proposing to issue agency decisions based on APC Panel recommendations through sub-regulatory guidance. We would use a process similar to the one currently used to set supervision levels for diagnostic services under the MPFS, which are adopted for provision of those services in the hospital outpatient setting. CMS' decisions (which would be based upon the Panel's recommendations) would be posted on the OPPS Web site for public review and comment, and would be effective either in July or January following the most recent APC Panel meeting, or only in January of the upcoming payment year. In setting the diagnostic supervision levels under the MPFS, there is no provision for public comment. However, given the strong stakeholder interest in this topic and the extent of prior dialogue with the various stakeholders, we believe it is important to provide some means of notice and comment on our proposed decisions prior to finalizing them.

The flexibility of a subregulatory process in comparison to rulemaking would allow stakeholders to submit requests for evaluations of services on a more frequent basis (at least twice a year at APC Panel meetings) rather than only annually, which most commenters requested. It also would give CMS the ability to respond more rapidly to any issues that may arise in access to care or patterns of care. Subjecting CMS' decisions to notice and comment rulemaking would provide a more structured, formal review of decisions, but changes could only be requested or made once a year due to the annual OPPS/ASC rulemaking cycle.

3. Evaluation Criteria

To begin evaluating services in CY 2012, we are proposing to use the same APC Panel process that is used to solicit services or categories of services from stakeholders to construct the agenda to solicit potential services for consideration of a change in supervision level. In addition, as discussed in section X.C.2. of this proposed rule, we are proposing that CMS would have the ability independently to ask the Panel to review the supervision level for one or more services as necessary. If we receive an unmanageable number of requests, we are proposing to prioritize requests by service volume, total expenditures and/or frequency of requests. We also are proposing to prioritize services requested for review through public comment on the CY 2010 and CY 2011 OPPS/ASC proposed rules. We are proposing to require requests to include justification for the change in supervision level that is sought, supported to the extent possible with clinical evidence. We also would consider these justifications in deciding which services to forward to the APC Panel for evaluation.

We are proposing to charge the Panel with recommending a supervision level (general, direct, or personal) to ensure an appropriate level of quality and safety for delivery of a given service, as defined by a CPT code. The Panel should take into consideration the context in which the service is delivered, that is, the clinical, payment, and quality context of a patient encounter. In recommending a supervision level to CMS, we are proposing that the Panel assess whether there is a significant likelihood that the supervisory practitioner would need to reassess the patient and modify treatment during or immediately following the therapeutic intervention, or provide guidance or advice to the individual who provides the service. In answering that question, the Panel would consider—

- Complexity of the service;
- Acuity of the patients receiving the service;
- Probability of unexpected or adverse patient event; and
- Expectation of rapid clinical changes during the therapeutic service or procedure.

These criteria include, but extend well beyond, the likelihood of the need to manage medical emergencies during or after the provision of the service. As we have stated in previous rules (74 FR 60580 and 75 FR 72007 and 72010), the supervisory responsibility is more than the mere capacity to respond to an emergency. It also includes being available to reassess the patient and potentially modify treatment as needed on a nonemergency basis. It includes the ability to redirect or take over performance of the service and to issue any additional necessary orders.

We are proposing that, in the event there has been a previous consideration and decision on the supervision standard for a service, we would consider the request and, as warranted, forward the request to the APC Panel for its review. For requests for review of a service that has already been considered, we are proposing to require the requestor to submit new evidence to support a change in policy, for example, evidence of a change in clinical practice patterns due to new techniques or new technology. If sufficient new information was provided with the request, CMS would send the request to the APC Panel, and the Panel would reconsider the service and make another recommendation to CMS, which could be the same or a different level of supervision than the current level for the service.

Finally, in the interim period while we work toward establishing the independent review process, we anticipate that we will extend the notice of nonenforcement of the requirement for direct supervision in CAHs and small rural hospitals as defined by the notice (available on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp*) another year, through CY 2012. The purpose of this proposed policy would continue to be to allow these facilities time to meet the direct supervision standard while we continue to deliberate on any policy alternatives. Under our current timeline, we would not complete policy decisions on many key services until sometime in 2012.

We note that we have not yet defined the terms ''personal supervision'' or ''general supervision'' for the hospital outpatient setting, except, as explained above, for general supervision in relation to extended duration services in § 410.27(a)(1)(v)(A). Because we are proposing to allow the independent review entity to recommend that CMS assign either personal or general supervision to other hospital outpatient therapeutic services, we are proposing to define these terms in the regulations at proposed new § 410.27(b)(1)(vi). We are proposing to use the definitions established for purposes of the MPFS as specified at § 410.32(b)(3). Specifically, ''personal supervision'' would have the same meaning as the definition specified at § 410.32(b)(3)(iii) and ''general supervision'' would have the same meaning as the definition specified in § 410.32(b)(3)(i), which is the same definition that we established for the general supervision portion of an extended duration service.

4. Conditions of Payment and Hospital Outpatient Therapeutic Services Described by Different Benefit Categories

With respect to the issue of application of the payment conditions in § 410.27 to services described by benefit categories other than section 1861(s)(2)(B) of the Act, we are proposing to amend our regulations to clarify our policy. Therapeutic services and supplies described by benefit categories other than the hospital outpatient ''incident to'' services under section 1861(s)(2)(B) of the Act are nevertheless subject to the conditions of payment in § 410.27 when they are furnished to hospital outpatients and paid under the OPPS or to CAHs under section 1834(g) of the Act.

We believe that this clarification could most readily be accomplished by more specifically defining the services and supplies described in the regulation text to which the requirements at § 410.27 apply. Accordingly, we are proposing to revise the description of the services and supplies addressed in § 410.27(a) by adding the term ''therapeutic'' so that paragraph (a) would read, ''Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service'' to outpatients. We are proposing to define these services, similar to the way they are currently defined in Section 20.5, Chapter 6, of the Medicare Benefit Policy Manual, to mean ''all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or practitioner in the treatment of the patient.'' We would also add the term ''therapeutic'' to the title of § 410.27 so that it would read, ''Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.''

We believe it is important that we continue to apply the requirements in § 410.27 to all hospital outpatient therapeutic services and supplies that are paid under the OPPS and to services furnished in CAHs that are paid under section 1834(g) of the Act. In addition to the supervision rules, the payment conditions in § 410.27 include rules regarding services furnished under arrangements and in PBDs. The goals of the ''under arrangements'' and PBD rules are different from the safety and quality goals of the supervision rules. They ensure clinical and financial integration between the main hospital and any on-campus or off-campus departments of hospitals. In particular, § 410.27(a)(1)(iii) subjects hospital outpatient services to the requirements in § 413.65 for PBDs of hospitals. The provider-based regulations in § 413.65 govern numerous aspects of PBD operations including quality assurance, accountability to hospital medical director staff, licensure, personnel management, how far the departments can be located from the main hospital, and assurance that the departments are serving the same population as the main provider. Section 410.27(e) subjects services to the ''under arrangement'' regulations at § 410.42(a) which govern the liabilities of the beneficiary and other parties when hospitals contract services out. It is important to reiterate that § 410.27 is applicable to all hospital outpatient therapeutic services. We note, for example, that ASCs are not permitted to enter into arrangements with hospitals to furnish hospital outpatient services. We believe we should clarify and reinforce our longstanding policy that hospitals are not permitted to furnish therapeutic services or surgery under arrangement with ASCs because under § 413.65(a)(1)(ii)(A), CMS does not make provider-based determinations regarding ASCs and under § 410.27(a)(1)(iii) therapeutic services must be furnished in provider-based space. Moreover, a hospital is not permitted to furnish services to hospital outpatients under arrangements with an ASC because ASCs are paid under section 1833(i)(2)(D) of the Act (the ASC payment system), not under section 1833(t) of the Act (the OPPS payment system). As a result, an ASC could not be a provider-based department of a hospital for purposes of § 410.27. If § 410.27 did not apply, an ASC could furnish hospital outpatient therapeutic services under arrangements and obtain payment at the OPPS rate rather than the ASC rate. This practice would distort the financial incentives within those payment systems, and would be contrary to the advice and determinations that have historically been made by CMS and other enforcement bodies such as the Office of the Inspector General.

In addition, § 410.27(a)(1)(ii) subjects hospital outpatient services to the incident to rules that CMS has historically applied to all therapeutic services. As we discussed above, these rules ensure that services are ordered by a physician (or appropriate nonphysician practitioner) and that he or she is directly involved in the delivery of care. Sections 410.27(b) and (c) subject services to other significant rules governing drugs and biologicals and emergency services.

Additionally, we believe that there is a similar level of clinical risk in the therapeutic hospital outpatient services covered under other benefit categories that are not explicitly defined as ''incident to'' services. For example, stereotactic radiosurgery (a radiation therapy service under section 1861(s)(4) of the Act) is a high risk and technically demanding surgical procedure. We do not believe that the current requirements under § 410.27 regarding supervision, under arrangement, provider-based, and other aspects of service, were intended to apply only to a subset of hospital outpatient therapeutic services and supplies, or that the agency ever intended to omit large classes of services that are routinely furnished to hospital outpatients from being governed by this regulation.

5. Technical Corrections to the Supervision Standards for Hospital Outpatient Therapeutic Services Furnished in Hospitals or CAHs

We recently noted that the text of §§ 410.27(b) and (c) includes cross-references to section § 410.168 of the regulations, which is obsolete. We believe that § 410.27(b) refers to § 410.168 in error and should instead reference § 410.29 (Limitations on drugs and biologicals). We are proposing to correct § 410.27(b) so that it cross-references § 410.29. It would then read, ''Drugs and biological are also subject to the limitations specified in § 410.29.'' In addition, we are proposing to update § 410.27(c) to cross-reference the

sections of the regulation that have replaced § 410.168, that is, Part 424, Subparts G and H. For this update, we are proposing to revise paragraph (c) to read, ''Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in subpart G of Part 424 of this chapter'' and to add a new paragraph (d) to read, ''Rules on emergency services furnished to outpatients in a foreign country are specified in subpart H of Part 424 of this chapter''. Accordingly, we are proposing to redesignate the existing paragraphs (d) through (f) of § 410.27 as paragraphs (e) through (g), respectively.

In addition, we noted that CAHs are not specifically named in the definition of nonsurgical extended duration therapeutic services at § 410.27(a)(1)(iv)(E). We are making a technical correction to insert the words ''or CAH'' after ''hospital'' in this paragraph. This is the same technical correction that we made throughout § 410.27 in the CY 2010 OPPS/ASC final rule with comment period, discussed above. This technical correction clarifies that CAHs are subject to all of the requirements of § 410.27 in the same manner as all other types of hospitals.

6. Summary

In summary, we are proposing to establish the Federal Advisory APC Panel as an independent review body that would evaluate individual outpatient therapeutic services for potential assignment by CMS of general (lower) or personal (higher) supervision. We are proposing to amend the APC Panel charter to render the Panel more appropriate for this task by expanding its scope to include the topic of supervision. We also are proposing to add two to four members to the Panel who would be representative of CAHs, so that there is broad representation of the types of hospitals that are subject to the supervision rules for payment. We are proposing to use the standard APC Panel protocols with respect to frequency of meetings and receiving requests for evaluation and reconsideration of services. However, CMS' decisions based on the Panel's recommendations would not be subject to notice and comment rulemaking, in contrast to recommendations by the Panel on issues other than supervision. We are proposing several means of prioritizing requests for evaluations, particularly if the Panel agenda could not accommodate all timely requests at a particular meeting. We also are proposing clinical and other evaluation criteria that the Panel would use in recommending a supervision level that would apply at the individual CPT code level. As we have not yet defined personal supervision or general supervision for all hospital outpatient therapeutic services, we are proposing definitions for these terms in this proposed rule.

We anticipate extending the notice of nonenforcement for direct supervision in CAHs and small rural hospitals as defined by the notice through CY 2012, because, even if the new APC Panel review process is adopted, we likely will not have finalized our policy decisions on many key services that are reviewed during that year. In addition, we are proposing to clarify our policy that the requirements under § 410.27 apply to outpatient therapeutic services and supplies furnished in hospitals and in CAHs, which includes services and supplies described by Medicare benefit categories other than section 1861(s)(2)(B) of the Act. To that end, we are proposing to redefine the services described in that section to clarify the nature and scope of the included services.

XI. Proposed OPPS Payment Status and Comment Indicators

A. Proposed OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs play an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The proposed CY 2012 status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS*. We note that, in the past, a majority of the Addenda referred to throughout the preamble of our OPPS/ASC proposed and final rules appeared in the printed version of the **Federal Register** as part of the annual rulemakings. However, beginning with this CY 2012 proposed rule, the Addenda will no longer appear in the printed version of the OPPS/ASC rules that are found in the **Federal Register**. Instead, these Addenda will be published and available only via the Internet on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS*.

For CY 2012, we are not proposing to make any changes to the definitions of status indicators that were listed in Addendum D1 of the CY 2011 OPPS/ASC final rule with comment period. The proposed CY 2012 status indicators and their definitions are listed in the tables under sections XI.A.1., 2., 3., and 4. of this proposed rule.

1. Proposed Payment Status Indicators to Designate Services That Are Paid under the OPPS

Indicator	Item/code/service	OPPS payment status
G	Pass-Through Drugs and Biologicals	Paid under OPPS; separate APC payment.
H	Pass-Through Device Categories	Separate cost-based pass-through payment; not subject to copayment.
K	Nonpass-Through Drugs and Nonimplantable Biologicals, including Therapeutic Radiopharmaceuticals.	Paid under OPPS; separate APC payment.
N	Items and Services Packaged into APC Rates	Paid under OPPS; payment is packaged into payment for other services. Therefore, there is no separate APC payment.
P	Partial Hospitalization	Paid under OPPS; per diem APC payment.
Q1	STVX-Packaged Codes	Paid under OPPS; Addendum B displays APC assignments when services are separately payable. (1) Packaged APC payment if billed on the same date of service as a HCPCS code assigned status indicator ''S,'' ''T,'' ''V,'' or ''X.'' (2) In all other circumstances, payment is made through a separate APC payment.

Indicator	Item/code/service	OPPS payment status
Q2	T-Packaged Codes	Paid under OPPS; Addendum B displays APC assignments when services are separately payable. (1) Packaged APC payment if billed on the same date of service as a HCPCS code assigned status indicator ''T.'' (2) In all other circumstances, payment is made through a separate APC payment.
Q3	Codes that may be paid through a composite APC	Paid under OPPS; Addendum B displays APC assignments when services are separately payable. Addendum M displays composite APC assignments when codes are paid through a composite APC. (1) Composite APC payment based on OPPS composite-specific payment criteria. Payment is packaged into a single payment for specific combinations of services. (2) In all other circumstances, payment is made through a separate APC payment or packaged into payment for other services.
R	Blood and Blood Products	Paid under OPPS; separate APC payment.
S	Significant Procedure, Not Discounted When Multiple.	Paid under OPPS; separate APC payment.
T	Significant Procedure, Multiple Reduction Applies	Paid under OPPS; separate APC payment.
U	Brachytherapy Sources	Paid under OPPS; separate APC payment.
V	Clinic or Emergency Department Visit	Paid under OPPS; separate APC payment.
X	Ancillary Services	Paid under OPPS; separate APC payment.

We are not proposing any changes to the definitions of status indicators listed above for the CY 2012 OPPS. The proposed CY 2012 status indicators and their definitions are displayed in both the table above and in Addendum D1 on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS*.

2. Proposed Payment Status Indicators to Designate Services That Are Paid under a Payment System Other Than the OPPS

We are not proposing to make any changes to the definitions of status indicators listed below for the CY 2012 OPPS.

Indicator	Item/code/service	OPPS payment status
A	Services furnished to a hospital outpatient that are paid under a fee schedule or payment system other than OPPS, for example.	Not paid under OPPS. Paid by fiscal intermediaries/MACs under a fee schedule or payment system other than OPPS. Services are subject to the deductible and coinsurance unless indicated otherwise.
	• Ambulance Services • Clinical Diagnostic Laboratory Services • Non-Implantable Prosthetic and Orthotic Devices • EPO for ESRD Patients • Physical, Occupational, and Speech Therapy • Routine Dialysis Services for ESRD Patients Provided in a Certified Dialysis Unit of a Hospital • Diagnostic Mammography	Not subject to deductible or coinsurance.
	• Screening Mammography	Not subject to deductible or coinsurance.
C	Inpatient Procedures	Not paid under OPPS. Admit patient. Bill as inpatient.
F	Corneal Tissue Acquisition; Certain CRNA Services; and Hepatitis B Vaccines.	Not paid under OPPS. Paid at reasonable cost.
L	Influenza Vaccine; Pneumococcal Pneumonia Vaccine	Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance.
M	Items and Services Not Billable to the Fiscal Intermediary/MAC	Not paid under OPPS.
Y	Non-Implantable Durable Medical Equipment	Not paid under OPPS. All institutional providers other than home health agencies bill to DMERC.

The proposed CY 2012 status indicators and their definitions displayed in the table above are also displayed in Addendum D1 on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS*.

3. Proposed Payment Status Indicators to Designate Services That Are Not Recognized under the OPPS But That May Be Recognized by Other Institutional Providers

We are not proposing changes to the definitions of status indicators listed below for the CY 2012 OPPS.

Indicator	Item/code/service	OPPS payment status
B	Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and13x).	Not paid under OPPS.

Indicator	Item/code/service	OPPS payment status
		• May be paid by fiscal intermediaries/MACs when submitted on a different bill type, for example, 75x (CORF), but not paid under OPPS. • An alternate code that is recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x) may be available.

The proposed status indicators and their definitions listed in the table above are also displayed in Addendum D1 on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS*.

4. Proposed Payment Status Indicators to Designate Services That Are Not Payable by Medicare on Outpatient Claims

We are not proposing changes to the definitions of payment status indicators listed below for the CY 2012 OPPS.

Indicator	Item/code/service	OPPS payment status
D	Discontinued Codes	Not paid under OPPS or any other Medicare payment system.
E	Items, Codes, and Services: • That are not covered by any Medicare outpatient benefit based on statutory exclusion. • That are not covered by any Medicare outpatient benefit for reasons other than statutory exclusion. • That are not recognized by Medicare for outpatient claims; alternate code for the same item or service may be available. • For which separate payment is not provided on outpatient claims.	Not paid by Medicare when submitted on outpatient claims (any outpatient bill type).

The proposed CY 2012 payment status indicators and their definitions listed in the table above are also displayed in Addendum D1 on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS*.

B. Proposed Comment Indicator Definitions

For the CY 2012 OPPS, we are proposing to use the same two comment indicators that are in effect for the CY 2011 OPPS.

• ''CH''—Active HCPCS codes in current and next calendar year; status indicator and/or APC assignment have changed or active HCPCS code that will be discontinued at the end of the current calendar year.

• ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

We are using the ''CH'' indicator in this proposed rule to call attention to proposed changes in the payment status indicator and/or APC assignment for HCPCS codes for CY 2012 compared to their assignment as of June 30, 2011. We believe that using the ''CH'' indicator in this proposed rule will help facilitate the public's review of the changes that we are proposing for CY 2012.

We are proposing to use the ''CH'' comment indicator in the CY 2012 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, would change in CY 2012 compared to their assignment as of December 31, 2011. We believe that using the ''CH'' indicator in the CY 2012 OPPS/ASC final rule with comment period will facilitate the public's review of the changes that we will make for CY 2012. The use of the comment indicator ''CH'' in association with a composite APC indicates that the configuration of the composite APC has changed from the CY 2012 OPPS/ASC final rule with comment period.

We are proposing to continue our current policy regarding the use of comment indicator ''NI.''

Any existing HCPCS code numbers with substantial revisions to the code descriptors for CY 2012 compared to the CY 2011 descriptors will be labeled with comment indicator ''NI'' in Addendum B to the CY 2012 OPPS/ASC final rule with comment period. However, in order to receive the comment indicator ''NI,'' the CY 2012 revision to the code descriptor (compared to the CY 2011 descriptor) must be significant such that the new code descriptor describes a new service or procedure for which the OPPS treatment may change. We use comment indicator ''NI'' to indicate that these HCPCS codes are open to comment on the CY 2012 OPPS/ASC final rule with comment period. Like all codes labeled with comment indicator ''NI,'' we will respond to public comments and finalize their OPPS treatment in the CY 2013 OPPS/ASC final rule with comment period.

In accordance with our usual practice, CPT and Level II HCPCS code numbers that are new for CY 2012 will also be labeled with comment indicator ''NI'' in Addendum B to the CY 2012 OPPS/ASC final rule with comment period.

Only HCPCS codes with comment indicator ''NI'' in the CY 2012 OPPS/ASC final rule with comment period will be subject to comment. HCPCS codes that do not appear with comment indicator ''NI'' in the CY 2012 OPPS/ASC final rule with comment period will not be open to public comment, unless we specifically request additional comments elsewhere in the final rule with comment period. The CY 2012 treatment of HCPCS codes that appear in the CY 2012 OPPS/ASC final rule with comment period to which comment indicator ''NI'' is not appended will be open to public comment during the comment period

for this proposed rule, and we will respond to those comments in the CY 2012 OPPS/ASC final rule with comment period.

For the CY 2012 OPPS, we are not proposing any changes to the definitions of the OPPS comment indicators for CY 2012. Their proposed definitions are listed in Addendum D2 on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS.*

XII. OPPS Policy and Payment Recommendations

A. MedPAC Recommendations

MedPAC was established under section 1805 of the Act to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to Congress not later than March and June of each year that contain its Medicare payment policy recommendations. This section describes recent recommendations relevant to the OPPS that have been made by MedPAC.

The March 1, 2011 MedPAC ''Report to Congress: Medicare Payment Policy'' included the following recommendation relating to the Medicare hospital IPPS and, in part, to the Medicare hospital OPPS:

Recommendation 3: ''The Congress should increase payment rates for the acute care hospital inpatient and outpatient prospective payment systems in 2012 by 1 percent. The Congress should also require the Secretary of Health and Human Services to make adjustments to inpatient payment rates in future years to fully recover all overpayments due to documentation and coding improvements.'' (page 60)

MedPAC further stated that: ''For outpatient hospital services, the Commission is concerned that significant payment disparities among Medicare's ambulatory care settings (hospital outpatient departments, ambulatory surgical centers, and physician offices) for similar services are fostering undesirable financial incentives. Physician practices and ambulatory surgical centers are being reorganized as hospital outpatient entities in part to receive higher reimbursements. The Commission believes that Medicare should seek to pay similar amounts for similar services, taking into account differences in quality of care and in the relative risks of the patient populations. The Commission is concerned by the trend to reorganize for higher reimbursement and will examine this issue. However, in the interim, the modest update of 1 percent is warranted in the hospital outpatient setting to slow the growing payment rate disparities among ambulatory care settings.'' (page 61)

CMS Response: We note that MedPAC's recommendation is for the Congress to increase IPPS and OPPS payment rates by 1 percent in 2010. Absent action by Congress, we are proposing to follow the statutory requirements that govern the amount of the annual OPD fee schedule increase factor to the OPPS for CY 2012. We discuss the proposed CY 2012 OPD fee schedule increase factor in section II.B. of this proposed rule.

We look forward to reviewing the results of MedPAC's examination of what it perceives as a trend towards reorganization of ambulatory surgical centers and physician offices as hospital outpatient departments to maximize program payment.

The full March 2011 MedPAC report can be downloaded from MedPAC's Web site at: *http://www.medpac.gov/documents/Mar11_EntireReport.pdf.*

B. APC Panel Recommendations

Recommendations made by the APC Panel meeting held on February 28 and March 1, 2011 are discussed in the sections of this proposed rule that correspond to topics addressed by the APC Panel. The reports and recommendations from the APC Panel's February 28 and March 1, 2011 meeting regarding payment under the OPPS for CY 2012 are available on the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.*

C. OIG Recommendations

The mission of the Office of the Inspector General (OIG), as mandated by Public Law 95–452, as amended, is to protect the integrity of the U.S. Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections.

On October 22, 2010, the OIG published a memorandum report entitled ''Payment for Drugs under the Hospital Outpatient Prospective Payment System'' (OIG–03–09–00420). The report may be viewed on the Web site at: *http://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf.* The OIG did not make any recommendations to CMS regarding Medicare payment for drugs and biologicals under the OPPS.

CMS Response: We appreciate the work of the OIG regarding the payment for drugs under the OPPS, and we will take the findings in its report into consideration in the development of our proposed payment policy for CY 2012.

XIII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative Authority for the ASC Payment System

Section 1832(a)(2)(F)(i) of the Act provides that benefits under Medicare Part B include payment for facility services furnished in connection with surgical procedures specified by the Secretary that are performed in an Ambulatory Surgical Center (ASC). To participate in the Medicare program as an ASC, a facility must meet the standards specified in section 1832(a)(2)(F)(i) of the Act, which are set forth in 42 CFR Part 416, Subpart B and Subpart C of our regulations. The regulations at 42 CFR Part 416, Subpart B describe the general conditions and requirements for ASCs, and the regulations at Subpart C explain the specific conditions for coverage for ASCs.

Section 141(b) of the Social Security Act Amendments of 1994, Public Law 103–432, required establishment of a process for reviewing the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act for intraocular lenses (IOLs) that belong to a class of new technology intraocular lenses (NTIOLs). That process was the subject of a final rule entitled ''Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers,'' published on June 16, 1999, in the **Federal Register** (64 FR 32198).

Section 626(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, added subparagraph (D) to section 1833(i)(2) of the Act, which required the Secretary to implement a revised ASC payment system to be effective not later than January 1, 2008. Section 626(c) of the MMA amended section 1833(a)(1) of the Act by adding new subparagraph (G), which requires that, beginning with implementation of the revised ASC payment system, payment for surgical procedures furnished in ASCs shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under the revised payment system.

Section 109(b) of the Medicare Improvements and Extension Act of 2006 of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA), Public Law 109–432, amended section 1833(i)

of the Act by redesignating clause (iv) as clause (v) and adding a new clause (iv) to paragraph (2)(D) and by adding new paragraph (7).

Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to implement the revised ASC payment system '' in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).'' Section 1833(i)(7)(A) of the Act states that the Secretary may provide that any ASC that does not submit quality measures to the Secretary in accordance with paragraph (7) will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year.

Section 1833(i)(7)(B) of the Act provides that, ''[e]xcept as the Secretary may otherwise provide,'' the hospital outpatient quality data provisions of subparagraphs (B) through (E) of section 1833(t)(17) of the Act, added by section 109(a) of the MIEA–TRHCA, shall apply to ASCs in a similar manner to the manner in which they apply under these paragraphs to hospitals under the Hospital OQR Program.

Sections 4104 and 10406 of the Affordable Care Act, Public Law 111–148, amended section 1833(a)(1) and (b)(1) of the Act to waive the coinsurance and the Part B deductible for those preventive services under section 1861(ddd)(3)(A) of the Act as described in section 1861(ww)(2) of the Act (excluding electrocardiograms) that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. Section 4104(c) of the Affordable Care Act amended section 1833(b)(1) of the Act to waive the Part B deductible for colorectal cancer screening tests that become diagnostic. These provisions apply to these items and services furnished in an ASC on or after January 1, 2011.

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act to require that, effective for CY 2011 and subsequent years, any annual update under the ASC payment system be reduced by a productivity adjustment, which is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). Application of this productivity adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

For a detailed discussion of the legislative history related to ASCs, we refer readers to the June 12, 1998 proposed rule (63 FR 32291 through 32292).

2. Prior Rulemaking

On August 2, 2007, we published in the **Federal Register** (72 FR 42470) the final rule for the revised ASC payment system, effective January 1, 2008 (the ''August 2, 2007 final rule''). In that final rule, we revised our criteria for identifying surgical procedures that are eligible for Medicare payment when furnished in ASCs and adopted the method we would use to set payment rates for ASC covered surgical procedures and covered ancillary services furnished in association with those covered surgical procedures beginning in CY 2008. We also established a policy for treating new and revised Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes under the ASC payment system. This policy is consistent with the OPPS to the extent possible (72 FR 42533).

In addition, we established a standard ASC ratesetting methodology that bases payment for most services on the list of ASC covered surgical procedures on the OPPS relative payment weight multiplied by the ASC conversion factor. We also established modifications to this methodology for subsets of services, such as device-intensive services (where the estimated device portion of the ASC payment is the same as that paid under the OPPS) and services that are predominantly performed in the office setting and covered ancillary radiology services (where ASC payment may be based on the MPFS non-facility practice expense (PE) Relative Value Units (RVUs)). Additionally, we established a policy for updating the conversion factor, the relative payment weights, and the ASC payment rates on an annual basis. We also annually update the list of procedures for which Medicare does not make an ASC payment.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66827), we updated and finalized the CY 2008 ASC rates and lists of covered surgical procedures and covered ancillary services. We also made regulatory changes to 42 CFR Parts 411, 414, and 416 related to our final policies to provide payments to physicians who perform non-covered ASC procedures in ASCs based on the facility PE RVUs, to exclude covered ancillary radiology services and covered ancillary drugs and biologicals from the categories of designated health services (DHS) that are subject to the physician self-referral prohibition, and to reduce ASC payments for surgical procedures when the ASC receives full or partial credit toward the cost of the implantable device.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68722), we updated and finalized the CY 2009 ASC rates and lists of covered surgical procedures and covered ancillary services.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60596), we updated and finalized the CY 2010 ASC rates and lists of covered surgical procedures and covered ancillary services. We also corrected some of those ASC rates in a correction notice published in the **Federal Register** on December 31, 2009 (74 FR 69502). In that correction notice, we revised the ASC rates to reflect changes in the MPFS conversion factor and PE RVUs listed for some CPT codes in Addendum B to the CY 2010 MPFS final rule with comment period (74 FR 62017), which were incorrect due to methodological errors and were subsequently corrected in a correction notice to that final rule with comment period (74 FR 65449). We also published a second correction notice in the **Federal Register,** to address changes to the ASC rates resulting from corrections to the PE RVUs identified subsequent to publication of the December 31, 2009 correction notice (75 FR 45700). Finally, we published a notice in the **Federal Register,** to reflect changes to CY 2010 ASC payment rates for certain ASC services due to changes to the OPPS and MPFS under the Affordable Care Act and to reflect technical changes to the ASC payment rates announced in prior correction notices (75 FR 45769).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71800), we updated and finalized the CY 2011 ASC rates and lists of covered surgical procedures and covered ancillary services. We corrected some of the ASC rates that were published in Addenda AA and BB, as well as errors in the preamble text, in a correction notice published in the **Federal Register** on March 11, 2011 (76 FR 13292). The corrections to the ASC Addenda were primarily due to changes to the MPFS conversion factor and PE RVUs listed for some CPT codes in Addendum B and Addendum C to the MPFS for CY 2011 which, in turn, affected office-

based and ancillary radiology payment under the ASC payment system. Following legislative changes to the MPFS for CY 2011 associated with passage of section 101 of the Medicare and Medicaid Extenders Act of 2010 that occurred after publication of the CY 2011 OPPS/ASC and MPFS final rules with comment periods, we posted revised ASC Addenda on our Web site to reflect associated changes to office-based and ancillary radiology payment under the ASC payment system.

3. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

The August 2, 2007 final rule established our policies for determining which procedures are ASC covered surgical procedures and covered ancillary services. Under §§ 416.2 and 416.166 of the regulations, subject to certain exclusions, covered surgical procedures are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and that would not be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered surgical procedures under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate for Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that crosswalk or are clinically similar to ASC covered surgical procedures (72 FR 42478). We note that we added over 800 surgical procedures to the list of covered surgical procedures for ASC payment in CY 2008, the first year of the revised ASC payment system, based on the criteria for payment that we adopted in the August 2, 2007 final rule as described above in this section.

In the August 2, 2007 final rule, we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: Brachytherapy sources; certain implantable items that have pass-through status under the OPPS; certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; certain drugs and biologicals for which separate payment is allowed under the OPPS; and certain radiology services for which separate payment is allowed under the OPPS. These covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment (72 FR 42495). Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). In addition, as discussed in detail in section XIII.B. of this proposed rule, because we base ASC payment policies for covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, we also provide quarterly updates for ASC services throughout the year (January, April, July, and October). The updates are to implement newly created Level II HCPCS and Category III CPT codes for ASC payment and to update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New Category I CPT codes, except vaccine codes, are released only once a year and, therefore, are implemented through the January quarterly update. New Category I CPT vaccine codes are released twice a year and thus are implemented through the January and July quarterly updates.

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new procedures, and procedures for which there is revised coding, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

B. Proposed Treatment of New Codes

1. Proposed Process for Recognizing New Category I and Category III CPT Codes and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims: (1) Category I CPT codes, which describe medical services and procedures; (2) Category III CPT codes, which describe new and emerging technologies, services, and procedures; and (3) Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes. CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect ASCs are addressed both through the ASC quarterly update Change Requests (CRs) and through the annual rulemaking cycle. CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes are recognized on Medicare claims) outside of the formal rulemaking process via ASC quarterly update CRs. This quarterly process offers ASCs access to codes that may more accurately describe items or services furnished and/or provides payment or more accurate payment for these items or services in a more timely manner than if we waited for the annual rulemaking process. We solicit comments on the new codes recognized for ASC payment and finalize our proposals related to these codes through our annual rulemaking process.

We finalized a policy in the August 2, 2007 final rule to evaluate each year all new Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations in the annual OPPS/ASC final rule with comment period regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether they are office-based procedures (72 FR 42533 through 42535). In addition, we identify new codes as ASC covered ancillary services based upon the final payment

policies of the revised ASC payment system.

In Table 41 below, we summarize our proposed process for updating the HCPCS codes recognized under the ASC payment system.

TABLE 41—PROPOSED COMMENT TIMEFRAME FOR NEW HCPCS CODES

OPPS/ASC quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2011	Level II HCPCS codes	April 1, 2011	CY 2012 OPPS/ASC proposed rule.	CY 2012 OPPS/ASC final rule with comment period.
July 1, 2011	Level II HCPCS codes	July 1, 2011	CY 2012 OPPS/ASC proposed rule.	CY 2012 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2011	CY 2012 OPPS/ASC proposed rule.	CY 2012 OPPS/ASC final rule with comment period.
October 1, 2011	Level II HCPCS codes	October 1, 2011	CY 2012 OPPS/ASC final rule with comment period.	CY 2013 OPPS/ASC final rule with comment period.
January 1, 2012	Level II HCPCS codes	January 1, 2012	CY 2012 OPPS/ASC final rule with comment period.	CY 2013 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes	January 1, 2012	CY 2012 OPPS/ASC final rule with comment period.	CY 2013 OPPS/ASC final rule with comment period.

This process is discussed in detail below. We have separated our discussion into two sections based on whether we are proposing to solicit public comments in this CY 2012 OPPS/ASC proposed rule (and responding to those comments in the CY 2012 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2012 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2013 OPPS/ASC final rule with comment period). We note that we sought public comment in the CY 2011 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2011. We also sought public comments in the CY 2011 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2010. These new codes, with an effective date of October 1, 2010, or January 1, 2011, were flagged with comment indicator ''N1'' in Addendum AA and BB to the CY 2011 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2011 OPPS/ASC final rule with comment period. We will respond to public comments and finalize our proposed ASC treatment of these codes in the CY 2012 OPPS/ASC final rule with comment period.

2. Proposed Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2011 for Which We Are Soliciting Public Comments in This CY 2012 OPPS/ASC Proposed Rule

In the April and July CRs, we made effective for April 1 or July 1, 2011, a total of 13 new Level II HCPCS codes and 6 new Category III CPT codes that were not addressed in the CY 2011 OPPS/ASC final rule with comment period. The 13 new Level II HCPCS codes describe covered ancillary services.

In the April 2011 ASC quarterly update (Transmittal 2185, CR 7343, dated March 25, 2011), we added four new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 42 below, these included HCPCS codes C9280 (Injection, eribulin mesylate, 1 mg), C9281 (Injection, pegloticase, 1 mg), C9282 (Injection, ceftaroline fosamil, 10 mg), and Q2040 (Injection, incobotulinumtoxin A, 1 unit). We note that HCPCS code Q2040 replaced HCPCS code C9278 (Injection, incobotulinumtoxin A, 1 unit) beginning April 1, 2011. HCPCS code C9278 was effective January 1, 2011, and deleted for dates of service April 1, 2011 and forward, because it was replaced with HCPCS code Q2040.

In the July 2011 quarterly update (Transmittal 2235, Change Request 7445, dated June 03, 2011), we added nine new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 43, we provided separate payment for HCPCS codes C9283 (Injection, acetaminophen, 10 mg), C9284 (Injection, ipilimumab, 1 mg), C9285 (Lidocaine 70 mg/tetracaine 70mg, per patch), C9365 (Oasis Ultra Tri-Layer matrix, per square centimeter), C9406 (Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries), Q2041 (Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco), Q2042 (Injection, hydroxyprogesterone caproate, 1 mg), Q2043 (Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion), and Q2044 (Injection, belimumab, 10 mg). We note that HCPCS code Q2041 is replacing HCPCS code J7184 and HCPCS code Q2043 is replacing HCPCS code C9273 beginning July 1, 2011.

We assigned payment indicator ''K2'' (Drugs and biologicals paid separately when provided integral to a surgical procedure on the ASC list; payment based on OPPS rate) to these 13 new Level II HCPCS codes to indicate that they are separately paid when provided in ASCs. We are soliciting public comment on the proposed CY 2012 ASC payment indicators and payment rates for the drugs and biologicals, as listed in Tables 42 and 43 below. Those HCPCS codes became payable in ASCs, beginning in April or July 2011, respectively, and are paid at the ASC rates posted for the appropriate calendar quarter on the CMS Web site at *http://www.cms.gov/ASCPayment/*.

The HCPCS codes listed in Table 42 are included in Addendum BB to this proposed rule. We note that all ASC addenda are referenced in section XVII. of this proposed rule and are only available via the Internet on the CMS Web site. Because HCPCS codes that became effective for July (listed in Table 43) are not available to us in time for incorporation into the Addenda to this OPPS/ASC proposed rule, our policy is to include these HCPCS codes and their proposed payment indicators and payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes and their final payment indicators and rates will be included in the appropriate Addendum to the CY 2012 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2011 ASC quarterly update CR and their proposed CY 2012 payment rates (based

on July 2011 ASP data) that are displayed in Table 43 are not included in Addendum BB to this proposed rule. The final list of covered ancillary services and the associated payment weights and payment indicators will be included in Addendum BB to the CY 2012 OPPS/ASC final rule with comment period, consistent with our annual update policy.

TABLE 42—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2011

CY 2011 HCPCS Code	CY 2011 Long descriptor	Proposed CY 2012 payment indicator
C9280	Injection, eribulin mesylate, 1 mg	K2
C9281	Injection, pegloticase, 1 mg	K2
C9282	Injection, ceftaroline fosamil, 10 mg	K2
Q2040	Injection, incobotulinumtoxin A, 1 unit	K2

TABLE 43—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2011

CY 2011 HCPCS Code	CY 2011 Descriptor	Proposed CY 2012 payment indicator	Proposed CY 2012 ASC payment rate
C9283	Injection, acetaminophen, 10 mg	K2	$0.11
C9284	Injection, ipilimumab, 1 mg	K2	127.20
C9285	Lidocaine 70 mg/tetracaine 70mg, per patch	K2	13.57
C9365	Oasis Ultra Tri-Layer matrix, per square centimeter	K2	10.60
C9406	Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries	K2	1,908.00
Q2041	Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco	K2	0.88
Q2042	Injection, hydroxyprogesterone caproate, 1 mg	K2	2.90
Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion.	K2	32,860.00
Q2044	Injection, belimumab, 10 mg	K2	39.15

Through the July 2011 quarterly update CR, we also implemented ASC payment for six new Category III CPT codes as ASC covered surgical procedures, effective July 1, 2011. These codes are listed in Table 44 below, along with their proposed payment indicators and proposed payment rates for CY 2011. Because new Category III CPT and Level II HCPCS codes that become effective for July are not available to us in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is to include the codes, their proposed payment indicators, and proposed payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes and their final payment indicators and rates will be included in Addendum AA to the CY 2012 OPPS/ASC final rule with comment period.

We are proposing to assign payment indicator ''G2'' (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) to all six of the new Category III CPT codes to be implemented in July 2011. We believe that these procedures would not pose a significant safety risk to Medicare beneficiaries or would not require an overnight stay if performed in ASCs. We are soliciting public comment on these proposed payment indicators and the payment rates for the new Category III CPT codes that were newly recognized as ASC covered surgical procedures in July 2011 through the quarterly update CR, as listed in Table 44 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2012 OPPS/ASC final rule with comment period.

TABLE 44—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2011 AS ASC COVERED SURGICAL PROCEDURES

CY 2011 HCPCS Code	CY 2011 Long descriptor	Proposed CY 2012 payment indicator	Proposed CY 2012 ASC payment rate
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest.	G2	$1,218.58
0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest.	G2	1,218.58
0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy.	G2	1,218.58
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intraoperative interrogation, programming, and repositioning, when performed).	G2	1,444.14

TABLE 44—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2011 AS ASC COVERED SURGICAL PROCEDURES—Continued

CY 2011 HCPCS Code	CY 2011 Long descriptor	Proposed CY 2012 payment indicator	Proposed CY 2012 ASC payment rate
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed).	G2	841.60
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed).	G2	1,126.88

In summary, for CY 2011, we are soliciting public comments on the proposed payment indicators and the payment rates, if applicable, for the new Level II HCPCS codes and Category III CPT codes that were newly recognized in April or July 2011 through the respective quarterly update CRs. These codes are listed in Tables 42, 43 and 44 of this proposed rule. We are proposing to finalize their payment indicators and their payment rates, if applicable, in the CY 2012 OPPS/ASC final rule with comment period.

3. Proposed Process for New Level II HCPCS Codes and Category I and III CPT Codes for Which We Will Be Soliciting Public Comments in the CY 2012 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and Category III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January ASC quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October ASC quarterly update CRs and incorporated these new codes in the final rule with comment period updating the ASC payment system for the following calendar year. All of these codes are flagged with comment indicator ''NI'' in Addenda AA and BB to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. The payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update.

We are proposing to continue this process for CY 2012. Specifically, for CY 2012, we are proposing to include in Addenda AA and BB to the CY 2012 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2012 that would be incorporated in the January 2012 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2011 or January 1, 2012, that would be released by CMS in its October 2011 and January 2012 ASC quarterly update CRs. These codes would be flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2012 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim payment status. Their payment indicators and payment rates, if applicable, would be open to public comment in the CY 2012 OPPS/ASC final rule with comment period and would be finalized in the CY 2013 OPPS/ASC final rule with comment period.

C. Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Proposed Additions to the List of ASC Covered Surgical Procedures

We conducted a review of all HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice changed the clinical appropriateness of these procedures for the ASC setting. Upon review, we did not identify any procedures that are currently excluded from the ASC list of procedures that met the definition of a covered surgical procedure based on our expectation that they would not pose a significant safety risk to Medicare beneficiaries or would require an overnight stay if performed in ASCs. Therefore, we are not proposing additions to the list of ASC covered surgical procedures for CY 2012.

b. Proposed Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS non-facility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS non-facility PE RVUs; payment based on MPFS non-facility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS non-facility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated it would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS non-facility PE RVU-based amount.

Consistent with our final policy to annually review and update the list of surgical procedures eligible for payment in ASCs, each year we identify surgical procedures as either temporarily office-based, permanently office-based, or non-

office-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2012 to Covered Surgical Procedures Designated as Office-Based

In developing this proposed rule, we followed our policy to annually review and update the surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2010 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator ''G2'' in CY 2011, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2*,'' ''P3*,'' or ''R2*'' in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72033 through 72038).

Based on our review of the CY 2010 volume and utilization data, we identified ten surgical procedures that we believe meet the criteria for designation as office-based. The data indicate that the procedures are performed more than 50 percent of the time in physicians' offices. Our medical advisors believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The 10 CPT codes we are proposing to permanently designate as office-based are listed in Table 45 below.

TABLE 45—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR PERMANENT OFFICE-BASED DESIGNATION FOR 2012

CY 2011 CPT code	CY 2011 long descriptor	CY 2011 ASC payment indicator	Proposed CY 2012 ASC payment indicator
0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level.	G2	R2
0214T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level (list separately in addition to code for primary procedure).	G2	R2
0215T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (list separately in addition to code for primary procedure).	G2	R2
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level.	G2	R2
0217T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; second level (list separately in addition to code for primary procedure).	G2	R2
0218T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; third and any additional level(s) (list separately in addition to code for primary procedure).	G2	R2
35475	Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel.	G2	P3
35476	Transluminal balloon angioplasty, percutaneous; venous	G2	P3
41530	Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session.	G2	P2
69801	Labyrinthotomy, with or without cryosurgery including other nonexcisional destructive procedures or perfusion of vestibuloactive drugs (single or multiple perfusions); transcanal.	G2	P3

We also reviewed CY 2010 volume and utilization data and other information for the 23 procedures finalized for temporary office-based status in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72036 through 72038). Among these 23 procedures, there were very few claims data for eight procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0124T (Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)); CPT code 0226T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed); CPT code 0227T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)); CPT code 0232T (Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed); CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies); CPT code 37761 (Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we are proposing to maintain their temporary office-based designations for CY 2012.

As a result of our review of the remaining fifteen procedures that have temporary office-based designations for CY 2011 for which we do have claims data, we are proposing that none of the procedures be designated as office-based in CY 2012. The 15 surgical procedure codes are:

- CPT code 21015 (Radical resection of tumor (e.g., malignant neoplasm), soft tissue of face or scalp; less than 2 cm);
- CPT code 21555 (Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; less than 3 cm);

- CPT code 21930 (Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm);
- CPT code 23075 (Excision, tumor, soft tissue of shoulder area, subcutaneous; less than 3 cm);
- CPT code 24075 (Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; less than 3 cm);
- CPT code 25075 (Excision, tumor, soft tissue of forearm and/or wrist area, subcutaneous; less than 3 cm);
- CPT code 26115 (Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; less than 1.5 cm);
- CPT code 27047 (Excision, tumor, soft tissue of pelvis and hip area, subcutaneous; less than 3 cm);
- CPT code 27327 (Excision, tumor, soft tissue of thigh or knee area, subcutaneous; less than 3 cm);
- CPT code 27618 (Excision, tumor, soft tissue of leg or ankle area, subcutaneous; less than 3 cm);
- CPT code 28039 (Excision, tumor, soft tissue of foot or toe, subcutaneous; 1.5 cm or greater);
- CPT code 28041 (Excision, tumor, soft tissue of foot or toe, subfascial (e.g., intramuscular); 1.5 cm or greater);
- CPT code 28043 (Excision, tumor, soft tissue of foot or toe, subcutaneous; less than 1.5 cm);
- CPT code 28045 (Excision, tumor, soft tissue of foot or toe, subfascial (e.g., intramuscular); less than 1.5 cm); and
- CPT code 28046 (Radical resection of tumor (e.g., malignant neoplasm), soft tissue of foot or toe; less than 3 cm).

The volume and utilization data for these CPT codes are sufficient to indicate that these procedures are not performed predominantly in physicians' offices and, therefore, should not be assigned an office-based payment indicator in CY 2012.

The proposed CY 2012 payment indicator designations for the 23 procedures that were temporarily designated as office-based in CY 2011 are displayed in Table 46 below. The procedures for which the proposed office-based designations for CY 2012 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

TABLE 46—PROPOSED CY 2012 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2011 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2011 CPT code	CY 2011 long descriptor	CY 2011 ASC payment indicator	Proposed CY 2012 ASC payment indicator**
21015	Radical resection of tumor (e.g., malignant neoplasm), soft tissue of face or scalp; less than 2 cm).	R2*	G2
21555	Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; less than 3 cm	P3*	G2
21930	Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm	P3*	G2
23075	Excision, tumor, soft tissue of shoulder area, subcutaneous; less than 3 cm	P3*	G2
24075	Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; less than 3 cm	P3*	G2
25075	Excision, tumor, soft tissue of forearm and/or wrist area, subcutaneous; less than 3 cm	P3*	G2
26115	Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; less than 1.5 cm.	P3*	G2
27047	Excision, tumor, soft tissue of pelvis and hip area, subcutaneous; less than 3 cm	P3*	G2
27327	Excision, tumor, soft tissue of thigh or knee area, subcutaneous; less than 3 cm	P3*	G2
27618	Excision, tumor, soft tissue of leg or ankle area, subcutaneous; less than 3 cm	P3*	G2
28039	Excision, tumor, soft tissue of foot or toe, subcutaneous; 1.5 cm or greater	P3*	G2
28041	Excision, tumor, soft tissue of foot or toe, subfascial (e.g., intramuscular); 1.5 cm or greater	R2*	G2
28043	Excision, tumor, soft tissue of foot or toe, subcutaneous; less than 1.5 cm	P3*	G2
28045	Excision, tumor, soft tissue of foot or toe, subfascial (e.g., intramuscular); less than 1.5 cm	P3*	G2
28046	Radical resection of tumor (e.g., malignant neoplasm), soft tissue of foot or toe; less than 3 cm	R2*	G2
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg.	R2*	R2*
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy.	R2*	R2*
0099T	Implantation of intrastromal corneal ring segments	R2*	R2*
0124T	Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication).	R2*	R2*
0226T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed.	R2*	R2*
0227T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies).	R2*	R2*
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed.	R2*	R2*
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	R2*	R2*

* If designation is temporary.

** Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being finalized for publication, current law authorizes a negative update to the MPFS payment rates for CY 2012. For a discussion of those rates, we refer readers to the CY 2012 MPFS proposed rule.

We invite public comment on these proposals.

c. ASC Covered Surgical Procedures Designated as Device-Intensive

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures. We assigned payment indicators ''H8'' (Device-intensive procedure on ASC list in CY 2007; paid at adjusted rate) and ''J8'' (Device-intensive procedure added to ASC list in CY 2008 or later; paid at adjusted rate) to identify the procedures that were eligible for ASC payment calculated according to the modified methodology, depending on whether the procedure was included on the ASC list of covered surgical procedures prior to CY 2008 and, therefore, subject to transitional payment as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68739 through 68742).

As discussed in section XIII.F.2. of this proposed rule, because the 4-year transition to the ASC payment rates under the standard methodology is complete and, therefore, identification of device-intensive procedures that are subject to transitional payment methodology is no longer necessary, we are proposing to delete payment indicator ''H8'' (Device-intensive procedure on ASC list in CY 2007; paid at adjusted rate). The device-intensive procedures for which the device-intensive payment methodology will apply in CY 2012 or later will be assigned payment indicator ''J8'' (Device-intensive procedure; paid at adjusted rate).

(2) Proposed Changes to List of Covered Surgical Procedures Designated as Device-Intensive for CY 2012

We are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive procedure payment methodology for CY 2012, consistent with the proposed OPPS device-dependent APC update, reflecting the proposed APC assignments of procedures, designation of APCs as device-dependent, and APC device offset percentages based on the CY 2010 OPPS claims and cost report data available for this proposed rule. The OPPS device-dependent APCs are discussed further in section II.A.2.d.(1) of this proposed rule.

The ASC covered surgical procedures that we are proposing to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2012 are listed in Table 47 below. The CPT code, the CPT code short descriptor, the proposed CY 2012 ASC payment indicator, the proposed CY 2012 OPPS APC assignment and title, and the proposed CY 2012 OPPS APC device offset percentage are also listed in Table 47 below. All of these procedures are included in Addendum AA to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

TABLE 47—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE–INTENSIVE DESIGNATION FOR CY 2012

CPT Code	Short descriptor	Proposed CY 2012 ASC payment indicator	Proposed CY 2012 OPPS APC	Proposed CY 2012 OPPS APC title	Proposed CY 2012 device-dependent APC offset percentage
24361	Reconstruct elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60
24363	Replace elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60
24366	Reconstruct head of radius	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60
25441	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60
25442	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60
25446	Wrist replacement	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60
27446	Revision of knee joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60
33206	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes.	71
33207	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes.	71
33208	Insertion of heart pacemaker	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker.	73
33212	Insertion of pulse generator	J8	0090	Insertion/Replacement of Pacemaker Pulse Generator.	73
33213	Insertion of pulse generator	J8	0654	Insertion/Replacement of a permanent dual chamber pacemaker.	74
33214	Upgrade of pacemaker system	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker.	73
33224	Insert pacing lead & connect	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker.	73
33225	Lventric pacing lead add-on	J8	0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads.	87
33240	Insert pulse generator	J8	0107	Insertion of Cardioverter-Defibrillator	88

TABLE 47—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE–INTENSIVE DESIGNATION FOR CY 2012—Continued

CPT Code	Short descriptor	Proposed CY 2012 ASC payment indicator	Proposed CY 2012 OPPS APC	Proposed CY 2012 OPPS APC title	Proposed CY 2012 device-dependent APC offset percentage
33249	Eltrd/insert pace-defib	J8	0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads.	87
33282	Implant pat-active ht record	J8	0680	Insertion of Patient Activated Event Recorders	72
53440	Male sling procedure	J8	0385	Level I Prosthetic Urological Procedures	61
53444	Insert tandem cuff	J8	0385	Level I Prosthetic Urological Procedures	61
53445	Insert uro/ves nck sphincter	J8	0386	Level II Prosthetic Urological Procedures	70
53447	Remove/replace ur sphincter	J8	0386	Level II Prosthetic Urological Procedures	70
54400	Insert semi-rigid prosthesis	J8	0385	Level I Prosthetic Urological Procedures	61
54401	Insert self-contd prosthesis	J8	0386	Level II Prosthetic Urological Procedures	70
54405	Insert multi-comp penis pros	J8	0386	Level II Prosthetic Urological Procedures	70
54410	Remove/replace penis prosth	J8	0386	Level II Prosthetic Urological Procedures	70
54416	Remv/repl penis contain pros	J8	0386	Level II Prosthetic Urological Procedures	70
55873	Cryoablate prostate	J8	0674	Prostate Cryoablation	57
61885	Insrt/redo neurostim 1 array	J8	0039	Level I Implantation of Neurostimulator Generator.	85
61886	Implant neurostim arrays	J8	0315	Level II Implantation of Neurostimulator Generator.	88
62361	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81
62362	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81
63650	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55
63655	Implant neuro-electrodes	J8	0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes.	64
63663	Revise spine eltrd perq aray	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55
63664	Revise spine eltrd plate	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55
63685	Insrt/redo spine n generator	J8	0039	Level I Implantation of Neurostimulator Generator.	85
64553	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55
64555	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55
64560	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55
64561	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55
64565	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55
64568	Implant neuro-electrodes	J8	0318	Implantation of Neurostimulator Electrodes, Cranial Nerve.	86
64575	Implant neuro-electrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64
64577	Implant neuro-electrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64
64580	Implant neuro-electrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64
64581	Implant neuro-electrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64
64590	Insrt/redo pn/gastr stimul	J8	0039	Level I Implantation of Neurostimulator Generator.	85
65770	Revise cornea with implant	J8	0293	Level VI Anterior Segment Eye Procedures	67
69714	Implant temple bone w/stimul	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60
69715	Temple bne implnt w/stimulat	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60
69717	Temple bone implant revision	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60
69718	Revise temple bone implant	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60
69930	Implant cochlear device	J8	0259	Level VII ENT Procedures	83

We invite public comment on these proposals.

d. ASC Treatment of Surgical Procedures Proposed for Removal From the OPPS Inpatient List for CY 2012

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. We evaluated each of the three procedures we are proposing to remove from the OPPS inpatient list for CY 2012 according to the criteria for exclusion from the list of covered ASC surgical procedures. We believe that these three procedures should continue to be excluded from the ASC list of covered surgical procedures for CY 2012 because they would be expected to pose a significant risk to beneficiary safety or to require an overnight stay in ASCs. A full discussion about the APC Panel's recommendations regarding the procedures we are proposing to remove from the OPPS inpatient list for CY 2012 may be found in section IX.B. of this proposed rule. The HCPCS codes for these three procedures and their long descriptors are listed in Table 48 below.

TABLE 48—PROCEDURES PROPOSED FOR EXCLUSION FROM THE ASC LIST OF COVERED PROCEDURES FOR CY 2012 THAT ARE PROPOSED FOR REMOVAL FROM THE CY 2012 OPPS INPATIENT LIST

CPT Code	Long descriptor
21346	Open treatment of nasomaxillary complex fracture (Lefort II type); with wiring and/or local fixation.
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery.
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (e.g., Fowler-Stephens).

We invite public comment on this proposal.

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2012 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary items and services because of changes that are being proposed under the OPPS for CY 2012. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2011 may be proposed for packaged status under the CY 2012 OPPS and, therefore, also under the ASC payment system for CY 2012. Comment indicator ''CH,'' discussed in section XIII.F. of this proposed rule, is used in Addendum BB to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) to indicate covered ancillary services for which we are proposing a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2012.

Except for the Level II HCPCS codes listed in Table 43 of this proposed rule, all ASC covered ancillary services and their proposed payment indicators for CY 2012 are included in Addendum BB to this proposed rule.

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy for the revised ASC payment system, the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year is used to calculate the national unadjusted payment rates for procedures with payment indicator ''G2.'' For procedures assigned payment indicator ''A2,'' our final policy established blended rates to be used during the transitional period and, beginning in CY 2011, ASC rates calculated according to the ASC standard ratesetting methodology. The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72024 through 72064), we updated the CY 2010 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2,'' ''G2,'' ''H8,'' and ''J8'' using CY 2009 data, consistent with the CY 2011 OPPS update. Payment rates for device-intensive procedures also were updated to incorporate the CY 2011 OPPS device offset percentages. Because transitional payments were no longer required in CY 2011, we calculated CY 2011 payments for procedures formerly subject to the transitional payment methodology (payment indicators ''A2'' and ''H8'') using the standard rate setting methodology, incorporating the device-intensive methodology, as appropriate.

Payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the MPFS non-facility PE RVU-based amount (we refer readers to the CY 2012 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72024 through 72064), we updated the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2011 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2011 payment rate for the procedure according to the final policy of the revised ASC payment system (§ 416.171(d)).

b. Proposed Update to ASC-Covered Surgical Procedure Payment Rates for CY 2012

We are proposing to update ASC payment rates for CY 2012 using the established rate calculation methodologies under § 416.171. Under § 416.171(c)(4), the transitional payment

rates are no longer used for CY 2011 and subsequent calendar years for a covered surgical procedure designated in accordance with § 416.166. Thus, we are proposing to calculate CY 2012 payments for procedures formerly subject to the transitional payment methodology (payment indicators ''A2'' and ''H8'') using the proposed CY 2012 ASC rate calculated according to the ASC standard ratesetting methodology, incorporating the device-intensive procedure methodology, as appropriate. We are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicator ''G2.'' We are proposing to modify or delete the payment indicators for procedures that were subject to transitional payment prior to CY 2011 (we refer readers to our discussion in section XIII.F.2. of this proposed rule).

We are proposing that payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') and device-intensive procedures that were not subject to transitional payment (payment indicator ''J8'') be calculated according to our established policies, incorporating the device-intensive procedure methodology as appropriate. Thus, we are proposing to update the payment amounts for device-intensive procedures based on the CY 2012 OPPS proposal that reflects updated OPPS device offset percentages, and to make payment for office-based procedures at the lesser of the CY 2012 proposed MPFS non-facility PE RVU-based amount or the proposed CY 2012 ASC payment amount calculated according to the standard ratesetting methodology.

c. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC policy with regard to payment for costly devices implanted in ASCs at no cost or with full or partial credit as set forth in § 416.179 is consistent with the OPPS policy. The proposed CY 2012 OPPS APCs and devices subject to the adjustment policy are discussed in section IV.B.2. of this proposed rule. The established ASC policy includes adoption of the OPPS policy for reduced payment to providers when a specified device is furnished without cost or with full or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68745).

Consistent with the OPPS, we are proposing to update the list of ASC covered device-intensive procedures and devices that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2012. Table 49 below displays the ASC covered device-intensive procedures that we are proposing would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2012. Specifically, when a procedure that is listed in Table 49 is performed to implant a device that is listed in Table 50 below, where that device is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost to the ASC or with full credit. We would provide the same amount of payment reduction based on the device offset amount in ASCs that would apply under the OPPS under the same circumstances. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure being furnished by the ASC.

We also are proposing to reduce the payment for implantation procedures listed in Table 49 by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more of the cost of the new device. The ASC would append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in Table 49 when the facility receives a partial credit of 50 percent or more of the cost of a device listed in Table 50 below. In order to report that they received a partial credit of 50 percent or more of the cost of a new device, ASCs would have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more of the cost of the replacement device. Beneficiary coinsurance would continue to be based on the reduced payment amount.

TABLE 49—PROPOSED CY 2012 PROCEDURES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

CPT code	Short descriptor	Proposed CY 2012 ASC payment indicator	Proposed CY 2012 OPPS APC	OPPS APC title	Proposed CY 2012 OPPS full APC offset percentage	Proposed CY 2012 OPPS partial APC offset percentage
24361	Reconstruct elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60	30
24363	Replace elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60	30
24366	Reconstruct head of radius	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60	30
25441	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60	30
25442	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60	30

TABLE 49—PROPOSED CY 2012 PROCEDURES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

CPT code	Short descriptor	Proposed CY 2012 ASC payment indicator	Proposed CY 2012 OPPS APC	OPPS APC title	Proposed CY 2012 OPPS full APC offset percentage	Proposed CY 2012 OPPS partial APC offset percentage
25446	Wrist replacement	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60	30
27446	Revision of knee joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60	30
33206	Insertion of heart pacemaker.	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes.	71	35
33207	Insertion of heart pacemaker.	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes.	71	35
33208	Insertion of heart pacemaker.	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker.	74	37
33212	Insertion of pulse generator	J8	0090	Insertion/Replacement of Pacemaker Pulse Generator.	73	37
33213	Insertion of pulse generator	J8	0654	Insertion/Replacement of a permanent dual chamber pacemaker.	74	37
33214	Upgrade of pacemaker system.	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker.	73	37
33224	Insert pacing lead & connect.	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker.	73	37
33225	Lventric pacing lead add-on	J8	0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads.	87	43
33240	Insert pulse generator	J8	0107	Insertion of Cardioverter-Defibrillator	88	44
33249	Eltrd/insert pace-defib	J8	0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads.	87	43
33282	Implant pat-active ht record	J8	0680	Insertion of Patient Activated Event Recorders.	72	36
53440	Male sling procedure	J8	0385	Level I Prosthetic Urological Procedures ..	61	30
53444	Insert tandem cuff	J8	0385	Level I Prosthetic Urological Procedures ..	61	30
53445	Insert uro/ves nck sphincter	J8	0386	Level II Prosthetic Urological Procedures	70	35
53447	Remove/replace ur sphincter.	J8	0386	Level II Prosthetic Urological Procedures	70	35
54400	Insert semi-rigid prosthesis	J8	0385	Level I Prosthetic Urological Procedures ..	61	30
54401	Insert self-contd prosthesis	J8	0386	Level II Prosthetic Urological Procedures	70	35
54405	Insert multi-comp penis pros.	J8	0386	Level II Prosthetic Urological Procedures	70	35
54410	Remove/replace penis prosth.	J8	0386	Level II Prosthetic Urological Procedures	70	35
54416	Remv/repl penis contain pros.	J8	0386	Level II Prosthetic Urological Procedures	70	35
61885	Insrt/redo neurostim 1 array	J8	0039	Level I Implantation of Neurostimulator Generator.	85	43
61886	Implant neurostim arrays	J8	0315	Level II Implantation of Neurostimulator Generator.	88	44
62361	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81	40
62362	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81	40
63650	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55	27
63655	Implant neuroelectrodes	J8	0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes.	64	32
63663	Revise spine eltrd perq aray	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55	27
63664	Revise spine eltrd plate	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55	27
63685	Insrt/redo spine n generator	J8	0039	Level I Implantation of Neurostimulator Generator.	85	43
64553	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55	27
64555	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55	27
64560	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.	55	27
64561	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	55	27
64565	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	55	27
64568	Implant neuroelectrodes	J8	0318	Implantation of Neurostimulator Electrodes, Cranial Nerve.	86	43

TABLE 49—PROPOSED CY 2012 PROCEDURES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

CPT code	Short descriptor	Proposed CY 2012 ASC payment indicator	Proposed CY 2012 OPPS APC	OPPS APC title	Proposed CY 2012 OPPS full APC offset percentage	Proposed CY 2012 OPPS partial APC offset percentage
64575	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64	32
64577	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64	32
64580	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64	32
64581	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	64	32
64590	Insrt/redo pn/gastr stimul	J8	0039	Level I Implantation of Neurostimulator Generator.	85	43
69714	Implant temple bone w/ stimul.	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60	30
69715	Temple bne implnt w/ stimulat.	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60	30
69717	Temple bone implant revision.	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60	30
69718	Revise temple bone implant	J8	0425	Level II Arthroplasty or Implantation with Prosthesis.	60	30
69930	Implant cochlear device	J8	0259	Level VII ENT Procedures	83	41

TABLE 50—PROPOSED DEVICES FOR WHICH THE ''FB'' OR ''FC'' MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2012 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT

CY 2011 Device HCPCS code	CY 2011 Short descriptor
C1721	AICD, dual chamber.
C1722	AICD, single chamber.
C1762	Conn tiss, human(inc fascia).
C1763	Conn tiss, non-human.
C1764	Event recorder, cardiac.
C1767	Generator, neurostim, imp.
C1771	Rep dev, urinary, w/sling.
C1772	Infusion pump, programmable.
C1776	Joint device (implantable).
C1778	Lead, neurostimulator.
C1779	Lead, pmkr, transvenous VDD.
C1781	Mesh (implantable).
C1785	Pmkr, dual, rate-resp.
C1786	Pmkr, single, rate-resp.
C1813	Prosthesis, penile, inflatab.
C1815	Pros, urinary sph, imp.
C1820	Generator, neuro rechg bat sys.
C1881	Dialysis access system.
C1882	AICD, other than sing/dual.
C1891	Infusion pump, non-prog, perm.
C1897	Lead, neurostim, test kit.
C1898	Lead, pmkr, other than trans.
C1900	Lead coronary venous.
C2618	Probe, cryoablation.
C2619	Pmkr, dual, non rate-resp.
C2620	Pmkr, single, non rate-resp.
C2621	Pmkr, other than sing/dual.
C2622	Prosthesis, penile, non-inf.
C2626	Infusion pump, non-prog, temp.
C2631	Rep dev, urinary, w/o sling.
L8614	Cochlear device/system.
L8680	Implt neurostim elctr each.
L8685	Implt nrostm pls gen sng rec.

TABLE 50—PROPOSED DEVICES FOR WHICH THE ''FB'' OR ''FC'' MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2012 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT—Continued

CY 2011 Device HCPCS code	CY 2011 Short descriptor
L8686	Implt nrostm pls gen sng non.
L8687	Implt nrostm pls gen dua rec.
L8688	Implt nrostm pls gen dua non.
L8690	Aud osseo dev, int/ext comp.

We invite public comment on these proposals.

d. Waiver of Coinsurance and Deductible for Certain Preventive Services

Section 1833(a)(1) and (b)(1) of the Act waives the coinsurance and the Part B deductible for those preventive services under section 1861(ddd)(3)(A) of the Act as described in section 1861(ww)(2) of the Act (excluding electrocardiograms) that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. Section 1833(b) of the Act also waives the Part B deductible for colorectal cancer screening tests that become diagnostic. In the CY 2011 OPPS/ASC final rule with comment period, we finalized our policies with respect to these provisions and identified the ASC covered surgical and ancillary services that are preventive services that are recommended by the USPSTF with a grade of A or B for which the coinsurance and the deductible are waived. For a complete discussion of our policies and identified services, please see the CY 2011 OPPS/ASC final rule with comment period (75 FR 72047 through 72049). We are proposing no changes to our policies or the list of services. We have identified these services with a double asterisk in Addenda AA and BB to this proposed rule.

e. Proposed Payment for the Cardiac Resynchronization Therapy Composite

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD). CRT performed by the implantation of an ICD along with a pacing electrode is referred to as ''CRT–D.'' As detailed in section II.A.2.e.(6) of this proposed rule, we are proposing to create an OPPS composite APC (Composite APC 8009 (Cardiac Resynchronization Therapy—ICD Pulse Generator and Leads)) which would be used when CPT code 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual

chamber system)) and CPT code 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator) are performed on the same date of service. We also are proposing to cap the OPPS payment rate for composite APC 8009 at the most comparable Medicare severity diagnosis-related group (MS–DRG) payment rate established under the IPPS that would be provided to acute care hospitals for providing CRT–D services to hospital inpatients. In other words, we are proposing to pay APC 8009 at the lesser of the APC 8009 median cost or the IPPS standardized payment rate for MS–DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization without Major Complication or Comorbidity). This would ensure appropriate and equitable payment to hospitals and that we do not create an inappropriate payment incentive to provide CRT–D services in one setting of care over another by paying more for CRT–D in the outpatient setting compared to the inpatient setting. Specifically, for the CY 2012 OPPS, we are proposing that if the APC 8009 median cost that we will calculate for the CY 2012 OPPS/ASC final rule with comment period exceeds the FY 2012 IPPS standardized payment rate for MS–DRG 227, we would establish the OPPS payment amount at the FY 2012 IPPS standardized payment amount for MS–DRG 227 (currently estimated at $26,365).

Because CPT code 33225 and CPT code 33249 are on the list of ASC covered surgical procedures, we are proposing to establish an ASC payment rate that is based on the OPPS payment rate applicable to APC 8009 when these procedures are performed on the same date of service in an ASC. Again, we do not want to create an inappropriate payment incentive to provide CRT–D services in one setting of care over another by paying more for CRT–D in ASCs compared to the hospital outpatient setting. Because CPT codes 33225 and 33249 are on the proposed list of device-intensive procedures for CY 2012, we are proposing to apply the usual device-intensive methodology based on the OPPS payment rate applicable to APC 8009 (which is the lesser of the APC 8009 median cost that we will calculate for the CY 2012 OPPS/ASC final rule with comment period or the FY 2012 IPPS standardized payment rate for MS–DRG 227). We also are proposing to create a HCPCS Level II G-code so that ASCs can properly report when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service to receive the appropriate CRT–D composite payment.

In a related issue, as detailed in section III.D.6 of this proposed rule, CPT codes 33225 and 33249 are the only procedures proposed for inclusion in APC 0108. We are proposing that these codes would be paid under APC 0108 only if they are not reported on the same date of service. Further, we are proposing to pay the OPPS payment rate for services that are assigned to APC 0108 at the lesser of the APC 0108 median cost or the IPPS standardized payment rate for MS–DRG 227. For ASC payment in CY 2012, we are proposing to apply the device-intensive methodology to calculate payment for CPT codes 33225 and 33249 based on the OPPS payment rate applicable to APC 0108 (which is the lesser of the APC 0108 median cost that we will calculate for the CY 2012 OPPS/ASC final rule with comment period or the FY 2012 IPPS standardized payment rate for MS–DRG 227).

We invite public comment on these proposals.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our final payment policies under the revised ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged under the OPPS. Thus, we established a final policy to align ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates, while we generally pay for separately payable radiology services at the lower of the MPFS non-facility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the OPPS relative payment weights rather than the MPFS non-facility RE RVU amount, regardless of which is lower. This modification to the ASC payment methodology for ancillary services was finalized in response to a CY 2011 OPPS/ASC proposed rule comment that suggested it is inappropriate to use the MPFS-based payment methodology for nuclear medicine procedures because the associated diagnostic radiopharmaceutical, though packaged under the ASC payment system, is separately paid under the MFPS. We set the payment indicator to ''Z2'' for nuclear medicine procedures in the ASC setting so that payment for these procedures would be based on the OPPS relative payment weight rather than the MPFS non-facility PE RVU-based amount to ensure that the ASC will be compensated for the cost associated with the diagnostic radiopharmaceuticals.

ASC payment policy for brachytherapy sources generally mirrors the payment policy under the OPPS. We finalized our policy in the CY 2008 OPPS/ASC final rule with comment period (72 FR 42499) to pay for brachytherapy sources applied in ASCs at the same prospective rates that were adopted under the OPPS or, if OPPS rates were unavailable, at contractor-priced rates. After publication of that rule, section 106 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173) mandated that, for the period January 1, 2008 through June 30, 2008, brachytherapy sources be paid under the OPPS at charges adjusted to cost. Therefore, consistent with our final overall ASC payment policy, we paid ASCs at contractor-priced rates for brachytherapy sources provided in ASCs during that period of time. Beginning July 1, 2008, brachytherapy sources applied in ASCs were to be paid at the same prospectively set rates that were finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 67165 through 67188). Immediately prior to the publication of the CY 2009 OPPS/ASC proposed rule, section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) amended section 1833(t)(16)(C) of the Act (as amended by section 106 of

the Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. 110–173) to extend the requirement that brachytherapy sources be paid under the OPPS at charges adjusted to cost through December 31, 2009. Therefore, consistent with final ASC payment policy, ASCs continued to be paid at contractor-priced rates for brachytherapy sources provided integral to ASC covered surgical procedures during that period of time.

Other separately paid covered ancillary services in ASCs, specifically corneal tissue acquisition and device categories with OPPS pass-through status, do not have prospectively established ASC payment rates according to the final policies of the revised ASC payment system (72 FR 42502 and 42509; § 416.164(b)). Under the revised ASC payment system, corneal tissue acquisition is paid based on the invoiced costs for acquiring the corneal tissue for transplantation. Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system. Currently, the only device that is eligible for pass-through payment in the OPPS is described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (Implantable)). Payment for HCPCS code C1749 under the ASC payment system is contractor priced.

b. Proposed Payment for Covered Ancillary Services for CY 2012

For CY 2012, we are proposing to update the ASC payment rates and make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2012 OPPS and ASC payment rates. The proposed CY 2012 OPPS payment methodologies for separately payable drugs and biologicals and brachytherapy sources are discussed in section II.A. and section V.B. of this proposed rule, respectively, and we are proposing to set the CY 2012 ASC payment rates for those services equal to the proposed CY 2012 OPPS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2012 payment for separately payable covered radiology services is based on a comparison of the CY 2012 proposed MPFS non-facility PE RVU-based amounts (we refer readers to the CY 2012 MPFS proposed rule) and the proposed CY 2012 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts. Alternatively, payment for a radiology service may be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged under the OPPS. The payment indicators in Addendum BB to this proposed rule indicate whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU-based amount or the ASC standard ratesetting methodology, or whether payment for a radiology service is packaged into the payment for the covered surgical procedure (payment indicator ''N1''). Radiology services that we are proposing to pay based on the ASC standard ratesetting methodology are assigned payment indicator ''Z2'' (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight) and those for which the proposed payment is based on the MPFS non-facility PE RVU-based amount are assigned payment indicator ''Z3'' (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS non-facility PE RVUs).

As finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the OPPS relative payment weights rather than the MPFS non-facility PE RVU-based amount, regardless of which is lower. We are proposing to continue this modification to the payment methodology and, therefore, set the payment indicator to ''Z2'' for these nuclear medicine procedures in CY 2012. In addition, because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the MFPS), we are proposing to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight and will, therefore, include the cost for the contrast agent. We have made proposed changes to the regulation text at § 416.171(d) to reflect this proposal.

Most covered ancillary services and their proposed payment indicators are listed in Addendum BB to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Cycle and Evaluation Criteria

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68176), we finalized our current process for reviewing applications to establish new classes of new technology intraocular lenses (NTIOLs) and for recognizing new candidate intraocular lenses (IOLs) inserted during or subsequent to cataract extraction as belonging to an NTIOL class that is qualified for a payment adjustment. Specifically, we established the following process:

- We announce annually in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published and the deadline for submission of public comments regarding those requests. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests.
- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—
  - Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments; and
  - Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68227), we finalized our proposal to base our determinations on consideration of the following three major criteria set out at 42 CFR 416.195:

- Criterion 1 (42 CFR 416.195(a)(1), (2)): The IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising;
- Criterion 2 (42 CFR 416.195(a)(3)): The IOL is not described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with the improved clinical outcome with designated members of an active or expired NTIOL class; and
- Criterion 3 (42 CFR 416.195(a)(4)): Evidence demonstrates that use of the

IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. The statute requires us to consider the following superior outcomes:

- Reduced risk of intraoperative or postoperative complication or trauma;
- Accelerated postoperative recovery;
- Reduced induced astigmatism;
- Improved postoperative visual acuity;
- More stable postoperative vision; or
- Other comparable clinical advantages.

Since implementation of the process for adjustment of payment amounts for NTIOLs that was established in the June 16, 1999 **Federal Register**, we have approved three classes of NTIOLs, as shown in the table entitled *CMS Approved NTIOLs,* with the associated qualifying IOL models, posted on the CMS Web site at: *http://www.cms.gov/ASCPayment/08_NTIOLs.asp#TopOfPage*.

2. NTIOL Application Process for Payment Adjustment

For a request to be considered complete, we require submission of the information that is found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lens (NTIOL)'' posted on the CMS Web site at: *http://www.cms.gov/ASCPayment/08_NTIOLs.asp#TopOfPage*. For each completed request for a new class that is received by the established deadline, a determination is announced annually in the final rule updating the ASC and OPPS payment rates for the next calendar year.

We also summarize briefly in the final rule with comment period the evidence that we reviewed, the public comments we received timely, and the basis for our determinations in consideration of applications for establishment of a new NTIOL class. When a new NTIOL class is created, we identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome. The date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class would be set prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

3. Requests to Establish New NTIOL Classes for CY 2012 and Deadline for Public Comments

We received four requests for review to establish a new NTIOL class for CY 2012 by the March 5, 2011 due date. Summaries of these requests follow.

a. *Requestor/Manufacturer:* Alcon Laboratories, Inc. (Alcon).

Lens Model Numbers: Acrysof Natural IQ and Acrysof Natural IOLs, Models SN60WF (aspheric optic, single piece), SN60AT (spherical optic, single piece), MN60MA (spherical optic, multi-piece), MN60AC (spherical optic, multi-piece).

Summary of the Request: Alcon submitted a request for CMS to determine that its Acrysof Natural IOLs meet the criteria for recognition as NTIOLs and to concurrently establish a new class of NTIOLs for ''blue-light-filtering IOLs that improve driving safety under glare conditions,'' with these IOLs as members of the class. We reviewed a similar request by Alcon during the CY 2011 NTIOL application cycle (75 FR 72052). As part of its CY 2012 request, Alcon submitted descriptive information about the candidate IOLs as outlined in the guidance document that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOLs by the FDA. This information included the approved labeling for the candidate IOLs, a summary of the IOLs' safety and effectiveness, a copy of the FDA's approval notifications, and instructions for their use.

In its CY 2012 request, Alcon asserts that its request is based on studies demonstrating that the Acrysof Natural IOLs with a blue-light-filtering chromophore filter light in a manner that approximates the human crystalline lens in the 400–475 nm blue light wavelength range to reduce glare that impairs the ability of the eye to differentiate objects from the background. Alcon further states that glare reduction can help beneficiaries avoid hazards that can be caused by glare. Alcon also states that at present there are no active or expired NTIOL classes that describe IOLs similar to the Acrysof Natural IOLs.

We established in the CY 2007 OPPS/ASC final rule with comment period that when reviewing a request for recognition of an IOL as an NTIOL and a concurrent request to establish a new class of NTIOLs, we would base our determination on consideration of the three major criteria at 42 CFR 416.195(a) and listed above. We have begun our review of Alcon's request to recognize its Acrysof Natural IOLs as NTIOLs and concurrently establish a new class of NTIOLs. We are soliciting public comment on these candidate IOLs with respect to the established three major NTIOL criteria.

First, for an IOL to be recognized as an NTIOL we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising. The approved labels for the Alcon IOLs all state the following: ''Alcon's proprietary blue light filtering chromophore filters light in a manner that approximates the human crystalline lens in the 400–475 nm blue light wavelength range.'' The FDA labels for these IOLs do not otherwise reference specific clinical benefits of blue light filtering. We are interested in public comments on the clinical relevance of blue light filtering in an IOL. Specifically, we are interested in public comments regarding the assertion that the specific blue light filtering properties associated with the candidate IOLs improve driving safety via the reduction of glare disability.

Second, according to 42 CFR 416.195(a)(3), we also require that the candidate IOL not be described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with improved clinical outcomes with designated members of an active or expired NTIOL class. In the CY 2007 OPPS final rule, in response to a comment we explained our interpretation of 42 CFR 416.195(a)(3) as follows:

''[R]evised § 416.195(a)(3) does not preclude from consideration as a member of a new class of NTIOL a lens that includes as one of its characteristics a class-defining characteristic associated with members of an active or expired class. Only if that shared characteristic were the predominant characteristic of the lens would it be precluded from approval as a new class of NTIOL. However, if the lens featured other characteristics, one or more of which predominated, that were clearly tied with improved clinical outcomes, the lens would not be disqualified from consideration as an NTIOL just because it also shared a characteristic with members of an active or expired class.'' (71 FR 68178).

As noted above, since implementation of the process for adjustment of payment amounts for NTIOLs that was established in the June 16, 1999 **Federal Register**, we have approved three

classes of NTIOLs: Multifocal and Reduction in Preexisting Astigmatism classes, both of which were created in 2000 and expired in 2005, and the Reduced Spherical Aberration class, which was created in 2006 and expired on February 26, 2011. As mentioned above, a table entitled *CMS Approved NTIOLs,* with the associated qualifying IOL models, is posted on the CMS Web site at: *http://www.cms.gov/ASCPayment/08_NTIOLs.asp#TopOfPage.* The class-defining characteristic specific to IOLs that are members of these three expired classes is evident in the name assigned to the class. For example, IOLs recognized as members of the reduced spherical aberration class are characterized by their aspheric design that results in reduced spherical aberration. Based on the information in the table entitled *CMS Approved NTIOLs,* a candidate IOL's predominant characteristic may not be described by any of the three expired NTIOL classes.

In the case of one of four of Alcon's candidate IOLs, the Acrysof Natural IQ Aspheric IOL model SN60WF, it is a member of the expired reduced spherical aberration NTIOL class (75 FR 72052). For the purposes of satisfying § 416.195(a)(3), CMS must be able to determine which lens characteristic is predominant for Alcon's model SN60WF, asphericity (resulting in reduced spherical aberration) or blue-light filtering. If the predominant characteristic is asphericity, then the model SN60WF IOL would be disqualified under § 416.195(a)(3). This determination is particularly relevant given that the clinical benefit attributed to both of these lens characteristics is improved night driving. To our knowledge, Alcon has not compared the IOL model SN60WF (a blue-light filtering aspheric IOL) to a non-blue-light filtering aspheric IOL to determine if there are any night driving benefits attributable to the blue-light filtering characteristic in addition to the improved night driving attributable to the aspheric optic. Such information would assist us in evaluating whether blue-light filtering predominates or is subordinate to the IOL's asphericity. We are soliciting public comments on whether blue-light filtering can be considered the predominant IOL characteristic for the model SN60WF IOL. We also welcome public comments that address whether blue light-filtering and the associated clinical benefits of the other three of Alcon's candidate IOLs (that is, SN60AT, MN60MA, MN60AC) are described by any of the expired NTIOL classes.

Third, our NTIOL evaluation criteria also require that an applicant submit evidence demonstrating that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison to currently available IOLs. We note that in the CY 2007 OPPS/ASC final rule with comment period, we sought comments as to what constitutes currently available IOLs for purposes of such comparisons, and we received several comments in response to our solicitation (71 FR 68178). We agreed with commenters that we should remain flexible with respect to our view of ''currently available lenses'' for purposes of reviewing NTIOL requests, in order to allow for consideration of technological advances in lenses over time. This means that we do not expect that ''currently available lenses'' would remain static over time and always necessarily default to the classic spherical monofocal IOL for every candidate NTIOL class. Therefore, we believe that ''currently available lenses'' for purposes of reviewing NTIOL requests should depend upon the class-defining characteristic and the associated purported improved clinical outcome of the candidate NTIOL. For example, for some candidate NTIOLs the most appropriate comparison IOL would be a spherical monofocal IOL, while other candidate NTIOLs may be more appropriately compared to aspheric IOLs.

For purposes of reviewing Alcon's request to establish a new NTIOL class for CY 2012, we are proposing that aspheric monofocal IOLs represent the currently available IOLs against which the candidate NTIOLs should be compared in order to establish a new class. According to publicly available data from Market Scope, LLC, IOLs with aspheric optics accounted for over 86 percent of the IOLs implanted in the United States during 2010. In addition, data submitted by Alcon shows that the overwhelming majority of IOLs sold by Alcon have aspheric optics. Furthermore, the aspheric design that results in reduced spherical aberration was the class defining characteristic for IOLs recognized as members of the expired reduced spherical aberration NTIOL class. The primary clinical outcome associated with reduced spherical aberration (for purposes of establishing it as an NTIOL class) was safer night driving (71 FR 4588). Alcon asserts that what makes its candidate IOLs superior to other currently available IOLs is improved driving safety under glare conditions. Glare conditions during driving primarily occur at night due to headlights from oncoming cars. The primary improved clinical outcome from reduced spherical aberration IOLs (an expired NTIOL class) was safer night driving and the purported primary improved clinical outcome from Alcon's blue light-filtering IOLs is also safer night driving. Therefore, the most relevant type of currently available IOLs against which the Alcon blue filtering IOLs should be compared is aspheric IOLs. In particular, the relevant comparison would be the performance of an aspheric blue-light filtering IOL versus an aspheric non-blue light filtering IOL. This comparison would test the hypothesis of whether blue-light filtering improved night driving in comparison to aspheric optics, which has been shown to improve night driving. We seek public comment on our view of ''currently available lenses'' for the purposes of evaluating Alcon's candidate IOLs against currently available IOLs.

We are reviewing the evidence submitted with Alcon's CY 2012 request. Although Alcon submitted various types of literature in support of its application, it relies primarily on two studies in support of its hypothesis that blue light filtering IOLs improve driving safety under glare conditions as compared to currently available IOLs. The first of these two submitted articles is: Hammond B, et al. Contralateral comparison of blue-filtering intraocular lenses: glare disability, heterochromic contrast, and photostress recovery, *Clinical Ophthalmology.* 2010;4:1465–1473 (Hammond 2010). This article compared visual performance (as measured by glare disability, heterochromic contrast threshold, and photostress recovery time) in eyes with blue-light-filtering IOLs versus contralateral eyes with IOLs that do not filter blue light. The second article, which Alcon describes as its ''pivotal study,'' is: Gray R, et al. Reduced effect of glare disability on driving performance in patients with blue light-filtering intraocular lenses, *J Cataract Refract Surg.* 2011;37:38–44. This study compared the effects of glare on driving performance using a driving simulator in patients who had implantation of a blue light-filtering acrylic IOL and those who had implantation of an acrylic IOL with no blue-light filter. Overall, the evidence submitted provides us with important information that is critical to our review of this request. However, in making our decision as to whether to establish a new class of NTIOL based on the primary characteristic of the candidate lenses, we are also interested in what other information the public

can contribute related to the asserted benefits of the blue light filtering IOL. Specifically, we are seeking public comment and relevant data on the following:

- Are there other peer-reviewed studies or other information that would support or disprove the claims of clinical benefit made by Alcon?
- How do you interpret the results of the Hammond 2010 study, given that the blue light-filtering group included patients with spherical blue light filtering IOLs and patients with aspheric blue light filtering IOLs?
- Does the Maxwellian optical system that was employed in the Hammond 2010 study mitigate the impact of the aspheric optics of some of the study subjects in the blue light-filtering group?
- Is the sample size used in both studies sufficient to conclude that a blue light-filtering IOL would reduce glare disability and improve driving safety in the Medicare population?
- What kind of study design would be appropriate to prove the claim of significant clinical benefit due to glare reduction on which the new class would be based?
- Are the submitted data enough to prove that the blue filtering optic is responsible for reduction in glare disability as asserted by applicant?
- Did these studies use an appropriate comparator IOL?

Furthermore, in accordance with our established NTIOL review process, we are also seeking public comments on all of the review criteria for establishing a new NTIOL class that would be based on the ability of the Acrysof Natural IOLs to filter blue light and subsequently help beneficiaries avoid hazards that can be caused by glare while driving. We will give all comments full consideration regarding Alcon's candidate IOLs.

b. *Requestor/Manufacturer:* Bausch & Lomb, Inc. (B&L).

Lens Model Numbers: Xact Foldable Hydrophobic Acrylic Ultraviolet Light-Absorbing Posterior Chamber Intraocular Lenses, Models X–60 and X–70 (Xact IOLs).

Summary of the Request: B&L submitted a request for CMS to determine that its Xact IOLs meet the criteria for recognition as NTIOLs and to concurrently establish a new class of NTIOLs for ''glistening-free'' IOLs. Glistenings are fluid-filled microvacuoles that can form within an IOL optic when the IOL is in an aqueous environment. According to B&L, ''glistenings have been associated with decreased contrast sensitivity, increased glare, decreased visual acuity, and impaired fundus visualization.'' B&L further states that ''in some cases, this has led to IOL explantation and exchange, which carries significant risks that increase the longer the IOL is implanted.'' As part of its request, B&L submitted descriptive information about the candidate IOLs as outlined in the guidance document that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOL by the FDA. This information included draft FDA labeling for the Xact IOLs. Final FDA labeling is currently pending.

In its CY 2012 request, B&L asserts that because the Xact IOLs are glistening-free, they eliminate the decreased contrast sensitivity, increased glare, decreased visual acuity, and impaired fundus visualization associated with glistenings, and may likewise decrease the need for explantations associated with those conditions. B&L also concludes that use of a glistening-free IOL results in measurable, clinically meaningful, improved outcomes in comparison with currently available IOLs. B&L also states that the glistening-free characteristic is not described by a previously-approved NTIOL class.

As with the other CY 2012 NTIOL applications discussed in this proposed rule, we will base our determination of the B&L application on consideration of the three major evaluation criteria that are discussed above. We have begun our review of B&L's request to recognize its Xact IOLs as NTIOLs and concurrently establish a new class of NTIOLs. We are soliciting public comment on these candidate IOLs with respect to the established NTIOL criteria as discussed above.

First, for an IOL to be recognized as an NTIOL we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising. The submitted FDA label for the Xact IOLs states the following:

''In the IDE [investigational device exemption] clinical trial, 'glistenings' were observed in some cases. Glistenings, known to sometimes occur in some other hydrophobic acrylic IOLs, are microscopic vacuoles within the optic of the IOL that are visible through the slit lamp as multiple small refractile specks. *Analysis of the clinical data confirmed no effect of glistenings on visual outcomes.*'' [Emphasis added.]

''Testing established that glistenings were eliminated by a change in the IOL hydration solution from 10.0% saline to 0.9% saline. This was confirmed in an additional clinical trial conducted outside of the United States. In this study, 172 eyes of 142 patients were examined at least once between 1 and 6 months, and 123 eyes of 101 patients were examined at least once between 6 months and 2 years. No glistenings were observed at any time.''

The FDA label for the Xact IOLs does not otherwise reference specific clinical benefits of the glistening-free property. In fact, the italicized sentence in the above-quoted language on the IDE study from the FDA label states that an ''[a]nalysis of the clinical data confirmed no effect of glistenings on visual outcomes.'' We are interested in public comments on the clinical relevance of glistenings in IOLs, and the incidence of glistenings severe enough to cause measurable visual symptoms in recently pseudophakic Medicare beneficiaries. In addition, we are interested in public comments regarding the assertion by B&L that the glistening-free property associated with the Xact IOLs would eliminate the decreased contrast sensitivity, increased glare, decreased visual acuity, and impaired fundus visualization associated with glistenings, and may likewise decrease the need for explantations associated with those conditions.

Second, we also require that the candidate IOL not be described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with improved clinical outcomes with designated members of an active or expired NTIOL class. We refer readers to the discussion above for more information on the three expired NTIOL classes. The proposed class-defining characteristic and associated clinical benefits of the Xact IOLs, specifically the glistening-free property, cannot be similar to the class-defining characteristics and associated benefits of the three expired NTIOL classes. We welcome public comments that address whether the proposed class-defining characteristic and associated clinical benefits of the candidate B&L IOLs are described by the expired NTIOL classes.

Third, our NTIOL evaluation criteria also require that an applicant submit evidence demonstrating that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison to currently available IOLs. As discussed above, we remain flexible with respect to our view of ''currently available lenses'' for purposes of reviewing NTIOL requests, in order to allow for consideration of technological advances in lenses over time. We also

believe that ''currently available lenses'' for purposes of reviewing NTIOL requests should depend upon the class-defining characteristic and the associated purported improved clinical outcome of the candidate NTIOL class. For purposes of reviewing B&L's request to establish a new NTIOL class for CY 2012, we believe that the full spectrum of currently available IOL materials should be represented in the comparator IOLs, but that the particular design of the optic (for example, aspheric versus spherical) is less critical to evaluating the benefits of glistening-free IOLs as glistenings are related more to the IOL optic material than to the optical surface characteristics of the IOL. We are seeking public comment on our view of ''currently available lenses'' for the purposes of evaluating B&L's candidate IOLs against currently available IOLs.

We are reviewing the evidence submitted with B&L's CY 2012 request. B&L submitted a variety of articles including studies and case reports focused on IOLs with glistenings. It is apparent from these articles that glistenings are a real phenomenon and that glistenings are primarily associated with acrylic hydrophobic IOLs, but they can also occur to some degree in IOLs of other material types. However, there are several significant questions with respect to glistenings, and we solicit public comment on these questions as follows:

- Is there a particular IOL material type that is more likely to result in symptomatic glistenings relative to other material types?
- What is the clinical significance (from the patient's perspective) of glistenings? More specifically, what evidence is available to demonstrate that glistenings cause any of the following:
  - Decreased contrast sensitivity;
  - Increased glare disability;
  - Decreased visual acuity;
  - Impaired fundus visualization;
  - Symptoms resulting in IOL explantations.
- What is the incidence of glistenings in IOLs currently available in the United States?
- If a certain level of severity of glistenings is required before they cause symptoms, what is the incidence of glistenings of this severity level in IOLs currently available in the United States?

c. *Requestor/Manufacturer:* Hoya Surgical Optics, Inc. (Hoya).

Lens Model Numbers: iSert IOL System, Model PY–60R.

Summary of the Request: Hoya submitted a request for CMS to determine that its iSert IOL System satisfies the criteria for recognition as an NTIOL and to concurrently establish a new class of NTIOLs for ''aseptically integrated IOL and injector systems.'' The iSert IOL System is an IOL preloaded in a plastic, sterile, disposable injection system. According to Hoya, the iSert System provides a lens injector with an integrated IOL inside it within a single, sterile package for delivery to the operating field. According to Hoya, the iSert System has the following benefits, in that compared to other IOLs it:

- Eliminates the risk of complications associated with improper processing of reusable forceps or injectors used for all other foldable IOLs;
- Accelerates postoperative recovery through decreased risk of ocular damage due to complications associated with improper processing of reusable forceps or injectors used for other foldable IOLs;
- Provides a clinical advantage compared to existing IOLs by allowing the IOL to be placed in the eye without contacting external ocular tissues or reusable injection instruments; and
- Improves overall safety of cataract/IOL surgery by reducing the number of reusable instruments that must be properly cleaned and sterilized between cases.

As part of its request, Hoya submitted descriptive information about the iSert System as outlined in the guidance document described above that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOL by the FDA. This information included the FDA labeling, the FDA letter of approval, and the summary of safety and effectiveness for the iSert System.

As with the other CY 2012 NTIOL requests, we will base our determination of the Hoya request on consideration of the three major criteria that are discussed above. We have begun our review of Hoya's request to recognize its iSert System as an NTIOL and concurrently establish a new class of NTIOLs. We are soliciting public comment on this candidate IOL with respect to the established NTIOL criteria.

First, for an IOL to be recognized as an NTIOL we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising. The FDA label for the iSert System states the following under the heading DEVICE DESCRIPTION:

''The Hoya iSert™ Model PY–60R Intraocular Lens (IOL) is an ultraviolet absorbing posterior chamber intraocular lens designed to be implanted posterior to the iris where the lens will replace the optical function of the natural crystalline lens. However, accommodation will not be replaced. PY–60R is loaded in a disposable injector consists [sic] of Case, Tip, Body, Slider, Rod, Plunger, and Screw.''

The FDA label for the iSert System states the following under the heading INDICATIONS:

''The Hoya iSert™ Model PY–60R Intraocular Lens is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed.''

The FDA label for the iSert™ System does not otherwise reference claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs. Section 416.195(a)(2) requires that ''[c]laims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs are approved by the FDA for use in labeling and advertising.'' The FDA label for the iSert System lacks any such claims. The only statement in the above-quoted language from the FDA label that is any different from the typical device description and indications for a standard spherical monofocal IOL is the statement that the ''PY–60R is loaded in a disposable injector consists [sic] of Case, Tip, Body, Slider, Rod, Plunger, and Screw.'' However, this statement merely describes the IOL as loaded in a disposable injector. It does not appear to describe a benefit or characteristic of the IOL itself. Therefore, it would appear that the Hoya iSert System PY–60R IOL would not satisfy the requirements of 42 CFR 416.195(a)(2). However, we are soliciting public comments on this matter and will give all comments full consideration regarding Hoya's candidate IOL.

d. Requestor/Manufacturer: Lenstec, Inc. (Lenstec)

Lens Model Numbers: Softec HD PS.

Summary of the Request: Lenstec submitted a request for CMS to determine that its Softec HD PS meets the criteria for recognition as an NTIOL and to concurrently establish a new class of NTIOLs that result in a ''reduction of postoperative residual refractive error.'' According to Lenstec, the Softec HD PS IOL achieves a ''reduction of postoperative residual refractive error'' by its availability in 0.25 diopter (D) increments with a tolerance of ±0.11 D, while all other

current monofocal IOLs are available in only 0.50 D increments with tolerances allowed up to ±0.40 D. According to Lenstec, patients implanted with the Softec HD PS are much more likely to be closer to the intended refractive outcome than those implanted with IOLs available only in 0.50 D increments. This greater refractive accuracy of the Softec HD PS is due to the chosen IOL power likely being closer to the calculated (desired) IOL power and because the tighter tolerance of the 0.25 D increment IOL results in the actual power of the implanted IOL to be closer to the power that the surgeon expects to implant into the patient. Lenstec also asserts that because the 0.25 D increment IOL provides greater IOL power accuracy, patients have less postoperative residual refractive error and hence reduced postoperative blur. As part of its request, Lenstec submitted descriptive information about the candidate IOLs as outlined in the guidance document that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOL by the FDA. This information included the FDA labeling, FDA approval letter, and summary of safety and effectiveness for the Softec HD PS IOL.

As with the other three CY 2012 NTIOL applications discussed above, we will base our determination of the Lenstec application on consideration of the three major evaluation criteria that are discussed above. We have begun our review of Lenstec's request to recognize its Softec HD PS IOL as an NTIOL and concurrently establish a new class of NTIOLs. We are soliciting public comment on this candidate IOL with respect to the established NTIOL criteria as discussed above.

First, for an IOL to be recognized as an NTIOL we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising. The submitted FDA label for the Softec HD PS IOL states under the heading DEVICE DESCRIPTION that ''[t]he [LENSTEC Softec HD PS] IOL is offered in quarter diopter increments from 15.0 to 25.0.'' The FDA label for the Softec HD PS IOL does not otherwise reference claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs. We are interested in public comments on whether an IOL being offered in quarter diopter increments can be considered a ''lens characteristic with established clinical relevance in comparison with currently available IOLs,'' as required by 42 CFR 416.195(a)(2), or whether IOL availability quarter diopter increments is more appropriately considered not a lens characteristic per se, but instead just a manufacturer specification. We are also interested in public comments on the clinical relevance of an IOL being available in quarter diopter increments.

Second, as required by 42 CFR 416.195(a)(3), the candidate IOL must not be described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with improved clinical outcomes with designated members of an active or expired NTIOL class. Refer to the discussion above for more information on the three expired NTIOL classes. Lenstec states the following in its application:

''The Softec HD IOL, the parent to the Softec HD PS, was first approved for marketing in the United States on April 17, 2010 and on March 15, 2006 in the ''Outside the US'' (OUS) environment. This IOL is included in the just-closed ''Reduced Spherical Aberration'' NTIOL category. The Softec HD PS was approved for marketing by the FDA on February 2, 2011. It is currently pending approval for OUS marketing. Both IOLs are single piece, hydrophilic acrylic, aspheric, monofocal IOLs. The difference between the two is that the Softec HD has previously been available in whole, 0.50 and 0.25 diopter increments, based on dioptric power. The Softec HD PS is offered only in the dioptric range of 15.0 D to 25.0 D, in 0.25 diopter increments (each of which is manufactured to a tolerance of ±0.11D).''

Based on this statement by Lenstec, the Softec HD PS is the same lens as the Softec HD, but the Softec HD PS is available only in 0.25 D increments for a specific power range instead of being available (as is the Softec HD) in 1.0, 0.5, and 0.25 D increments. The Softec HD was included in the expired Reduced Spherical Aberration NTIOL class, and both of these IOLs share the asphericity characteristic that defines the expired Reduced Spherical Aberration NTIOL class. It appears to us that the predominant characteristic of the Softec HD PS is asphericity, as it affects the optical characteristics of the lens. Although the availability of the Softec HD PS in 0.25 D increments allows more IOL power choices for the surgeon, it does not appear to affect the functionality of the IOL. We request comments regarding what characteristic of the Softec HD PS is predominant, asphericity or availability of the IOL in 0.25 D increments.

Third, our NTIOL evaluation criteria also require that an applicant submit evidence demonstrating that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison to currently available IOLs. As discussed above, we remain flexible with respect to our view of ''currently available lenses'' for purposes of reviewing NTIOL requests, in order to allow for consideration of technological advances in lenses over time. We also believe that ''currently available lenses'' for purposes of reviewing NTIOL requests should depend upon the class-defining characteristic and the associated purported improved clinical outcome of the candidate NTIOL class. For purposes of reviewing Lenstec's request to establish a new NTIOL class for CY 2012, we believe that the full spectrum of currently available monofocal IOLs should be represented in the comparator IOLs. Lenstec asserts that what makes its candidate IOL superior to other currently available IOLs is improved IOL power accuracy as compared to IOLs available in 0.50 D increments, and because the Softec HD PS provides greater IOL power accuracy patients implanted with it have less postoperative residual refractive error and hence reduced post-operative blur.

We are reviewing the evidence submitted with Lenstec's CY 2012 request. Lenstec submitted information and reviewed the literature on IOL optics related to the Softec HD PS. Lenstec relies primarily on one study that is the subject of an article that is currently in press and another unpublished study to support its hypothesis that the Softec HD PS IOL results in less postoperative refractive error than other IOLs. The first study submitted by Lenstec was the study that it conducted under an IDE for FDA approval of the Softec HD PS IOL. This study is being published in the journal, *Contact Lens and Anterior Eye* (Brown DC, Gills JP 3rd,& et al. Prospective multicenter trial assessing effectiveness, refractive predictability and safety of a new aberration free, bi-aspheric intraocular lens. *Cont Lens Anterior Eye.* 2011 May 24. [Epub ahead of print]), and is available on the Internet at *http://www.sciencedirect.com/science/article/pii/S1367048411000634.* Refractive accuracy was not a planned outcome variable in this study. There was no control group in this study that would have allowed the investigators to control for all of the variables that impact post-cataract surgery refractive outcome and/or isolate the effect of the availability of the Softec HD PS IOL in

quarter diopter increments. Lenstec compared the postoperative refractive errors of these study subjects to the results from an unrelated study performed outside of the United States (using IOLs that were available only in 0.50 D increments) and concluded based on this comparison that implantation of the Softec HD PS IOL, which is available in quarter diopter increments, results in superior refractive outcomes as compared to other IOLs.

The second study is a retrospective study of cataract cases with aspheric monofocal IOL implantation between 2009 and 2011. Of the 118 eligible eyes, 67 were implanted with IOLs available in 0.25 D increments and labeled with a manufacturing tolerance of ±0.11D (the labeled group) and 51 were implanted with IOLs available in 0.50 D increments without a labeled manufacturing tolerance (the unlabeled group). Postoperative outcomes were assessed, and prediction error was calculated and compared between groups. Mean error of prediction was −0.03 (±0.35) D for the labeled group and −0.05 (±0.46) D for the unlabeled group (p = 0.64) post optimization. Mean absolute error of prediction was statistically significantly smaller in the labeled group (0.26 ± 0.23 D) than the unlabeled group (0.37 ± 0.28 D, p = 0.04). It was observed that within ± 0.25 D prediction error was achieved in 63 percent of the patients in the labeled group compared to 43 percent in the unlabeled group (p = 0.03), and for within ±0.50 D, 84 percent and 69 percent (p = 0.06), respectively. We request comments from the public regarding the Lenstec NTIOL request and the evidence submitted by Lenstec, and in particular would like the public to comment on the following:

- What is the clinical significance (from the patient's perspective) of a small amount of residual spherical refractive error after cataract surgery?
- What is the likelihood that a Medicare beneficiary receiving a monofocal IOL will require some form of postoperative refractive correction (that is, post-cataract surgery glasses), which is a Medicare benefit?
- If the overwhelming majority of Medicare beneficiaries receiving a monofocal IOL will require some form of postoperative refractive correction (that is, post-cataract surgery glasses), does that lessen the clinical significance of reduced postoperative residual refractive error?
- Are the studies described above properly designed to test Lenstec's hypothesis?
- Do the studies described above adequately prove Lenstec's hypothesis?

All comments on these requests must be received by August 1, 2011. The announcement of CMS's determinations regarding these requests will appear in the CY 2012 OPPS/ASC final rule with comment period. If a determination of membership of the candidate IOLs in a new NTIOL class is made, this determination will be effective 30 days following the date that the final rule with comment period is published in the **Federal Register**.

4. Proposed Payment Adjustment

The current payment adjustment for a five-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2012.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we also created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC list of covered services prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule with comment period to indicate new HCPCS codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' is also assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In the CY 2012 OPPS/ASC final rule with comment period, we will respond to public comments and finalize the ASC treatment of all codes that are labeled with comment indicator ''NI'' in ASC Addendum AA and BB for CY 2011. These addenda can be found in a file labeled ''January 2011 ASC Approved HCPCS Code and Payment Rates to Reflect the Medicare and Medicaid Extenders Act of 2010'' in the ASC Addenda Update section of the CMS Web site.

The ''CH'' comment indicator is used in Addenda AA and BB to this CY 2012 proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) to indicate that a new payment indicator is proposed for assignment to an active HCPCS code for the next calendar year; an active HCPCS code is proposed for addition to the list of procedures or services payable in ASCs; or an active HCPCS code is proposed for deletion at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment. The full definitions of the proposed payment indicators and comment indicators are provided in Addenda DD1 and DD2 to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

2. Proposed ASC Payment and Comment Indicators

The revised ASC payment system included a four-year transition to payment rates under the standard methodology for the procedures on the ASC list in CY 2007. CY 2011 was the first year of full payment under the standard methodology for the revised ASC payment system. Payment indicators ''A2'' (Surgical procedure on ASC list in CY 2007, payment based on OPPS relative payment weight) and ''H8'' (Device-intensive procedure on

ASC list in CY 2007; paid at adjusted rate) were developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and were, therefore, subject to transitional payment prior to CY 2011.

Because the four-year transitional payment period has ended and it is no longer necessary to identify device-intensive procedures that are subject to transitional payments, we are proposing to delete the ASC payment indicator ''H8.'' We are proposing that all device-intensive procedures, for which the modified rate calculation methodology will apply, be assigned payment indicator ''J8'' in CY 2012 and later. In addition, we are proposing to modify the definition for payment indicator ''J8'' by removing ''added to ASC list in CY 2008 or later'' as this distinction is no longer necessary.

Although payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we are proposing to retain payment indicator ''A2'' because it is used to identify procedures that are exempted from application of the office-based designation.

As detailed in section XIV.K. of this proposed rule, we are proposing to establish an ASC Quality Reporting Program with the collection of seven claims-based quality measures beginning in CY 2012. We are proposing to require ASCs to report on ASC claims a quality data code (QDC) to be used for reporting quality data. We are proposing that an ASC would need to add a QDC to any claim involving a proposed claims-based quality measure. CMS is in the process of developing QDCs for each proposed claims-based quality measure. The QDC will be a CPT Category II code or a HCPCS Level II G-code if an appropriate CPT code is not available. More information on the QDCs that will be associated with the proposed quality measures will be provided in the CY 2012 OPPS/ASC final rule with comment period. Additionally, CMS is proposing to create a new ASC payment indicator ''M5'' (Quality measurement code used for reporting purposes only; no payment made) for assignment to the QDC to clarify that no payment is associated with the QDC for that claim. We are proposing that this proposed payment indicator be effective January 1, 2012.

We are not proposing any changes to the definitions of the ASC comment indicators for CY 2012. We refer readers to Addenda DD1 and DD2 to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet at the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2012 update.

We invite public comment on these proposals.

G. ASC Policy and Payment Recommendations

MedPAC was established under section 1805 of the Act to advise Congress on issues affecting the Medicare program. Subparagraphs (B) and (D) of section 1805(b)(1) of the Act require MedPAC to submit reports to Congress not later than March 1 and June 15 of each year that present its Medicare payment policy reviews and recommendations and its examination of issues affecting the Medicare program, respectively. The March 2011 MedPAC ''Report to the Congress: Medicare Payment Policy'' included the following recommendation relating specifically to the ASC payment system for CY 2012:

Recommendation 5: The Congress should implement a 0.5 percent increase in payment rates for ambulatory surgical center services in calendar year 2012 concurrent with requiring ambulatory surgical centers to submit cost and quality data.

CMS Response: In the August 2, 2007 final rule (72 FR 42518 through 42519), we adopted a policy to update the ASC conversion factor for consistency with section 1833(i)(2)(C) of the Act, which requires that, if the Secretary has not updated the ASC payment amounts in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI–U) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute set the update at zero for CY 2008 and CY 2009. We indicated that we planned to implement the annual updates through an adjustment to the conversion factor under the ASC payment system beginning in CY 2010 when the statutory requirement for a zero update no longer applies. Further, we noted that we would update the conversion factor for the CY 2010 ASC payment system by the percentage increase in the CPI–U, consistent with our policy as codified under § 416.171(a)(2).

As we indicated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622), we did not require ASCs to submit cost data to the Secretary for CY 2010. We explained that the 2006 GAO report, ''Medicare: Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System'' (GAO–07–86), concluded that the APC groups in the OPPS reflect the relative costs of surgical procedures performed in ASCs in the same way they reflect the relative costs of the same procedures when they are performed in HOPDs. Consistent with the GAO findings, CMS is using the OPPS as the basis for the ASC payment system, which provides for an annual revision of the ASC payment rates under the budget neutral ASC payment system.

In addition, we noted that, under the methodology of the revised ASC payment system, we do not utilize ASC cost information to set and revise the payment rates for ASCs, but instead rely on the relativity of hospital outpatient costs developed for the OPPS, consistent with the recommendation of the GAO. Furthermore, we explained that we have never required ASCs to routinely submit cost data and expressed our concern that a new Medicare requirement for ASCs to do so could be administratively burdensome for ASCs.

In 2009, MedPAC made a similar recommendation to that made in Recommendation 5 above. In light of that MedPAC recommendation, in the CY 2010 OPPS/ASC proposed rule (74 FR 35391), we solicited public comment on the feasibility of ASCs submitting cost information to CMS, including whether costs should be collected from a sample or the universe of ASCs, the administrative burden associated with such an activity, the form that such a submission could take considering existing Medicare requirements for other types of facilities and the scope of ASC services, the expected accuracy of such cost information, and any other issues or concerns of interest to the public on this topic.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60623), we summarized and responded to these comments. As noted in that final rule with comment period, commenters expressed varied opinions regarding the feasibility of requiring ASCs to submit cost data to the Secretary. Some commenters believed that requiring ASC to submit such data would not be an insurmountable obstacle and pointed out that other small facilities submit cost reports to CMS. They argued that ASC cost reports are necessary to assess the adequacy of Medicare payments and evaluate the ASC update. Other commenters, however, opposed the requirement that ASCs submit cost data to CMS because they believed such a requirement would be unnecessary and administratively burdensome. Commenters generally supported a requirement that ASCs report quality data. We refer readers to the CY 2010

OPPS/ASC final rule with comment period for a full discussion of the comments we received on the feasibility of requiring ASCs to report cost and quality data (74 FR 60623). Consistent with our CY 2010 policy, we proposed not to require ASCs to submit cost data to the Secretary for CY 2011 (75 FR 46356 through 463557). We stated that we continue to believe that our established methodology results in appropriate payment rates for ASCs. For CY 2012, consistent with this policy and for the same reasons, we are not proposing to require ASCs to submit cost data.

Section 109(b) of the MIEA–TRHCA (Pub. L. 109–432) gives the Secretary the authority to implement ASC quality measure reporting and to reduce the payment update for ASCs that fail to report those required measures. We are proposing to require ASCs to report seven quality measures in CY 2012. Details associated with ASC quality reporting proposed for CY 2012 are discussed in section XIV.K. of this proposed rule.

Finally, we are not proposing to implement MedPAC's recommended CY 2012 ASC update of 0.5 percent. The annual update to the ASC payment system is the CPI–U. Section 3401(k) of the Affordable Care Act required that the annual ASC payment update be reduced by a productivity adjustment. As discussed in section XIII.H.2.b. of this proposed rule, the Secretary estimates that the CPI–U is 2.3 percent and the MFP adjustment is 1.4 percent. Therefore, we are proposing a 0.9 percent update for CY 2012.

H. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007 as required under section 1833(i)(2)(E) of the Act (72 FR 42522).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across hospital outpatient, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures and covered ancillary radiology services, excluding nuclear medicine procedures, the established policy is to set the relative payment weights so that the national unadjusted ASC payment rate does not exceed the MPFS unadjusted non-facility PE RVU-based amount. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage indices to the labor-related share, which is 50 percent of the ASC payment amount. Beginning in CY 2008, CMS accounted for geographic wage variation in labor cost when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003. The reclassification provision provided at section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available raw pre-floor and pre-reclassified hospital wage indices results in the most appropriate adjustment to the labor portion of ASC costs. In addition, use of the unadjusted hospital wage data avoids further reductions in certain rural statewide wage index values that result from reclassification. We continue to believe that the unadjusted hospital wage indices, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs.

We note that in certain instances there might be urban or rural areas for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indices for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). We have applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 Hinesville-Fort Stewart, GA, and CBSA 22 Rural Massachusetts. In CY 2011, we identified another area, specifically, CBSA 11340 Anderson, SC, for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. Generally, we would use the methodology described above; however in this situation all of the areas contiguous to CBSA 11340 Anderson, SC, are rural. Therefore, in the CY 2011 OPPS/ASC final rule with comment (75 FR 72058 through 72059), we finalized our proposal to set the ASC wage index by calculating the average of all wage indices for urban areas in the State when all contiguous areas to a CBSA are rural and there is no IPPS hospital

whose wage index data could be used to set the wage index for that area. In other situations, where there are no IPPS hospitals located in a relevant labor market area, we will continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indices for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

2. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2012 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS non-facility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42531 through 42532). Consistent with our established policy, we are proposing to scale the CY 2012 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2010, we are proposing to compare the total payment weight using the CY 2011 ASC relative payment weights (calculated under the ASC standard ratesetting methodology) with the total payment weight using the CY 2012 ASC relative payment weights (calculated under the ASC standard ratesetting methodology) to take into account the changes in the OPPS relative payment weights between CY 2011 and CY 2012. We would use the ratio of CY 2011 to CY 2012 total payment weight (the weight scaler) to scale the ASC relative payment weights for CY 2012. The proposed CY 2012 ASC scalar is 0.9373 and scaling would apply to the ASC relative payment weights of the covered surgical procedures and covered ancillary radiology services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment weight between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We currently have available 98 percent of CY 2010 ASC claims data.

To create an analytic file to support calculation of the weight scaler and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2010 ASC claims by provider and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2010 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the proposed rule, is posted on the CMS Web site at: *http://www.cms.gov/ASCPayment/01_Overview.asp#TopOfPage.*

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2012 ASC payment system, we are proposing to calculate and apply the pre-floor and pre-reclassified hospital wage indices that are used for ASC payment adjustment to the ASC conversion factor, just as the OPPS wage index adjustment is calculated and applied to the OPPS conversion factor. For CY 2012, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2010 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2012 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2010 ASC utilization and service-mix and the proposed CY 2012 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2011 pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2012 pre-floor and pre-reclassified hospital wage indices. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2011 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2012 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0003 (the proposed CY 2012 ASC wage index budget neutrality adjustment) to the CY 2011 ASC conversion factor to calculate the proposed CY 2012 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated the ASC payment amounts in a calendar year, the payment amounts ''shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.'' Because the Secretary does update the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI–U (referred to as the CPI–U update factor).

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that ''any annual update under [the ASC payment] system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)'' (which we refer to as the MFP adjustment) effective with the calendar year beginning January 1, 2011. Clause (iv) authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064), we revised § 416.160 and § 416.171 to reflect this provision of the Affordable Care Act (we note that these regulations do not reflect any reduction in the annual update for failure to report on quality measures because CMS had not implemented an ASC quality reporting program).

As discussed in section XIV.K. of this proposed rule, we are proposing that ASCs begin submitting data on quality

measures in CY 2012 for the CY 2014 payment determination. Because any reduction to the annual update under the ASC Quality Reporting Program will not occur until CY 2014, we are not proposing any changes to the payment methodology. We intend to address payment changes based on failure to submit quality data under the ASC Quality Reporting Program in a future rulemaking.

Without regard to the ASC Quality Reporting Program and in accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the ''percentage increase'' in the CPI–U, which we interpret cannot be a negative number. Thus, in the instance where the percentage change in the CPI–U for a year is negative, we are proposing to hold the CPI–U update factor for the ASC payment system to zero. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, then requires that the Secretary reduce the CPI–U update factor (which would be held to zero if the CPI–U percentage change is negative) by the MFP adjustment, and states that application of the MFP adjustment may reduce this percentage change below zero. If the application of the MFP adjustment to the CPI–U percentage increase would result in a MFP-adjusted CPI–U update factor that is less than zero, then the annual update to the ASC payment rates would be negative and payments would decrease relative to the prior year. Illustrative examples of how the MFP adjustment would be applied to the ASC payment system update are found in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064).

For this proposed rule, for the 12-month period ending with the midpoint of CY 2012, the Secretary estimates that the CPI–U is 2.3 percent. The Secretary estimates that the MFP adjustment is 1.4 percentage points based on the methodology for calculating the MFP adjustment finalized in the CY 2011 MPFS final rule with comment period (75 FR 73391 through 73399) as revised by the proposal discussed in the CY 2012 MPFS proposed rule. Therefore, we are proposing to reduce the CPI–U of 2.3 percent by the MFP adjustment specific to this CPI–U of 1.4 percentage points, resulting in an MFP-adjusted CPI–U update factor of 0.9 percent. Therefore, we are proposing to apply a 0.9 percent MFP-adjusted update to the CY 2011 ASC conversion factor.

For CY 2012, we also are proposing to adjust the CY 2011 ASC conversion factor ($41.939) by the wage adjustment for budget neutrality of 1.0003 in addition to the MFP-adjusted update factor of 0.9 percent discussed above, which results in a proposed CY 2012 ASC conversion factor of $42.329.

3. Display of Proposed CY 2012 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) display the proposed updated ASC payment rates for CY 2012 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the proposed CY 2012 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''Subject to Multiple Procedure Discounting'' indicates that the surgical procedure will be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session. Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2012. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that the payment indicator assignment is an interim assignment that is open to comment on the final rule with comment period.

The values displayed in the column titled ''CY 2012 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2012. The payment weights for all covered surgical procedures and covered ancillary services whose ASC payment rates are based on OPPS relative payment weights are scaled for budget neutrality. Thus, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the proposed CY 2012 payment rate displayed in the ''CY 2012 Payment'' column, each ASC payment weight in the ''CY 2012 Payment Weight'' column is multiplied by the proposed CY 2012 conversion factor of $42.329. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the CPI–U update factor as reduced by the productivity adjustment (as discussed in section XV.H.2.b. of this proposed rule).

In Addendum BB, there are no relative payment weights displayed in the ''CY 2012 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''CY 2012 Payment'' column displays the proposed CY 2012 national unadjusted ASC payment rates for all items and services. The proposed CY 2012 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in April 2011.

XIV. Hospital Outpatient Quality Reporting Program Updates and ASC Quality Reporting Program

A. Background

1. Overview

CMS has implemented quality measure reporting programs for multiple settings of care. These programs promote higher quality, more efficient health care for Medicare beneficiaries. The quality data reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (Hospital OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), has been generally modeled after the quality data reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (Hospital IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). Both of these quality reporting programs for hospital services, as well as the program for physicians and other eligible professionals, known as the Physician Quality Reporting System (formerly known as the Physician Quality Reporting Initiative (PQRI)), have financial incentives for the reporting of quality data to CMS. CMS also has implemented quality reporting programs for home health agencies and skilled nursing facilities that are based on conditions of participation, and an end-stage renal disease (ESRD) Quality

Incentive Program (76 FR 628 through 646) that links payment to performance.

In implementing the Hospital OQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal is ultimately to align the clinical quality measure requirements of the Hospital OQR Program and various other programs, including the Hospital IQR Program, and the proposed ASC Quality Reporting Program, with the reporting requirements implemented under the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the burden of reporting can be reduced. In developing this and other quality reporting programs, as well as the Hospital Inpatient Value-Based Purchasing (Hospital Inpatient VBP) Program, we applied the following principles for the development and use of measures:

- Pay-for-reporting, public reporting, and value-based purchasing programs should rely on a mix of standards, processes, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience of care measures. To the extent practicable and appropriate, outcome and patient experience of care measures should be adjusted for risk factors or other appropriate patient population or provider characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider category.
- The collection of information burden on providers should be minimized to the extent possible. To this end, we continuously seek to align our measures with the adoption of meaningful use standards for health information technology (HIT), so that data can be submitted and calculated via certified EHR technology with minimal burden.
- To the extent practicable and feasible, and recognizing differences in statutory authorities, measures used by CMS should be endorsed by a national, multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We invite public comment on these principles.

2. Statutory History of the Hospital Outpatient Quality Reporting (Hospital OQR) Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Technical Specification Updates and Data Publication

a. Maintenance of Technical Specifications for Quality Measures

Technical specifications for each Hospital OQR measure are listed in the Hospital OQR Specifications Manual, which is posted on the CMS QualityNet Web site at *http://www.QualityNet.org.* We maintain the technical specifications for the measures by updating this Hospital OQR Specifications Manual and including detailed instructions and calculation algorithms. In some cases where the specifications are available elsewhere, we may include links to Web sites hosting technical specifications. These resources are for hospitals to use when collecting and submitting data on required measures.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for making updates to the technical specifications that we use to calculate Hospital OQR measures. This process is used when changes to the measure specifications are necessary due to changes in scientific evidence, treatment guidelines, or consensus among affected parties. Changes due to these reasons may not coincide with the timing of our regulatory actions, but nevertheless should be made so that the Hospital OQR measures are calculated based on the most up-to-date scientific and consensus standards. We indicated that notification of technical changes to the measure specifications is made via the QualityNet Web site, *http://www.QualityNet.org,* and in the Hospital OQR Specifications Manual. The notification of changes to the measure technical specifications occurs no less than 3 months before any changes become effective for purposes of reporting under the Hospital OQR Program.

The Hospital OQR Specifications Manual is released every 6 months and addenda are released as necessary. This release schedule provides at least 3 months of advance notice for substantial changes such as changes to ICD–9, CPT, NUBC, and HCPCS codes, and at least 6 months of advance notice for changes to data elements that would require significant systems changes.

b. Publication of Hospital OQR Program Data

Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under Hospital OQR available to the public. It also states that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. To meet these requirements, data that a hospital has submitted for the Hospital OQR Program are typically displayed on CMS Web sites such as the *Hospital Compare* Web site, *http://www.hospitalcompare.hhs.gov,* after a preview period. The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care. This information motivates beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, providing additional incentives to hospitals to improve the quality of care that they furnish.

Under our current policy, we publish quality data by the corresponding hospital CCN, and indicate instances where data from two or more hospitals are combined to form the publicly reported measures on the *Hospital Compare* Web site. This approach is consistent with the approach taken under the Hospital IQR Program. Consistent with our current policy, we make Hospital OQR data publicly available whether or not the data have been validated for payment purposes.

In general, we strive to display hospital quality measures on the *Hospital Compare* Web site as soon as possible after they have been adopted and have been reported to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other, non-interactive, CMS Web sites such as *http://www.cms.hhs.gov/HospitalQualityInits/*. Publicly reporting the information in this manner, though not on the interactive *Hospital Compare* Web site, allows us to meet the requirement under section 1833(t)(17)(E) of the Act for establishing procedures to make quality data submitted available to the public following a preview period. When we display hospital quality information on

non-interactive CMS Web sites, affected parties would be notified via CMS listservs, CMS e-mail blasts, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare.*

We also require hospitals to complete and submit a registration form (''participation form'') in order to participate in the Hospital OQR Program. With submission of this participation form, participating hospitals agree that they will allow CMS to publicly report the quality measure data submitted under the Hospital IQR Program, including measures that we calculate using Medicare claims.

B. Proposed Revision to Measures Previously Adopted for the Hospital OQR Program for the CY 2012, CY 2013, and CY 2014 Payment Determinations

1. Background

We refer readers to the following OPPS/ASC final rules with comment periods for a history of measures adopted for the Hospital OQR Program, including lists of: 11 measures adopted for the CY 2011 payment determination (74 FR 60637); 15 measures adopted for the CY 2012 payment determination (75 FR 72083 through 72084); 23 measures adopted for the CY 2013 payment determination (75 FR 72090); and 23 measures adopted for the CY 2014 payment determination (75 FR 72094). The table below also shows the 23 measures previously adopted for these payment determinations:

HOSPITAL OQR PROGRAM MEASURES PREVIOUSLY ADOPTED FOR THE CY 2011, CY 2012, CY 2013, AND CY 2014 *** PAYMENT DETERMINATIONS

OP–1: Median Time to Fibrinolysis.
OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
OP–4: Aspirin at Arrival.
OP–5: Median Time to ECG.
OP–6: Timing of Antibiotic Prophylaxis.
OP–7: Prophylactic Antibiotic Selection for Surgical Patients.
OP–8: MRI Lumbar Spine for Low Back Pain.
OP–9: Mammography Follow-up Rates.
OP–10: Abdomen CT—Use of Contrast Material.
OP–11: Thorax CT—Use of Contrast Material.
OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data.*
OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.*
OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).*
OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.*
OP–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with *Probable Cardiac Chest Pain*) Received Within 60 minutes of Arrival.**
OP–17: Tracking Clinical Results between Visits.**
OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.**
OP–19: Transition Record with Specified Elements Received by Discharged Patients.**
OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.**
OP–21: ED–Median Time to Pain Management for Long Bone Fracture.**
OP–22: ED–Left Without Being Seen.**
OP–23: ED–Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival.**

* New measure adopted beginning with the CY 2012 payment determination.
** New measure adopted beginning with the CY 2013 payment determination.
*** All 23 measures were adopted for the CY 2014 payment determination.

2. Proposed Revision to Hospital OQR Program Measures Previously Adopted for the CY 2013 Payment Determination

In the CY 2011 OPPS/ASC final rule with comment period, we finalized the adoption of the chart-abstracted measure OP–22—Left Without Being Seen (75 FR 72088 through 72089). This measure was endorsed (NQF #0499) as part of an NQF project entitled ''National Voluntary Consensus Standards for Emergency Care.'' This measure assesses the percentage of patients who leave the Emergency Department (ED) without being evaluated by qualified medical personnel, which is an indication of ED overcrowding, and lack of timely access to care. We are proposing that beginning with the CY 2013 payment determination, hospitals would submit aggregate numerator and denominator counts once a year using a Web-based form available through the QualityNet Web site for this measure. This proposed process is different from that which is used to collect other chart-abstracted measures because it would not require hospitals to submit patient-level information for this measure, and would not require quarterly submission of data. We believe this proposed process will reduce the potential data collection and submission burden for this measure.

We are proposing that for the CY 2013 payment determination, data submission for this measure would occur between July 1, 2012 and August 15, 2012. We also are proposing that for the CY 2013 payment determination, the aggregate counts for the numerator (the total number of patients who left without being evaluated by a physician/advance practice nurse/physician's assistant) and the denominator (total number of patients who signed in to be evaluated for emergency services) would be submitted by hospitals and would span the time period from January 1, 2011 through December 31, 2011. We invite public comment on this proposed approach to data collection for OP–22 for the CY 2013 Hospital OQR Program and subsequent payment determinations, and on the time period to be assessed for this measure for the CY 2013 payment determination. The updated specifications for this measure will be made available in the July 2011 Hospital OQR Specifications Manual.

C. Proposed New Quality Measures for the CY 2014 and CY 2015 Payment Determinations

1. Considerations in Expanding and Updating Quality Measures Under the Hospital OQR Program

In general, when selecting measures for the Hospital OQR Program, we take into account several considerations and goals. These include: (a) expanding the types of measures beyond process of care measures to include an increased number of outcome measures, efficiency measures, and patients' experience-of-care measures; (b) expanding the scope of hospital services to which the measures apply; (c) considering the burden on hospitals in collecting chart-abstracted data; (d) harmonizing the measures used in the Hospital OQR Program with other CMS quality programs to align incentives and promote coordinated efforts to improve quality; (e) seeking to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims data bases; and (f) weighing the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital OQR Program.

Specifically, we assign priority to quality measures that assess performance on: (a) conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and (c) conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. We used and continue to use these criteria to guide our decisions regarding what measures to add to the Hospital OQR Program measure set.

In the CY 2009 OPPS/ASC final rule with comment period, we adopted four claims–based quality measures that do not require a hospital to submit chart-abstracted clinical data (73 FR 68766). This supports our goal of expanding the measures for the Hospital OQR Program while minimizing the burden upon hospitals and, in particular, without significantly increasing the chart abstraction burden. In addition to claims-based measures, we are considering registries and EHRs as alternative ways to collect data from hospitals.

A registry is a collection of clinical data for purposes of assessing clinical performance, quality of care, and opportunities for quality improvement. Many hospitals submit data to and participate in existing registries. In addition, registries often capture outcome information and provide ongoing quality improvement feedback to registry participants. Instead of requiring hospitals to submit the same data to CMS that they are already submitting to registries, we could collect the data directly from the registries with the permission of the hospital, thereby enabling us to expand the Hospital OQR Program measure set without increasing the burden of data collection for those hospitals participating in the registries. The data that we would receive from registries would be used to calculate quality measures required under the Hospital OQR Program, and would be publicly reported like other Hospital OQR Program quality measures, encouraging improvements in the quality of care. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60633), we responded to public comments on such an approach.

In the CY 2009 OPPS/ASC final rule with comment period, we also stated our intention to explore mechanisms for data submission using EHRs (73 FR 68769). When we refer to the term Qualified EHR, we intend for it to have the same meaning as set forth by the Office of the National Coordinator for Health Information Technology (ONC) (45 CFR 170.102) which has adopted the statutory definition of Qualified EHR found in section 3000(13) of the Public Health Service Act. That section defines a Qualified EHR as ''an electronic record of health-related information on an individual that—(A) includes patient demographic and clinical health information, such as medical history and problem lists; and (B) has the capacity—(i) to provide clinical decision support; (ii) to support physician order entry; (iii) to capture and query information relevant to health care quality; and (iv) to exchange electronic health information with, and integrate such information from other sources.'' Additionally, when we refer to the term, Certified EHR Technology, we intend for it to have the same meaning as set forth by the ONC at 45 CFR 170.102 as follows: ''Certified EHR Technology'' means (1) A complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary; or (2) a combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

Establishing a data submission mechanism using EHRs will require interoperability between EHRs and our data collection systems, additional infrastructure development on the part of hospitals and CMS, and the adoption of standards for the capturing, formatting, and transmission of data elements that make up the measures. However, once these activities are accomplished, the adoption of measures that rely on data obtained directly from EHRs would enable us to expand the Hospital OQR Program measure set with less cost and burden to hospitals. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60633 through 60634), we responded to public comments on such an approach.

Continuing to reduce our reliance on the chart-abstraction mechanism would allow us and hospital outpatient departments to devote available resources towards maximizing the potential of registries and EHRs for quality measurement reporting. Both mechanisms hold the promise of more sophisticated and timely reporting of clinical quality measures. Clinical data registries allow the collection of more detailed data, including outcomes. Registries can also provide feedback and quality improvement information based on reported data. Finally, clinical data registries can also receive data from EHRs, and therefore, serve as an alternative means to reporting clinical quality data extracted from an EHR.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72174), we added new measures over a three year period for the CY 2012, CY 2013, and CY 2014 payment determinations. We believe this process will assist hospitals in planning, meeting future reporting requirements, and implementing quality improvement efforts. We will also have more time to develop, align, and implement the infrastructure necessary to collect data on the measures and make payment determinations. The fact that we finalized measures for a three year period of time (for example, for the CY 2012, CY 2013 and CY 2014 payment determinations in the CY 2011 OPPS/ASC final rule with comment period) does not preclude us from proposing to adopt additional measures or changing the list of measures for these payment determinations through

subsequent rulemaking cycles that affect these future payment determinations.

We have previously expanded the Hospital OQR Program measure set dramatically by adopting measures over several payment determinations in order to allow hospital outpatient departments adequate time to plan and implement the reporting of quality data for the CY 2012, CY 2013 and CY 2014 payment determinations. In this proposed rule, we are proposing to add new measures to the existing Hospital OQR measure set for the CY 2014 payment determination and are proposing to add new measures for the CY 2015 payment determination.

2. Proposed New Hospital OQR Program Quality Measures for the CY 2014 Payment Determination

As stated above, the CY 2014 measure set for the Hospital OQR Program currently contains 23 measures that we adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72094). In this proposed rule, we are proposing to adopt a number of additional measures for the CY 2014 measure set.

a. Proposed New National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) Measure for the CY 2014 Payment Determination: Surgical Site Infection (NQF #0299)

Healthcare Associated Infections (HAIs) is a topic area widely acknowledged by HHS, the Institute of Medicine (IOM), the National Priorities Partnership, and others as a high priority requiring measurement and improvement. HAIs are among the leading causes of death in the United States. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths.[1] It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs. HAIs are largely preventable through interventions such as better hygiene and advanced scientifically tested techniques for surgical patients. Therefore, many health care consumers and organizations are calling for public disclosure of HAIs, arguing that public reporting of HAI rates provides the information health care consumers need to choose the safest hospitals, and gives hospitals an incentive to improve infection control efforts. This proposed measure is currently collected by the National Healthcare Safety Network (NHSN) as part of State-mandated reporting and surveillance requirements for hospitals in some States. Additionally, data submission for this measure through EHRs may be possible in the near future.

The NHSN is a secure, Internet-based surveillance system maintained and managed by the CDC, and can be utilized by all types of healthcare facilities in the United States, including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and long term care facilities. The NHSN is provided free of charge to hospitals. The NHSN enables healthcare facilities to collect and use data about HAIs, clinical practices known to prevent HAIs, the incidence or prevalence of multidrug-resistant organisms within their organizations, and other adverse events. Some States use the NHSN as a means for healthcare facilities to submit data on HAIs mandated through their specific State legislation. Currently, 21 States require hospitals to report HAIs using the NHSN, and the CDC supports more than 4,000 hospitals that are using NHSN.

Increasingly, more surgical procedures are being performed in hospital outpatient department settings and ASCs. Therefore, we have determined that this measure is ''appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings'' as required under section 1833(t)(17)(C)(i) of the Act. This proposed HAI measure assesses the percentage of surgical site infections occurring within 30 days after an NHSN-defined operative procedure if no implant is left in place or within one year if an implant is in place, and the infection appears to be related to the operative procedure. Infections are identified on original admission or upon readmission to the facility of original operative procedure within the relevant time frame (30 days for no implants; within 1 year for implants). The specifications for this proposed HAI measure can be found at *http://www.cdc.gov/nhsn/psc.html.*

We also believe that this measure meets the requirement under section 1833(t)(17)(C)(i) of the Act that measures selected for the Hospital OQR Program ''reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.'' This measure was NQF-endorsed in 2007 and was adopted by the Hospital Quality Alliance in 2008. We note that this measure also was adopted for the Hospital IQR Program beginning with the FY 2014 payment determination (75 FR 50211) and its adoption into the Hospital OQR Program would further our goal of aligning measures across programs where feasible.

We are proposing that submission of data for this proposed NHSN measure for the CY 2014 payment determination would relate to infection events occurring between January 1, 2013 and June 30, 2013. We are proposing that hospital outpatient departments use the existing NHSN infrastructure and protocols that already exist for this proposed measure to report it for Hospital OQR Program purposes. We invite public comment on our proposal to adopt this HAI measure into the Hospital OQR Program for the CY 2014 payment determination.

b. Proposed New Chart-Abstracted Measures for the CY 2014 Payment Determination

In the CY 2011 OPPS/ASC final rule with comment period, we stated that we would not finalize five proposed NQF-endorsed diabetes care measures because we were in the process of refining the chart-abstracted numerator definitions for these measures (75 FR 72091). We also stated that we intended to again propose to adopt these measures for the CY 2014 payment determination. We now are proposing to adopt these five diabetes care measures for the CY 2014 payment determination as chart-abstracted measures. These five measures are: (1) Hemoglobin A1c Management (NQF #0059); (2) Diabetes Measure Pair: A. Lipid Management: Low Density Lipoprotein Cholesterol (LDL–C) < 130, B. Lipid Management: LDL–C < 100 (NQF #0064); (3) Diabetes: Blood Pressure Management (NQF #0061); (4) Diabetes: Eye Exam (NQF #0055); and (5) Diabetes: Urine Protein Screening (NQF #0062). We note that these five measures are electronically specified. We hope to be able to collect such information via EHRs in the future, and we solicit comments on using EHR for data collection in the future. In addition, we are proposing to adopt another new chart-abstracted measure, Cardiac Rehabilitation Patient Referral from an Outpatient Setting (NQF #0643), for the CY 2014 payment determination. Below are descriptions of each of these six proposed new chart-abstracted measures.

[1] McKibben L., Horan, T.: Guidance on public reporting of healthcare-associated infections: recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005; 33:217–26.

(1) Proposed Diabetes Measure: Hemoglobin A1c Management (NQF #0059)

In general, diabetes mellitus is a chronic disease that impacts the lives of a large portion of the population and consumes a significant amount of U.S. healthcare dollars. With the prevalence of diabetes in the Medicare-eligible population expected to double, costs are expected to increase almost fourfold to $171 million.[2] Uncontrolled diabetes often leads to biochemical imbalances that can lead to acute life-threatening events, such as diabetic ketoacidosis and hyperosmolar, or nonketotic coma. In patients with insulin-dependent diabetes, the risk of development or progression of retinopathy, nephropathy, and neuropathy can be reduced by 50 to 75 percent by intensive outpatient treatment of hyperglycemia compared to conventional treatment. Early treatment may help slow or halt the progression of diabetic complications, and following the guidelines for screening may assist those patients with no outward sign of diabetic complications to be identified earlier through regular screening tests. Some guidelines recommend that the HgA1c level be tested during an initial assessment and in follow-up assessments which should occur at no longer than 3-month intervals.[3] Other guidelines recommend that the HgA1c level be tested at least twice a year in patients with stable glycemic control and who are meeting treatment goals, and quarterly in patients whose HgA1c level does not meet target glycemic goals.[4]

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Because this measure is NQF-endorsed, we believe that this measure meets the requirement of reflecting consensus among affected parties. However, we note that consensus among affected parties can be reflected through means other than NQF endorsement. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting, in which many patients with diabetes are treated.

Lower HgA1c levels are associated with reduced microvascular and neuropathic complications of diabetes. This NQF-endorsed measure measures the percentage of adult patients with diabetes aged 18–75 years with a most recent HgA1c level greater than 9 percent (poor control). The specifications for this measure are located in Appendix A (beginning page A–60) of the 2008 NQF Report titled ''National Voluntary Consensus Standards for Ambulatory Care—Part 1'' available at the following link: *http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_Ambulatory_Care%E2%80%93Part_1.aspx.*

Glycosylated hemoglobin (HA1c) assay measures average blood glucose over the preceding two to three months, rather than just one point in time. HgA1c values fluctuate less frequently than fasting glucose values and give clinicians a better integrated view of the patient's average blood sugar over time. High HgA1c is a more reliable indicator of chronic high blood sugar. We invite public comment on this proposed measure.

(2) Proposed Diabetes Measure Pair: A. Lipid Management: Low Density Lipoprotein Cholesterol (LDL–C) < 130, B. Lipid Management: LDL–C < 100 (NQF #0064)

LDL–C measures the development of atherosclerotic plaque which increases the cardiac events risk for diabetic patients, who already face heart disease death rates that are about two to four times higher than these rates are for non-diabetic patients.[5] Improved dyslipidemia management helps to mitigate the risk for cardiovascular disease. Lipid-lowering therapy for diabetics has been a consistent recommendation in several guidelines, prompted by randomized trials supporting statin therapy to lower the risk of cardiovascular involvement for this population. Despite the evidence basis and guideline support, only a minority of patients with diabetes are prescribed statin treatment or achieve target LDL–C goals.[6]

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Because this measure is NQF-endorsed, we believe that this measure meets the requirement of reflecting consensus among affected parties. However, we note that consensus among affected parties can be reflected through means other than NQF endorsement. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting which serves many patients with diabetes who often have high level of LDL–C.

Early treatment of hyperlipidemia as indicated by high level of LDL–C may help to slow or halt the progression of cardiovascular disease and impact the quality of the life of the diabetic patient, affecting the patient's life expectancy and decreasing costs involved in treating diabetic complications. This NQF-endorsed measure assesses: (i) The percentage of adult patients with diabetes aged 18–75 years whose most recent LDL–C test result was < 130 mg/dl; and (ii) the percentage of adult patients with diabetes aged 18–75 years whose most recent LDL–C test result during the measurement year was < 100 mg/dl. The specifications for this measure are located in Appendix A (beginning page A–60) of the 2008 NQF Report titled ''National Voluntary Consensus Standards for Ambulatory Care—Part 1'' available at the following link: *http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_Ambulatory_Care%E2%80%93Part_1.aspx.* We invite public comment on this proposed measure.

(3) Proposed Diabetes Measure: Blood Pressure Management (NQF #0061)

Blood pressure control reduces the risk of cardiovascular disease and microvascular complications in patients with diabetes. Well-controlled blood pressure impacts the quality of the life of the diabetic patient, affects the patient's life expectancy, and decreases the costs involved in treating diabetic complications.

[2] Huang, E.S., Basu, A., O'Grady, M., Capretta, J.C.: Projecting the future diabetes population size and related costs for the U.S. Diabetes Care. 2009;32 (12):2225–29.

[3] The American Association of Clinical Endocrinologists Medical Guidelines for the Management of Diabetes Mellitus: The AACE System of Intensive Diabetes Self-Management—2002 Update.

[4] American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care. 2008 Jan:31 (Suppl 1):S12–54.

[5] American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care. 2007 Jan;30 (Suppl 1):S8–15.

[6] Das, S.R., Vaeth, P.A., Stanek, H.G., de Lemos, J.A., Dobbins, R.L., McGuire, D.K.: Increased cardiovascular risk associated with diabetes in Dallas County. Am Heart J 2006;151:1087–93.

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Because this measure is NQF-endorsed, we believe that this measure meets the requirement of reflecting consensus among affected parties. However, we note that consensus among affected parties can be reflected through means other than NQF endorsement. This measure is appropriate for measuring the quality of care in the hospital outpatient departments which serve many patients with diabetes and suffer from high blood pressure.

Early treatment of high blood pressure may help slow or halt the progression of kidney involvement and damage.[7] This NQF-endorsed measure measures the percentage of patient visits with blood pressure measurement recorded among all patient visits by patients aged > 18 years with diagnosed hypertension. The specifications for this measure are located in Appendix A (beginning page A–60) of the 2008 NQF Report titled ''National Voluntary Consensus Standards for Ambulatory Care—Part 1'' available at the following link: *http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_Ambulatory_Care%E2%80%93Part_1.aspx.* We invite public comment on this proposed measure.

(4) Proposed Diabetes Measure: Eye Exam (NQF #0055)

A dilated eye exam helps to detect the risk for vision-threatening diabetic retinopathy which is prevalent among people with diabetes. Data from the 2011 National Diabetes Fact Sheet shows that diabetes is the leading cause of new cases of blindness among adults aged 20–74 years.[8] However, dilated eye exams for diabetic patients can prevent retinopathy through early detection [9] and stereoscopic retinal photography is sometimes used to grade diabetic retinopathy severity.

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Because this measure is NQF-endorsed, we believe that this measure meets the requirement of reflecting consensus among affected parties. However, we note that consensus among affected parties can be reflected through means other than NQF endorsement. This measure is appropriate for measuring quality of care in the hospital outpatient departments which serve many patients with diabetes who are at risk for diabetic retinopathy.

This NQF-endorsed measure measures the percentage of adult patients with diabetes age 18 to 75 years who received a dilated eye exam or seven standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist, or imaging to verify diagnosis from stereoscopic photos during the reporting year, or during the prior year, if the patient is at low risk for retinopathy. A patient is considered low risk if the patient has no evidence of retinopathy in the prior year. The specifications for this measure are located in Appendix A (beginning page A–60) of the 2008 NQF Report titled ''National Voluntary Consensus Standards for Ambulatory Care—Part 1'' available at the following link: *http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_Ambulatory_Care%E2%80%93Part_1.aspx.* We invite public comment on this proposed measure.

(5) Proposed Diabetes Measure: Urine Protein Screening (NQF #0062)

Urine protein screening for microalbumin detects an abnormal amount of protein albumin leaks in the urine by the capillaries of the kidney. High levels of blood sugar in uncontrolled diabetes can cause damage to the capillaries in the kidneys. Diabetics accounted for 44 percent of new cases of kidney disease. In 2005, a total of 178,689 diabetics with ESRD were on dialysis or received a kidney transplant in the United States and Puerto Rico.[10] In 2009, MedPAC reported costs for the 330,000 Medicare recipients receiving dialysis treatment for ESRD at over $8 billion.[11]

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Because this measure is NQF-endorsed, we believe that this measure meets the requirement of reflecting consensus among affected parties. However, we note that consensus among affected parties can be reflected through means other than NQF endorsement. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient departments which serve many patients with diabetes who are at risk for kidney diseases.

Early urine screenings for microalbumin may prevent kidney disease from worsening to ESRD. This NQF-endorsed measure measures the percentage of adult diabetic patients ages 18–75 years with at least one test for microalbumin during the measurement year or who had evidence of medical attention for existing nephropathy (diagnosis of nephropathy or documentation of microalbuminuria or albuminuria). The specifications for this measure are located in Appendix A (beginning page A–60) of the 2008 NQF Report titled ''National Voluntary Consensus Standards for Ambulatory Care—Part 1'' available at the following link: *http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_Ambulatory_Care%E2%80%93Part_1.aspx.* We invite public comment on this proposed measure.

(6) Proposed Cardiac Rehabilitation Measure: Patient Referral From an Outpatient Setting (NQF #0643)

Cardiac rehabilitation improves the quality of life, reduces modifiable cardiovascular risk factors, enhances adherence to medications, and lowers

[7] Centers for Disease Control and Prevention. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 20112007. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 20112008.

[8] Centers for Disease Control and Prevention. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 20112007. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 20112008.

[9] American Diabetes Association. Standards of medical care in diabetes. Diabetes Care. 2007 Jan;30 (Suppl 1):S8–15.

[10] Centers for Disease Control and Prevention. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2007. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2008.

[11] MedPAC. Outpatient dialysis service: assessing payment adequacy and updating payments. Report to the Congress: Medicare payment policy. 2009 Mar; 131–56.

morbidity and mortality.[12] Despite these benefits, cardiac rehabilitation is significantly underutilized by patients with heart disease and there is significant geographical variation in referral rates and lower use in women, non-whites, older patients and patients on Medicaid.[13] A recent study of Medicare beneficiaries, using 70,040 matched pairs of patients hospitalized for coronary conditions or revascularization procedures, found that mortality rates were 21 percent to 34 percent lower in cardiac rehabilitation users compared to nonusers.[14] Evidence from registries which include a cardiac rehabilitation performance measure indicated that only about 18 percent of eligible patients were referred to cardiac rehabilitation.[15] Under our regulations, 42 CFR 410.49, cardiac rehabilitation is covered for patients who have had one or more of the following: an acute myocardial infarction within the preceding 12 months, current stable angina, individuals who have undergone coronary bypass surgery, a percutaneous coronary intervention or coronary stenting, heart valve repair or replacement, or a heart-lung transplant.

In May 2010, the NQF endorsed two cardiac rehabilitation referral performance measures as part of the call for care coordination performance measures. These measures are: (1) Cardiac Rehabilitation: Patient Referral From an Inpatient Setting (NQF #0642)—The percentage of patients admitted to the hospital with a qualifying cardiovascular disease (CVD) event who are referred to an early outpatient cardiac rehabilitation/secondary prevention program; and (2) Cardiac Rehabilitation: Patient Referral From an Outpatient Setting (NQF #0643)—The percentage of patients evaluated in an outpatient setting who in the previous 12 months experienced an acute myocardial infarction or chronic stable angina or who have undergone coronary artery bypass (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery (CVS), or cardiac transplantation who have not already participated in an early outpatient cardiac rehabilitation/secondary prevention program for the qualifying event and who are referred to an early outpatient cardiac rehabilitation/secondary prevention program unless there is a documented medical or patient oriented reason why a referral was not made. We are proposing to adopt the second (NQF #0643) of these measures for the CY 2014 Hospital OQR Program. The measure specifications are located in Appendix A (Pages A4 and A5) of the 2010 NQF consensus report entitled '' Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination'' which is available at the following link: *http://www.qualityforum.org/Publications/2010/10/Preferred_Practices_and_Performance_Measures_for_Measuring_and_Reporting_Care_Coordination.aspx.*

This proposed measure targets patients who have experienced a qualifying cardiovascular event. These patients are commonly seen in hospital outpatient departments and, for this reason, we believe that the proposed measure is appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings as required under section 1833(t)(17)(C)(i) of the Act. The measure also is NQF-endorsed, and therefore meets the requirement that measures selected for the program ''reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities'' under section 1833(t)(17)(C)(i) of the Act.

We are proposing to adopt the NQF-endorsed Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure for CY 2014 payment determination. The goal of this measure is to improve the delivery of cardiac care in order to reduce cardiovascular mortality and morbidity and optimize the health of patients suffering from CVD.

We invite public comment on this proposed measure.

c. Proposed New Structural Measures

For the CY 2014 payment determination, we are proposing to add two structural measures: 1) Safe Surgery Checklist Use; and 2) Hospital Outpatient Volume for Selected Outpatient Surgical Procedures. In general, structural measures assess the characteristics and capacity of the provider to deliver quality health care.

(1) Proposed Safe Surgery Checklist Use Measure

This proposed structural measure assesses whether a hospital outpatient department utilizes a Safe Surgery checklist that assesses whether effective communication and safe practices are performed during three distinct perioperative periods: (1) the period prior to the administration of anesthesia; (2) the period prior to skin incision; and (3) the period of closure of incision and prior to the patient leaving the operating room. The use of such checklists has been credited with dramatic decreases in preventable harm, complications and post-surgical mortality.[16] In November 2010, the New England Journal of Medicine (NEJM) published a study concluding that surgical complications were reduced by one-third, and mortality by nearly half, when a safe surgery checklist was used.[17]

We believe that effective communication and the use of safe surgical practices during surgical procedures will significantly reduce preventable surgical deaths and complications. For example, mistakes in surgery can be prevented by ensuring that the correct surgery is performed on the correct patient and at the correct place on the patient's body.[18] A safe surgery checklist would also reduce the potential for human error, which we believe would increase the safety of the surgical environment.

The safe surgery checklists of which we are aware typically include safe surgery practices corresponding to three critical perioperative periods: the period prior to the administration of anesthesia, the period prior to skin incision, and the period of closure of incision and prior to the patient leaving the operating room. Some examples of safe surgery practices that can be performed during each of these three perioperative periods are shown in the table below:

[12] Wenger, N.K.: Current status of cardiac rehabilitation. J. Am Coll Cardiol 2008; 51:1619–1631.

[13] Suaya, J.A., Shepard, D.S., Normand, S.L., et al.: Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. Circulation. 2007; 116:1653–62.

[14] Suaya, J.A., Stason, W.B.; Ades, P.A., et al.: Cardiac rehabilitation and survival in older coronary patients. J. Am Coll Cardiol. 2009;54:25–33.

[15] Chan, P.S., Oetgen, W.J., Buchanan, D., Mitchell, K., et al.: Cardiac performance measure compliance on outpatients: the American College of Cardiology and National Cardiovascular Data Registry's PINNACLE (Practice Innovation and Clinical Excellence) program. J. Am Coll Cardiol 2010;561(1): 8–14.

[16] Haynes, A.B.; Weiser, T.G.; Berry, W.G. et. al (2009). ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population.''. New England Journal of Medicine. 360: 491–499.

[17] de Vries En, Prins HA, Crolla RMPH, et al. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med 2010;363: 1928–37.

[18] Hospital National Patient Safety Goals. The Joint Commission Accreditation Hospital Manual, 2011. *http://www.jointcommission.org/standards_information/npsgs.aspx*

First critical point (period prior to administering anesthesia)	Second critical point (period prior to skin incision)	Third critical point (period of closure of incision and prior to patient leaving the operating room)
• Verbal confirmation of patient identity. • Mark surgical site. • Check anesthesia machine/medication. • Assessment of allergies, airway and aspiration risk.	• Confirm surgical team members and roles. • Confirm patient identity, procedure, and surgical incision site. • Administration of antibiotic prophylaxis within 60 minutes before incision. • Communication among surgical team members of anticipated critical events. • Display of essential imaging as appropriate.	• Confirm the procedure. • Complete count of surgical instruments and accessories. • Identify key patient concerns for recovery and management of the patient.

One example of a checklist that lists safe surgery practices during each of these three perioperative periods is the World Health Organization Surgical Safety Checklist, which was adopted by The World Federation of Societies of Anesthesiologists as an international standard of practice. This checklist can be found at: *http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html*.

The adoption of a structural measure that assesses Safe Surgery Checklist use would align our patient safety initiatives with those of several surgical specialty societies including: The American College of Surgeons' Nora Institute for Patient Safety, the American Society of Anesthesiologists, The Joint Commission, the National Association for Healthcare Quality and the Association of periOperative Registered Nurses (AORN). For this proposed structural measure, a hospital outpatient department would indicate whether or not it uses a safe surgery checklist for its surgical procedures that includes safe surgery practices during each of the three critical perioperative periods discussed above. The measure would assess whether the hospital uses a safe surgery checklist in the hospital outpatient department for surgical procedures, but would not require a hospital to report whether it uses a checklist in connection with any individual outpatient procedures.

The proposed Safe Surgery Checklist structural measure is not NQF-endorsed. However, we believe that consensus among affected parties can be reflected through means other than NQF endorsement including: consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment. The proposed safe surgery checklist measure assesses the adoption of a best practice for surgical care that is broadly accepted and in widespread use among affected parties. In addition to being adopted by The World Federal of Societies of Anesthesiologists, the use of a safe surgery checklist is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety, which is comprised of the American Association of Nurse Anesthetists, American College of Surgeons, American Association of Surgical Physician Assistants, American Society of Anesthesiologists, American Society of PeriAnesthesia Nurses, AORN, and Association of Surgical Technologists. Two State agencies (Oregon, South Carolina), the Veterans Health Administration,[19] numerous hospital systems, State hospital associations (such as California, and South Carolina), national accrediting organizations and large private insurers have endorsed the use of a safe surgery checklist as a best practice for reducing morbidity, mortality, and medical errors.[20, 21] Because the use of a safe surgery checklist is a widely accepted best practice for surgical care, we believe that the proposed structural measure of Safe Surgery Checklist use reflects consensus among affected parties. We also note that The Joint Commission has included safe surgery checklist practices among those to be used to achieve National Patient Safety Goals adopted for 2011 for surgeries performed in ambulatory settings and hospitals.

For CY 2014 payment determination, we are proposing that data collection for this structural measure for hospital outpatient departments will be from July 1, 2013 through August 15, 2013 for the time period January 1, 2012 through December 31, 2012. These data will be collected via a Web-based tool available on the QualityNet Web site that is currently employed for the collection of structural measures for the Hospital IQR Program and the Hospital OQR Program. We invite public comments on our proposal to add this new structural measure to the CY 2014 Hospital OQR Program measure set.

(2) Proposed Hospital Outpatient Department Volume for Selected Outpatient Surgical Procedures Measure

There is substantial evidence in recent peer-reviewed clinical literature that volume of surgical procedures, particularly of high risk surgical procedures, is related to better patient outcomes, including decreased surgical errors and mortality [1], [2], [3]. This may be attributable to greater experience and/or surgical skill, greater comfort with and, hence, likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure. For this reason, the National Quality Forum has previously endorsed measures of total all-patient surgical volume for Isolated CABG and Valve Surgeries (NQF #0124), Percutaneous Coronary Intervention (PCI) (NQF #0165), Pediatric Heart Surgery (NQF #0340), Abdominal Aortic Aneurism Repair (NQF #357), Esophageal Resection (#0361), and Pancreatic Resection (NQF #0366). Additionally, many consumer-oriented Web sites that display health care quality information required to be reported under State law (California, New York, Texas, Washington, Florida, Illinois, Michigan, Oregon) and private organizations (Leapfrog Group, U.S. News & World Report) are reporting procedure volume, in addition to provider performance on surgical process (SCIP measures) and outcome measures (SSI, Patient Safety

[19] Neily, J; Mills, PD, Young-Xu, Y. (2010). ''Association between implementation of a Medical Team Training Program and Surgical Mortality''. JAMA. 304 (15): 1693–1700.

[20] Haynes, AB; Weiser, TG; Berry, WR et al (2009) ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population''. NEJM. 360:491–499.

[21] Birkmeyer, JD (2010) ''Strategies for Improving Surgical Quality—Checklists and Beyond.'' NEJM. 363: 1963–1965.

[1] Livingston, E.H.; Cao, J ''Procedure Volume as a Predictor of Surgical Outcomes''. JAMA. 2010;304(1):95–97.

[2] David R. Flum, D.R.; Salem, L.; Elrod, J.B.; Dellinger, E.P.; Cheadle, A. Chan, L. ''Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures''. *JAMA. 2005;294(15):1903–1908.*

[3] Schrag, D; Cramer, L.D.; Bach, P.B.; Cohen, A.M.; Warren, J.L.; Begg, C.B ''Influence of Hospital Procedure Volume on Outcomes Following Surgery for Colon Cancer'' *JAMA. 2000; 284 (23): 3028–3035.*

Indicators, and Mortality), in order to provide more context to consumers choosing a health care provider. The currently NQF-endorsed measures of procedure volume (noted above) relate to surgeries performed only in inpatient settings, and would not be applicable to the types of procedures approved to be performed in HOPDs and ASCs.

The table below, which shows the proportion of procedures during calendar year 2010 performed in hospital outpatient departments stratified by broad categories, reveals that most hospital outpatient procedures (99%) fall into one of 8 categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.

CY 2010 HOSPITAL OUTPATIENT DATA

Procedure category	Percent of total services
Cardiovascular	75.50
Chest	0.00
Ear	0.20
Endocrine	0.10
Eye	1.70
Gastrointestinal	5.70
Genitourinary	2.70
Hemic & Lymphatic	0.30
Maternity	0.00
Musculoskeletal	3.80
Nervous System	2.80
Radiology	0.10
Respiratory	1.00
Skin	6.20

CY 2010 HOSPITAL OUTPATIENT DATA—Continued

Procedure category	Percent of total services
Total	100.00

Because surgical volume is associated with better quality, and surgical procedures are performed in hospital outpatient departments, we believe that surgical volume is appropriate for measuring the quality of these eight categories of surgical procedures performed in an HOPD. For the CY 2014 payment determination, we are proposing that HOPDs would report all-patient volume data with respect to these eight categories between the dates July 1, 2013 and August 15, 2013 with respect to the time period January 1, 2012 through December 31, 2012. In other words, under this proposal, an HOPD would report its CY 2012 all-patient volume data for these eight categories of procedures during the 45 day window of July 1, 2013 to August 15, 2013. The table below lists the specific HCPCS codes for each of the 8 procedure categories for which hospitals would be required to report the all-patient volume data. Like the other structural measures in the Hospital OQR program, data on this proposed measure would be collected via an online Web-based tool that will be made available to HOPDs via the QualityNet Web site.

We invite public comment on this proposal.

In summary, for the CY 2014 payment determination, in addition to the 23 measures we previously adopted in the CY 2011 OPPS/ASC final with comment period, we are proposing to adopt 1 new NHSN HAI measure, 6 additional new chart-abstracted measures, and 2 new structural measures. With respect to the proposed surgical site infection HAI measure, HOPDs would be required to report the data to the NHSN beginning with January 1, 2013 to through June 30, 2013 infection events and would be required to use the procedures set out by the NHSN. We are proposing that submission of data on the five proposed diabetes measures and the proposed cardiac rehabilitation measure would begin with first quarter CY 2013 (January 1, 2013 to March 31, 2013) encounters. With respect to the proposed structural measures, we are proposing that HOPDs submit data between July 1, 2013 and August 15, 2013 with respect to a calendar year 2012 reporting time period.

We invite public comments on these proposals for the CY 2014 payment determination. The proposed complete measure set for the Hospital OQR Program CY 2014 payment determination, including the measures we adopted in the CY 2011 OPPS/ASC final rule with comment period, is reflected in the table below.

CY 2014 HOSPITAL OQR PROGRAM MEASURE SET REFLECTING MEASURES PREVIOUSLY ADOPTED AND THE PROPOSED ADDITION OF 1 NHSN HAI MEASURE, 6 CHART-ABSTRACTED MEASURES, AND 2 STRUCTURAL MEASURES

OP–1: Median Time to Fibrinolysis.
OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
OP–4: Aspirin at Arrival.
OP–5: Median Time to ECG.
OP–6: Timing of Antibiotic Prophylaxis.
OP–7: Prophylactic Antibiotic Selection for Surgical Patients.
OP–8: MRI Lumbar Spine for Low Back Pain.
OP–9: Mammography Follow-up Rates.
OP–10: Abdomen CT—Use of Contrast Material.
OP–11: Thorax CT—Use of Contrast Material.
OP–12: The Ability for Providers with HIT to Receive. Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data.*
OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.*
OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).*
OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.*
OP–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival.**
OP–17: Tracking Clinical Results between Visits.**
OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.**
OP–19: Transition Record with Specified Elements Received by Discharged Patients.**
OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.**
OP–21: ED–Median Time to Pain Management for Long Bone Fracture.**
OP–22: ED–Patient Left Without Being Seen.**
OP–23: ED–Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival.**
OP–24: Surgical Site Infection.***
OP–25: Diabetes: Hemoglobin A1c Management.***
OP–26: Diabetes Measure Pair: A Lipid management: low density lipoprotein cholesterol (LDL–C) <130, B Lipid management: LDL–C <100.***
OP–27: Diabetes: Blood Pressure Management.***

CY 2014 HOSPITAL OQR PROGRAM MEASURE SET REFLECTING MEASURES PREVIOUSLY ADOPTED AND THE PROPOSED ADDITION OF 1 NHSN HAI MEASURE, 6 CHART-ABSTRACTED MEASURES, AND 2 STRUCTURAL MEASURES—Continued

OP–28: Diabetes: Eye Exam.***
OP–29: Diabetes: Urine Protein Screening.***
OP–30: Cardiac Rehabilitation Patient Referral From an Outpatient Setting.***
OP–31: Safe Surgery Checklist Use.***
OP–32: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures.***

Procedure category	Corresponding HCPCS codes
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, 0170T.
Eye	65000 through 68999, 0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T.
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T.
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T.
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727.
Genitourinary	50000 through 58999, 0193T, 58805.
Cardiovascular	33000 through 37999.
Respiratory	30000 through 32999.

* New measure for the CY 2012 payment determination.
** New measure for the CY 2013 payment determination.
*** Proposed new measure for the CY 2014 payment determination.

3. Proposed Hospital OQR Program Measures for the CY 2015 Payment Determination

a. Proposed Retention of CY 2014 Hospital OQR Measures for the CY 2015 Payment Determination

In general, unless otherwise specified, we retain measures from one payment determination to the next. Accordingly, we are proposing that all of the measures we finalize for the CY 2014 payment determination continue to be used for the CY 2015 payment determination. We invite public comment on this proposal.

b. Proposed New NHSN HAI Measure for the CY 2015 Payment Determination

For the measure set to be used for the CY 2015 payment determination, we are proposing to adopt an additional HAI measure entitled Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF #0431). This measure is currently collected by the CDC via the NHSN.

Rates of serious illness and death resulting from influenza and its complications are increased in high-risk populations such as persons over 50 years or under four years of age, and persons of any age who have underlying conditions that put them at an increased risk. HCP can acquire influenza from patients and can transmit influenza to patients and other HCP. Many HCP provide care for, or are in frequent contact with, patients with influenza or patients at high risk for complications of influenza. The involvement of HCP in influenza transmission has been a long-standing concern.[22] [23] [24]

Vaccination is an effective preventive measure against influenza, and can prevent many illnesses, deaths, and losses in productivity.[25] HCP are considered a high priority for expanding influenza vaccine use. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients and reduce disease burden and healthcare costs. Results of several studies indicate that higher vaccination coverage among HCP is associated with lower incidence of nosocomial influenza.[26] [27] [28] Such findings have led some to call for mandatory influenza vaccination of HCP.[29] [30] [31] [32] [33]

Until recently, vaccination coverage among HCP has been well below the national Healthy People 2010 target of 60 percent,[34] but preliminary data suggest 62 percent of HCP reported receiving seasonal influenza vaccine in 2009–2010.[35] Only 37 percent reported

[22] Maltezou, H.C., Drancourt, M.: Nosocomial influenza in children. Journal of Hospital Infection 2003; 55:83–91

[23] Hurley, J.C., Flockhart, S.: An influenza outbreak in a regional residential facility. Journal of Infection Prevention 2010; 11:58–61

[24] Salgado, C.D., Farr, B.M., Hall, K.K., Hayden, F.G.: Influenza in the acute hospital setting. The Lancet Infectious Diseases 2002; 2:145–155.

[25] Wilde, J.A., McMillan, J.A., Serwint, J., Butta, J., O'Riordan, M.A., Steinhoff, M.C.: Effectiveness of influenza vaccine in health care professionals: a randomized trial. The Journal of the American Medical Association 1999; 281:908–913.

[26] Salgado, C.D., Giannetta, E.T., Hayden, F.G., Farr, B.M.: Preventing influenza by improving the vaccine acceptance rate of clinicians. Infection Control and Hospital Epidemiology 2004; 25: 923–928.

[27] Potter, J., Stott, D.J., Roberts, M.A., et al.: Influenza vaccination of health-care workers in long-term-care hospitals reduces the mortality of elderly patients. Journal of Infectious Diseases 1997; 175:1–6.

[28] Hayward, A.C., Harling, R., Wetten, S., et al.: Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. British Medical Journal 2006; 333:1241–1246.

[29] Talbot, T.R., Bradley, S.F., Cosgrove, S.E., et al.: SHEA position paper: Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. Infection Control and Hospital Epidemiology 2005; 26:882–890

[30] American College of Physicians (ACP), ACP policy on influenza vaccination of health care workers. *http://www.acponline.org/running_practice/quality_improvement/projects/adult_immunization/flu_hcw.pdf.*

[31] Greene, L.R., Cain, T.A., Dolan, S.A. et al.: APIC position paper: influenza immunization of healthcare personnel. Association of Professionals in Infection Control (APIC). November 2008.*http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Influenza/APIC_Position_Paper_Influenza_11_7_08final_revised.pdfhttp://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Influenza/APIC_Position_Paper_Influenza_11_7_08final_revised.pdf.*

[32] National Patient Safety Foundation (NPSF), Mandatory flu vaccinations for healthcare workers. Press Release, November 18, 2009. *http://www.npsf.org/pr/pressrel/2009–11-18.php.*

[33] Infectious Diseases Society of America (IDSA), IDSA policy on mandatory immunization of health care workers against seasonal and 2009 H1N1 influenza. Infectious Diseases Society of America (IDSA). September 30, 2009. *http://www.idsociety.org/HCWimmunization/.*

[34] Walker, F.J., Singleton, J.A., Lu, P., Wooten, K.G., Strikas, R.A.: Influenza vaccination of healthcare workers in the United States, 1989–2002. Infection Control and Hospital Epidemiology 2006; 27:257–265.

[35] *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e209a1.htm* Influenza Vaccination of Health-Care Personnel.

Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices.

receiving the 2009 pandemic A/H1N1 vaccine.[36]

HCP refers to all personnel working in healthcare settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air.[37] HCP may include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (for example, clerical, dietary, housekeeping, laundry, security, maintenance, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients. Settings in which HCP may work include, but are not limited to, acute care hospitals, long-term care facilities, skilled nursing facilities, rehabilitation centers, physicians' offices, urgent care centers, outpatient clinics, home health agencies, and emergency medical services.

Currently, four States have ''offer'' laws for influenza vaccination of HCP, meaning that vaccine must be offered to HCP by healthcare facilities; and three States (Alabama, California, and New Hampshire) have ''ensure'' laws for influenza vaccination of HCP, meaning that vaccination of non-immune HCP is mandatory in the absence of a specified exemption or refusal; and, additionally, numerous hospitals and other healthcare facilities have established policies requiring mandatory influenza vaccination of their HCP.[38]

Currently, no State requires that hospitals report this measure to NHSN. However, approximately 13 hospitals (including long term acute care and rehabilitation), outpatient hemodialysis centers, long term care facilities, and ambulatory surgical centers are currently reporting HCP immunization data to NHSN. In September 2009, CDC released the Healthcare Personnel Safety (HPS) Component of NHSN, which complements Patient Safety and Biovigilance components available in NHSN. The HPS Component replaced CDC's National Surveillance System for Health Care Workers (NaSH) and is comprised of two modules: the Blood/Body Fluid Exposure Module and the Influenza Vaccination and Management and Exposure Module.[39] Currently, participation in either module is voluntary. The current Influenza Vaccination and Management and Exposure Module may soon offer options for healthcare facilities to submit vaccination summary data. NHSN plans to partner with vendor-based surveillance systems to permit periodic data extractions into NHSN.

The modules feature basic, custom, and advanced analysis capabilities available in real-time, which allow individual healthcare facilities to compile and analyze their own data, as well as benchmark these results to aggregate NHSN estimates. The HPS Component can assist participating facilities in developing surveillance and analysis capabilities to permit the timely recognition of HCP safety problems and prompt interventions with appropriate measures. Influenza vaccination data submitted to CDC will ultimately capture regional trends on the yearly uptake of the vaccine, prophylaxis and treatment for healthcare personnel, as well as the elements within yearly influenza campaigns that succeed or require improvement. At the State and national levels, the HPS Component will aid in monitoring rates and trends.

Due to the significant impact of HCP influenza vaccination on patient outcomes, we believe this measure is appropriate for measuring the quality of care in hospital outpatient departments. Healthcare Personnel (HCP) Influenza Vaccination is one of the HAI measures that we proposed to adopt for the FY 2015 Hospital IQR Program in the FY 2012 IPPS/LTCH PPS proposed rule. This measure assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. The specifications for this measure are available at *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.*

The proposed HCP Influenza Vaccination measure is NQF-endorsed for the hospital setting and applies to the hospital outpatient setting. Therefore, this measure meets the requirement for measure selection under section 1833(t)(17)(C)(i) of the Act. We are proposing to adopt the Influenza Vaccination Coverage among Healthcare Personnel measure that is collected by the CDC via the NHSN. The NHSN proposed reporting mechanism for this proposed HAI measure is discussed in greater detail in section XIV.C.2.a. of this proposed rule. Data submission for this NHSN proposed measure would relate to immunizations from October 1, 2013 through March 31, 2014 for the CY 2015 payment determination. We are proposing that hospital outpatient departments use the NHSN infrastructure and protocol to report the measure for Hospital OQR purposes. We invite public comment on our proposal to adopt this HAI measure into the Hospital OQR Program for the CY 2015 payment determination.

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2015 PAYMENT DETERMINATION

OP–1: Median Time to Fibrinolysis.
OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
OP–4: Aspirin at Arrival.
OP–5: Median Time to ECG.
OP–6: Timing of Antibiotic Prophylaxis.
OP–7: Prophylactic Antibiotic Selection for Surgical Patients.
OP–8: MRI Lumbar Spine for Low Back Pain.
OP–9: Mammography Follow-up Rates.
OP–10: Abdomen CT—Use of Contrast Material.
OP–11: Thorax CT—Use of Contrast Material.

[36] Centers for Disease Control and Prevention., Interim results: Influenza A (H1N1) 2009 and Monovalent Seasonal Influenza Vaccination Coverage Among Health-Care Personnel—United States August 2009- January 2010. Morbidity and Mortality Weekly Report (MMWR); 59:357–362. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5912a1.htm.*

[37] Adapted from: Pearson ML., Bridges CB., Harper SA.,: Influenza vaccination of health-care personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). Morbidity and Mortality Weekly Report (MMWR) 2006; 55:1–16. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm.*

[38] For additional information regarding healthcare facilities' influenza vaccine policies, please see: *http://www.immunize.org/honor%2Droll/.http://www.immunize.org/honor%2Droll/.*

[39] Available at: *http://www.cdc.gov/nhsn/hps.htmlhttp://www.cdc.gov/nhsn/hps.html.*

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2015 PAYMENT DETERMINATION—Continued

OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data.*
OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.*
OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).*
OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.*
OP–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with *Probable Cardiac Chest Pain*) Received Within 60 minutes of Arrival.**
OP–17: Tracking Clinical Results between Visits.**
OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.**
OP–19: Transition Record with Specified Elements Received by Discharged Patients.**
OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.**
OP–21: ED–Median Time to Pain Management for Long Bone Fracture.**
OP–22: ED–Patient Left Without Being Seen.**
OP–23: ED–Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan .Interpretation Within 45 minutes of Arrival.**
OP–24: Surgical Site Infection (via NHSN).***
OP–25: Diabetes: Hemoglobin A1c Management.***
OP–26: Diabetes Measure Pair: A Lipid management: low density lipoprotein cholesterol (LDL–C) <130, B Lipid management: LDL–C <100.***
OP–27: Diabetes: Blood Pressure Management.***
OP–28: Diabetes: Eye Exam.***
OP–29: Diabetes: Urine Protein Screening.***
OP–30: Cardiac Rehabilitation Patient Referral From an Outpatient Setting.***
OP–31: Safe Surgery Checklist Use.***
OP–32: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures.***

Procedure Category	Corresponding HCPCS codes
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, 0170T.
Eye	65000 through 68999, 0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T.
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T.
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T.
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727.
Genitourinary	50000 through 58999, 0193T, 58805.
Cardiovascular	33000 through 37999.
Respiratory	30000 through 32999.

OP–33: Influenza Vaccination Coverage among Healthcare Personnel (HCP).****

* New measure for the CY 2012 payment determination.
** New measure for the CY 2013 payment determination.
*** Proposed new measure for the CY 2014 payment determination.
**** Proposed new measure for the CY 2015 payment determination.

D. Possible Quality Measures Under Consideration for Future Inclusion in the Hospital OQR Program

The current measure set for Hospital OQR includes measures that assess imaging efficiency patterns, care transitions, and the use of HIT. We are proposing in this proposed rule to add measures to the CY 2014 and CY 2015 measure sets addressing diabetes care, HAIs, referrals for cardiac rehabilitation, and Safe Surgery Checklist use. Thus, the measures that we have previously adopted for the Hospital OQR Program, as well as the proposed measures being proposed in this proposed rule, address infection outcomes and infection control processes. In previous years' rulemakings, we have provided lists of measures that are under consideration for future adoption into the Hospital OQR measure set. Below is a list of potential measurement areas that we are considering for future Hospital OQR payment determinations (beginning with CY 2015) for which we are soliciting public comment. In particular, we seek comment on the inclusion of Patient Experience of Care Measures in the Hospital OQR measure set for a future payment determination, such as existing Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups and the CAHPS Surgical Care Survey, sponsored and submitted by the American College of Surgeons (ACS) and the Surgical Quality Alliance (SQA).

We also intend to align the surgical safety measures across the HOPD and ASC settings and would seek to utilize comparable data to assess patient safety in these settings. We seek comment on the potential submission of such measures by HOPDs via quality codes submitted on claims in the future. We also seek comment on the inclusion of measures of Anesthesia related Complications in the Hospital OQR measurement set.

MEASURES AND MEASUREMENT TOPICS UNDER CONSIDERATION FOR FUTURE HOSPITAL OQR PROGRAM PAYMENT DETERMINATIONS BEGINNING WITH CY 2015

Measures for future development:
Procedure Specific Measures:
Colonoscopy and other Endoscopy measures.
Cataract Surgery measures.
Cancer Care:
Adjuvant Chemotherapy is Considered or Administered within 4 Months of Surgery to Patients Under Age 80 with AJCC III Colon Cancer.

MEASURES AND MEASUREMENT TOPICS UNDER CONSIDERATION FOR FUTURE HOSPITAL OQR PROGRAM PAYMENT DETERMINATIONS BEGINNING WITH CY 2015—Continued

Adjuvant Hormonal Therapy for Patients with Breast Cancer.
Needle Biopsy to Establish Diagnosis of Cancer Precedes Surgical Excision/Resection.
Heart Failure:
Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
Heart Failure: Left Ventricular Ejection Fraction Assessment.
Heart Failure: Combination Medical Therapy for Left Ventricular Systolic Dysfunction.
Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction.
Heart Failure: Counseling regarding Implantable Cardioverter-Defibrillator (ICD) Implantation for Patients with Left Ventricular Systolic Dysfunction on Combination Medical Therapy.
Heart Failure: Patients with Left Ventricular Systolic Dysfunction on Combination Medical Therapy.
Heart Failure: Symptom Management.
Heart Failure: Symptom and Activity Assessment.
Heart Failure: Patient Education.
Heart Failure: Overuse of Echocardiography.
Heart Failure: Post-Discharge Appointment for Heart Failure Patients.
Surgical Safety:
Patient Fall.
Patient Burn.
Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
Hospital Transfer/Admission.
Patient Experience-of-Care:
Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups.
CAHPS Surgical Care Survey.
Anesthesia Related Complications:
Death.
Cardiac Arrest.
Perioperative Myocardial Infarction.
Anaphylaxis.
Hyperthermia.
Transfusion Reaction.
Stroke, Cerebral Vascular Accident, or Coma following anesthesia.
Visual Loss.
Medication Error.
Unplanned ICU admission.
Patient intraoperative awareness.
Unrecognized difficult airway.
Reintubation.
Dental Trauma.
Perioperative aspiration.
Vascular access complication, including vascular injury or pneumothorax.
Pneumothorax following attempted vascular access or regional anesthesia.
Infection following epidural or spinal anesthesia.
Epidural hematoma following spinal or epidural anesthesia.
High Spinal.
Postdural puncture headache.
Major systemic local anesthetic toxicity.
Peripheral neurologic deficit following regional anesthesia.
Infection following peripheral nerve block.
Additional Measurement Topics:
NQF Serious Reportable Events in Healthcare.
Medication Reconciliation.
Chemotherapy.
Post-discharge follow up.
Post-discharge ED visit within 72 hours.
Breast cancer detection rate.

We invite public comment on these measures and other topics that we might consider proposing to adopt beginning with the Hospital OQR Program CY 2015 payment determination. We also are seeking suggestions and rationales to support the adoption of measures and topics for the Hospital OQR Program which do not appear in the table above.

E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2012 Payment Update

1. Background

Section 1833(t)(17)(A) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), requires that hospitals that fail to report data required to be submitted on the measures selected by the Secretary, in the form and manner, and at a time, required by the Secretary under section 1833(t)(17) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor, that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the

applicable OPD fee schedule increase factor for a subsequent payment year.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772), we discussed how the payment reduction for failure to meet the administrative, data collection, and data submission requirements of the Hospital OQR Program affected the CY 2009 payment update applicable to OPPS payments for HOPD services furnished by the hospitals defined under section 1886(d)(1)(B) of the Act to which the program applies. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. All other hospitals paid under the OPPS receive the full OPPS payment update without the reduction.

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site): ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' ''U,'' or ''X.'' In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770), we adopted a policy that payment for all services assigned these status indicators would be subject to the reduction of the national unadjusted payment rates for applicable hospitals, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T,'' and brachytherapy sources with assigned status indicator ''U,'' which were paid at charges adjusted to cost in CY 2009. We excluded services assigned to New Technology APCs from the list of services subject to the reduced national unadjusted payment rates because the OPD fee schedule increase factor is not used to update the payment rates for these APCs.

In addition, section 1833(t)(16)(C) of the Act, as amended by section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), specifically required that brachytherapy sources be paid during CY 2009 on the basis of charges adjusted to cost, rather than under the standard OPPS methodology. Therefore, the reduced conversion factor also was not applicable to CY 2009 payment for brachytherapy sources because payment would not be based on the OPPS conversion factor and, consequently, the payment rates for these services were not updated by the OPD fee schedule increase factor. However, in accordance with section 1833(t)(16)(C) of the Act, as amended by section 142 of the MIPPA, payment for brachytherapy sources at charges adjusted to cost expired on January 1, 2010. Therefore, in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60641), we finalized our CY 2010 proposal, without modification, to apply the reduction to payment for brachytherapy sources to hospitals that fail to meet the quality data reporting requirements of the Hospital OQR Program for brachytherapy services furnished on and after January 1, 2010.

The OPD fee schedule increase factor, or market basket update, is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To implement the requirement to reduce the market basket update for hospitals that fail to meet reporting requirements, we calculate two conversion factors: a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative weights by the reduced conversion factor. To determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiply the final full national unadjusted payment rate in Addendum B to the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for those hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply in those cases when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. We believe that these adjustments continue to be equally applicable to payments for hospitals that do not meet the Hospital OQR Program requirements. Similarly, outlier payments will continue to be made when the criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. This policy conforms to current practice under the IPPS. We continued this policy in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642), and in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this CY 2012 OPPS/ASC proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2012

We are proposing to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a

reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2012 annual payment update factor. For the CY 2012 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of $68.052 by the proposed full conversion factor of $69.420. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2012 OPPS, we are proposing to apply the reporting ratio, when applicable, to all HCPCS codes to which we have assigned status indicators ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' ''U,'' and ''X'' (other than new technology APCs to which we have assigned status indicators ''S'' and ''T''). We are proposing to continue to exclude services paid under New Technology APCs. We are proposing to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also are proposing to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we are proposing to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We invite public comments on these proposals.

F. Extraordinary Circumstances Extension or Waiver for CY 2012 and Subsequent Years

In our experience, there have been times when hospitals have been unable to submit required quality data due to extraordinary circumstances that are not within their control. It is our goal to not penalize hospitals for such circumstances and we do not want to unduly increase their burden during these times. Therefore, in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60046 through 60047), we adopted a process for hospitals to request and for CMS to grant extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the hospital. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103), we retained these procedures with some modifications. For CY 2012 and subsequent years, we are proposing to retain these procedures with one modification. We are proposing to extend these procedures to the submission of medical record documentation for purposes of complying with our validation requirement for the Hospital OQR Program.

Under this process, in the event of extraordinary circumstances, such as a natural disaster, not within the control of the hospital, for the hospital to receive consideration for an extension or waiver of the requirement to submit quality data or medical record documentation for one or more quarters, a hospital would submit to CMS a request form that would be made available on the QualityNet Web site. The following information should be noted on the form:

- Hospital CCN;
- Hospital Name;
- CEO and any other designated personnel contact information, including name, e-mail address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);
- Hospital's reason for requesting an extension or waiver;
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the hospital would again be able to submit Hospital OQR data and/or medical record documentation, and a justification for the proposed date.

The request form would be signed by the hospital's CEO. A request form would be required to be submitted within 45 days of the date that the extraordinary circumstance occurred.

Following receipt of such a request, CMS would—

(1) Provide a written acknowledgement using the contact information provided in the request, to the CEO and any additional designated hospital personnel, notifying them that the hospital's request has been received;

(2) Provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of our decision; and

(3) Complete our review of any CY 2012 request and communicate our response within 90 days following our receipt of such a request.

We note that we might also decide to grant waivers or extensions to hospitals that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane) affects an entire region or locale. If we make the determination to grant a waiver or extension to hospitals in a region or locale, we would communicate this decision to hospitals and vendors through routine communication channels, including but not limited to e-mails and notices on the QualityNet Web site.

We invite public comment on this proposal to retain our existing process for granting extraordinary circumstances extensions or waivers, and to extend this process to the submission of medical record documentation, for the Hospital OQR Program.

G. Proposed Requirements for Reporting of Hospital OQR Data for CY 2013 and Subsequent Years

To participate in the Hospital OQR Program, hospitals must meet administrative, data collection and submission, and data validation requirements (if applicable). Hospitals that do not meet Hospital OQR Program requirements, as well as hospitals not participating in the Program and hospitals that withdraw from the Program, will not receive the full OPPS payment rate update. Instead, in accordance with section 1833(t)(17)(A) of the Act, those hospitals will receive a reduction of 2.0 percentage points to their OPD fee schedule increase factor for the applicable payment year. We established the payment determination requirements for the CY 2012 payment update in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099 through 72106).

With respect to the payment determinations for CY 2013 and subsequent years, we are proposing to implement the requirements listed below. Most of these requirements are the same as the requirements we implemented for the CY 2012 payment determination, with some proposed modifications.

1. Administrative Requirements for CY 2013 and Subsequent Years

To participate in the Hospital OQR Program, we are proposing that several administrative steps be completed. These steps are the same as those we finalized for the CY 2012 payment determination and would require the hospital to:

- Identify a QualityNet security administrator who follows the registration process located on the QualityNet Web site (*http://www.QualityNet.org*) and submits the information to the appropriate CMS-designated contractor. All CMS-designated contractors would be identified on the QualityNet Web site. The same person may be the QualityNet security administrator for both the

Hospital IQR Program and the Hospital OQR Program. Based on our experience, we believe that the QualityNet security administrator typically fulfills a variety of tasks related to the hospital's ability to participate in the Hospital OQR Program, such as: creating, approving, editing and/or terminating QualityNet user accounts within the organization; monitoring QualityNet usage to maintain proper security and confidentiality measures; and serving as a point of contact for information regarding QualityNet and the Hospital OQR Program. However, the main purpose of the QualityNet Administrator is to serve as a contact for security purposes. Because of CMS information systems security requirements, the hospital would be required to maintain a current QualityNet security administrator for as long as the hospital participates in the program. While only a single QualityNet security administrator would be required for program purposes, we suggest to hospitals that it may be beneficial to have more than one QualityNet security administrator for back-up purposes.

- Register with QualityNet, regardless of the method used for data submission.
- Complete and submit an online participation form if this form (or a paper Notice of Participation form) has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CCN. For Hospital OQR Program purposes, hospitals that share the same CCN would be required to complete a single online participation form. At this time, the participation form for the Hospital OQR Program is separate from the participation form required for the Hospital IQR Program and completing a form for each program is required. Agreeing to participate includes acknowledging that the data submitted to the CMS-designated contractor would be submitted to CMS, shared with one or more other CMS contractors that support the implementation of the Hospital OQR Program, and be publicly reported.

We are proposing to retain the procedures and update the deadlines for submitting the participation form which we established in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100):

Hospitals with Medicare acceptance dates on or after January 1 of the year prior to the annual payment update affected: For the CY 2013 and subsequent years payment updates, we are proposing that any hospital that has a Medicare acceptance date on or after January 1 of the year prior to the annual payment update affected (for example, 2012 would be the year prior to the affected CY 2013 annual payment update), including a new hospital and hospitals that have merged, must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date on the CMS Certification and Survey Provider Enhanced Reporting (CASPER) system. Hospitals typically receive a package notifying them of their new CCN after they receive their Medicare acceptance date. The Medicare acceptance date is the earliest date that a hospital can receive Medicare payment for the services that it furnishes. Completing the participation form would include supplying the name and address of each hospital campus that shares the same CCN.

The use of the Medicare acceptance date as beginning the timeline for Hospital OQR Program participation allows us to monitor more effectively hospital compliance with the requirement to complete a participation form because a hospital's Medicare acceptance date is readily available to CMS through its data systems. In addition, providing an extended time period to register for the program would allow newly functioning hospitals sufficient time to get their operations fully functional before having to collect and submit quality data.

We are aware that Medicare acceptance dates may be back-dated. In that event, we would consider a hospital's request to allow additional time to elect to participate.

Hospitals with Medicare acceptance dates before January 1 of the year prior to the affected annual payment update: For the CY 2013 and subsequent years payment update, we are proposing that any hospital that has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update (for example, 2012 would be the year prior to the affected CY 2013 annual payment update) that is not currently participating in Hospital OQR and wishes to participate in the Hospital OQR Program must submit a participation form by March 31 of the year prior to the affected annual payment update. We are proposing a deadline of March 31, because we believe it would give hospitals sufficient time to decide whether they wish to participate in the Hospital OQR Program, as well as put into place the necessary staff and resources to timely report data for first quarter of the year's services. This requirement would apply to all hospitals whether or not the hospital billed for payment under the OPPS.

For the CY 2013 and subsequent years payment updates, we are proposing that any Hospital OQR participating hospital that wants to withdraw may do so at any time from January 1 to November 1 of the year prior to the affected annual payment update. A hospital that withdraws during this time period for any annual payment update would not be able to later sign up to participate for that payment update, would receive a 2.0 percentage point reduction to its OPD fee schedule increase factor for that year, and would be required to submit a new participation form in order to participate in any future year of the Hospital OQR Program. We note that once a hospital has submitted a participation form, it is considered to be an active Hospital OQR Program participant until such time as the hospital submits a withdrawal form to CMS or is designated as closed in the CMS CASPER system.

We invite public comment on these proposed Hospital OQR Program administrative requirements for the CY 2013 and subsequent years' payment determinations.

2. Form, Manner, and Timing of Data Submission for CY 2013 and Subsequent Years

We are proposing that, to be eligible to receive the full OPD fee schedule increase factor for any payment determination, hospitals must comply with our submission requirements for chart-abstracted data, population and sampling data, claims-based measure data, and structural quality measure data, including all-patient volume data.

a. Proposed CY 2013 and CY 2014 Data Submission Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS

With respect to the proposed chart-abstracted measures for which hospitals would submit data directly to CMS, we are proposing for CY 2013 and CY 2014 that participating hospitals submit chart-abstracted data for each applicable quarter by the deadline posted on the QualityNet Web site; there must be no lapse in data submission. For the CY 2013 program, we are proposing that the applicable quarters would be as follows: 3rd quarter CY 2011, 4th quarter CY 2011, 1st quarter CY 2012, and 2nd quarter CY 2012. Hospitals that did not participate in the CY 2012 Hospital OQR Program, but would like to participate in the CY 2013 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2012, would begin data submission with respect to 1st quarter CY 2012 encounters using the

CY 2013 measure set that was finalized in the CY 2012 OPPS/ASC final rule with comment period. For those hospitals with Medicare acceptance dates on or after January 1, 2012, data submission must begin with the first full quarter following the submission of a completed online participation form.

For the CY 2014 program, we are proposing that the applicable quarters for previously finalized measures would be as follows: 3rd quarter CY 2012, 4th quarter CY 2012, 1st quarter CY 2013, and 2nd quarter CY 2013. With respect to our proposed measures (5 Diabetes measures and 1 Cardiac Rehabilitation measure), the applicable quarters would be 1st quarter CY 2013 and 2nd quarter CY 2013. Hospitals that did not participate in the CY 2013 Hospital OQR Program, but would like to participate in the CY 2014 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2013, would begin data submission with respect to 1st quarter CY 2013 encounters using the CY 2014 measure set that was finalized in the CY 2013 OPPS/ASC final rule with comment period. For those hospitals with Medicare acceptance dates on or after January 1, 2013, data submission must begin with the first full quarter following the submission of a completed online participation form.

We are proposing that hospitals must submit all required data according to the data submission schedule that is made available on the QualityNet Web site (*https://www.QualityNet.org*). This Web site meets or exceeds all current HIPAA requirements. Submission deadlines would be, in general, approximately 4 months after the last day of each calendar quarter. Thus, for example, the proposed submission deadline for data for services furnished during the first quarter of CY 2012 (January–March, 2012) would be on or around August 1, 2012. The actual submission deadlines would be posted on the *http://www.QualityNet.org* Web site.

We are proposing that hospitals submit chart-abstracted data to the OPPS Clinical Warehouse using either the CMS Abstraction and Reporting Tool for Outpatient Department (CART–OPD) measures or the tool of a third-party vendor that meets the measure specification requirements for data transmission to QualityNet.

We are proposing that hospitals must collect Hospital OQR data from outpatient hospital encounters to which the required measures apply. In previous rulemakings, we have utilized various terms for describing the unit of care for outpatient hospital reporting, including encounter, episode, episode of care, and discharge. We note that for outpatient hospital services, the term encounter is explicitly used and defined in the Medicare Benefit Policy Manual (Pub. 100–02), Chapter 6, Section 20.3, which states ''A hospital outpatient 'encounter' is a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.'' For Medicare outpatient services, the terms episode and episode of care also are used. When discussing inpatient services, the Medicare Benefit Policy Manual specifically refers to discharges; the term encounter is not used in reference to inpatient services. Thus, for Hospital OQR, we are examining encounters, episodes, or episodes of care and would use these terms in connection with the Hospital OQR Program.

We will make every effort to ensure that data elements common to both inpatient and outpatient settings are defined consistently for purposes of quality reporting (such as ''time of arrival'').

We are proposing that hospitals must submit quality data using the CCN under which the care was furnished.

To be accepted into the OPPS Clinical Warehouse and to meet data submission requirements, data submissions, at a minimum, must be timely, complete, and accurate. Data submissions are considered to be ''timely'' when data are successfully accepted into the OPPS Clinical Warehouse on or before the reporting deadline. A ''complete'' submission would be determined based on whether the data satisfy the sampling criteria that are published and maintained in the Hospital OQR Specifications Manual, and must correspond to both the aggregate number of encounters submitted by a hospital and the number of Medicare claims the hospital submits for payment; requirements for utilizing the option of sampling are discussed below.

We strongly recommend that hospitals review OPPS Clinical Warehouse feedback reports and the Hospital OQR Provider Participation Reports that are accessible through their QualityNet accounts. These reports enable hospitals to verify whether the data they or their vendors submitted were accepted into the OPPS Clinical Warehouse and the date/time that such acceptance occurred. We also note that irrespective of whether a hospital submits data to the OPPS Clinical Warehouse itself or uses a vendor to complete the submissions, the hospital is responsible for ensuring that Hospital OQR requirements are met.

b. Eligibility To Voluntarily Sample and Proposed Data Submission Exception for Low Patient Volume for CY 2013 and Subsequent Years

If a hospital has a sufficiently large number of eligible encounters with respect to a measure, the hospital has the option to sample those encounters and submit data only for these sampled encounters, rather than submitting data on all of the eligible encounters. This sampling scheme, which includes the minimum number of encounters that a hospital must have in order to sample, is set out in the Hospital OQR Specifications Manual at least 3 months in advance of each data submission deadline. We note that sampling is not required and hospitals may submit more cases than the minimum set by our sampling scheme and may submit up to all of their cases if they desire to do so. We changed the notification timeframe for this sampling scheme to at least 3 months from at least 4 months to be consistent with the Hospital OQR Specifications Manual release schedule. If a hospital chooses to sample for a particular quarter, the hospital must meet the sampling requirements for the required chart-abstracted measures that quarter.

In addition, to reduce the burden on hospitals that treat a low number of patients but otherwise meet the submission requirements for a particular quality measure, we are proposing to continue our policy that hospitals that have five or fewer encounters (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter would not be required to submit patient level data for the entire measure topic for that quarter. Even if hospitals would not be required to submit patient level data because they have five or fewer encounters (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter, we note that they may voluntarily do so.

c. Proposed Population and Sampling Data Requirements Beginning With the CY 2013 Payment Determination and for Subsequent Years

During the past three years of the Hospital OQR Program, the submission of population and sampling data was not required, though hospitals could submit, on a voluntary basis, the aggregate numbers of outpatient encounters which are eligible for submission under the Hospital OQR Program and sample size counts. These aggregated numbers of outpatient

encounters represent the number of outpatient encounters in the universe of all possible cases eligible for data reporting under the Hospital OQR Program. For the CY 2012 payment update, we proposed, but did not adopt, a policy to require submission of this population and sample size data.

We are now proposing that beginning with the CY 2013 payment determination, hospitals must submit on a quarterly basis, aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted.

Under this proposal, a hospital would submit on a quarterly basis an aggregate population and sample size count with respect to each measure regardless of whether any patients met the inclusion criteria for the measure population. For example, if a hospital did not treat any patients who met the inclusion criteria for a specific measure, the hospital would still be required to submit a zero for its quarterly aggregate population and sample count to meet the requirement.

Our analysis of third quarter CY 2010 outpatient hospital submitted data shows that for hospitals that submitted abstracted data for encounters, at least 99 percent of these providers voluntarily reported both population and sampling data. Data completeness was also assessed by comparing reported Medicare cases to submitted claim counts, minimum encounter count thresholds based on reported population sizes, and minimum sample size thresholds based on reported population sizes. We found that less than 10 percent of hospitals differed significantly in their Medicare self-reported encounters versus Medicare claim counts in the Clinical Warehouse, and less than 20 percent did not meet case count or sample size minimum thresholds. Based upon this analysis, we believe that hospitals have had sufficient time to become familiar with Hospital OQR data reporting and have developed data systems necessary to support this proposed requirement; in fact recent data suggest that the vast majority of hospitals have done so.

We are proposing that the deadlines for the reporting of aggregate numbers of outpatient hospital encounters and sample size counts would be the same as those for reporting data for chart–abstracted measures, and these deadlines would be posted on the data submission schedule that would be available on the QualityNet Web site. Hospitals would be permitted to submit this information prior to the deadline; this would allow us to advise hospitals regarding their incomplete submission status as appropriate and give hospitals sufficient time to make appropriate revisions before the data submission deadline.

We plan to use the aggregate population and sample size data to assess data submission completeness to the OPPS Clinical Warehouse and adherence to sampling requirements for Medicare and non-Medicare patients.

d. Proposed Claims-Based Measure Data Requirements for the CY 2013 and CY 2014 Payment Determinations

For the claims-based measures, we are proposing to calculate the measures using the hospital's Medicare claims data as specified in the Hospital OQR Specifications Manual; no additional data submission is required for hospitals. For the CY 2013 and CY 2014 payment updates, we would utilize paid Medicare FFS claims for services furnished from January 1, 2010 to December 31, 2010 and January 1, 2011 to December 31, 2011, respectively.

e. Proposed Structural Measure Data Requirements for the CY 2013 and CY 2014 Payment Determinations

For the CY 2013 payment determination, we are proposing that hospitals would be required to submit data on the structural measures, including OP–17: Tracking Clinical Results between Visits, between July 1, 2012 and August 15, 2012 with respect to the time period of January 1, 2011 to December 31, 2011.

As discussed above, we are proposing to adopt two new structural measures for the CY 2014 payment determination, OP–31: Safe Surgery Checklist Use, and OP–32: Hospital Outpatient Department Volume for Selected Outpatient Surgical Procedures. We are proposing that for the CY 2014 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2013 and August 15, 2013 with respect to the time period from January 1, 2012 to December 31, 2012.

f. Proposed Data Submission Deadlines for the Proposed NHSN HAI Surgical Site Infection Measure for the CY 2014 Payment Determination

As discussed above, we are proposing to adopt a new HAI measure for the CY 2014 payment determination: surgical site infection. We are proposing to use the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site (*http://www.cdc.gov/nhsn*) for detailed data submission and reporting procedures. We believe that these procedures are feasible because they are already widely used by over 4,000 hospitals reporting HAI data to the NHSN. Our proposal seeks to reduce hospital burden by aligning CMS data submission and reporting procedures with NHSN procedures currently used by hospitals, including hospitals complying with 28 State HAI reporting requirements. The submission timeframes for the CY 2014 payment determination that we are proposing to use for the proposed HAI measure are shown below. Hospitals would be required to submit their quarterly data to the NHSN for Hospital OQR purposes according to the schedule shown in the table below (any updates to this schedule made by CMS will be posted on the QualityNet Web site).

PROPOSED SUBMISSION TIMEFRAME FOR THE PROPOSED SURGICAL SITE INFECTION MEASURE FOR THE CY 2014 PAYMENT DETERMINATION

CY 2013 Infection events	CDC–NHSN collection and quarterly report	Final submission deadline for hospital OQR program CY 2014 payment determination
Q1 (Jan 1 to Mar 31, 2013)	January 31st to August 1st	August 1, 2013.
Q2 (Apr 1 to Jun 30, 2013)	April 30th to November 1st	November 1, 2013.

Hospitals would have until the Hospital OQR final submission deadline to submit their quarterly data to NHSN. After the final Hospital OQR Program submission deadline has occurred for each CY 2013 quarter to be used toward

the CY 2014 payment determination, we will obtain the hospital-specific calculations generated by the NHSN for the Hospital OQR Program.

g. Proposed Data Submission Requirements for OP–22, ED–Patient Left Without Being Seen, for the CY 2013 and CY 2014 Payment Determinations

With respect to OP–22: ED–Patient Left Without Being Seen, we are proposing that hospitals would be required to submit data once for each of the CY 2013 and CY 2014 payment determinations via a Web-based tool located on the QualityNet Web site. For the CY 2013 payment determination, hospitals would be required to submit data between July 1, 2012 and August 15, 2012 with respect to the time period from January 1, 2011 to December 31, 2011. For the CY 2014 payment determination, hospitals would be required to submit data between July 1, 2013 and August 15, 2013 with respect to the time period of January 1, 2012 to December 31, 2012.

We invite public comment on these proposals for data collection and submission requirements.

3. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS: Proposed Data Validation Approach for the CY 2013 Payment Determination

a. Randomly Selected Hospitals

Similar to our approach for the CY 2012 payment determination(75 FR 72103 through 72106), we are proposing to validate chart-abstracted data submitted directly to CMS from randomly selected hospitals for the CY 2013 payment determination. To reduce hospital burden and to facilitate our efforts to reallocate resources in the event that we finalize the targeting proposal discussed below, for the CY 2013 payment determination, we are proposing to reduce the number of randomly selected hospitals from 800 to 450. We have found that hospitals are consistently reporting high accuracy rates for chart-abstracted measures and that variation among hospitals is relatively low. We believe that this low level of variation between hospitals will allow us to reduce the sample size while not diminishing our ability to make statistical inferences from the sample. Thus, we believe that we can safely reduce sample size and still have sufficient case numbers for purposes of validation. Because these 450 hospitals will be selected randomly, every Hospital OQR Program participating hospital will be eligible each year for validation selection. To be eligible for random selection for validation, a hospital must be coded as open in the OSCAR system at the time of selection and must have submitted at least 10 encounters to the OPPS Clinical Warehouse during the data collection period for the CY 2013 payment determination. We are proposing this 10 encounter minimum so that we have a sufficient sample size for calculating a statistically valid validation score.

b. Proposed Use of Targeting Criteria for Data Validation Selection for CY 2013

(1) Background

In the CY 2011 OPPS/ASC proposed rule (75 FR 46381), we stated that we were considering building upon what we proposed as a validation approach for the Hospital OQR Program. We noted that we were considering, in addition to selecting a random sample of hospitals for validation purposes, selecting targeted hospitals based on criteria designed to measure whether the data these hospitals have reported raises a concern regarding data accuracy. Because hospitals had gained little experience with validation under the Hospital OQR at that time, we noted that we were considering this approach for possible use beginning with the CY 2013 payment determination. Examples of targeting criteria suggested for inclusion:

- Abnormal data patterns identified such as consistently high Hospital OQR measure denominator exclusion rates resulting in unexpectedly low denominator counts;
- Whether a hospital had previously failed validation;
- Whether a hospital had not been previously selected for validation for 2 or more consecutive years;
- Whether a hospital had low submitted case numbers relative to population sizes; or
- Whether a hospital had any extreme outlier values for submitted data elements.

We invited comment on whether, in addition to random sampling for validation, we should use targeted validation and, if so, what criteria for targeting we should adopt.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106) we responded to the comments we received and noted that for the CY 2013 payment determination, Hospital OQR Program data reporting will have been completed for four payment determinations: CYs 2009, 2010, 2011, and 2012. Further, hospitals will have had the opportunity to learn from the validation process. We also stated that we intended to propose to implement validation targeting criteria for CY 2013 and subsequent years in the CY 2012 OPPS/ASC proposed rule.

(2) Proposed Targeting Criteria for Data Validation Selection for CY 2013

In addition to proposing to randomly select 450 hospitals for validation, we are proposing to select up to an additional 50 hospitals based upon targeting criteria. A hospital could be selected for validation based on targeting criteria if it:

- Fails the validation requirement that applies to the CY 2012 payment determination; or
- Has an outlier value for a measure based on the data it submits. We are proposing to define an ''outlier value'' for purposes of this targeting as a measure value that appears to deviate markedly from the measure values for other hospitals. For a normally distributed variable, nearly all values of the variable lie within 3 standard deviations of the mean; very few values lie past the 3 standard deviation mark. One definition of an outlier is a value that exceeds this threshold.[40] In order to target very extreme values, we are proposing to target hospitals that greatly exceed this threshold; such extreme values strongly suggest that data submitted is inaccurate. Specifically, we are proposing to select hospitals for validation if their measure value for a measure is greater than 5 standard deviations from the mean, placing the expected occurrence of such a value outside of this range at 1 in 1,744,278. If more than 50 hospitals meet either of the above targeting criteria, then up to 50 would be selected randomly from this pool of hospitals.

c. Encounter Selection

For each selected hospital (random or targeted), we are proposing to validate up to 48 randomly selected patient encounters (12 per quarter; 48 per year) from the total number of encounters that the hospital successfully submitted to the OPPS Clinical Warehouse. If a selected hospital has submitted less than 12 encounters in one or more quarters, only those encounters available would be validated. For each selected encounter, a designated CMS contractor would request that the hospital submit the supporting medical record documentation that corresponds to the encounter.

[40] Ruan, Da, Chen, Guoguing, Kerre, Etienne E., and Wets, Geert, (2010), *Intelligent Data Mining: Techniques and Applications, Studies in Computational Intelligence,* Vol. 5, Page 318.

We continue to believe that validating a larger number of encounters per hospital for fewer hospitals at the measure level has several benefits. We believe that this approach is suitable for the Hospital OQR Program because it will: produce a more reliable estimate of whether a hospital's submitted data have been abstracted accurately; provide more statistically reliable estimates of the quality of care delivered in each measured hospital as well as at a national level; and reduce overall burden, for example in submitting validation documentation, because hospitals most likely will not be selected to undergo validation each year, and a smaller number hospitals per year will be selected.

For all selected hospitals, we will not be selecting cases stratified by measure or topic; our interest is whether the data submitted by hospitals accurately reflects the care delivered and documented in the medical record, not what the accuracy is by measure or whether there are differences by measure or topic. We are proposing to validate data for April 1, 2011 to March 31, 2012 encounters as this provides a full year of the most recent data possible to use for purposes of completing the validation in time to make the CY 2013 payment determinations.

d. Validation Score Calculation

For the CY 2013 payment determination, we are proposing to use the validation calculation approach finalized for the CY 2012 payment determination with validation being done for each selected hospital. Specifically, we are proposing to conduct a measures level validation by calculating each measure within a submitted record using the independently abstracted data and then comparing this to the measure reported by the hospital; a percent agreement would then be calculated. We would also compare the measure category for quality measures with continuous units of measurement, such as time, so that for these measures, both the category and the measure would need to match.

To receive the full OPPS OPD fee schedule increase factor for CY 2013, we are proposing that hospitals must attain at least a 75 percent reliability score, based upon the proposed validation process. We are proposing to use the upper bound of a two-tailed 95 percent confidence interval to estimate the validation score. If the calculated upper limit is above the required 75 percent reliability threshold, we would consider a hospital's data to be ''validated'' for payment purposes. Because we are more interested in whether the measure has been accurately reported, we would continue to focus on whether the measure data reported by the hospital matches the data documented in the medical record as determined by our reabstraction. We are proposing to calculate the validation score using the same methodology we finalized for the CY 2012 payment determination (75 FR 72105). We also are proposing to utilize the same medical record documentation submission procedures that we also finalized for the CY 2012 payment determination (75 FR 72104) with one modification; we are proposing to shorten the time period given to hospitals to submit medical record documentation to the CMS contractor from 45 calendar days to 30 calendar days. This proposed change in submission timeframe will align the process with requirements in 42 CFR 476.78(b)(2), which allow 30 days for chart submission in the context of QIO review. We are proposing this deadline of 30 days also to reduce the time for data validation completion to increase timeliness of providing hospitals with feedback on their abstraction accuracy.

4. Additional Data Validation Conditions Under Consideration for CY 2014 and Subsequent Years

We continue to consider building upon our validation approach of targeting hospitals to address data quality concerns and to ensure that our payment decisions are made using accurate data. Thus, we are requesting public comment on the following additional targeting criteria to select hospitals for validation:

- Whether a hospital that was open under its current CCN and had not been selected for validation in the previous 3 years. This is consistent with validation targeting criteria we recently proposed to implement for the CY 2015 Hospital IQR Program (76 FR 25920 through 25921).
- Whether a hospital had submitted a low number of encounters relative to population sizes; or
- Whether a hospital reported significant numbers of ''Unable to Determine'' data elements.

We welcome public comment on these proposals, and are specifically interested in receiving public comments on definitions of what low numbers relative to population sizes and what would constitute significant numbers of ''Unable to Determine'' data elements.

H. Proposed Hospital OQR Reconsideration and Appeals Procedures for CY 2013 and Subsequent Years

When the Hospital IQR Program was initially implemented, it did not include a reconsideration process for hospitals. Subsequently, we received many requests for reconsideration of those payment decisions and, as a result, established a process by which participating hospitals would submit requests for reconsideration. We anticipated similar concerns with the Hospital OQR Program and, therefore, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), we stated our intent to implement for the Hospital OQR Program a reconsideration process modeled after the reconsideration process we implemented for the Hospital IQR Program. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a reconsideration process that applied to the CY 2010 payment decisions. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60654 through 60655), we continued this process for the CY 2011 payment update. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106 through 72108), we continued this process for the CY 2012 payment update with some modification.

We are proposing to continue this process for the CY 2013 payment determination and subsequent years. Under this proposed process, a hospital seeking reconsideration must—

- Submit to CMS, via QualityNet, a Reconsideration Request form that will be made available on the QualityNet Web site; this form must be submitted by February 3 of the affected payment year (for example, for the CY 2013 payment determination, the request must be submitted by February 3, 2013) and must contain the following information:

oo Hospital CCN.

oo Hospital Name.

oo CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital.

oo Hospital basis for requesting reconsideration. This must identify the hospital's specific reason(s) for believing it met the affected year's Hospital OQR Program requirements and should receive the full OPD fee schedule increase factor.

oo CEO and any additional designated hospital personnel contact information, including name, e-mail address, telephone number, and mailing address

(must include physical address, not just a post office box).

oo A copy of all materials that the hospital submitted to comply with the requirements of the affected year's Hospital OQR Program. Such material might include, but may not be limited to, the applicable Notice of Participation form or completed online registration form, and measure data that the hospital submitted via QualityNet.

• Paper copies of all the medical record documentation that it submitted for the initial validation (if applicable). We are proposing that hospitals would submit this documentation to a designated CMS contractor which would have authority to review patient level information. We would post the address where hospitals are to send this documentation on the QualityNet Web site.

• To the extent that the hospital is requesting reconsideration on the basis that CMS has determined it did not meet an affected year's validation requirement, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score would be eligible to be reconsidered. We would review the data elements that were labeled as mismatched as well as the written justifications provided by the hospital, and make a decision on the reconsideration request.

We note that, consistent with our policy for CY 2012 reconsiderations, reconsideration request forms would not need to be signed by the hospital's CEO.

Following receipt of a request for reconsideration, CMS would—

• Provide an e-mail acknowledgement, using the contact information provided in the reconsideration request, to the CEO and any additional designated hospital personnel notifying them that the hospital's request has been received.

• Provide a formal response to the hospital CEO and any additional designated hospital personnel, using the contact information provided in the reconsideration request, notifying the hospital of the outcome of the reconsideration process.

We intend to complete any reconsideration reviews and communicate the results of these determinations within 90 days following the deadline for submitting requests for reconsideration.

We also propose to apply the same policies that we finalized for the CY 2012 payment determination regarding the scope of our review when a hospital requests reconsideration because it failed our validation requirement. These policies are as follows:

• If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more data elements were classified as mismatches, we would only consider the hospital's request if the hospital timely submitted all requested medical record documentation to the CMS contractor each quarter under the validation process.

• If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more medical records it submitted during the quarterly validation process was classified as an invalid record selection (that is, the CMS contractor determined that one or more medical records submitted by the hospital did not match what was requested, thus resulting in a zero validation score for the encounter(s)), our review would initially be limited to determining whether the medical documentation submitted in response to the designated CMS contractor's request was the correct documentation. If we determine that the hospital did submit the correct medical documentation, we would abstract the data elements and compute a new validation score for the encounter. If we conclude that the hospital did not submit the correct medical record documentation, we would not further consider the hospital's request.

• If a hospital requests reconsideration on the basis that it disagrees with a determination that it did not submit the requested medical record documentation to the CMS contractor within the proposed 30 calendar day timeframe, our review would initially be limited to determining whether the CMS contractor received the requested medical record documentation within 30 calendar days, and whether the hospital received the initial medical record request and reminder notice. If we determine that the CMS contractor timely received paper copies of the requested medical record documentation, we would abstract data elements from the medical record documentation submitted by the hospital and compute a validation score for the hospital. If we determine that the hospital received two letters requesting medical documentation but did not submit the requested documentation within the 30 calendar day period, we would not further consider the hospital's request.

If a hospital is dissatisfied with the result of a Hospital OQR reconsideration decision, the hospital would be able to file an appeal under 42 CFR Part 405, Subpart R (PRRB appeal).

We invite public comment on our proposed CY 2013 Hospital OQR Program reconsideration and appeals procedures.

I. Electronic Health Records (EHRs)

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of EHRs (also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from EHRs to a CMS data repository (70 FR 47420 through 47421). We sought to prepare for future EHR submission of quality measures by sponsoring the creation of electronic specifications for quality measures under consideration for the Hospital IQR Program. Through the EHR Incentive Programs we expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS, in the future, to receive, quality measures via hospital EHRs for Hospital IQR Program measures. We expect the Hospital IQR and Hospital OQR Programs to transition to the use of certified EHR technology, for measures that otherwise require information from the clinical record. This would allow us to collect data for measures without the need for manual chart abstraction. In the FY 2012 IPPS/LTCH PPS proposed rule (75 FR 25894), we identified FY 2015 as a potential transition date to move to EHR-based submission and phase out manual chart abstraction. We also anticipate such a transition for hospital outpatient measures, although likely somewhat after the transition for hospital inpatient measures. This is a result of the fact that the clinical quality measures in the EHR Incentive Program currently are primarily aligned with the Hospital IQR Program, rather than the Hospital OQR Program. Our goals are to align the hospital quality reporting programs, to seek to avoid redundant and duplicative reporting of quality measures for hospitals, and to rely largely on EHR submission for measures based on clinical record data.

J. 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs

1. Background

Under section 4102(a) of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), eligible hospitals and CAHs may qualify for incentive payments if they successfully demonstrate meaningful

use of certified EHR technology. The final rule for the Medicare EHR Incentive Program (75 FR 44314) established the Stage 1 criteria for meaningful use, which include, among other requirements, that eligible hospitals and CAHs report clinical quality measures (CQMs) to CMS, in addition to meeting other objectives and measures described in the final rule. The final rule also requires that for the 2012 payment year and subsequent years, an eligible hospital or CAH using certified EHR technology must submit information on the specified clinical quality measures electronically. However, for the 2011 payment year, eligible hospitals and CAHs are required to submit CQM results as calculated by certified EHR technology through attestation, rather than submit the information electronically. In the final rule (75 FR 44380), we also stated that we anticipated that we would have completed the necessary steps to have the capacity to receive information on CQMs electronically for the 2012 payment year. However, we also acknowledged that if we do not have the capacity to accept electronic reporting of CQMs in 2012, consistent with sections 1848(o)(2)(B)(ii) and 1886(n)(3)(B)(ii) of the Act, we would continue to rely on attestation for reporting CQMs as a requirement for demonstrating meaningful use of certified EHR technology for the 2012 payment year.

We also stated in the final rule that, with respect to electronic submission of information on clinical quality measures, certified EHR technology will be required to transmit calculated clinical quality measure results under the PQRI 2009 Registry XML specification. We noted that this was the only such standard that the certified EHR technology would be able to support based on the standards that have been adopted for certified EHR technology (75 FR 44435; see also 45 CFR 170.205(f)).

Since the publication of the final rule, we have determined that it is not feasible to receive electronically the information necessary for clinical quality measure reporting based solely on the use of PQRI 2009 Registry XML Specification content exchange standard as is required for certified EHR technology. This is because the specification is tailored to the elements required for 2009 PQRI Registry XML submission, rather than constituting a more generic standard. As a result, we are proposing to modify the requirement that clinical quality measure reporting must be done electronically. Specifically, we are proposing that for the 2012 payment year and subsequent years, eligible hospitals and CAHs may continue to report clinical quality measure results as calculated by certified EHR technology by attestation, as for the 2011 payment year. Alternatively, for the 2012 payment year, eligible hospitals and CAHs would be able to participate in the proposed FY 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs (Electronic Reporting Pilot) which is further described below. We are proposing to revise our regulations at § 495.8(b)(2)(ii) and proposing to add § 495.8(b)(2)(vi) that would reflect these proposals for reporting CQMs through attestation and the Electronic Reporting Pilot.

2. Proposed Electronic Reporting Pilot

Section 1886(n)(3)(B)(ii) of the Act provides authority for the Secretary to accept information on CQMs electronically on a pilot basis. For payment year 2012, we are proposing that eligible hospitals and CAHs participating in the Medicare EHR Incentive Program may meet the CQM reporting requirement of the EHR Incentive Program for payment year 2012 by participating in the proposed Electronic Reporting Pilot. We are proposing that participation in this Electronic Reporting Pilot would be voluntary and that eligible hospitals and CAHs may continue to attest to the results of CQMs calculated by certified EHR technology as they did for the 2011 payment year.

We would encourage participation in the proposed Electronic Reporting Pilot in view of our desire to adequately pilot electronic submission of CQMs and to move to a system of reporting where eligible hospitals and CAHs can qualify for CQM reporting for both the Hospital IQR and Hospital OQR Programs, and the EHR Incentive Program. We strongly encourage eligible hospitals and CAHs to participate in the proposed Electronic Reporting Pilot as it provides opportunities to test the interoperability and functionality of the certified EHR technology that they have implemented. We believe that the participation of eligible hospitals and CAHs in the proposed Electronic Reporting Pilot would help advance EHR-based reporting in the Hospital IQR and Hospital OQR Programs.

Eligible hospitals and CAHs would need to be registered in order to participate in the proposed Electronic Reporting Pilot. Eligible hospitals and CAHs wishing to participate in the proposed Electronic Reporting Pilot for the CQMs would register by indicating their desire and intent to participate in the proposed Electronic Reporting Pilot as part of the attestation process for the Medicare EHR Incentive Program. We are proposing that eligible hospitals and CAHs that participate in the proposed Electronic Reporting Pilot and meet its submission requirements would satisfy the requirements for reporting clinical quality measures under the Medicare EHR Incentive Program. Such eligible hospitals and CAHs would therefore not need to attest to the results of clinical quality measures calculated by certified EHR technology. As described below, for the purpose of the proposed Electronic Reporting Pilot, CMS would calculate the results of the clinical quality measures for eligible hospitals and CAHs based on patient level data submitted for Medicare patients. The proposed Electronic Reporting Pilot would require eligible hospitals and CAHs to submit information on the same 15 CQMs that were listed in Table 10 of the final rule (75 FR 44418 through 44420) for the Medicare and Medicaid EHR Incentive Programs and such information would be obtained from the certified EHR technology used by the eligible hospital or CAH.

We are proposing that electronic submission of the 15 CQMs through this proposed Electronic Reporting Pilot would be sufficient to meet the core objective for reporting CQMs for the Medicare EHR Incentive Program for the 2012 payment year. Since the reporting of CQMs is only one of the 14 core meaningful use objectives for eligible hospitals and CAHs for the Medicare EHR Incentive Program, an eligible hospital or CAH that chooses to participate in the proposed Electronic Reporting Pilot would still be required to meet and attest to the other core and menu set objectives and their associated measures using the attestation module for the program on the CMS Web site.

After the eligible hospital or CAH had attested and CMS has received electronic submission of the CQMs from an eligible hospital or CAH participating in the proposed Electronic Reporting Pilot, CMS would determine whether the eligible hospital or CAH has successfully met all the requirements for the Medicare EHR Incentive Program. We expect this determination would be made within 2 months after the end of the payment year and not later than November 30, 2013. Eligible hospitals and CAHs who do not meet the reporting requirements through the Electronic Reporting Pilot may meet such requirement through attestation. We are proposing that eligible hospitals and CAHs, alternatively, may attest, but still participate in the proposed Electronic Reporting Pilot.

3. CQM Reporting Under the Proposed Electronic Reporting Pilot

Under § 495.6(f)(9), we require Medicare eligible hospitals and CAHs (which would include those participating in the proposed Electronic Reporting Pilot) to successfully report hospital clinical quality measures to CMS in the manner specified by CMS. We are proposing that eligible hospitals and CAHs participating in the proposed Electronic Reporting Pilot must submit CQM data on all 15 CQMs listed in Table 10 of the final rule (75 FR 44418 through 44420) to CMS, via a secure portal based on data obtained from the eligible hospital or CAH's certified EHR technology.

In the final rule for the Medicare and Medicaid EHR Incentive Programs, we stated that we will require eligible hospitals and CAHs to report aggregate-level CQM data (75 FR 44432). However, we note that for the purpose of the proposed Electronic Reporting Pilot, we are proposing that eligible hospitals and CAHs participating in the proposed Electronic Reporting Pilot would submit patient-level CQM data for Medicare patients only. Aside from requiring attestation to other objectives/measures based on data for all patients, specifically, we are proposing that eligible hospitals and CAHs participating in the proposed Electronic Reporting Pilot would: (1) Submit CQM data on Medicare patients only; (2) submit Medicare patient-level data from which CMS may calculate CQM results using a uniform calculation process, rather than aggregate results calculated by the eligible hospital or CAH's certified EHR technology; (3) submit one full Federal fiscal year of CQM data, regardless of the eligible hospital or CAH's year of participation in the Medicare and Medicaid EHR Incentive Programs; and (4) use electronic specifications for transmission as specified by CMS which we expect would be Level 1 QRDA.

As noted previously, for the proposed Electronic Reporting Pilot, CQM data on which the eligible hospital or CAH's submission is based must be obtained from certified EHR technology. However, the functionality of reporting these CQMs to CMS will not rely on the certification process. Eligible hospitals and CAHs participating in the proposed Electronic Reporting Pilot would report CQMs based on a pilot measurement period of one full Federal fiscal year (October 1, 2011 through September 30, 2012), regardless of whether the eligible hospital or CAH is in its first year of participation in the Medicare and Medicaid EHR Incentive Programs. The period for submitting information on CQMs under the proposed Electronic Reporting Pilot would be October 1, 2012 through November 30, 2012, which is the 60 days following the close of the measurement period. The CQM reporting format would be as specified by CMS, which we expect would be Quality Data Reporting Architecture (QRDA) Level 1. We would offer a test period beginning July 1, 2012, which would allow eligible hospitals, CAHs, or their designee to submit CQM reports to CMS with the requirements that would be used in the proposed Electronic Reporting Pilot. The test period would remain open. Additional details including educational materials about participation in the proposed Electronic Reporting Pilot would be provided on the QualityNet Web site at *http://www.qualitynet.org*.

We invite public comment on the proposed Electronic Reporting Pilot discussed above.

K. Proposed ASC Quality Reporting Program

1. Background

Section 109(b) of the MIEA TRHCA amended section 1833(i) of the Act by re-designating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to implement the revised ASC payment system ''in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).'' Section 1833(i)(7)(A) of the Act states that the Secretary may provide that any ASC that does not submit quality measures to the Secretary in accordance with paragraph (7) will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. It also specifies that a reduction for one year cannot be taken into account in computing any annual increase factor for a subsequent year.

Section 1833(i)(7)(B) of the Act provides that, ''[e]xcept as the Secretary may otherwise provide,'' the hospital outpatient quality data provisions of subparagraphs (B) through (E) of section 1833(t)(17) of the Act shall apply to ASCs in a similar manner to the manner in which they apply under these paragraphs to hospitals under the Hospital OQR Program and any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ASC, the setting of an ASC, or services of an ASC, respectively. Section 1833(t)(17)(B) of the Act requires that hospitals submit quality data in a form and manner, and at a time, that the Secretary specifies.

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Section 1833(t)(17)(C)(ii) of the Act allows the Secretary to select measures that are the same as (or a subset of) the measures for which data are required to be submitted under the Hospital IQR Program. Section 1833(t)(17)(D) of the Act gives the Secretary the authority to replace measures or indicators as appropriate, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice. Section 1833(t)(17)(E) of the Act requires the Secretary to establish procedures for making data submitted under the Hospital OQR Program available to the public. Such procedures include providing hospitals with the opportunity to review their data before these data are released to the public. For a more detailed discussion of the provisions in § 1833(t)(17) of the Act, please see section XIV.A.3.b. of this proposed rule.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68780), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60656), and the CY 2011 OPPS/ASC final rule with comment period (75 FR 72109), we did not implement a quality data reporting program for ASCs. We determined that it would be more appropriate to allow ASCs to acquire some experience with the revised ASC payment system, which was implemented for CY 2008, before implementing new requirements, such as public reporting of quality measures. However, in these rules, we indicated that we intended to implement the provisions of section 109(b) of the MIEA-TRHCA in the future.

In preparation for proposing an ASC quality reporting program, in the CY 2011 OPPS/ASC proposed rule, we solicited public comment on the following measures under consideration for ASC quality data reporting: (1) Patient Fall in the ASC; (2) Patient Burn; (3) Hospital Transfer/Admission; (4) Wrong Site, Side, Patient, Procedure,

Implant; (5) Prophylactic IV Antibiotic Timing; (6) Appropriate Surgical Site Hair Removal; (7) Surgical Site Infection (SSI); (8) Medication Administration Variance (MAV); (9) Medication Reconciliation; and (10) VTE Measures: Outcome/Assessment/Prophylaxis (75 FR 46383).

In addition to preparing to propose implementation of an ASC quality reporting program, the Department developed a plan to implement a value-based purchasing (VBP) program for payments under the Medicare program under title XVIII of the Act for ASCs as required by section 3006(f) of the Affordable Care Act, as added by section 10301(a) of the Affordable Care Act. We also have recently submitted a Report to Congress, as required by section 3006(f)(4) of the Affordable Care Act, entitled ''Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan'' that contains this plan. This report is found on our Web site at: *http://www.cms.gov/ASCPayment/downloads/C_ASC_RTC%202011.pdf*. Currently, we do not have express statutory authority to implement an ASC VBP Program. Should there be legislation to authorize CMS to implement an ASC VBP program, we will develop the program and propose it through rulemaking.

In this proposed rule, we are proposing to implement the ASC Quality Reporting Program beginning with the CY 2014 payment determination, with data collection beginning in CY 2012 for most of the measures to be used for the CY 2014 payment determination.

2. ASC Quality Reporting Program Measure Selection

a. Proposed Timetable for Selecting ASC Quality Measures

We are proposing to adopt measures for three CY payment determinations for the ASC Quality Reporting Program in this rulemaking. Therefore, in this proposed rule, we are proposing to adopt measures for the CYs 2014, 2015, and 2016 payment determinations. To the extent that we finalize some or all of the measures for future payment determinations, we would not be precluded from proposing to adopt additional measures or changing the list of measures for future payment determinations through annual rulemaking cycles so that we may address changing program needs arising from new legislation or from changes in HHS and CMS priorities. Under this approach, in the CY 2013 or CY 2014 rulemaking cycle, we could propose any additions or revisions to the measures we adopted in the CY 2012 rulemaking cycle for the CY 2014 payment determination or for future payment determinations. This is consistent with our approach to proposing measures for multiple payment determinations for the Hospital IQR and Hospital OQR Programs. We believe this proposed process will assist ASCs in planning, meeting future reporting requirements, and implementing quality improvement efforts. We also would have more time to develop, align, and implement the infrastructure necessary to collect data on the measures and make payment determinations. This flexibility would enable us to adapt the program to support changes in HHS and CMS priorities and any new legislative requirements. We invite public comments on this proposal.

b. Considerations in the Selection of Measures for the ASC Quality Reporting Program

Section 1833(i)(7)(B) of the Act states that § 1833(t)(17)(C) of the Act shall apply with respect to ASC services in a similar manner in which they apply to hospitals for the Hospital OQR Program, except as the Secretary may otherwise provide. The requirements at 1833(t)(17)(C)(i) of the Act state that measures developed shall ''be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.''

In selecting proposed measures for the ASC Quality Reporting Program and other quality reporting programs, we have focused on measures that have a high impact on and support HHS and CMS priorities for improved health care outcomes, quality, safety, efficiency and satisfaction for patients. Our goal for the future is to expand any measure set adopted for ASC quality reporting to address these priorities more fully and to align ASC quality measure requirements with those of other reporting programs as appropriate, including the Hospital OQR Program, the Hospital IQR Program, the Physician Quality Reporting System, and reporting requirements implemented under the HITECH Act so that the burden for reporting will be reduced. In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, as we have noted in previous rulemaking for the Hospital OQR Program (75 FR 72065), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment.

In developing this and other quality reporting programs, as well as the Hospital Inpatient VBP Program, we applied the following principles for the development and use of measures. We invite public comment on these principles in the ASC quality reporting context.

- Pay-for-reporting, public reporting, and value-based purchasing programs should rely on a mix of standards, process, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider/supplier characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of measures appropriate to the specific provider/supplier category that reflects the level of care and the most important areas of service and measures for that provider/supplier.
- The collection of information should minimize the burden on providers/suppliers to the extent possible. To this end, we will continuously seek to align our measures with the adoption of meaningful use standards for HIT, so that data can be submitted and calculated via certified EHR technology with minimal burden.
- To the extent practicable and feasible, and within the scope of our statutory authorities for various quality reporting and value-based purchasing programs, measures used by CMS should be endorsed by a national, multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We believe that ASC facilities are similar, insofar as the delivery of surgical and related nonsurgical services, to HOPDs. Similar standards and guidelines can be applied between

hospital outpatient departments and ASCs with respect to surgical care improvement, given that many of the same surgical procedures are provided in both settings. Measure harmonization assures that comparable care in different settings can be evaluated in similar ways, which further assures that quality measurement can focus more on the needs of a patient with a particular condition rather than on the specific program or policy attributes of the setting in which the care is provided. In general, our goal is to adopt harmonized measures that assess the quality of care given across settings and providers/suppliers and to use the same measure specifications based on clinical evidence and guidelines for the care being assessed regardless of provider/supplier type or setting. This harmonization goal is also supported by a commenter to the CY 2011 OPPS/ASC proposed rule, who recommended CMS align ASC quality measures with State and other Federal requirements (75 FR 72109).

Our CY 2014 measure proposals for ASCs align closely with those discussed in the Report to Congress entitled ''Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan'' and with those proposed for future consideration in the CY 2011 OPPS/ASC proposed rule (75 FR 46383). Furthermore, the measures that we are proposing for ASCs fall into the parameter of our stated framework for the ASC Quality Reporting Program, discussed above. The initial measure set that we are proposing for the CY 2014 payment determination addresses outcome measures and infection control process measures. Six of the eight initial measures that we are proposing for the CY 2014 payment determination are recommended by the ASC Quality Collaborative (ASC QC) and are NQF-endorsed. The seventh measure that we are proposing is appropriate for measuring ambulatory surgical care, is NQF-endorsed, is currently in use in the Physician Quality Reporting System, and is similar to a measure that is being utilized in the Hospital OQR program, and therefore aligns across settings in which outpatient surgery is performed. We are proposing collecting these seven measures via ''quality data codes'' to be placed on Part B claims submitted by ASCs for Medicare fee-for-service patients beginning January 1, 2012. The eighth measure we are proposing for the ASC Quality CY 2014 payment determination is an outcome measure of Surgical Site Infection (SSI) to be submitted in 2013 via the CDC's National Healthcare Safety Network (NHSN). Similarly, hospital inpatient departments will begin reporting this measure to the CDC under the Hospital IQR Program in 2012, and we are also currently proposing in this rule that hospital outpatient departments begin reporting this measure to the CDC under the Hospital OQR Program in 2013. Thus, this measure would be aligned across quality reporting programs for facilities performing surgery.

3. Proposed ASC Quality Measures for the CY 2014 Payment Determination

a. Proposed Claims-Based Measures Requiring Submission of Quality Data Codes (QDCs) Beginning January 1, 2012

We are proposing to adopt seven NQF-endorsed claims-based measures, six of which were developed by the ASC QC. The ASC QC is a cooperative effort of organizations and companies formed in 2006 with a common interest in ensuring that ASC quality data is measured and reported in a meaningful way. Stakeholders in the ASC QC include ASC corporations, ASC associations, professional societies and accrediting bodies that focus on ASC quality and safety. The ASC QC initiated a process of standardizing ASC quality measure development through evaluation of existing nationally endorsed quality measures to determine which could be directly applied to the outpatient surgery facility setting. The ASC QC in its ASC Quality Measure Implementation Guide version 1.4 states that ''it focused on outcomes and processes that ASC facilities could influence or impact, outcomes that ASC facilities would be aware of given their limited contact with the patient, and outcomes that would be understandable and important to key stakeholders in ASC care, including patients, providers and payers.''

The ASC QC developed and pilot-tested five facility-level measures (Patient Burn; Patient Fall in the ASC; Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; Hospital Transfer/Admission, and Prophylactic IV Antibiotic Timing) for feasibility and usability. On November 15, 2007, these five measures were endorsed by the NQF. On September 25, 2008, a sixth ASC QC-developed facility-level measure, ''Appropriate Surgical Site Hair Removal'' was NQF-endorsed as ''Ambulatory Surgery Patients with Appropriate Method of Hair Removal.'' Of the six ASC QC measures, the Prophylactic IV Antibiotic Timing and Ambulatory Surgery Patients with Appropriate Method of Hair Removal measures are infection control process measures, and the rest are outcome measures. All six of these measures were listed as under consideration in the CY 2011 OPPS/ASC proposed rule (75 FR 46383). We are proposing these six measures for use in the CY 2014 payment determination.

The seventh claims-based measure we are proposing for the CY 2014 payment determination is Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin. This measure was developed by the American Medical Association's (AMA's) Physician Consortium for Performance Improvement, a national, diverse, physician-led group that identifies, develops, and promotes implementation of evidence-based clinical performance measures that reflect best practices. This measure is NQF-endorsed. It is an infection control process measure and is currently adopted in the Hospital IQR Program and Physician Quality Reporting System (PQRS).

We are proposing to collect all seven measures using the claims-based quality data codes (QDCs) data collection mechanism. We are proposing to require ASCs to report on ASC claims a quality data code (QDC) to be used for reporting quality data. We are proposing that an ASC would need to add a QDC to any claim involving a proposed claims-based quality measure. CMS is in the process of developing QDCs for each proposed claims-based quality measure. The QDC will be a CPT Category II code or a HCPCS Level II G-code if an appropriate CPT code is not available. More information on the QDCs that will be associated with the proposed quality measures will be provided in the CY 2012 OPPS/ASC final rule with comment period. Additionally, CMS is proposing to create a new ASC payment indicator ''M5'' (Quality measurement code used for reporting purposes only; no payment made) for assignment to the QDC to clarify that no payment is associated with the QDC for that claim. If one or more of these measures are finalized as proposed, an ASC would need to begin submitting these QDCs on any Medicare Part B claims pertaining to the measures on January 1, 2012.

For the first six measures listed, the ASC QC measures specifications can be found at *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf.*[41] For the seventh measure, the specifications can be found on the PQRS Web site at: *http://www.cms.gov/apps/ama/license.asp?file=/pqrs/downloads/2011_*

[41] ASC Quality Measures: Implementation Guide Version 1.4, ASC Quality Collaboration, December 2010.

PhysQualRptg_MeasureSpecifications Manual_033111.pdf.

These seven proposed measures are discussed in more detail below:

(1) Patient Burns (NQF #0263)

The ASC Quality Measures: Implementation Guide Version 1.4 states that every patient receiving care in an ASC setting has the potential to experience a burn during an episode of care, given the multitude of factors that could pose risks for patient burns in the surgical and procedural settings. The Guide cited a recent publication from the ECRI Institute that relates an increased risk of burns associated with newer electrosurgical devices due to their application of higher electrical current for longer time intervals. Other common sources of burns in a surgical setting include chemical and thermal sources, and radiation, scalds, and fires. Clinical practice guidelines for reducing the risk of burns have been established by the American Society of Anesthesiologists (ASA) and Association of Operating Room Nurses (AORN).

This NQF-endorsed measure assesses the percentage of ASC admissions experiencing a burn prior to discharge. The NQF-endorsed specifications for ASC QC measure can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf.* The ASC QC in their ASC Quality Measure Implementation Guide version 1.4 defines a ''burn'' for purposes of this measure as ''[u]nintended tissue injury caused by any of the six recognized mechanisms: scalds, contact, fire, chemical, electrical or radiation (e.g., warming devices, prep solutions, and electrosurgical unit or laser).'' We believe that this measure would allow stakeholders to develop a better understanding of the incidence of these events and further refine means to ensure prevention.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs since they serve surgical patients who may face the risk of burns during ambulatory surgical procedures. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

(2) Patient Fall (NQF #0266)

Falls, particularly in the elderly, can cause injury and loss of functional status, and falls in healthcare settings can be prevented through assessment of risk, care planning, and patient monitoring. Healthcare settings are being called upon to report patient falls and to take steps to reduce the risk of falls. The ASC QC indicates in their ASC quality measure implementation guide the use of anxiolytics, sedatives, and anesthetic agents may put patients undergoing outpatient surgery at increased risk for falls. Guidelines and best practices for the prevention of falls, and management of patients after falls have been made available by the Agency for Healthcare Research and Quality (*http://www.ahrq.gov/qual/transform.htm*), and the National Center for Patient Safety (*http://www.patientsafety.gov*).

This NQF-endorsed measure assesses the percentage of ASC admissions experiencing a fall in the ASC. The NQF-endorsed specifications for this ASC QC measure can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf.* The ASC QC in their ASC Quality Measure Implementation Guide version 1.4 defines a ''fall'' as ''a sudden, uncontrolled, unintentional, downward displacement of the body to the ground or other object, excluding falls resulting from violent blows or other purposeful actions'', which is consistent with the definition set forth by the National Center for Patient Safety.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs because it was specifically developed to measure quality of surgical care furnished by ASCs, as measured by patient falls. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is NQF-endorsed.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare fee-for-service beneficiaries from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

(3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)

Surgeries and procedures performed on the wrong site/side, and wrong patient can result in significant impact on patients, including complications, serious disability or death. While the prevalence of such serious errors may be rare, such events are considered serious reportable events, and are included in the NQF's *Serious Reportable Events in Healthcare 2006 Update.*[42] The Joint Commission (a not-for-profit organization that accredits and certifies health care organizations and programs in the US) has issued a Universal Protocol to prevent such serious surgical errors.[43] The proposed NQF-endorsed measure assesses the percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant. The ASC QC in their *ASC Quality Measures: Implementation Guide Version 1.4* defines ''wrong'' as ''not in accordance with intended site, side, patient, procedure or implant.'' The NQF-endorsed specifications for this ASC QC measure can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf.*

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs because the measure assesses the quality of surgical care provided in ASCs as measured by the percentage of surgical errors. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

(4) Hospital Transfer/Admission (NQF #0265)

The transfer or admission of a surgical patient from an outpatient setting to an acute care setting can be an indication of a complication, serious medical error, or other unplanned negative patient outcome. While acute intervention may be necessary in these circumstances, a high rate of such incidents may indicate suboptimal practices or patient selection criteria. The proposed NQF-endorsed measure assesses the rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC. The ASC QC defines ''hospital transfer/admission'' as ''any transfer/admission from an ASC directly to an acute care hospital, including hospital emergency room.''

The NQF-endorsed specifications for this ASC QC measure can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf.* The ASC QC believes that this ''measure would allow ASCs to assess their guidelines for procedures performed in the facility and patient selection if transfers/admissions are determined to be at a level higher than expected. If commonalities are found in patients who are transferred or admitted, guidelines may require revision.''

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses outpatient surgical care quality in the form of the rate of surgical outpatients needing acute care interventions. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

(5) Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)

Timely preoperative administration of intravenous antibiotics to surgical patients is an effective practice in reducing the risk of developing a surgical site infection, which in turn is associated with reduced health care burden and cost, and better patient outcomes.[44] [45] [46] The measurement of

[42] *http://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx.*

[43] Joint Commission. Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. Available at *http://www.jointcommission.org/standards_information/up.aspx.* Last accessed December 14, 2010.

[44] Classen, D. et al.: The timing of prophylactic administration of antibiotics and the risk of surgical wound infection. NEJM. 1992;326(5):281–286.

[45] Silver, A. et al.: Timeliness and use of antibiotic prophylaxis in selected inpatient surgical procedures. The Antibiotic Prophylaxis Study Group. Am J Surg. 1996;171(6):548–552.

timely antibiotic administration for surgical patients is occurring in the Hospital IQR Program, Hospital OQR Program and the Physician Quality Reporting System. The NQF-endorsed ASC QC measure assesses the rate of ASC patients who received IV antibiotics ordered for surgical site infection prophylaxis on time. The NQF-endorsed specifications for this ASC QC measure can be found at: *http://www.ascquality.org/documents/ASCQuality CollaborationImplementationGuide.pdf.*

The ASC QC measure implementation guide defines ''antibiotic administered on time'' as ''[a]ntibiotic infusion * * * initiated within one hour prior to the time of the initial surgical incision or the beginning of the procedure (e.g., introduction of endoscope, insertion of needle, inflation of tourniquet) or two hours prior if vancomycin or fluoroquinolones are administered.'' The measure also defines ''prophylactic antibiotic'' as ''an antibiotic prescribed with the intent of reducing the probability of an infection related to an invasive procedure. For purposes of this measure, the following antibiotics are considered prophylaxis for surgical site infections: Ampicillin/sulbactam, Aztreonam, Cefazolin, Cefmetazole, Cefotetan, Cefoxitin, Cefuroxime, Ciprofloxacin, Clindamycin, Ertapenem, Erythromycin, Gatifloxacin, Gentamicin, Levofloxacin, Metronidazole, Moxifloxacin, Neomycin and Vancomycin.'' All prophylactic IV antibiotics administered for surgical site infection would need to have their infusion initiated within the one hour time frame, except for vancomycin or fluoroquinolones, where infusion must be initiated within the two hours time frame. The ASC QC Guide states that ''[i]n cases involving more than one antibiotic, all antibiotics must be given within the appropriate time frame in order for the case to meet criteria.'' The timing of the antibiotic starts at the time the antibiotic is initiated with a preoperative order.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses the quality of care for surgical patients in an outpatient setting as measured by timely antibiotic administration. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDCs data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

(6) Ambulatory Surgery Patients With Appropriate Method of Hair Removal (NQF #0515)

The ASC QC[47] cited evidence that ''[r]azors can cause microscopic cuts and nicks to the skin, not visible to the eye. Use of razors prior to surgery increases the incidence of wound infection when compared to clipping, depilatory use or no hair removal at all.''[48] A 1999 guideline issued by the CDC suggests that if hair must be removed from a surgical site, that it preferably be done with clippers rather than razors in order to minimize cuts and nicks to the skin which may increase the risk of a surgical site infection.[49] In 2002, the Association of Operating Room Nurses published similar guidelines for appropriate hair removal.[50] While a similar measure is being considered for retirement from the Hospital IQR Program because it displays a high degree of performance with little variability or room for improvement, we believe that there is significant, variability in practice and level of adherence to this guideline in outpatient surgical settings such as ASCs is not known, and accordingly, this measure is still appropriate for use in the ASC setting. We are proposing to adopt the NQF-endorsed measure to capture the percentage of ASC admissions with appropriate surgical site hair removal. The NQF-endorsed specifications for this ASC QC measure can be found at: *http://www.ascquality.org/documents/ASCQualityCollaboration ImplementationGuide.pdf.*

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses quality of surgical care performed in ASCs, as measured by appropriate surgical site hair removal. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures that we restrict the measure population to the population for which

[46] Dounis, E., Tsourvakas, S., Kalivas, L., and Giamacellou, H.: Effect of time interval on tissue concentrations of cephalosporins after tourniquet inflation. Highest levels achieved by administration 20 minutes before inflation. Acta Orthop Scand. 1995;66(2):158–60.

[47] ASC QC Quality measures: Implementation Guide version 1.4. ASC Quality Collaboration. December 2010.

[48] Seropian, R., Reynolds, B.M.: Wound infections after preoperative depilatory versus razor preparation. Am J Surg.1971 Mar;121(3):251–4.

[49] *http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf.*

[50] Association of Operating Room Nurses. Recommended practices for skin preparation of patients. AORN J. 2002 Jan;75(1):184–7.

CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of CY 2014 payment determination.

(7) Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin (NQF #0268)

Surgical outcomes are affected by the selection of appropriate antibiotics. Current guidelines indicate that first or second generation cephalosporins are effective for prevention of surgical site infections in most cases. The goal of this proposed measure is to ensure safe, cost-effective, broad spectrum antibiotics are used as a first line prophylaxis unless otherwise indicated. This measure was developed by the AMA's Physician Consortium for Performance Improvement, a national, diverse, physician-led group that identifies, develops, and promotes implementation of evidence-based clinical performance measures that reflect best practices. This measure received NQF-endorsement under a 2008 project entitled ''Hospital Care: Specialty Clinician Performance Measures,'' and it assesses the percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin or cefuroxime for antimicrobial prophylaxis. While we recognize that this measure is not specifically endorsed for the ASC setting, we believe that this measure is highly relevant for use in ASCs because it assesses adherence to best practices for use of prophylactic antibiotics for outpatient surgical patients. Accordingly, we propose to adopt an application of this NQF-endorsed measure for use in the ASC Quality Reporting Program. The measure specifications for this proposed measure can be found at: *http://www.cms.gov/pqrs/downloads/2011_PhysQualRptg_MeasuresGroups_SpecificationsManual_033111.pdf?agree=yes&next=Accept.*

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate for measurement of quality care in an ASC because it specifically assesses quality care, as measured by adherence to best practices for prophylactic antibiotics provided for outpatient surgical patients. It is not feasible or practicable to adopt an NQF-endorsed measure of prophylactic antibiotic selection specifically for ASCs because there is no such NQF-endorsed measure. We note that section 1833(t)(17) of the Act does not require that each measure we adopt for the ASC Quality Reporting Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt measures that are not NQF-endorsed or measures that have not been endorsed for the ASC setting.

The proposed adoption of this measure in the ASC Quality Reporting Program also is consistent with our goal to align measures across settings, as it is also used in the Physician Quality Reporting System, and a similar measure (NQF #0528) has been implemented in the Hospital OQR Program and the Hospital IQR Program.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all surgical patients, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

b. Surgical Site Infection Rate (NQF #0299)

HAIs are among the leading causes of death in the United States. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths.[51] It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs. HAIs are largely preventable for surgical patients through application of perioperative best practices such as those listed in the CDC's SSI prevention guidelines. Therefore, many health care consumers and organizations are calling for public disclosure of HAIs, arguing that public reporting of HAI rates provides the information health care consumers need to choose the safest hospitals, and gives hospitals an incentive to improve infection control efforts. This proposed measure is currently collected by the National Healthcare Safety Network (NHSN) as part of State-mandated reporting and surveillance requirements for hospitals in some States. Additionally, data submission for this measure through EHRs may be possible in the near future.

This measure is NQF-endorsed and we are also proposing to adopt it for the CY 2014 Hospital OQR Program. It also has been adopted for the FY 2014 Hospital IQR Program. Because we are proposing the same measure for Hospital OQR program in this rule, we refer readers to the discussion of this measure in section XIV.C.2.a. of this proposed rule. The measure specifications can be found at *http://www.cdc.gov/nhsn/psc.html.* The NQF describes this measure as the ''percentage of surgical site infection events occurring within thirty days after the operative procedure if no implant is left in place, or [within] one year if an

[51] McKibben. L., Horan, T.: Guidance on public reporting of healthcare-associated infections: recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005;33:217–26.

implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure.''

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. Increasingly, surgical procedures are being performed in hospital outpatient department settings and ASCs. We believe this measure is appropriate for measuring quality of care in ASCs because it applies to outcomes for surgical patients undergoing procedures that are performed in ASCs. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is endorsed by the NQF. The proposed adoption of this measure in the ASC Quality Reporting Program also is consistent with our goal to align measures across settings because we have proposed this measure for the Hospital OQR Program for CY 2014 payment determination and have previously adopted it for Hospital IQR Program for the FY 2014 payment determination. Therefore, we are proposing to adopt the Surgical Site Infection Rate measure that is collected by the CDC via the NHSN for the ASC Quality Reporting Program for the CY 2014 payment determination.

Data submission for this measure for the CY 2014 payment determination would begin with infection events occurring on or after January 1, 2013 through June 30, 2013. The proposed reporting mechanism for this proposed HAI measure via the NHSN is discussed in greater detail in section XIV.C.2.a. of this proposed rule. We invite public comment on this proposed measure and the reporting mechanism.

In summary, we are proposing to adopt 7 claims-based measures using the QDC data collection mechanism, and one NHSN HAI measure of Surgical Site Infection Rate for a total of eight measures for ASCs for the CY 2014 payment determination. We believe the proposal falls within our stated framework for the ASC Quality Reporting Program. For the CY 2014 payment determination, we are proposing that data submission for the claims-based measures begin on January 1, 2012 and end December 31, 2012. For the CY 2014 payment determination, we are proposing that data submission for the NHSN-based SSI measure begin with infection events occurring between January 1, 2013 and June 30, 2013. This proposed measure is currently collected by the NHSN as part of State-mandated reporting and surveillance requirements for hospitals in some States.

The NHSN is a secure, Internet-based surveillance system maintained and managed by the CDC, and can be utilized by all types of healthcare facilities in the United States, including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ASCs, and long term care facilities. The NHSN reporting infrastructure is provided free of charge to healthcare providers/suppliers to access and use for reporting data regarding healthcare safety and infections. The NHSN enables healthcare facilities to collect and use data about HAIs, clinical practices known to prevent HAIs, the incidence or prevalence of multidrug-resistant organisms within their organizations, and other adverse events. Some States use the NHSN as a means for healthcare facilities to submit data on HAIs mandated through their specific State legislation. We invite public comments on our proposals. The proposed measures for ASCs for the CY 2014 payment determination are listed below with the ASC prefix:

ASC Program Measurement Set Proposed for the CY 2014 Payment Determination

[Data submission to occur in 2012 and 2013]

ASC–1: Patient Burn.*
ASC–2: Patient Fall.*
ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.*
ASC–4: Hospital Transfer/Admission.*
ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing.*
ASC–6: Ambulatory Surgery Patients with Appropriate Method of Hair Removal.*
ASC–7: Selection of Prophylactic Antibiotic First OR Second Generation Cephalosporin.*
ASC–8: Surgical Site Infection Rate.**

* Data submission proposed to begin in CY 2012.
** Data submission proposed to begin in CY 2013.

4. Proposed ASC Quality Measures for CY 2015 Payment Determination

a. Retention of Measures Adopted for the CY 2014 Payment Determination in the CY 2015 Payment Determination

In general, unless we otherwise specify in the retirement section of a rule, we propose to retain measures from one CY payment determination to another. We are proposing to retain the eight measures we are proposing to adopt for the CY 2014 payment determination, if they are finalized in the CY 2012 OPPS/ASC final rule with comment period, for the CY 2015 payment determination. We invite public comments on this proposal.

b. Proposed Structural Measures for the CY 2015 Payment Determination

For the CY 2015 payment determination, we are proposing to adopt two structural measures: Safe Surgery Checklist Use, and ASC Facility Volume Data on Selected ASC Surgical Procedures. We discuss these proposals below.

(1) Safe Surgery Checklist Use

A sound surgery safety checklist could minimize the most common and avoidable risks endangering the lives and well-being of surgical patients. The purpose of this proposed structural measure is to assess whether ASCs are using a safe surgery checklist that covers effective communication and helps ensure that safe practices are being performed at three critical perioperative periods: prior to administration of anesthesia, prior to incision, and prior to the patient leaving the operating room. The use of such checklists has been credited with dramatic decreases in preventable harm, complications and

post-surgical mortality.[52] In November 2010, the New England Journal of Medicine published a study concluding that surgical complications were reduced by one-third, and mortality by nearly half, when a safe surgery checklist was used.[53]

We believe that effective communication and the use of safe surgical practices during surgical procedures will significantly reduce preventable surgical deaths and complications. Some examples of safe surgery practices that can be performed during each of these three perioperative periods are shown in the table below:

First critical point (prior to administering anesthesia)	Second critical point (prior to skin incision)	Third critical point (prior to patient leaving the operating room)
• Verbal confirmation of patient identity. • Mark surgical site. • Check anesthesia machine/medication. • Assessment of allergies, airway and aspiration risk.	• Confirm surgical team members and roles. • Confirm patient identity, procedure, and surgical incision site. • Administration of antibiotic prophylaxis within 60 minutes before incision. • Communication among surgical team members of anticipated critical events. • Display of essential imaging as appropriate.	• Confirm the procedure. • Complete count of surgical instruments and accessories. • Identify key patient concerns for recovery and management of the patient.

For example, mistakes in surgery can be prevented by ensuring that the correct surgery is performed on the correct patient and at the correct place on the patient's body.[54] A safe surgery checklist would also reduce the potential for human error, which would increase the safety of the surgical environment. An example of a checklist that employs safe surgery practices at each of these three perioperative periods is the World Health Organization Surgical Safety Checklist, which was adopted by The World Federation of Societies of Anesthesiologists as an international standard of practice. This checklist can be found at: *http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html.*

The adoption of a structural measure that assesses Safe Surgery Checklist Use would align our patient safety initiatives with those of several surgical specialty societies including: the American College of Surgeons' Nora Institute for Patient Safety, the American Society of Anesthesiologists, The Joint Commission, the National Association for Healthcare Quality and the AORN. The measure would assess whether the ASC uses a safe surgery checklist in general, and would not require an ASC to report whether it uses a checklist in connection with any individual procedures.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. This measure is appropriate for the measurement of quality of care furnished by ASCs because it pertains to best practices for surgeries, and ASCs perform ambulatory surgeries. It also reflects consensus among affected parties. As stated in section XIV.C.2.c.1 of this proposed rule, we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment. The proposed safe surgery checklist measure assesses the adoption of a best practice for surgical care that is broadly accepted and in widespread use among affected parties. In addition to being adopted by The World Federation of Societies of Anesthesiologists, the use of a safe surgery checklist is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety,[55] which is comprised of the American Association of Nurse Anesthetists, the American College of Surgeons, the American Association of Surgical Physician Assistants, the American Society of Anesthesiologists, the American Society of PeriAnesthesia Nurses, AORN, and the Association of Surgical Technologists. Two State agencies (Oregon, South Carolina), the Veterans Health Administration,[56] numerous hospital systems, State hospital associations (such as California and South Carolina), national accrediting organizations and large private insurers have endorsed the use of a safe surgery checklist as a best practice for reducing morbidity, mortality, and medical errors.[57] [58] Because the use of a safe surgery checklist is a widely accepted best practice for surgical care, we believe that the proposed structural measure of Safe Surgery Checklist Use reflects consensus among affected parties. We also note that The Joint Commission has included safe surgery checklist practices among those to be used to achieve National Patient Safety Goals adopted for 2011 for surgeries performed in ambulatory settings and hospitals.[59] The Safe Surgery Checklist Use structural measure is not NQF-endorsed, and there is no NQF-endorsed measure of safe surgery checklist use despite the broad acceptance and widespread endorsement of this practice. Therefore, it is not feasible or practicable to adopt an NQF-endorsed measure of safe surgery checklist use because there is no such NQF-endorsed measure. We note that section 1833(t)(17) of the Act does not require that each measure we adopt for the ASC Quality Reporting Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the

[52] Haynes, A.B.; Weiser, T.G.; Berry, W.G. et. al (2009). ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population''. New England Journal of Medicine. 360: 491–499.

[53] de Vries EN, Prins HA, Crolla RMPH, et al. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med 2010;363: 1928–37.

[54] Hospital National Patient Safety Goals. The Joint Commission Accreditation Hospital Manual, 2011. *http://www.jointcommission.org/standards_information/npsgs.aspx.*

[55] *http://www.cspsteam.org/safesurgerychecklist/safesurgerychecklist.html.*

[56] Neily, J; Mills, PD, Young-Xu, Y. (2010). ''Association between implementation of a Medical Team Training Program and Surgical Mortality''. JAMA. 304 (15): 1693–1700.

[57] Haynes, AB; Weiser, TG; Berry, WR et al (2009) ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population''. NEJM. 360:491–499.

[58] Birkmeyer, JD (2010) ''Strategies for Improving Surgical Quality—Checklists and Beyond.'' NEJM. 363: 1963–1965.

[59] *http://www.jointcommission.org/standards_information/npsgs.aspx.*

ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. We note that the proposed adoption of this measure in the ASC Quality Reporting Program is consistent with our goal to align measures across settings because we are also proposing the same measure for the Hospital OQR Program for CY 2014 payment determination.

For the CY 2015 payment determination, we are proposing that data collection for this structural measure for ASCs would begin on July 1, 2013 and end on August 15, 2013 for the entire time period from January 1, 2012 through December 31, 2012. In other words, an ASC would report whether their facility employed a safe surgery checklist that covered each of the three critical perioperative periods for the entire calendar year of 2012 during the 45-day window from July 1 through August 15, 2013. The information for this structural measure would be collected via an online Web-based tool that will be made available to ASCs via the QualityNet Web site. This collection mechanism is also used to collect structural measures and other information for other programs, specifically for the Hospital IQR and Hospital OQR programs.

We invite public comments on our proposal to add this new structural measure to the ASC quality measurement set and the submission process for the CY 2015 payment determination.

(2) ASC Facility Volume Data on Selected ASC Surgical Procedures

There is substantial evidence in recent peer-reviewed clinical literature that volume of surgical procedures, particularly of high risk surgical procedures, is related to better patient outcomes, including decreased surgical errors and mortality.[60] [61] [62] This may be attributable to greater experience and/or surgical skill, greater comfort with and hence likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure. For this reason, the National Quality Forum has endorsed measures of total all-patient surgical volume for Isolated CABG and Valve Surgeries (NQF #0124), Percutaneous Coronary Intervention (PCI) (NQF #0165), Pediatric Heart Surgery (NQF #0340), Abdominal Aortic Aneurism Repair (NQF #357), Esophageal Resection (#0361), and Pancreatic Resection (NQF #0366). Additionally, many consumer-oriented Web sites reporting health care quality information sponsored by States (California, New York, Texas, Washington, Florida, Illinois, Michigan, Oregon) and private organizations (Leapfrog Group, U.S. News & World Report) are reporting procedure volume, in addition to provider performance on surgical process (SCIP measures) and outcome measures (SSI, Patient Safety Indicators, and Mortality), because it provides beneficial performance information to consumers choosing a health care provider. The currently NQF-endorsed measures of procedure volume (noted above) relate to surgeries only performed in inpatient settings, and would not be applicable to the types of procedures approved to be performed in HOPDs and ASCs.

The recently issued Report to Congress entitled ''Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan'' included an analysis of CY 2009 ASC claims for Medicare beneficiaries. When stratified by specialty category, CMS identified six procedure categories that historically constitute 98.5 percent of the total volume of procedures performed in ASCs: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary. We are proposing that ASCs submit all patient volume data on these six broad categories of surgical procedures as a structural measure to be used for the ASC Quality Reporting Program CY 2015 payment determination. In section XIV.C.2.c.(2) of this proposed rule, we are also proposing that HOPDs submit similar all patient volume data for eight broad procedure categories.

Structural measures assess whether a provider/facility possesses conditions for the care of patients that are associated with better quality. Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. Because surgical volume is associated with better quality, and surgical procedures are performed in ASCs, we believe that surgical volume is appropriate for measuring the quality of these six categories of surgical procedures performed in ASCs. We have previously established for other programs that we believe consensus among affected parties can be reflected through various means including widespread use among industry stakeholders. We believe that the ASC Facility Volume Data on Selected ASC Surgical Procedures structural measure reflects consensus among affected parties as being associated with quality of surgical care because of recent evidence published in well-respected and widely circulated peer-reviewed clinical literature, and because of its widespread reporting among States and private stakeholders on Web sites featuring quality information. Because the current volume measures are endorsed for inpatient procedures, many of which are not performed in outpatient settings such as ASCs, it is not feasible or practicable to utilize NQF endorsed measures of volume for ASCs. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. For the CY 2015 payment determination, we are proposing that ASCs would report these data with respect to these six categories between the dates July 1, 2013 and August 15, 2013 with respect to the time period January 1, 2012 through December 31, 2012. In other words, under this proposal, an ASC would report its CY 2012 all-patient volume data for these six categories of procedures during the 45-day window of July 1 to August 15, 2013. The table below lists the HCPCS codes for which hospitals would be required to report all-patient volume data. Like the structural measures in the Hospital OQR program, data on this proposed measure would be collected via an online Web-based tool that will be made available to ASCs via the QualityNet Web site. This collection mechanism is also used to collect structural measures and other information for other programs (Hospital IQR and Hospital OQR). We invite public comment on this proposal.

In summary, for the CY 2015 payment determination, we are proposing to

[60] Livingston, E.H.; Cao, J ''Procedure Volume as a Predictor of Surgical Outcomes''. JAMA. 2010;304(1):95–97.

[61] David R. Flum, D.R.; Salem, L.; Elrod, J.B.; Dellinger, E.P.; Cheadle, A. Chan, L. ''Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures''. *JAMA. 2005;294(15):1903–1908.*

[62] Schrag, D; Cramer, L.D.; Bach, P.B.; Cohen, A.M.; Warren, J.L.; Begg, C.B '' Influence of Hospital Procedure Volume on Outcomes Following Surgery for Colon Cancer'' *JAMA. 2000; 284 (23): 3028–3035.*

retain the eight measures proposed for the CY 2014 payment determination, if they are adopted in the final rule with comment period, and to add two structural measures. We invite public comments on these proposals for the CY 2015 payment determination. The proposed measures for ASCs for CY 2015 payment determination are listed below:

PROPOSED ASC PROGRAM MEASUREMENT SET FOR THE CY 2015 PAYMENT DETERMINATION

ASC–1: Patient Burn.
ASC–2: Patient Fall.
ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4: Hospital Transfer/Admission.
ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6: Ambulatory Surgery Patients with Appropriate Method of Hair Removal.
ASC–7: Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin.
ASC–8: Surgical Site Infection Rate.

PROPOSED ASC PROGRAM MEASUREMENT SET FOR THE CY 2015 PAYMENT DETERMINATION

ASC–9: Safe Surgery Checklist Use*
ASC–10: ASC Facility Volume Data on Selected ASC Surgical Procedures*

Procedure category	Corresponding HCPCS codes
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, 0170T.
Eye	65000 through 68999, 0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T.
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T.
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T.
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727.
Genitourinary	50000 through 58999, 0193T, 58805.

*New proposed measures for CY 2015 payment determination.

5. Proposed ASC Quality Measures for the CY 2016 Payment Determination

a. Retention of Measures Adopted for the CY 2015 Payment Determination in the CY 2016 Payment Determination

In general, unless otherwise specified in the retirement section of a rule, we propose to retain measures from one CY payment determination to the next. We are proposing to retain the ten measures we are proposing to adopt for the CY 2015 payment determination, if they are finalized in an OPPS/ASC final rule with comment period, for the CY 2016 payment determination. We invite public comment on this proposal.

b. Proposed HAI Measure: Influenza Vaccination Coverage Among Healthcare Personnel (HCP) (NQF #0431)

The Influenza Vaccination among Healthcare Personnel measure assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. The specifications for this measure are available at *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.*

For the ASC CY 2016 payment determination, we are proposing to adopt this NQF-endorsed HAI measure. We also are proposing to adopt this measure for the Hospital OQR Program for the CY 2015 payment determination. We refer readers to the discussion in section XIV.C.3.b. of this proposed rule for a detailed description of this measure.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate for measuring quality of care in ASCs due to the significant impact of HCP influenza vaccination on the spread of influenza among patients. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is endorsed by the NQF.

We are proposing that ASCs use the NHSN infrastructure and protocol to report the measure for ASC Quality Reporting Program purposes. Collection of data via the NHSN for this measure will begin with immunizations from October 1, 2013 to March 31, 2014 for the CY 2016 payment determination. We invite public comment on our proposal to adopt this HAI measure into the ASC Quality Reporting Program for the CY 2016 payment determination.

In summary, for the CY 2016 payment determination, we are proposing to retain the ten measures that we adopt for the CY 2015 payment determination (if these proposals are finalized in a final rule) and to add one NHSN HAI measure. The proposed measures for ASCs for the CY 2016 payment determination are listed below:

PROPOSED ASC PROGRAM MEASUREMENT SET FOR THE CY 2016 PAYMENT DETERMINATION

ASC–1: Patient Burn.
ASC–2: Patient Fall.
ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4: Hospital Transfer/Admission.
ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6: Ambulatory Surgery Patients with Appropriate Method of Hair Removal.

PROPOSED ASC PROGRAM MEASUREMENT SET FOR THE CY 2016 PAYMENT DETERMINATION—Continued

ASC–7: Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin.
ASC–8: Surgical Site Infection Rate.
ASC–9: Safe Surgery Checklist Use.
ASC–10: ASC Facility Volume Data on Selected ASC Surgical Procedures.

Procedure category	Corresponding HCPCS codes
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, 0170T.
Eye	65000 through 68999, 0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T.
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T.
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T.
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727.
Genitourinary	50000 through 58999, 0193T, 58805.

ASC–11: Influenza Vaccination Coverage among Healthcare Personnel.*

*New proposed measure for CY 2016 payment determination.

6. ASC Measure Topics for Future Consideration

Below is a list of future measurement areas that we are considering for future ASC Quality Reporting Program payment determinations for which we seek comment.

In particular, we seek comment on the inclusion of Patient Experience of Care Measures in the ASC Quality Reporting Program measure set for a future payment determination, such as existing Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups and the CAHPS Surgical Care Survey, sponsored and submitted by the American College of Surgeons (ACS) and the Surgical Quality Alliance (SQA). We also, in particular, seek comment on the inclusion of procedure-specific measures for cataract surgery, colonoscopy and endoscopy, and for measures of Anesthesia Related Complications in the ASC Quality Reporting Program measure set.

MEASURES AND MEASUREMENT TOPICS UNDER CONSIDERATION FOR FUTURE PAYMENT DETERMINATIONS

Patient Experience of Care:
- Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups.
- CAHPS Surgical Care Survey.

Procedure Specific Measures:
- Colonoscopy and other Endoscopy measures.
- Cataract Surgery measures.

Anesthesia Related Complications:
- Death.
- Cardiac Arrest.
- Perioperative Myocardial Infarction.
- Anaphylaxis.
- Hyperthermia.
- Transfusion Reaction.
- Stroke, Cerebral Vascular Accident, or Coma following anesthesia.
- Visual Loss.
- Medication Error.
- Unplanned ICU admission.
- Patient intraoperative awareness.
- Unrecognized difficult airway.
- Reintubation.
- Dental Trauma.
- Perioperative aspiration.
- Vascular access complication, including vascular injury or pneumothorax.
- Pneumothorax following attempted vascular access or regional anesthesia.
- Infection following epidural or spinal anesthesia.
- Epidural hematoma following spinal or epidural anesthesia.
- High Spinal.
- Postdural puncture headache.
- Major systemic local anesthetic toxicity.
- Peripheral neurologic deficit following regional anesthesia.
- Infection following peripheral nerve block.

Additional Future Measurement Topics:
- NQF Serious Reportable Events in Healthcare.
- Medication administration variance.
- Medication reconciliation.
- Venous thromboembolism measures: outcome/assessment/prophylaxis.
- Presence of Physician during Entire Recovery Period.
- Post-discharge follow up.
- Post-discharge ED visit within 72 hours.

We invite public comment on these quality measures and measurement topics so that we may consider proposing to adopt them for future ASC Quality Reporting Program payment determinations beginning with the CY 2015 payment determination. We also are seeking suggestions for additional measures and rationales for the ASC Quality Reporting Program that are not listed in the table above.

7. Technical Specification Updates and Data Publication

a. Maintenance of Technical Specifications for Quality Measures

We are proposing to provide technical specifications, and in some cases, links to technical specifications hosted on external third party Web sites, for the ASC Quality Reporting Program measure in a Specifications Manual, to be posted after publication of the CY 2012 OPPS/ASC final rule with comment period, on the CMS QualityNet Web site at *http://www.QualityNet.org*. Currently, the specifications for the proposed ASC measures for the CY 2014, CY 2015 and CY 2016 payment determinations, with the exception of the two structural measures, can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf; http://www.cms.gov/apps/ama/license.asp?file=/pqrs/downloads/2011_PhysQualRptg_MeasureSpecificationsManual_033111.pdf; http://www.cdc.gov/nhsn/psc.html;* and *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf*. The specifications for the two structural measures are included in the discussion above and in the table of measures proposed for the CY 2015 payment determination.

We are proposing to maintain the technical specifications for the measures adopted for the ASC quality reporting program by updating this Specifications Manual and including detailed instructions and calculation algorithms as appropriate. In some cases where the specifications are available elsewhere, we may include links to Web sites hosting technical specifications. We currently use this same process for Hospital OQR Program measures, as discussed above in section XIV.A.3.a. of this proposed rule. We are proposing to follow the same technical specification maintenance process for the ASC Quality Reporting Program measures and we invite public comments on this proposal.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for updates to the technical specifications that we use to calculate Hospital OQR Program measures. This process is used when changes to the measure specifications are necessary due to changes in scientific evidence or other substantive changes, thereby giving CMS the option to seek re-endorsement of that measure. We note that NQF endorsement of an OQR measure is not required under sections 1833(i)(2)(D)(iv), (i)(7) or (t)(17) of the Act. The legal standard for adopting Hospital OQR measures is consensus among affected parties, and to the extent feasible and practicable, measures that are set forth by a consensus building entity. The legal standard for adopting ASC measures is this same standard, except as the Secretary may otherwise provide. Changes of this nature to measures adopted for the ASC Quality Reporting Program may not coincide with the timing of our regulatory actions, but nevertheless require inclusion in the measure specifications so that measures are calculated based on the most up-to-date scientific standards and, in some instances, consensus standards.

For the Hospital OQR Program, we indicated that notification of changes to the measure specifications is available on the QualityNet Web site, *http://www.QualityNet.org,* and in the Hospital OQR Program Specifications Manual and would occur no less than 3 months before any changes become effective for purposes of reporting under the Hospital OQR Program. The Hospital OQR Program Specifications Manual is released every 6 months and addenda are released as necessary providing at least 3 months of advance notice for substantial changes such as changes to ICD–9, CPT, NUBC, and HCPCS codes, and at least 6 months notice for substantive changes to data elements that would require significant systems changes. We are proposing to follow the same subregulatory process for the ASC Quality Reporting Program for updates to the technical specifications. We invite public comments on this proposal.

b. Publication of ASC Quality Reporting Program Data

Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under the Hospital OQR Program available to the public. It also states that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. These requirements under section 1833(t)(17)(E) of the Act also apply to the ASC Quality Reporting Program except as the Secretary may otherwise provide. We are proposing to make data that an ASC has submitted for the ASC Quality Reporting Program available on a CMS Web site after providing ASCs an opportunity to preview the data to be made public. We are proposing that these data would be displayed at the CMS Certification Number (CCN) level. Publishing this information encourages beneficiaries to work with their doctors and ASCs to discuss the quality of care ASCs provide to patients, thereby providing an additional incentive to ASCs to improve the quality of care that they furnish. We intend to propose more detail on the publication of data in a later rulemaking. We solicit public comment on these proposed processes of making ASC quality data available to the public.

8. Proposed Requirements for Reporting of ASC Quality Data for the CY 2014 Payment Determination

To participate in the ASC Quality Reporting Program for the CY 2014 payment determination, we are proposing that ASCs must meet data collection and data submission requirements. We intend to propose administrative requirements, data validation and data completeness requirements, reconsideration and appeals processes, and CY 2015 payment determination reporting requirements in the CY 2013 OPPS/ASC proposed rule with comment period.

a. Proposed Data Collection and Submission Requirements for the Proposed Claims-Based Measures

We are proposing that, to be eligible for the full CY 2014 ASC annual payment update, ASCs would be required to submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. For the CY 2014 payment determination, we are proposing to utilize Medicare fee-for-service ASC claims for services furnished between January 1, 2012 and December 31, 2012.

We are proposing to consider an ASC as participating in the ASC Quality Reporting Program for CY 2014 payment determination if the ASC includes QDCs specified for the program on their CY 2012 claims relating to the proposed measures if finalized. As no determinations will be made affecting payment until the CY 2014 annual payment update, we are proposing this approach as to reduce ASC burden. We intend to provide additional details regarding participation notification and

other administrative requirements in CY 2013 rulemaking.

We are proposing that data completeness for claims-based measures would be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claim. We intend to propose how we will assess data completeness for claims-based measures in the CY 2013 OPPS/ASC proposed rule. We request public comment on these proposals and are specifically interested in receiving public comment on what constitutes complete data in regard to our proposed ASC claims-based measures utilizing QDCs and methods to assess completeness.

b. Proposed Data Submission Deadlines for the Proposed Surgical Site Infection Rate Measure

As discussed above, we are proposing to adopt a HAI measure, Surgical Site Infection Rate, for the CY 2014 payment determination. We are proposing to use the data submission and reporting standard procedures that have been set forth by the CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site (*http://www.cdc.gov/nhsn*) for detailed data submission and reporting procedures. Our proposal seeks to reduce ASC burden by aligning CMS data submission and reporting procedures with NHSN procedures currently utilized by healthcare providers and suppliers. The submission timeframes for the CY 2014 payment determination that we are proposing to use for the proposed Surgical Site Infection Rate measure are shown below. ASCs must submit their quarterly data to NHSN for ASC Quality Data Reporting purposes within the date intervals shown in the table below (any updates to this schedule will be posted on the QualityNet Web site).

PROPOSED SUBMISSION TIMEFRAME FOR THE PROPOSED SURGICAL SITE INFECTION RATE MEASURE FOR THE CY 2014 PAYMENT DETERMINATION

CY 2013 infection events	CDC–NHSN collection and quarterly report	Final submission deadline for ASC quality reporting CY 2014 payment determination
Q1 (Jan 1 to Mar 31, 2013)	January 31st to August 1st	August 1, 2013
Q2 (Apr 1 to Jun 30, 2013)	April 30th to November 1st	November 1, 2013

We request public comments on these proposals.

XV. Proposed Changes to Whole Hospital and Rural Provider Exceptions to the Physician Self-Referral Prohibition: Exception for Expansion of Facility Capacity; and Proposed Changes to Provider Agreement Regulations Relating to Patient Notification Requirements

A. Background

Section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain ''designated health services'' (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral. The Act establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions that pose no risk of program or patient abuse.

Section 1877(d) of the Act sets forth additional exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes DHS. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers. In order for an entity to qualify for the exception, the DHS must be furnished in a rural area (as defined in section 1886(d)(2) of the Act) and substantially all of the DHS furnished by the entity must be furnished to individuals residing in a rural area. Section 1877(d)(3) of the Act provides an exception, known as the ''whole hospital'' exception, for ownership or investment interests in a hospital located outside of Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

B. Changes Made by the Affordable Care Act

1. Provisions Relating to Exceptions to Ownership and Investment Prohibition (Section 6001(a) of the Affordable Care Act)

Section 6001(a) of the Affordable Care Act amended the whole hospital and rural provider exceptions to impose additional restrictions on physician ownership or investment in hospitals. The statute defines a ''physician owner or investor'' in a hospital as a physician or immediate family member of a physician who has a direct or indirect ownership or investment interest in a hospital. We will refer to hospitals with such ''physician owners or investors'' as ''physician-owned hospitals.''

We addressed section 6001(a) of the Affordable Care Act in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71800). In § 411.362, we implemented most of the requirements of section 6001(a) of the ACA, including patient safety requirements. In sections XV.B.2. and C. of this proposed rule, we address the process for a hospital to request an exception to the prohibition on expansion of facility capacity under section 6001(a)(3) of the Affordable Care Act. In section D. of this proposed rule, we address related patient notification requirements in the provider agreement regulations.

2. Provisions of Section 6001(a)(3) of the Affordable Care Act

The amended whole hospital and rural provider exceptions provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act to set forth that the Secretary shall establish and implement an exception process to the prohibition on expansion of facility capacity. Referrals are prohibited if made by physician owners or investors after facility expansion and prior to the Secretary granting an exception. Exceptions for expanding

facility capacity will protect only those referrals made after the exception is granted. In this proposed rule, we set forth proposed regulations for this process at § 411.362(c) and related definitions at § 411.362(a).

The proposed regulations at § 411.362(c) set forth the process for a hospital to request an exception. Proposed new § 411.362(c)(2) outlines the requirements for an applicable hospital request and § 411.362(c)(3) outlines the requirements for a high Medicaid facility request. These terms are defined at sections 1877(i)(3)(E) and 1877(i)(3)(F) of the Act. The statute is clear that an applicable hospital may apply for an exception up to once every 2 years. Using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we are proposing to interpret the statute to impose the same 2-year frequency limit to apply also to high Medicaid facilities as discussed in section XV.C.2. of this proposed rule.

We are proposing to set forth the elements required for a complete request for an exception under proposed new § 411.362(c)(4). The opportunity for community input (required by section 1877(i)(3)(A)(ii) of the Act) and timing of a complete request are described in proposed § 411.362(c)(5). Under proposed § 411.362(c)(5), we are proposing to provide an opportunity for individuals and entities in the community in which the hospital is located to provide input with respect to the hospital's request for an exception. For purposes of this proposed rule, when the statute refers to an ''application,'' we use the term ''request.''

Because section 1877(i)(3)(D) of the Act provides that any increase in the number of operating rooms, procedure rooms, and beds for which a hospital is licensed pursuant to being granted an exception may occur only in facilities on the hospital's main campus, we are proposing a definition of the ''main campus of the hospital'' at § 411.362(a), as discussed below. Additionally, we are proposing a definition of the ''baseline number of operating rooms, procedure rooms, and beds'' for purposes of section 1877(i)(3)(C)(ii) of the Act.

Section 1877(i)(3)(H) of the Act provides that the Secretary shall publish the final decision with respect to an application in the **Federal Register** no later than 60 days after receiving a complete application. Under section XV.C.4. of this proposed rule, below, we discuss our proposal for publishing decisions in the **Federal Register** as well as on the CMS Web site.

Under section 1877(i)(3)(A) of the Act, the Secretary must promulgate regulations concerning the process for a hospital to apply for an exception by January 1, 2012, and implement this process on February 1, 2012. We anticipate an effective date of January 1, 2012, for these proposed regulations. Below, we set out our proposals related to the exception process in greater detail.

C. Proposed Changes Relating to the Process for an Exception to the Prohibition on Expansion of Facility Capacity

In order to conform our regulations to the amendments made to the rural provider and whole hospital exceptions by section 6001(a)(3) of the Affordable Care Act, we are proposing to add two definitions in § 411.362(a) and a new § 411.362(c) to establish the process by which an applicable hospital or high Medicaid facility may request an exception to the prohibition on expansion of facility capacity. We are proposing to define the terms ''baseline number of operating rooms, procedure rooms, and beds'' and ''main campus of the hospital''. The process we are proposing sets forth the relevant data sources and the elements of a complete request for an exception.

1. Applicable Hospital

Below we separately discuss each of the statutory criteria that a hospital must satisfy to qualify as an ''applicable hospital''. We are proposing the processes by which a hospital can determine whether it satisfies each criterion. The proposed data requirements for each criterion are further discussed in each section below.

We are proposing that data from the CMS Healthcare Cost Report Information System (HCRIS) be used to determine whether a hospital satisfies the inpatient admission, bed capacity, and bed occupancy criteria. We currently consider HCRIS to contain a sufficient amount of data for a particular fiscal year if HCRIS contains data from at least 6,100 hospitals for that fiscal year. Therefore, we are proposing that HCRIS must contain data from at least 6,100 hospitals for a particular year in order for that year's data to be used under the exception process. If HCRIS does not contain sufficient data for that year, data from the most recent year(s) that satisfy the threshold should be used.

CMS will post the average percent of total inpatient Medicaid admissions per county, the average bed capacity per State, the national average bed capacity, and the average bed occupancy per State on the CMS Web site at: *http://www.cms.gov/physicianselfreferral/85_physician_owned_hospitals.asp.* Hospitals can access these data to assess whether they satisfy the respective criteria to qualify as an applicable hospital. CMS will make a reasonable effort to ensure that the data contained in HCRIS are correct and complete at the time of disclosure. We are soliciting public comment on proposing and justifying alternative data sources other than HCRIS that could result in more accurate determinations as to whether a hospital satisfies the relevant criteria.

a. Percentage Increase in Population

Section 1877(i)(3)(E)(i) of the Act provides that an applicable hospital means a hospital that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the application date) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by the Bureau of the Census.

To determine the percentage increase in population in the county and State in which the hospital is located, we are proposing at § 411.362(c)(2)(i) that the hospital use population estimates provided by the Bureau of the Census. If the hospital is located in an area referred to by the Bureau of the Census as a county equivalent area, such as an independent city, borough, or census area, the hospital should use the Bureau of the Census estimates for the county equivalent area in which it is located. For the remainder of this subsection, ''county'' refers to both a county and a county equivalent area.

We recognize that the Bureau of the Census may not provide county and State population size estimates that are current as of the date that a hospital submits its request for an exception. We are proposing that a hospital should use only the most recent estimates available to perform the necessary calculations. For example, if a hospital submits a request for an exception in 2012, but the most recent year for which the Bureau of the Census has estimates is 2010, the hospital should perform the necessary calculations using estimates for years 2010 and 5 years prior.

We are proposing also that the hospital use county and State population estimates for the same years. For example, if a hospital submits a request for an exception in 2012 and the most recent year for which the Bureau of the Census has State and county population estimates is 2011 and 2010, respectively, the hospital should perform the necessary calculations

using estimates for years 2010 and 5 years prior. We are proposing to review a request based on the population estimates available as of the date that a hospital submits its request even if the Bureau of the Census updates its estimates after the hospital submits its request and prior to our decision.

b. Inpatient Admissions

Section 1877(i)(3)(E)(ii) of the Act provides that an applicable hospital means a hospital that has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located. We are proposing at § 411.362(c)(2)(ii) to require hospitals to calculate inpatient admissions using filed hospital cost report discharge data. We are proposing that, in calculating the hospital's annual percent of total Medicaid inpatient admissions, the hospital should divide the number of discharges for the year that are paid for under Medicaid by the total number of discharges for the year paid for by any governmental or private payor. We are soliciting public comment on other data sources that could be used to provide an accurate estimate of the annual percent of total Medicaid inpatient admissions for the applicable hospital and for all hospitals in the same county.

The statute does not specify the number of years for which the hospital's annual percent of total inpatient admissions under Medicaid must be equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located. We are proposing at § 411.362(c)(2)(ii) that a hospital must satisfy this criterion for each of the 3 most recent fiscal years for which data are available as of the date the hospital submits a request. We invite public comment on whether 3 years of data are sufficient to indicate a legitimate need by the hospital to increase its number of operating rooms, procedure rooms, and beds and, if not, how many years of data we should consider in evaluating a request for an exception.

We are proposing at § 411.362(c)(2)(ii) that the hospital would estimate its annual percentage of total inpatient admissions under Medicaid. The hospital would reference its own filed cost reports for the 3 most recent fiscal years for which data are available. We are proposing that we would review a request based on the data available as of the date the hospital submits its request. We plan to issue guidance to further address the process for a hospital to estimate its annual percentage of total inpatient admissions under Medicaid. The guidance will also explain how CMS will determine and provide the average percentages of inpatient admissions under Medicaid for each county.

c. Nondiscrimination

Section 1877(i)(3)(E)(iii) of the Act provides that an applicable hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. We are proposing to incorporate this requirement at § 411.362(c)(2)(iii) of the regulations.

d. Bed Capacity

Section 1877(i)(3)(E)(iv) of the Act provides that an applicable hospital means a hospital that is located in a State in which the average bed capacity in the State is less than the national average bed capacity. The statute does not specify a time period over which a State's average bed capacity must be less than the national average bed capacity. We are proposing at § 411.362(c)(2)(iv) that the State average bed capacity must be less than the national average bed capacity for each of the 3 most recent fiscal years for which data are available as of the date that a hospital submits its request. We invite public comment on whether 3 years of data are sufficient to indicate a legitimate need by the hospital to increase its number of operating rooms, procedure rooms, and beds and, if not, how many years of data we should consider in evaluating any request for an exception.

Under our proposed process, CMS would use filed hospital cost reporting data to determine State and national average bed capacities. We plan to issue guidance explaining how CMS will determine and provide the average bed capacities. We are proposing that we would review a request based on the data available as of the date a hospital submits its request.

e. Bed Occupancy

Section 1877(i)(3)(E)(v) of the Act provides that an applicable hospital means a hospital that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located. The statute does not specify the time period over which the hospital's average bed occupancy rate must be greater than the State average bed occupancy rate. We are proposing at § 411.362(c)(2)(v) that the hospital's bed occupancy rate must be greater than the State average bed occupancy rate for each of the 3 most recent fiscal years for which data are available as of the date that a hospital submits its request. We invite public comment on whether 3 years of data are sufficient to indicate a legitimate need by the hospital to increase the number of its operating rooms, procedure rooms, and beds and, if not, how many years of data we should consider in evaluating any request for an exception.

We are proposing at § 411.362(c)(2)(v) that the hospital use filed hospital cost reporting data to calculate its own average bed occupancy rate. We plan to issue guidance explaining how the hospital can calculate its bed occupancy rate. The guidance would also explain how CMS will determine and provide the State bed occupancy rates. We are proposing that we would review a request based on the data available as of the date that the hospital submits its request.

2. High Medicaid Facility

Below we separately discuss each of the statutory criteria that a hospital must satisfy to qualify as a ''high Medicaid facility.'' We are proposing the processes by which a hospital can determine whether it satisfies each criterion. The proposed data requirements for each criterion are further discussed in the sections below.

As discussed in section XV.C.1. of this proposed rule, we currently consider HCRIS to contain a sufficient amount of data for a particular fiscal year once HCRIS contains data from at least 6,100 hospitals for that year. Therefore, we are proposing that HCRIS must contain data from at least 6,100 hospitals for a particular year in order for that year's data to be used under the exception process. If HCRIS does not contain sufficient data for that year, data from the most recent year(s) that satisfies the threshold should be used.

a. Number of Hospitals in County

Section 1877(i)(3)(F)(i) of the Act provides that a high Medicaid facility means a hospital that is not the sole hospital in a county. We are proposing to incorporate this requirement into the regulations at § 411.362(c)(3)(i).

b. Inpatient Admissions

Section 1877(i)(3)(F)(ii) of the Act provides that a high Medicaid facility means a hospital that, with respect to each of the 3 most recent years for which data are available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other

hospital located in the county in which the hospital is located. We are proposing to incorporate this requirement at § 411.362(c)(3)(ii) of the regulations.

We are proposing at § 411.362(c)(3)(ii) that the hospital estimate its annual percentages of total inpatient admissions under Medicaid for each of the 3 most recent fiscal years for which data are available. We also are proposing that the hospital estimate the annual percentage of such admissions for all other hospitals located in the county in which the hospital is located for each of the 3 most recent fiscal years for which data are available. We are proposing that we would review a request based on the data available as of the date that the hospital submits its request.

We are proposing to require the applicant hospital to use filed hospital cost reporting discharge data as a proxy for inpatient admissions under Medicaid. CMS will post the data necessary for a hospital to calculate the annual percentage of total inpatient admissions under Medicaid for all other hospitals located in the county in which the hospital is located on the CMS Web site at: *http://www.cms.gov/physicianselfreferral/85_physician_owned_hospitals.asp*. We plan to issue guidance that further describes the process for hospitals to estimate inpatient admissions under Medicaid.

c. Nondiscrimination

Section 1877(i)(3)(F)(iii) of the Act provides that a high Medicaid facility does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. We are proposing to incorporate this requirement at § 411.362(c)(3)(iii) of the regulations.

3. Procedure for Submitting a Request

We are not creating an application form that a hospital must complete to apply for an exception to the prohibition on expansion of facility capacity. Rather, we are proposing that a hospital submit to CMS a request that includes the information and documentation set forth in proposed § 411.362(c)(4)(ii).

We are proposing that each request must include: (i) the name and address, National Provider Identification number(s) (NPI), Tax Identification Number(s) (TIN), and CMS Certification Number(s) (CCN) of the hospital; (ii) the county in which the hospital is located; and (iii) the name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the hospital. Each request must include a clear statement as to whether the hospital is requesting an exception as an applicable hospital or a high Medicaid facility. We are proposing that each request submitted by a hospital must include a clear explanation of how it satisfies the criteria using the information discussed in sections XV.C.1. or 2. of this proposed rule. This includes performing, recording, and submitting all calculations necessary to submit a complete request. The hospital's request must state that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. Finally, we encourage hospitals to clearly label all documentation submitted with a request and indicate the criteria for which the documentation provides supporting information.

We are proposing at § 411.362(c)(4)(ii)(E) that each request must include documentation supporting the hospital's calculation of the hospital's baseline number of operating rooms, procedure rooms, and beds as defined at section 1877(i)(3)(C)(iii) of the Act; the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits its request; and the additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

Finally, we are proposing at § 411.362(c)(4)(iii) that each request must include a certification signed by an authorized representative of the hospital attesting that all of the information provided is true and correct to the best of his or her knowledge and belief.

We are proposing at § 411.362(c)(4)(i) that a hospital must either mail an original and one copy of its request to CMS or submit its request electronically. If a hospital submits its request electronically, the hospital must also submit an original, hard copy of the required certification.

4. Community Input

Section 1877(i)(3)(A)(ii) of the Act provides that individuals and entities in the community in which the applicable hospital is located shall have an opportunity to provide input on the applicable hospital's request for an exception to the prohibition against facility expansion. We are proposing to incorporate this provision in proposed § 411.362(c)(5) of the regulations. We are proposing that the community input must take the form of written comments. In addition, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we are proposing that individuals and entities in the community in which a high Medicaid facility is located may have the same opportunity to submit written comments.

We are proposing at § 411.362(c)(5) that a hospital must disclose on any public Web site for the hospital that it is requesting an exception. The notice should be accessible to the public and should remain posted from the time a request is submitted to CMS until a decision is finalized by CMS. Once CMS has received the statements, certifications, and documentation required for a hospital's request, CMS will report that the hospital is requesting an exception on the CMS *Hospital Listserv* and will post the hospital's request for an exception on the CMS Web site. For specific information on how to subscribe to the CMS *Hospital Listserv*, please access the CMS Web site at *http://www.cms.gov/MLNProducts/downloads/MailingLists_FactSheet.pdf*. In addition, we are proposing that a notice of the hospital's request will be published in the **Federal Register**. We are proposing at § 411.362(c)(5) to allow individuals and entities in the community 30 days from the date of the notice's publication in the **Federal Register** to submit written comments.

Examples of community input include documentation demonstrating that the hospital does not satisfy one or more of the data criteria or that the hospital discriminates against beneficiaries. These are examples only; we are not restricting the types of community input that may be submitted. We are proposing at § 411.362(c)(5) that written comments must be submitted by mail or electronically to CMS.

We are proposing at § 411.362(c)(5)(i) that we will consider a request complete if CMS does not receive any written comments during the 30-day period after notice of the hospital's request is published in the **Federal Register**.

If CMS receives written comments, CMS will notify the hospital in writing. We are proposing at § 411.362(c)(5)(ii) to allow the hospital 30 days after CMS notifies the hospital of the written comments to submit information and documentation that rebut the written comments. We will consider the request complete at the end of the 30-day period provided for the hospital's rebuttal, regardless of whether the hospital

submits additional information or documentation. We reserve the right to perform our own calculations based on a review of the material submitted and of information generally available to CMS.

5. Permitted Increase

Section 1877(i)(3)(C)(i) of the Act provides that a hospital granted an exception from the Secretary may increase the number of operating rooms, procedure rooms, and beds for which the hospital is licensed above its baseline number of operating rooms, procedure rooms, and beds. If the hospital has been granted a previous exception from the Secretary, the hospital may increase above the number of operating rooms, procedure rooms, and beds for which the hospital is licensed after application of the most recent increase under such an exception.

a. Amount of Permitted Increase

Section 1877(i)(3)(C)(ii) of the Act provides that the Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital. We are proposing to incorporate this provision at § 411.362(c)(6)(i) of the regulations.

Using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we are proposing to similarly limit the increase in the number of operating rooms, procedure rooms, and beds for which a high Medicaid facility may request an exception. We are soliciting public comment on whether the proposed limit would be sufficient to balance the intent of the general prohibition on expansion with the purpose of the exception process to provide the opportunity to expand in areas where a sufficient need for access to high Medicaid facilities is demonstrated.

A hospital must determine its baseline facility capacity to ensure that an expansion is within the limits set forth at section 1877(i)(3)(C)(ii) of the Act and to submit a complete request. Section 1877(i)(3)(C)(iii) of the Act defines the ''baseline number of operating rooms, procedure rooms, and beds'' as the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed as of [March 23, 2010] (or, in the case of a hospital that did not have a provider agreement in effect as of such date but does have such an agreement in effect on December 31, 2010, the effective date of such provider agreement). We are proposing to incorporate this definition, with the clarification that it also applies to high Medicaid facilities, at § 411.362(a) of the regulations.

b. Location of Permitted Increase

Section 1877(i)(3)(D) of the Act provides that any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed may occur only in facilities on the main campus of the applicable hospital. We are proposing to incorporate this provision at proposed § 411.362(c)(6)(ii) of the regulations. We are proposing to define the term ''main campus'' as the term ''campus'' is defined at § 413.65(a)(2). Using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we are proposing that, with respect to high Medicaid facilities, the limitation on expansion of hospital capacity, as set forth at section 1877(i)(1)(B) of the Act, similarly applies to the number of operating rooms, procedure rooms, and licensed beds on the ''campus'' of the high Medicaid facility.

6. Decisions

Section 1877(i)(3)(H) of the Act states that the Secretary shall publish in the **Federal Register** the final decision with respect to an application for an exception to the prohibition against facility expansion not later than 60 days after receiving a complete application. We are proposing to codify this provision at § 411.362(c)(7). To facilitate access to decisions, we are proposing to post our decisions on the CMS Web site as well. The posted information will include the hospital's name, address, county, and our final decision. If an exception is granted under this section, we will also post the number of operating rooms, procedure rooms, and beds by which the hospital may expand under the granted exception. We believe that posting decisions on the CMS Web site will enable us to inform the public and the affected community of our decisions in a timely manner and in a centralized location.

7. Limitation on Review

Section 1877(i)(3)(I) of the Act provides that there shall be no administrative or judicial review of the process, either under section *1869*, section *1878*, or otherwise. We incorporated this limitation on review at proposed § 411.362(c)(8) of the regulations. We interpret this limitation on review to mean that CMS' decision with respect to whether a hospital qualifies for an exception is not reviewable.

8. Frequency of Request

Section 1877(i)(3)(B) of the Act provides that the exception process shall permit an applicable hospital to apply for an exception up to once every 2 years. We are incorporating this provision at § 411.362(c)(1). Using our authority under sections 1871 and 1877 of the Act, we similarly are proposing to permit a high Medicaid facility to submit a request for an exception up to once every 2 years from the date of a CMS decision on the hospital's most recent request. We are proposing to consider the date of a CMS decision to be the date of the letter sent to the requesting party.

D. Proposed Changes Related to Provider Agreement Regulations on Patient Notification Requirements

Section 1866 of the Act states that a provider of services shall be qualified to participate in the Medicare program and shall be eligible for Medicare payments if it files a Medicare provider agreement and abides by the requirements applicable to Medicare provider agreements. These requirements are incorporated in our existing regulations at 42 CFR Part 489, Subparts A and B (Provider Agreements and Supplier Approval). Section 5006 of the Deficit Reduction Act of 2005 mandated the Secretary to develop a strategic and implementing plan to address certain issues with respect to physician ownership of specialty hospitals. As part of that plan, we used our authority under sections 1866, 1820(e)(3), and 1861(e)(9) of the Act (as well as our general rulemaking authority under sections 1102 and 1871 of the Act) to impose certain additional requirements on physician-owned hospitals as part of their provider agreements. These new requirements were established in the FY 2008 IPPS final rule with comment period (72 FR 47385 through 47391) and the FY 2009 IPPS final rule (73 FR 48686 through 48688).

Specifically, we added a new provision to require that all hospitals and CAHs: (1) furnish all patients written notice at the beginning of their inpatient hospital stay or outpatient service if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week; and (2) describe how the hospital or CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present in the

hospital or CAH. These requirements are codified at § 489.20(w). The requirements of §§ 489.20(u) and (w) were made applicable to both inpatient hospital stays and outpatient services because, as we stated in the FY 2008 IPPS final rule with comment period, these provisions are in the interest of the health and safety of all individuals who receive services in these institutions. The notice requirements are intended to permit individuals to make more informed decisions regarding their treatment.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72251), we stated that we saw no reason to treat the safety of hospital inpatients differently than hospital outpatients, and, thus, applied these patient safety requirements to hospital inpatients and outpatients. We continue to believe that both hospital inpatients and outpatients should receive these disclosures prior to admission. However, after hospitals in general informed us that it would be unduly burdensome to provide disclosures to *all* outpatients, and hospitals with emergency departments reported the individual notice requirement makes the registration process more cumbersome and time-consuming than is desirable in the emergency department setting, we revisited this issue. We have reconsidered the patient safety requirements related to patient notification of physician presence, and in this proposed rule, we are proposing that hospital outpatients would need to receive such disclosures only where the risk of an emergency or the length of the outpatient visit make their situations more like that of hospital inpatients. Under this proposal, disclosures would be required only for those outpatients receiving observation services, surgery, or any other procedure requiring anesthesia. Signage would be required for hospital outpatients in the emergency department, as we recognize the merit of finding a less cumbersome manner to provide the required notice in this setting. Other hospital outpatient encounters are relatively short and, in many cases, scheduled in advance. The risk of emergency is relatively low in most of these scheduled encounters. As a result, we believe the safety of these particular hospital outpatients would not be compromised in any way if hospitals were not required to provide disclosures in these circumstances.

In this proposed rule, we are proposing to revise paragraph (w)(1) of § 489.20 to reduce the categories of outpatients who must be notified if a hospital does not have a physician on site 24 hours per day/7 days per week. We are proposing that only those outpatients who receive observation services, surgery, or services involving anesthesia, must receive such written notice. We believe this change would reduce burden, but ensure that notice goes to those categories of patients who are more likely to find themselves in a situation where a physician is not present when an emergency develops. (We note that we are not making any changes to similar patient safety requirements for physician-owned hospitals at § 411.362(b)(5)(i).) We are proposing to add a provision that notice would be required at the beginning of a planned or unplanned inpatient stay or outpatient visit, and we provide explanation of when a planned or unplanned stay or visit begins. We are proposing to add a provision to state that an unplanned stay or visit begins at the earliest point at which the patient presents to the hospital. The current regulation describes when a stay or visit begins by referring to the time when a package of information is provided regarding scheduled preadmission testing and registration for a planned hospital admission or outpatient service. However, many admissions to the hospital are unplanned admissions of patients who present on an unscheduled visit to the emergency department. Therefore, it was necessary to clarify when we considered such unplanned stays or visits begin.

We are proposing to add a new paragraph (w)(2) to § 489.20 (existing paragraph (w)(2) would be redesignated as discussed below) that would require a hospital that is a main provider that has one or more remote locations of a hospital or satellites to make the determination of whether notice is required separately at each location providing inpatient services. We are proposing to use the terms ''main provider,'' ''remote location of a hospital,'' and ''satellite'' as these terms are defined at § 413.65(a)(2), § 412.22(h), or § 412.25(e), as applicable. We are proposing that notice would be required for all applicable patients, that is, all inpatients and applicable outpatients, at each location at which inpatient services are furnished and at which a doctor of medicine or doctor of osteopathy is not present 24 hours per day/7 days per week. We are proposing to move language that is currently in paragraph (w)(1) to a new paragraph (w)(3), governing the content of the written notice. We are proposing to redesignate existing paragraph (w)(2), which requires the hospital to receive a signed acknowledgment from the patient who has received a notice that the patient understands that a physician may not be present during all hours in which services are furnished to the patient, as paragraph (w)(4) and to revise the redesignated paragraph. We are proposing to add a provision to state that, before providing an outpatient service to an outpatient for whom a notice is required, the hospital must receive the signed acknowledgment. This revision would make this requirement consistent with our proposed revisions to paragraph (w)(1) limiting the notice requirement to certain categories of outpatients.

We are proposing to add a new paragraph (w)(5) which would require every hospital that has a dedicated emergency department in which a doctor of medicine or doctor of osteopathy is not present 24 hours per day/7 days per week to post a notice conspicuously in a place or places likely to be noticed by all individuals entering the dedicated emergency department. ''Dedicated emergency department'' would have the meaning found in existing § 489.24(b) of the regulations. We would require the notice to state that the hospital does not have a doctor of medicine or doctor of osteopathy present in the hospital 24 hours per day/7 days per week, and to indicate how the hospital will meet the needs of any patient with an emergency medical condition, as that term is defined in § 489.24(b), at a time when no doctor of medicine or doctor of osteopathy is present within the hospital. In the event that there is a decision to admit a patient from the emergency department as an inpatient, the individualized written disclosure and acknowledgment would have to be made at the time the patient is admitted.

XVI. Additional Proposals for the Hospital Value-Based Purchasing (Hospital VBP) Program

A. Hospital VBP Program

1. Legislative Background

Section 3001(a) of the Affordable Care Act added section 1886(o) to the Act. This section requires the Secretary to establish a hospital inpatient value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital Inpatient Value-Based

Purchasing Program (Hospital VBP Program) to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction of 1.0 percent to the FY 2013 base operating DRG payment amount for each discharge, as required by section 1886(o)(7)(B)(i) of the Act.

Section 1886(o)(1)(C) of the Act provides that the Hospital VBP Program applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term ''hospital,'' with respect to a fiscal year: (1) a hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program) for such fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary cited deficiencies that pose ''immediate jeopardy'' to the health or safety of patients; and (3) a hospital for which there are not a minimum number (as determined by the Secretary) of measures for the performance period for the fiscal year involved, or for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

2. Overview of the Hospital Inpatient VBP Program Final Rule

We recently issued the Hospital Inpatient VBP Program Final Rule, which implemented the Hospital VBP Program gram under section 1886(o) of the Act (76 FR 26490 through 26547). The Hospital Inpatient VBP Program Final Rule was developed based on extensive research we conducted on hospital value-based purchasing, including research that formed the basis of a 2007 report we submitted to Congress, entitled ''Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program.'' This report is available on our Web site (*https://www.cms.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf*) and takes into account input from stakeholders and other interested parties.

As described more fully in the Hospital Inpatient VBP Program Final Rule, we adopted for the FY 2013 Hospital VBP Program 13 measures that we have already adopted for the Hospital IQR Program, categorized into two domains (76 FR 26495 through 26511). We grouped 12 clinical process of care measures into a clinical process of care domain, and placed the HCAHPS survey measure into a patient experience of care domain. We adopted a 3-quarter performance period from July 1, 2011 through March 31, 2012 for these measures (76 FR 26494 through 26495). To determine whether a hospital meets the proposed performance standards for these measures, we will compare each hospital's performance during this performance period to its performance during a 3-quarter baseline period from July 1, 2009 through March 31, 2010 (76 FR 26493 through 26495).

We also finalized a methodology for assessing the total performance of each hospital based on performance standards under which we will score each hospital based on achievement and improvement ranges for each applicable measure. We will calculate a Total Performance Score for each hospital by combining the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, weighting each domain score (for the FY 2013 Hospital VBP Program, the weights will be clinical process of care = 70 percent, patient experience of care = 30 percent), and adding together the weighted domain scores. We will convert each hospital's Total Performance Score into a value-based incentive payment using a linear exchange function. We refer readers to the Hospital Inpatient VBP Program Final Rule for further explanation of the details of the FY 2013 Hospital VBP Program (76 FR 26490 through 26547).

For FY 2014, we adopted 13 outcome measures comprised of 3 mortality measures, 2 AHRQ composite measures, and 8 hospital-acquired condition (HAC) measures (76 FR 26511). These measures are discussed fully in the Hospital Inpatient VBP Program Final Rule (76 FR 26510 through 26511). These finalized outcome measures for FY 2014 are set forth below.

FINALIZED OUTCOME MEASURES FOR THE FY 2014 HOSPITAL VBP PROGRAM

Mortality Measures (Medicare Patients):
- Acute Myocardial Infarction (AMI) 30-day mortality rate.
- Heart Failure (HF) 30-day mortality rate.
- Pneumonia (PN) 30-day mortality rate.

AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) Composite Measures:
- Complication/patient safety for selected indicators (composite).
- Mortality for selected medical conditions (composite).

Hospital Acquired Condition Measures:
- Foreign Object Retained After Surgery.
- Air Embolism.
- Blood Incompatibility.
- Pressure Ulcer Stages III & IV.
- Falls and Trauma: (Includes: Fracture, Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock).
- Vascular Catheter-Associated Infection.
- Catheter-Associated Urinary Tract Infection (UTI).
- Manifestations of Poor Glycemic Control.

3. Proposed Additional FY 2014 Hospital VBP Program Measures

For the FY 2014 Hospital VBP Program, we are proposing to retain all 13 of the clinical process of care and patient experience of care measures that we adopted for the FY 2013 Hospital VBP Program. We also are proposing to add one measure to the clinical process of care domain: SCIP–Inf–9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2. This measure was specified for the Hospital IQR Program beginning with FY 2011 and subsequent payment determination years (74 FR 43869 through 43870), and information about the measure first appeared on *Hospital Compare* in December 2010. Thus, we believe that this measure meets the requirement in section 1886(o)(2)(C)(i) of the Act to be included in the Hospital VBP Program because it has been specified for the Hospital IQR Program and will have been displayed on *Hospital Compare* for at least one year before the applicable performance period begins. In addition, SCIP–Inf–9 is NQF-endorsed (#453).

The measure is relevant for the Hospital VBP Program because it assesses a practice that reduces Catheter Associated Urinary Tract Infection (CAUTI), and improves patient safety, which is highlighted as one of the Institute of Medicine's six quality aims

along with effectiveness, patient-centeredness, timeliness, efficiency, and equity. SCIP–Inf–9 is one of the NQF-endorsed SCIP infection prevention measures; these measures are referenced as a whole among the metrics listed in the HHS Action Plan to Prevent HAIs. This Action Plan can be found at the following Web site: *http://www.hhs.gov/ash/initiatives/hai/actionplan/*. Furthermore, this measure meets other criteria considered for measure selection for the Hospital VBP Program, such as not being ''topped-out'' and displaying meaningful variability among hospitals. Therefore, we believe it would be a meaningful measure to include in the Hospital VBP Program.

The table below lists the clinical process of care and patient experience of care measures we are proposing to adopt for the FY 2014 Hospital VBP Program. We note that these measures are currently NQF-endorsed and we will continue to monitor these measures to ensure that they reliably measure hospital quality, for example, ensuring that, among other things, these measures are not ''topped-out,'' and their measurement criteria remain endorsed by NQF and/or are otherwise appropriate. To the extent we determine that these measures are topped-out, we may choose not to finalize them.

PROPOSED CLINICAL PROCESS OF CARE AND PATIENT EXPERIENCE OF CARE MEASURES FOR THE FY 2014 HOSPITAL VBP PROGRAM

Measure ID	Measure description
Clinical Process of Care Measures	
Acute myocardial infarction:	
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival.
Heart Failure:	
HF–1	Discharge Instructions.
Pneumonia:	
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.
Healthcare-associated infections:	
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients.
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.
SCIP–Inf–9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2.
Surgeries:	
SCIP–Card–2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.
SCIP–VTE–1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered.
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.
Patient Experience of Care Measures	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.*

* Proposed dimensions of the HCAHPS survey for use in the FY 2014 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital.

We invite public comment on these proposals.

4. Proposed Minimum Numbers of Cases and Measures for the Outcome Domain for the FY 2014 Hospital VBP Program

a. Background

Section 1886(o)(1)(C)(ii)(III) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year. Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. In the Hospital Inpatient VBP Program Final Rule, we adopted 13 outcome measures for the FY 2014 Hospital VBP Program (76 FR 26511), but we did not adopt a minimum number of cases for such measures to apply to hospitals, nor did we adopt a minimum number of measures necessary for the outcome domain to be included in the Total Performance Score.

Under section 1886(o)(1)(C)(iii) of the Act, in determining the minimum number of reported measures and cases under sections 1886(o)(1)(C)(ii)(III) and (IV), the Secretary must conduct an independent analysis of what minimum numbers would be appropriate. As described in the Hospital Inpatient VBP Final Rule (76 FR 26528 through 26529), to fulfill this requirement, we commissioned Brandeis University to perform an independent analysis that examined technical issues concerning the minimum number of cases per measure and the minimum number of measures per hospital for clinical process of care measures needed to derive reliable domain scores. Based on that analysis, we finalized our policy to exclude any clinical process of care measures for which a hospital reported fewer than 10 cases, and to exclude from the Hospital VBP Program any hospital to which fewer than 4 of the clinical process of care measures applied. We also finalized our proposal to exclude any hospital reporting fewer than 100 HCAHPS surveys during the performance period (76 FR 26529 through 26531).

To determine the minimum numbers of measures and cases that should be required for the outcome domain, we again commissioned Brandeis University to perform an independent analysis. This analysis examined hospital performance on the 13 finalized outcome measures using data from the proposed baseline periods (discussed below) for the FY 2014 Hospital VBP Program. As we did to analyze the reliability of scores in the clinical process of care domain, different minimum numbers of cases and measures were tested to determine the combination of minimum numbers of

cases and measures that would lead to reliable scores in the outcome domain while allowing the maximum number of hospitals to be scored for the Hospital VBP Program. Concurrent with the Brandeis analysis, we contracted with researchers at Mathematica Policy Research (Mathematica) to explore the minimum number of cases a hospital would need to report for each individual outcome measure.

b. Proposed Minimum Number of Cases for Mortality Measures, AHRQ Composite Measures, and HAC Measures

The analyses by Brandeis and Mathematica determined that in order to receive a score on a mortality measure, the hospital would need to report a minimum of 10 cases, and in order to receive a score on an AHRQ composite measure, a hospital would need to report a minimum of 3 cases. Consistent with these analyses, we are proposing that these case minimums would apply for the FY 2014 Hospital VBP Program.

Mathematica also examined the minimum number of cases a hospital would need to report in order to receive a reliable score on each HAC measure. Along with reliability concerns, when conducting this analysis, Mathematica also took into consideration our view, more fully explained in section XVI.A.6.d. of this proposed rule, that the incidence of HACs raises significant safety and quality concerns for patients and for the Medicare program. Therefore, we believe that a hospital should be held accountable when HACs occur in all instances in order to protect and promote patient safety. Mathematica concluded that a minimum of one Medicare claim would be sufficient to compute an accurate score on each HAC measure, and in accordance with this conclusion, we are proposing that hospitals be evaluated based on the presence or absence of HAC occurrences, regardless of the number of Medicare cases a hospital treats, as long as the hospital submits at least one Medicare claim during the performance period. As we discuss further below, we anticipate that all participating hospitals will submit at least one Medicare claim during the performance period, which would be sufficient for the hospitals to receive a score on seven of the eight HAC measures.

c. Proposed Minimum Numbers of Measures for Outcome Domain

Brandeis researchers also analyzed the reliability of the outcome domain scores for hospitals depending upon the total number of outcome measures on which they reported. The analysis showed that the data provide a meaningful and sufficiently reliable indication of outcomes for hospitals in the outcome domain as long as the hospitals submit the minimum number of cases (discussed above) on each of 11 outcome measures for FY 2014. Specifically, the analysis found that using at least 11 outcome measures per hospital provided sufficiently comparable reliability of hospitals' scores in the outcome domain (particularly in terms of rank ordering relative to other hospitals) as compared with what hospitals' scores would have been if they had reported on more outcome measures. Brandeis concluded that this 11 measure minimum could be comprised of the 8 HAC measures, together with 3 measures comprised of any combination of the 3 mortality measures and the 2 AHRQ composite measures.

We note that, in conducting its analysis, Brandeis evaluated how the outcome domain score would be affected if a hospital reported all eight finalized HAC measures. However, one of these HAC measures, Foreign Object Retained After Surgery, will not apply to a very small subset of hospitals that do not perform surgeries. Taking this into account, as well as our own further analysis which shows that the reliability of the outcome domain score would not be significantly different as a statistical matter, we are proposing that the minimum number of measures a hospital would need to report in order to receive a score on the outcome domain is 10, comprised of 7 of the 8 HAC measures (all but the Foreign Object Retained After Surgery measure), along with 3 other measures comprised of any 3 of the other outcome measures (for example, 2 AHRQ composite measures and 1 mortality measure, or 3 mortality measures). We believe that this proposal is consistent with the conclusions reached by Brandeis. In addition, from an inclusiveness standpoint, we believe that a 10 measure minimum will maximize hospital participation in the FY 2014 Hospital VBP Program.

Furthermore, because we believe that every domain is an important component of an accurate Total Performance Score, we are proposing that, in order for a hospital to receive a Total Performance Score and be included in the FY 2014 Hospital VBP Program, the hospital must have enough cases and measures to report on all finalized domains. This proposed requirement should not impose any new barrier to hospitals or greatly reduce the number of hospitals in the FY 2014 Hospital VBP Program as compared to the FY 2013 Hospital VBP Program, when hospitals will only be scored on clinical process of care and patient experience of care measures. This is because, as stated above, an analysis of the existing data shows that virtually all hospitals participating in the FY 2014 Hospital VBP Program will report on a sufficient number of cases and measures to receive outcome domain scores in addition to the clinical process and patient experience domain scores for FY 2014.

We invite public comment on the proposed minimum numbers of cases and measures required for the FY 2014 Hospital VBP Program. We also invite public comment on the proposed requirement that hospitals must report on all four domains (if finalized) to receive a Total Performance Score for the FY 2014 Hospital VBP Program.

5. Proposed Performance Periods and Baseline Periods for FY 2014 Measures

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program for a fiscal year that begins and ends prior to the beginning of such fiscal year.

a. Proposed Clinical Process of Care Domain and Patient Experience of Care Domain Performance Period and Baseline Period

For the FY 2014 Hospital VBP Program, we are proposing a 9-month (3-quarter) performance period from April 1, 2012 to December 31, 2012 for the clinical process of care and patient experience of care domain measures. As described in the Hospital Inpatient VBP Final Rule (76 FR 26494 through 26495), due to various statutory deadlines and other challenges we faced in implementing the FY 2013 Hospital VBP Program in a timely fashion, we adopted a 3-quarter performance period for the clinical process of care and patient experience of care domains for the FY 2013 payment determination. We have stated our intent to move to a 12-month performance period when feasible. While a 12-month performance period is not yet feasible for FY 2014, we believe that this proposed 3-quarter performance period will allow us to notify hospitals of the amount of their value-based incentive payment at least 60 days before the start of FY 2014. It would also allow us to consider selecting CY 2013, a 12-month performance period, as the performance period for the FY 2015 Hospital VBP Program. In addition, this proposed performance period for FY 2014 would begin immediately after the end of the FY 2013 performance period, provide

reliable performance information, and ensure that incentive payments can be made beginning with October 1, 2013 discharges.

As we explained in the Hospital Inpatient VBP Program Final Rule (76 FR 26485), we believe that baseline data should be used from a comparable 9-month (3-quarter) period. Therefore, we are proposing April 1, 2010 to December 31, 2010 as the baseline period for these proposed measures for FY 2014. We invite public comment on these proposals.

b. Proposed Outcome Domain Performance Periods and Baseline Periods

In the Hospital Inpatient VBP Program proposed rule, we proposed an 18-month performance period of July 1, 2011 to December 31, 2012 and an 18-month baseline period of July 1, 2008 to December 31, 2009 for the three mortality outcome measures currently specified under the Hospital IQR Program (MORT–30–AMI, MORT–30–HF, MORT–30–PN). In response to public comment and for reasons discussed in the Hospital Inpatient VBP Program Final Rule (76 FR 26494), we adopted a 12-month performance period of July 1, 2011 to June 30, 2012 and a 12-month baseline period of July 1, 2009 to June 30, 2010 for these measures.

In the Hospital Inpatient VBP Program Final Rule, we stated that we would begin the performance period for the proposed HAC and AHRQ measures 1 year after such measures were included on *Hospital Compare.* Because all the finalized HAC and AHRQ measures were included on *Hospital Compare* on March 3, 2011, we finalized March 3, 2012 as the start of the performance period for these measures in the Hospital Inpatient VBP Program Final Rule (76 FR 26494 through 26495). We stated in the Hospital Inpatient VBP Program Final Rule (76 FR 26495) that we would propose the end performance period date for these measures in this proposed rule.

In order for the HAC and AHRQ measures to be scored for the FY 2014 Hospital VBP Program, the performance period for these measures would need to end by the fourth quarter of FY 2012 to allow us sufficient time to collect and process the necessary claims data. We note that this time period needs to be longer for HAC and AHRQ measures than for clinical process and patient experience measures, which are based on chart-abstracted data and surveys rather than claims. Claims data require at least three months following a given calendar quarter to process and necessitate two additional months to complete measure calculation, including risk adjustment, statistical modeling, quality assurance, programming, and generating reports on patient-level data, which is provided to hospitals.

Therefore, we are proposing to adopt a nearly 7-month performance period for the HAC and AHRQ measures for FY 2014 by selecting September 30, 2012 as the end of the performance period. While we would prefer to use a 12-month performance period, analysis of existing data indicates that a 7-month performance period would provide sufficiently robust values on these critical measures.

As stated above, because we believe that a comparable period should be selected for the baseline data, we are proposing to set March 3, 2010 to September 30, 2010 as the baseline period for the proposed HAC and AHRQ measures for the FY 2014 Hospital VBP Program. We invite public comment on these proposals.

The following tables include all proposed and finalized baseline and performance periods for the FY 2013 and FY 2014 program years.

FY 2013 HOSPITAL VBP PROGRAM BASELINE AND PERFORMANCE PERIODS

Domain	Baseline period	Performance period
Clinical Process	July 1, 2009–March 31, 2010	July 1, 2011–March 31, 2012.
Patient Experience	July 1, 2009–March 31, 2010	July 1, 2011–March 31, 2012.

FY 2014 HOSPITAL VBP PROGRAM BASELINE AND PERFORMANCE PERIODS

Domain	Baseline period	Performance period
Clinical Process *	April 1, 2010–December 31, 2010	April 1, 2012–December 31, 2012.
Patient Experience *	April 1, 2010–December 31, 2010	April 1, 2012–December 31, 2012.
Efficiency *	May 15, 2010–90 days prior to February 14, 2011	May 15, 2012–February 14, 2013.
Outcomes		
• Mortality	• July 1, 2009–June 30, 2010	• July 1, 2011–June 30, 2012.
• HAC *	• March 3, 2010–September 30, 2010	• March 3, 2012–September 30, 2012.
• AHRQ *	• March 3, 2010–September 30, 2010	• March 3, 2012–September 30, 2012.

* *Proposed*

6. Proposed Performance Standards for the FY 2014 Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established and announced not later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. Achievement and improvement standards are discussed more fully in the Hospital Inpatient VBP Program Final Rule (76 FR 26511 through 26513). In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

(1) Mortality Measures

In the Hospital Inpatient VBP Program Final Rule, we finalized the achievement performance standard (achievement threshold) for each of the proposed FY 2014 Hospital VBP

Program mortality measures at the median of hospital performance (50th percentile) during the applicable baseline period. We also finalized the improvement performance standard (improvement threshold) for each mortality measure at each specific hospital's performance on each measure during the baseline period of July 1, 2009 to June 30, 2010 (76 FR 26511 through 76 FR 26512). In addition, we finalized the precise achievement thresholds for these mortality measures (76 FR 26513), as shown below:

ACHIEVEMENT THRESHOLDS FOR THE FY 2014 HOSPITAL VBP PROGRAM MORTALITY OUTCOME MEASURES

[Displayed as survival rates]

Measure ID	Measure description	Performance standard (achievement threshold)	Benchmark
Mortality Outcome Measures			
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate	0.8477	0.8673
MORT–30–HF	Heart Failure (HF) 30-Day Mortality Rate	0.8861	0.9042
MORT–30 PN	Pneumonia (PN) 30-Day Mortality Rate	0.8818	0.9021

(2) Proposed Medicare Spending per Beneficiary Measure

In section IV.B.3.b.(2)(A) of the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25927), we proposed to calculate a ratio of the Medicare spending per beneficiary amount for each hospital to the median Medicare spending per beneficiary amount across all hospitals during the performance period. We proposed to set the achievement threshold at the median Medicare spending per beneficiary ratio across all hospitals during the performance period. The proposed value of the achievement performance standard (achievement threshold) for the Medicare Spending per Beneficiary measure would be 1.0. This would be the middle ratio, or the Medicare spending per beneficiary for the median hospital divided by the median Medicare spending per beneficiary for all hospitals.

Likewise, in section IV.B.3.b.(2)(B) of the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25927 through 25928), we proposed to set the improvement performance standard (improvement threshold) for the proposed Medicare spending per beneficiary measure at the hospital's own Medicare spending per beneficiary ratio, as calculated during the proposed baseline period. We also proposed to set the achievement performance benchmark at the mean of the lowest decile of Medicare spending per beneficiary ratios during the performance period, and that the improvement benchmark would be equal to the achievement performance benchmark for the performance period, which is the mean of the lowest decile of Medicare spending per beneficiary ratios. We refer readers to the FY 2012 IPPS/LTCH proposed rule for a complete discussion of these proposals.

b. Proposed Clinical Process of Care and Patient Experience of Care FY 2014 Performance Standards

As discussed in section XVI.B.5.a. of this proposed rule, we are proposing to adopt a 9-month (3-quarter) performance period of April 1, 2012 to December 31, 2012 for the clinical process of care and patient experience of care measures for the FY 2014 Hospital VBP Program. To set achievement and improvement performance standards for these proposed measures for the FY 2014 Hospital VBP Program, we are proposing to use the same approach adopted in the Hospital Inpatient VBP Program Final Rule. That approach, as well as our rationale for adopting it, is explained in detail at 76 FR 26511 through 76 FR 26513. We are proposing to set the achievement performance standard (achievement threshold) for each proposed measure at the median of hospital performance (50th percentile) during the proposed baseline period of April 1, 2010 through December 31, 2010. We also are proposing to set the improvement performance standard (improvement threshold) for each of the proposed measures at each specific hospital's performance on the applicable measure during the proposed baseline period of April 1, 2010 through December 31, 2010. We are proposing to set each benchmark for each measure as the mean of the top decile performance of applicable hospitals during the proposed baseline period. We invite public comment on these proposals.

We set out proposed achievement performance standards for the proposed clinical process of care and patient experience of care measures using the applicable baseline period data in the table below.

PROPOSED ACHIEVEMENT PERFORMANCE STANDARDS FOR PROPOSED FY 2014 CLINICAL PROCESS OF CARE AND PATIENT EXPERIENCE OF CARE MEASURES

Measure ID	Measure description	Performance standard (achievement threshold)	Benchmark
Process of Care Measures			
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.8066	0.9630
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0.9344	1.0000
HF–1	Discharge Instructions	0.9266	1.0000
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.	0.9730	1.0000
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	0.9446	1.0000
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0.9807	1.0000
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients	0.9813	1.0000
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	0.9663	0.9996

PROPOSED ACHIEVEMENT PERFORMANCE STANDARDS FOR PROPOSED FY 2014 CLINICAL PROCESS OF CARE AND PATIENT EXPERIENCE OF CARE MEASURES—Continued

Measure ID	Measure description	Performance standard (achievement threshold)	Benchmark
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	0.9634	1.0000
SCIP–Inf–9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2	0.9286	0.9989
SCIP–Card–2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.	0.9565	1.0000
SCIP–VTE–1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered.	0.9462	1.0000
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.	0.9492	0.9983
Patient Experience of Care Measure			
HCAHPS			
	Communication with Nurses	75.79%	84.99%
	Communication with Doctors	79.57%	88.45%
	Responsiveness of Hospital Staff	62.21%	78.08%
	Pain Management	68.99%	77.92%
	Communication about Medicines	59.85%	71.54%
	Hospital Cleanliness & Quietness	63.54%	78.10%
	Discharge Information	82.72%	89.24%
	Overall Rating of Hospital	67.33%	82.55%

c. AHRQ Measures

For the reasons we have discussed in the Hospital Inpatient VBP Program Final rule (76 FR 26514), we are proposing to set the achievement performance standard (achievement threshold) for each AHRQ composite measure at the median of hospital performance (50th percentile) during the proposed baseline period of March 3, 2010 to September 30, 2010. We are proposing to set the benchmark for each AHRQ composite measure at the mean of the top decile of hospital performance during the proposed baseline period of March 3, 2010 to September 30, 2010. We also are proposing to set the improvement performance standard (improvement threshold) for each of the proposed measures at each specific hospital's performance on the applicable measure during the proposed baseline period of March 3, 2010 to September 30, 2010.

d. HAC Measures

We adopted eight HAC measures in the Hospital Inpatient VBP Final Rule. For each of these eight HAC measures, at least one quarter of hospitals achieved a 100 percent rating based on administrative data for all IPPS hospitals participating in the Hospital IQR Program for Medicare discharges from October 1, 2008 through June 30, 2010 (that is, they do not have any reportable HAC occurrences). In addition, based on the administrative data from October 1, 2008 through June 30, 2010, at least one half of all hospitals achieved a measure rate of 100 percent on six of the eight HAC measures (Foreign Object Retained After Surgery; Air Embolism; Blood Incompatibility; Pressure Ulcer Stages III and IV; Catheter-Associated UTI; Manifestations of Poor Glycemic Control). Accordingly, the achievement threshold for these measures would be zero if we proposed to set performance standards for each individual measure using the same methodology that we finalized with respect to the mortality measures.

We believe that the HAC measures are extremely important in promoting patient safety, improving quality of care, and reducing costs. According to a 2010 HHS Office of the Inspector General report, entitled ''Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries'' (*http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf*), an estimated 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays. We believe that all the finalized HAC measures assess the presence of conditions and outcomes that are reasonably preventable if high quality care is furnished to the Medicare beneficiary. We also believe that the incidence of HACs in general raises major patient safety issues for Medicare beneficiaries. Outcome measures, including HAC outcome measures, are widely regarded by the provider community as strongly indicative of the quality of medical care and as integral to reporting and improving quality and patient safety. Therefore, we believe it is important to include HAC outcome measures in the Hospital VBP Program.

For these reasons, we are proposing that our topped-out policy would not apply to the HAC measures. We also are proposing to treat the eight individual HAC measures as a single aggregate HAC score for purposes of scoring, and believe that this approach will enable us to calculate meaningful distinction among hospitals and variation in hospital performance. In addition, this aggregation of the scores for the HAC measures ensures that the HAC measures do not unduly outweigh the remainder of the measures in the outcome domain. Accordingly, in taking into account our HAC policy and reliability concerns, we are proposing to set achievement performance standards, benchmarks, and improvement performance standards based on hospital combined performance on seven or eight HAC measures, as applicable, during the proposed performance or baseline period. Because certain hospitals will report on only seven of the eight HAC measures, we are proposing separate standards for hospital performance depending on whether the hospitals report on seven or eight HAC measures. As discussed more fully below, we are also proposing to score hospital performance on the HAC measures by combining hospital performance scores on each of the HAC measures to calculate a single, aggregate HAC score for this purpose.

As finalized in the Hospital Inpatient VBP Program Final Rule (76 FR 26514), we are proposing to set the achievement performance standard (achievement

threshold) for the HAC aggregate score for those hospitals that report on all eight of the HAC measures at the median of hospital performance (50th percentile) of those hospitals reporting on all eight of the HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010. We are proposing to set the achievement performance standard (achievement threshold) for the HAC aggregate score for those hospitals that report on seven of the HAC measures at the median of hospital performance (50th percentile) on only those seven measures for those hospitals reporting on either seven or eight of the HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010.

We are proposing to set the benchmark for the HAC aggregate score for those hospitals that report on all eight of the HAC measures at the mean of the top decile of hospital performance for those hospitals reporting on all eight HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010. We are proposing to set the benchmark for the HAC aggregate score for those hospitals that report on seven of the HAC measures at the mean of the top decile of hospital performance on only those seven measures for hospitals reporting on either seven or eight of the HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010.

We also are proposing to set the improvement performance standard (improvement threshold) for the HAC aggregate score at each specific hospital's performance during the proposed baseline period of March 3, 2010 to September 30, 2010, whether the hospitals report on seven or eight HAC measures. Please see below for further discussion of the aggregate HAC scoring methodology.

We note that the performance standards for the HAC aggregate score are displayed in the table below as a score composed of all eight individual HAC measures. We recognize that all hospitals report on seven of these individual measures, and nearly all (about 95 percent) of hospitals report all eight. However, a small number of hospitals do not report on the Foreign Object Removal after Surgery HAC measure. We believe that any numerical differences between the HAC performance standards for hospitals reporting on seven of eight HAC measures compared to the standards for hospitals reporting on all eight HAC measures will be statistically insignificant. However, we intend to provide updated performance standards in the CY 2012 OPPS/ASC final rule with comment period for those hospitals only reporting on seven of the eight HAC measures.

We invite public comment on the proposed methodology for setting performance standards for the aggregate HAC score for HAC measures finalized for the FY 2014 Hospital VBP Program. We specify the proposed performance standards for the aggregate HAC score (all eight measures) and AHRQ measures using the proposed baseline period data in the table below. We note that, for both AHRQ and HAC measures, a lower value represents better performance on the measures. Thus, a ''perfect'' score on each measure would be a 0.00.

PROPOSED ACHIEVEMENT PERFORMANCE STANDARDS FOR FY 2014 HAC * AND AHRQ MEASURES

Measure ID	Measure description	Performance standard (achievement threshold)	Benchmark
	Outcome Measures		
HACs **	Hospital Acquired Conditions per 1,000 (aggregated)	0.00109	0.0000
AHRQ Composite	Complication/patient safety for selected indicators (composite)	0.4006	0.2754
AHRQ Composite	Mortality for selected medical conditions (composite)	0.7542	0.6130

* Finalized HACs for use in the FY 2014 Hospital VBP Program include: Foreign Object Retained After Surgery, Air Embolism, Blood Incompatibility, Pressure Ulcer Stages III & IV, Falls and Trauma, Vascular Catheter Associated Infections, Catheter Associated Urinary Tract Infection, and Manifestations of Poor Glycemic Control.

** HAC performance standards were calculated using data from hospitals reporting on 8 HAC measures. The final rule will include the performance standards for hospitals reporting on seven HAC measures.

7. Proposed FY 2014 Hospital VBP Program Scoring Methodology

a. Proposed FY 2014 Domain Scoring Methodology

In the Hospital Inpatient VBP Program Final Rule, we adopted a methodology for scoring all clinical process of care, patient experience of care, and outcome measures. As noted in the Hospital Inpatient VBP Program Final Rule, this methodology outlines an approach that we believe is well-understood by patient advocates, hospitals and other stakeholders because it was developed during a year-long process that involved extensive stakeholder input, and was presented by us in a report to Congress. Further, we have conducted extensive research on a number of other scoring models for the Hospital VBP Program to ensure a high level of confidence in the scoring methodology (76 FR 26514). In addition, we believe that, for simplicity and consistency of the Hospital VBP Program, it is important to score hospitals under the same methodology for subsequent fiscal years, with appropriate modifications to accommodate new domains and measures. Therefore, we are proposing to use the same scoring methodology for these measures in the FY 2014 Hospital VBP Program, with the changes discussed below for HAC measures. We also refer readers to discussion of the proposed Medicare Spending per Beneficiary measure in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25927 through 25928). We invite public comment on this proposal.

b. Proposed HAC Measures Scoring Methodology

We are proposing to score the HAC measures using an aggregated HAC rate based on the unweighted average of the rates of the individual HAC measures. However, as explained above, we are aware that hospitals may only report on seven of the eight finalized HAC measures. This is because some hospitals do not perform surgeries, and therefore would not submit eligible claims that would be the basis for the Foreign Object Retained After Surgery HAC measure. The remaining seven HAC measures would apply to all hospitals, however, because all hospitals that participate in the Hospital VBP Program will submit eligible claims for these measures. We also anticipate that most hospitals will report on all

eight of the individual HAC measures because most hospitals that participate in the Hospital VBP Program perform surgeries and would submit eligible surgical claims that would be the basis for the Foreign Object Retained After Surgery HAC measure. Accordingly, we are proposing that the aggregate HAC score for each hospital be calculated as the equally weighted average of the rates on all HAC measures for which the hospital reports Medicare claims, which will most often be an equally weighted average of the rates on all eight measures, but may be scores on seven of the HAC measures. As stated above, the HAC aggregate score will be calculated if a hospital submits at least one Medicare claim during the performance period. For example, if a hospital submits one or more Medicare claims during the performance period, and those claims do not indicate any HAC occurrences, the hospital will receive a perfect score on all applicable HAC measures. The aggregate HAC rate would then be used to assign points in accordance with the proposed performance standards discussed above to calculate an individual hospital's aggregate HAC achievement and improvement scores. The single aggregate HAC score would be the greater of the hospital's achievement or improvement score. The hospital's aggregate HAC score would be combined with the hospital's score on other outcome measures to derive an outcome domain score, with the aggregate HAC score weighted equally with the other outcome measures in the domain. We note that in assigning points for this aggregate HAC score, lower aggregate HAC scores represent better performance. We believe our proposed aggregate scoring methodology for HAC measures allows us to meaningfully score hospitals on these critical patient safety measures.

We welcome public comment on this proposal.

8. Ensuring HAC Reporting Accuracy

For the FY 2013 Hospital VBP Program, the validation process we adopted for the Hospital IQR Program will ensure that the Hospital VBP data are accurate (76 FR 26537 through 26538). In addition, Medicare Administrative Contractors (MACs) review claims to ensure that accurate Medicare payments are made. This claims review ensures that HAC data included on the claims are accurately reported both for the Hospital IQR Program and the Hospital VBP Program. In addition, we are considering proposing to adopt additional targeting to assess the accuracy of HAC data reported on claims. Specifically, we are considering targeting a subset of hospitals that report zero or an aberrantly low percentage of HACs on Medicare fee-for-service IPPS claims relative to the overall national average of HACs.

This consideration is supported by our analysis of HAC rates calculated using data from Medicare fee-for-service claims from October 1, 2008 through June 30, 2010. We publicly released these rates in March 2011, and they can be found on our Web site at: *http://www.cms.gov/HospitalQualityInits/06_HACPost.asp#TopOfPage.* This analysis revealed a range in hospital-reporting of the eight HACs from a low of 0.0001 percent (that is, 1 discharge out of every 100,000 applicable discharges) of hospital inpatient discharges (23 discharges) reporting a blood incompatibility, to a high of 0.0564 percent (that is, 56.4 discharges out of every 100,000 applicable discharges) reporting Falls and Trauma. According to this analysis, however, these HAC rates appear to be underreported occurrences when compared to similar HAI measures. For example, the Catheter Associated Urinary Tract Infection (CAUTI) measure rate was 5.4 percent, or 54 out of every 1,000 eligible discharges, as reported in the AHRQ 2008 National Healthcare Quality Report. This rate is more than 125 times greater than the national HAC reported CAUTI rate of 0.317 out of every 1,000 eligible discharges. While we recognize that definitional differences in the measures might contribute to this rate difference, we also believe that underreporting of HAC claims data contributed to this difference. It is important to note that the 5.4 percent CAUTI rate was calculated using medical record documentation as a data source and a random sample of Medicare beneficiaries for acute care hospital stays, as discussed in a separate Federal report about healthcare quality (AHRQ 2008 National Healthcare Quality Report). We note that this analysis is exploratory in nature, and we cannot definitively conclude any systematic underreporting by any particular hospitals. Nonetheless, we believe that this analysis provides sufficient information for CMS to consider development of a HAC validation process to assess potential underreporting by hospitals and ensure accurate reporting among all hospitals reporting HACs on Medicare claims. Our goal is to improve quality and patient safety through accurate reporting of hospital quality data and accurately linking quality to payment in the Hospital VBP Program. We strive to ensure accurate reporting, and we believe that validating a random subset of hospitals that report an aberrantly low number of HACs would strengthen our overall effort to link value to quality. We welcome public comments regarding our consideration of a HAC validation process. We also note that we intend to take appropriate action if we discover systematic underreporting of HAC and other adverse event information, including, where appropriate, reporting such instances to the HHS Office of the Inspector General for its review.

9. Proposed Domain Weighting for FY 2014 Hospital VBP Program

For the FY 2013 Hospital VBP Program, we adopted a weighting scheme that weights the clinical process of care domain at 70 percent of the Total Performance Score, and weights the patient experience of care domain at 30 percent. However, the addition of the outcome domain and the proposed addition of an efficiency domain necessitate the adoption of a different domain weighting scheme than we adopted for the FY 2013 Hospital VBP Program. We discuss below the factors we considered in determining the appropriate weight to propose for each domain in the FY 2014 Hospital VBP Program.

As we have previously stated, we believe that the patient's experience associated with receiving inpatient services in a hospital is important in determining the hospital's overall quality of care for purposes of the Hospital VBP Program. However, we also believe that a majority of the Total Performance Score should be based on the objective data submitted by hospitals on the measures selected for the Hospital VBP Program. Thus, as we finalized for the FY 2013 Hospital VBP Program, we are proposing to weight the patient experience of care domain at 30 percent for the FY 2014 Hospital VBP Program. We believe that this weighting proposal appropriately incentivizes hospitals to provide patient-centered care across the full spectrum of their services. As we stated in the Hospital Inpatient VBP Program Final Rule (76 FR 26491), we believe that domains need not be given equal weight, and that over time, scoring methodologies should be weighted more towards outcomes, patient experience of care and functional status measures (measures assessing physical and mental capacity, capability, well-being and improvement). Consistent with this policy and our analysis showing that many of the clinical process of care

measures are nearly topped-out, we are proposing to reduce the weighting for the clinical process of care domain to 20 percent. We also are proposing to weight the outcome domain at 30 percent of the Total Performance Score for the FY 2014 Hospital VBP Program. Because we believe that scoring hospitals on outcome measures will improve treatment outcomes and patient safety, we intend to propose increasing the weighting for the outcome domain in subsequent fiscal years as more outcome measures become available.

As we indicated in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25927 through 25928), we believe that efficiency is an important component of improving outcomes, the patient experience of care and the overall quality of care provided to Medicare beneficiaries in the inpatient hospital setting. However, we also recognize the importance of clinical quality based upon industry standards of care and the patients' experience of care. Accordingly, we are proposing to weight the efficiency domain at 20 percent of the Total Performance Score for the FY 2014 Hospital VBP Program.

Therefore, we are proposing the following domain weights for the FY 2014 Total Performance Score: outcome domain = 30 percent; clinical process of care domain = 20 percent; patient experience of care domain = 30 percent; and efficiency domain = 20 percent. Under this proposed weighting scheme, the clinical care-related domains (process of care and outcome domains) would, together, constitute 50 percent of the total performance score (20 percent for clinical process of care and 30 percent for outcome), the patient experience of care domain would constitute 30 percent, and the efficiency domain would constitute 20 percent. We believe that this proposed weighting scheme will hold hospitals accountable for all aspects of patient care, including clinical outcomes and efficiency.

We invite public comment on the proposed weighting of the four proposed domains to be used in the calculation of the Total Performance Score for the FY 2014 Hospital VBP Program.

B. Proposed Review and Correction Process Under the Hospital VBP Program

1. Background

Section 1886(o)(10)(A)(i) of the Act requires the Secretary to make information available to the public regarding individual hospital performance in the Hospital VBP Program, including: (1) Performance of the hospital on each measure that applies to the hospital; (2) the performance of the hospital with respect to each condition or procedure; and (3) the hospital's Total Performance Score. To meet this requirement, we stated our intention in the Hospital Inpatient VBP Program Final Rule to publish hospital scores with respect to each measure, each hospital's condition-specific score (that is, the performance score with respect to each condition or procedure, for example, AMI, HF, PN, and SCIP), each hospital's domain-specific score, and each hospital's Total Performance Score on Hospital Compare (76 FR 26534 through 26536). We intend to make proposals related to making this information publicly available in future rulemaking.

Section 1886(o)(10)(A)(ii) of the Act requires the Secretary to ensure that each hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to each hospital under section 1886(o)(10)(A)(i) of the Act prior to such information being made public.

For the FY 2013 Hospital VBP Program, the finalized measures consist of chart-abstracted clinical process of care measures and a patient experience of care measure. We are proposing that hospitals will have an opportunity to review and correct chart-abstracted data and patient experience data through the processes discussed below. We intend to make additional proposals regarding the review and correction of outcome measures, efficiency measures, and domain, condition, and Total Performance Scores in future rulemaking.

2. Proposed Review and Corrections of Data Submitted to the QIO Clinical Warehouse on Chart-Abstracted Process of Care Measures and Measure Rates

We are proposing that the process utilized to give hospitals an opportunity to review and correct data submitted on the Hospital IQR Program chart-abstracted measures also be used to allow hospitals to correct data and measure rates on chart-abstracted measures for the Hospital VBP Program. Under this proposed process, hospitals would continue to have the opportunity to review and correct data they submit on all Hospital IQR Program chart-abstracted measures, whether or not the measure is adopted as a measure for the Hospital VBP Program. We are proposing to use the Hospital IQR Program's data submission, review, and correction processes, which will allow for review and correction of data on a continuous basis as it is being submitted for the Hospital IQR Program, which in turn would allow hospitals to correct data and measure rates used to calculate the Hospital VBP Program Total Performance Score for those hospitals that participate in both programs. We believe this process would satisfy the requirement in section 1886(o)(10)(A)(ii) of the Act to allow hospitals to review and submit corrections for one of the pieces of information that will be made public with respect to each hospital—the measure rates for chart-abstracted measures. For hospitals that do not participate in the Hospital IQR Program but do participate in the Hospital VBP Program, such as Maryland hospitals, we intend to make proposals regarding how those hospitals will be able to review and correct their Hospital VBP data in future rulemaking.

Under the Hospital IQR Program, hospitals currently have an opportunity to submit, review, and correct any of the chart-abstracted information submitted to the QIO Clinical Warehouse for the full 4½ months following the last discharge date in a calendar quarter. (We note that in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25915), we proposed to reduce the submission period from 4½ months to 104 days.) Hospitals can begin submitting data on the first discharge day of any reporting quarter. Hospitals are encouraged to submit data early in the submission schedule so that they can identify errors and resubmit data before the quarterly submission deadline. Users are able to view and make corrections to the data that they submit within 24 hours of submission. The data are populated into reports that are updated nightly with all data that have been submitted and successfully processed for the previous day. Hospitals are able to view a report each quarter which shows the numerator, denominator and percentage of total for each Clinical Measure Set and Strata. That report contains the hospital's performance on each measure set/strata submitted to the QIO Clinical Warehouse. The numerator is the number of cases that satisfies the conditions of the performance measure, and a denominator is the number of successfully accepted cases in the measure population evaluated by the performance measure. The percentage of total is calculated by using the numerator divided by the denominator multiplied by 100. This measure rate is the same as the Hospital VBP measure rate.

We believe that 4½ months is sufficient time for hospitals to be able to submit, review data, make corrections to the data, and view their percentage of total, or measure rate, on each Clinical Measure Set/Strata for use in both the

Hospital IQR and Hospital VBP Programs. Additionally, because this process is familiar to most hospitals, use of this existing framework reduces the burden that could have been placed on hospitals that participate in the Hospital IQR Program if they had to learn a new process for submitting data for the Hospital VBP Program. Following the period in which hospitals can review and correct data and measure rates for chart-abstracted measures as specified above, we propose that hospitals will have no further opportunity to correct such data or measure rates.

We are proposing that once the hospital has an opportunity to review and correct data related to chart-abstracted measures submitted in the Hospital IQR Program, we will consider that the hospital has been given the opportunity to review and correct this data and measure rates for purposes of the Hospital VBP Program, and these measure rates will be used to calculate domain, condition, and Total Performance Scores for the Hospital VBP Program without further review and correction. We invite public comment on this proposal.

3. Proposed Review and Correction Process for Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Data

We are proposing a ''two-phase'' process for the review and correction of HCAHPS data. Under this proposed process, hospitals would have the opportunity to review and correct data they submitted on all HCAHPS Hospital IQR Program items in the first phase, whether or not such items or combination of items are adopted as HCAHPS dimensions for the Hospital VBP Program. In the second phase, hospitals would have the opportunity to review the patient-mix and mode adjusted HCAHPS scores (details on the HCAHPS adjustment process may be found at: *http://www.hcahpsonline.org/files/Final%20Draft%20Description%20of%20HCAHPS%20Mode%20and%20PMA%20with%20bottom%20box%20modedoc%20April%2030,%202008.pdf*) on dimensions that we will use to score hospitals under the Hospital VBP Program to determine whether they believe CMS calculated their scores on these dimensions correctly. We believe that this proposal for a two-phase review process will expedite hospital review and correction of data. We also believe that this proposal will improve quality of care because hospitals will be able to timely review their HCAHPS scores and respond efficiently in improving patient care to address areas of weakness reflected in their scores. We are not proposing to release any patient level data to the public. This proposed review process would only grant each hospital the authority to review and correct the hospital's patient-level data.

a. Phase One: Review and Correction of HCAHPS Data Submitted to the QIO Clinical Warehouse

For the first phase of the HCAHPS review and correction process, we proposed to reduce the HCAHPS submission deadline under the Hospital IQR Program by one week in order to create a 1-week period for hospitals to review and correct their HCAHPS data. We included this proposal to reduce the submission deadline in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25916). Currently, hospitals have approximately 14 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse. Under this proposal, hospitals would have approximately 13 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse and a 1-week period to review and correct that data. During the 13-week submission period, hospitals would be able to resubmit their data to make corrections to the patient-level records. The 1-week review and correction period would occur immediately after the 13-week data submission deadline.

The proposed 1-week review and correction period would allow hospitals to provide missing data or replace incorrect data in the data files they have submitted to the QIO Clinical Warehouse. The 1-week review and correction period will allow hospitals to identify any issues with the data they had submitted in the 13-week submission period. Hospitals will have the opportunity to review frequency distributions of all of their submitted data items, which include hospital summary information, patient administrative data, and patient survey responses, and resubmit their HCAHPS data files to correct identified issues during the 1-week review and correction period. We define the term ''review and correct'' to mean that hospitals can correct their existing data records, but not add new data records. Accordingly, hospitals would not be allowed to add new patient-level records or remove existing patient-level records during the review and correction period. Following the conclusion of the 1-week review and correction period, hospitals would not be allowed to review, correct, or submit additional HCAHPS data for the applicable calendar quarter.

b. Phase Two: Review and Correction of HCAHPS Scores for the Hospital VBP Program

In the second phase of the proposed HCAHPS review and correction process, hospitals would be given the opportunity to review their scores on the HCAHPS items that will be used in the Hospital VBP Program. These HCAHPS scores are constructed after the data that hospitals had submitted have been analyzed to identify and remove incomplete surveys and after adjustments for the effects of patient-mix and survey mode have been applied. (Details on the HCAHPS adjustment process may be found at: *http://www.hcahpsonline.org/files/Final%20Draft%20Description%20of%20HCAHPS%20Mode%20and%20PMA%20with%20bottom%20box%20modedoc%20April%2030,%202008.pdf*.) Hospitals would have approximately 1 week to examine their HCAHPS dimension scores for the applicable Hospital VBP Program performance period. A participating hospital would have the opportunity to question CMS if the hospital believes its scores were miscalculated. We would respond to a hospital's inquiries by checking the calculation and, if necessary, recalculating the hospital's HCAHPS scores. In this proposed second phase of the HCAHPS review and correction process, hospitals would not be allowed to change or submit new HCAHPS data or delete existing data. Their right to correct information during this period would be limited to reviewing their HCAHPS dimension scores and notifying CMS of any errors in its calculation of those scores. We intend to propose the procedural aspects of the second phase of the proposed HCAHPS review and correction process in the FY 2013 IPPS/LTCH PPS proposed rule. In summary, for the chart-abstracted and patient experience of care measures, we are proposing that existing procedures for submission, review, and correction related to chart-abstracted measures under the Hospital IQR Program, coupled with the proposed two phase review of HCAHPS scores discussed above, would constitute an opportunity for review and correction of measure data and measure rates under the Hospital VBP Program. Because these procedures give hospitals the opportunity to review and correct the data and/or measure rates, such data and measure rates may be used to calculate domain, condition, and Total Performance Scores for the Hospital VBP Program. We intend to make proposals related to making this

information publicly available, and to make additional proposals regarding the review and correction of outcome measures, efficiency measures, and domain, condition, and Total Performance Scores in future rulemaking. We invite public comment on these proposals.

XVII. Files Available to the Public via the Internet

In the past, a majority of the Addenda to which we referred throughout the preamble of the OPPS/ASC proposed and final rules appeared in the printed version of the **Federal Register** as part of the annual rulemakings. However, beginning with this CY 2012 proposed rule, the Addenda of the proposed and final rules will be published and available only via the Internet on the CMS Web site. We note that our existing regulations at §§ 416.166(b), 416.171(b), and 416.173 provide for the annual publication of the covered surgical procedures and the payment rates under the ASC payment system in the **Federal Register**. In this proposed rule, we are proposing to revise these three regulations to reflect the option of annually publishing the Addenda containing the covered surgical procedures and payment rates under the ASC payment system via the Internet on the CMS Web site.

To view the Addenda of the CY 2012 OPPS/ASC proposed rule pertaining to the CY 2012 proposed payments under the OPPS, go to the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD* and select ''1525–P'' from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled ''2012 OPPS NPRM Addenda'' at the bottom of the page.

To view the Addenda of the CY 2012 OPPS/ASC proposed rule pertaining to the CY 2012 proposed payments under the ASC payment system, go to the CMS Web site at: *http://www.cms.gov/ASCPayment/ASCRN/* and select ''1525–P'' from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled ''Addendum AA, BB, DD1, and DD2'' at the bottom of the page.

A. Information in Addenda Related to the Proposed CY 2012 Hospital OPPS

Addenda A and B provide various data pertaining to the proposed CY 2012 payment for items and services under the OPPS. Specifically, Addendum A includes a list of all proposed APCs to be payable under the OPPS, including the proposed scaled relative weights, the proposed national unadjusted payment rates, the proposed national unadjusted copayments, and the proposed minimum unadjusted copayments for each APC that we are proposing for CY 2012. Addendum B includes a list of all active HCPCS codes, including the proposed APC assignments, the proposed scaled relative weights, the proposed national unadjusted payment rates, the proposed national unadjusted copayments, the proposed minimum unadjusted copayments, and the proposed payment status indicators and proposed comment indicators for CY 2012 OPPS.

For the convenience of the public, we also are including on the CMS Web site a table that displays the HCPCS code data in Addendum B sorted by APC assignment, identified as Addendum C.

Addendum D1 defines the proposed payment status indicators that we are proposing to use in Addenda A and B. Addendum D2 defines the proposed comment indicators that are used in Addendum B. Addendum E lists the HCPCS codes that are proposed to be only payable to hospitals as inpatient procedures and that are not payable under the OPPS for CY 2012. Addendum L contains the proposed out-migration wage adjustment for CY 2012. Addendum M lists the HCPCS codes that are proposed to be members of a composite APC and identifies the proposed composite APC to which each is assigned. This addendum also identifies the proposed status indicator for each HCPCS code and a proposed comment indicator if there is a proposed change in the code's status with regard to its membership in the composite APC. Each of the HCPCS codes included in Addendum M has a single procedure payment APC, listed in Addendum B, to which it is assigned when the criteria for assignment to the composite APC are not met. When the criteria for payment of the code through the composite APC are met, one unit of the composite APC payment is paid, thereby providing packaged payment for all services that are assigned to the composite APC according to the specific I/OCE logic that applies to the APC. We refer readers to the discussion of composite APCs in section II.A.2.e. of this proposed rule for a complete description of the proposed composite APCs.

Addendum N, ''Proposed Bypass Codes for Creating 'Pseudo' Single Procedure Claims for CY 2012 OPPS,'' contains a list of the HCPCS codes that we are proposing to use to create ''pseudo'' single claims from multiple procedure claims so that the most claims data can be used to set median costs for the CY 2012 OPPS. We refer readers to section II.A.1.b. of this proposed rule for a full discussion of the use of this file in the proposed 2012 OPPS ratesetting process. Addendum N contains the following elements for the proposed CY 2012 bypass codes: (1) HCPCS code; (2) short descriptor; (3) overall bypass indicator; and (4) an indicator if the code was not used as a bypass code in ratesetting activities prior to this CY 2012 proposed rule. The addendum was previously issued as a table (usually Table 1) in the preamble of the applicable proposed or final rule. We are issuing it as an addendum in this proposed rule because it is lengthy and users can better analyze the file if it is furnished in Excel format on the CMS Web site.

B. Information in Addenda Related to the Proposed CY 2012 ASC Payment System

Addenda AA and BB provide various data pertaining to the proposed CY 2012 payment for the covered surgical procedures and covered ancillary services for which ASCs may receive separate payment. Addendum AA lists, for CY 2012, the proposed ASC covered surgical procedures, whether the procedure is proposed to be subject to multiple procedure discounting, the proposed comment and payment indicators for each procedure, and the proposed payment weights and rates for each procedure. Addendum BB displays, for CY 2012, the proposed ASC covered ancillary services, the proposed comment and payment indicators for each service, and the proposed payment weights and rates for each service.

Addendum DD1 defines the proposed payment indicators that are used in Addenda AA and BB. Addendum DD2 defines the proposed comment indicators that are used in Addenda AA and BB.

To view the Addenda that pertain to the list of proposed surgical procedures to be excluded from Medicare payment if furnished in ASCs, go to the CMS Web site at: *http://www.cms.gov/ASCPayment/ASCRN/* and select ''1525–P'' from the list of regulations. The proposed excluded ASC procedures are contained in the zipped folder titled ''Addendum EE'' at the bottom of the page. The proposed excluded procedures listed in Addendum EE are surgical procedures that are assigned to the OPPS inpatient list, are not covered by Medicare, are reported using a CPT unlisted code, or have been determined to pose a significant safety risk to a Medicare beneficiary when performed in an ASC or for which standard medical practice dictates that the beneficiary typically requires active

medical monitoring and care at midnight following the procedure.

The Medicare Physician Fee Schedule (MPFS) data files are located at the CMS Web site at: *http://www.cms.gov/PhysicianFeeSched/.*

The links to all of the FY 2012 IPPS proposed wage index-related tables (that are used for the CY 2012 OPPS) are accessible on the CMS Web site at: *http://www.cms.gov/AcuteInpatientPPS/WIFN.*

XVIII. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comments on each of the issues outlined above as discussed below that contained information collection requirements.

B. Requirements in Regulation Text

This proposed rule contains the following proposed information collection requirements specified in the regulatory text:

1. ICRs Regarding Basic Commitments of Providers (§ 489.20)

Section 489.20(w) contains a physician presence disclosure requirement that requires disclosure when a doctor of medicine or a doctor of osteopathy is not onsite 24 hours per day, 7 days per week. The burden associated with the physician presence disclosure requirement is the time and effort necessary for each hospital and CAH to develop a standard notice to furnish to its patient, obtain the required patients signatures, and maintain a copy in the patient's medical record. Although this requirement is subject to the PRA, the associated burden is approved under OMB control number 0938–1034.

Our proposed amendment to § 489.20(w) would require that, for hospitals and CAHs that are not physician owned, the existing physician presence disclosure requirement regarding outpatient services would apply only to outpatients receiving observation services, surgery, and procedures requiring anesthesia. The burden associated with this requirement would be greatly reduced and includes revisions to the time and effort necessary for each hospital and CAH to revise and disseminate the existing standard notice to its patients. The requirements in § 489.20(w) apply to all hospitals as defined in § 489.24(b). We estimate that there are approximately 2,597 hospitals and CAHs that may not have a doctor or medicine or a doctor of osteopathy onsite at all times. We estimate that it will take each hospital or CAH 4 hours to develop or amend and review a disclosure form on a one-time basis, 30 seconds to make each disclosure, another 30 seconds to obtain the patient's signature, and an additional 30 seconds to include a copy of the notice in the patient's medical record. We estimate that on average each hospital or CAH that is subject to the disclosure requirement will make 1966 disclosures per year. The estimated annual burden associated with developing an amended form, obtaining patient signatures, and copying and recording the form is 137,872 hours at a cost of approximately $2,551,148.

2. ICRs Regarding Exceptions Process Related to the Prohibition of Expansion of Facility Capacity (§ 411.362)

As discussed in section XV. of this proposed rule, our proposed new § 411.362(c) would establish and implement a process under which an applicable hospital or high Medicaid facility may apply for an exception to the prohibition on expansion of facility capacity. A physician-owned hospital would be allowed to request an exception under proposed § 411.362(c) by providing information to CMS regarding the hospital's baseline number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of March 23, 2010, and specifying the increase in the number of operating rooms, procedure rooms and beds it is requesting under the exceptions process. In addition, the hospital would have to provide supporting documentation to CMS regarding the criteria it must satisfy. We estimate that 265 physician-owned hospitals would request an exception. We estimate that it would take each hospital 8 hours and 17.5 minutes to complete the request process at the cost of $417.74 for each hospital. Overall, the annual burden for this process is estimated at approximately 2,153 hours at the cost of approximately $110,707. These estimates do not include time or cost burden estimates for hospitals to read and provide rebuttal statements in response to community input comments, which is included in the proposed regulation, and the associated time and costs for the hospital to send them to CMS. Due to the voluntary nature of this criterion, time and cost burden estimates would be difficult to anticipate as this is an unknown variable.

PROPOSED REVISED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 489.20	0938–1034	2,597	1,966	0.019	* 137,872	18.50	2,551,148	0	2,551,148
§ 411.362	0938–New	265	265	8.29	2,153	51.42	110,707	0	110,707
Total		2,862	2,231		140,025				2,661,855

* Represents the revised burden estimate associated with the requirement. It does not reflect the burden currently approved under OCN 0938–1034.

C. Proposed Associated Information Collections Not Specified in Regulatory Text

In this proposed rule, we make reference to proposed associated information collection requirements that are not discussed in the regulation text contained in this document. The following is a discussion of those requirements.

1. Hospital Outpatient Quality Reporting (Hospital OQR) Program

As previously stated in section XIV. of this proposed rule, the Hospital OQR Program has been generally modeled after the quality data reporting program for the Hospital IQR Program. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72110 and 72111 through 72114) for a detailed discussion of Hospital OQR Program information collection requirements we have previously finalized.

2. Hospital OQR Program Measures for the CY 2012, CY 2013, CY 2014, and CY 2015 Payment Determinations

a. Previously Adopted Hospital OQR Program Measures for the CY 2012, CY 2013, and CY 2014 Payment Determinations

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766), we retained the 7 chart-abstracted measures we used in CY 2009 and adopted 4 new claims-based imaging measures for the CY 2010 payment determination, bringing the total number of quality measures for which hospitals must submit data to 11 measures. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637), we required hospitals to continue to submit data on the same 11 measures for the CY 2011 payment determination. The burden associated with the aforementioned data submission requirements is currently approved under OCN: 0938–1109 and expires October 31, 2013.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72094), we adopted measures for the CY 2012, CY 2013, and CY 2014 payment determinations.

For the CY 2012 payment determination, we retained the 7 chart-abstracted measures and the 4 claims-based imaging measures we used for the CY 2011 payment determination. We also adopted 1 structural HIT measure that tracks HOPDs' ability to receive lab results electronically, and 3 claims-based imaging efficiency measures. These actions bring the total number of measures for the CY 2012 payment determination for which hospitals must submit data to 15 measures. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72112 through 72113), we discussed the burden associated with these information collection requirements.

For the CY 2013 payment determination, we required that hospitals continue to submit data for all of the quality measures that we adopted for the CY 2012 payment determination. We also adopted 1 structural HIT measure assessing the ability to track clinical results between visits, 6 new chart-abstracted measures on the topics of HOPD care transitions and ED efficiency, as well as 1 chart-abstracted ED–AMI measure that we proposed for the CY 2012 payment determination but which we decided to finalize for the CY 2013 payment determination. These actions bring the total number of quality measures for the CY 2013 payment determination for which hospitals must submit data to 23 measures.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72094), for the CY 2014 payment determination, we retained the CY 2013 payment determination measures, but did not adopt any additional measures. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72112 through 72113), we discussed the burden associated with these information collection requirements.

The 23 measures that we adopted in the CY 2011 OPPS/ASC final rule with comment period to be used for the CY 2012 through CY 2014 payment determinations are listed in the table below.

HOSPITAL OQR PROGRAM MEASUREMENT SET ADOPTED IN THE CY 2011 OPPS/ASC FINAL RULE WITH COMMENT PERIOD TO BE USED FOR THE CY 2012, CY 2013, AND CY 2014 PAYMENT DETERMINATIONS

OP–1: Median Time to Fibrinolysis.
OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
OP–4: Aspirin at Arrival.
OP–5: Median Time to ECG.
OP–6: Timing of Antibiotic Prophylaxis.
OP–7: Prophylactic Antibiotic Selection for Surgical Patients.
OP–8: MRI Lumbar Spine for Low Back Pain.
OP–9: Mammography Follow-up Rates.
OP–10: Abdomen CT—Use of Contrast Material.
OP–11: Thorax CT—Use of Contrast Material.
OP–12: The Ability for Providers with HIT to Receive. Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data.
OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.
OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.
OP–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival.
OP–17: Tracking Clinical Results between Visits.
OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
OP–19: Transition Record with Specified Elements Received by Discharged Patients.
OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
OP–21: ED–Median Time to Pain Management for Long Bone Fracture.
OP–22: ED–Patient Without Being Seen.
OP–23: ED–Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival.

b. Additional Proposed Hospital OQR Program Measures for CY 2014

In the CY 2011 OPPS/ASC final rule with comment period, we did not adopt any new measures for the CY 2014 payment determination. In this CY 2012 OPPS/ASC proposed rule, we are proposing to add, for the CY 2014 payment determination, 6 chart-abstracted measures, 2 structural measures (including hospital outpatient volume data for selected outpatient surgical procedures), and 1 HAI surgical site infection measure. Thus, for the CY 2014 payment determination, we are proposing that there would be a total of 32 measures. The complete proposed measure set we are proposing for the CY 2014 payment determination, including measures we have previously adopted, is shown below.

PROPOSED CY 2014 HOSPITAL OQR PROGRAM MEASURE SET REFLECTING MEASURES PREVIOUSLY ADOPTED AND THE PROPOSED ADDITIONS

OP–1: Median Time to Fibrinolysis.
OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
OP–4: Aspirin at Arrival.
OP–5: Median Time to ECG.
OP–6: Timing of Antibiotic Prophylaxis.
OP–7: Prophylactic Antibiotic Selection for Surgical Patients.
OP–8: MRI Lumbar Spine for Low Back Pain.
OP–9: Mammography Follow-up Rates.
OP–10: Abdomen CT—Use of Contrast Material.
OP–11: Thorax CT—Use of Contrast Material.
OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data.*
OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery.*
OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).*
OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.*
OP–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival.**
OP–17: Tracking Clinical Results between Visits.**
OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.**
OP–19: Transition Record with Specified Elements Received by Discharged Patients.**
OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.**
OP–21: ED–Median Time to Pain Management for Long Bone Fracture.**
OP–22: ED–Patient Left Before Being Seen.**
OP–23: ED–Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival.**
OP–24: Surgical Site Infection.***
OP–25: Hemoglobin A1c Poor Control in Diabetic Patients.***
OP–26: Low Density Lipoprotein (LDL–C) Control in Diabetic Patients.***
OP–27: High Blood Pressure Control in Diabetic Patients.***
OP–28: Dilated Eye Exam in Diabetic Patients.***
OP–29: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients.***
OP–30: Cardiac Surgery Referral.***
OP–31: Safety Surgery Checklist.***
OP–32: Hospital Outpatient Department Volume for Selected Outpatient Surgical Procedures.***

* New measure for the CY 2012 payment determination.
** New measure for the CY 2013 payment determination.
*** Proposed new measure for the CY 2014 payment determination.

We will calculate the claims-based measures using Medicare FFS claims data and do not require additional hospital data submissions, and we are using the same data submission requirements related to the chart-abstracted quality measures that are submitted directly to CMS that we used for the CY 2011 and CY 2012 payment determinations. For the structural measures, including the collection of all-patient volume for selected outpatient procedures; hospitals will enter data into a Web-based collection tool during a specified collection period once annually. For the collection of HAI data, we are proposing that hospitals would use the NHSN infrastructure and protocol to report the measure for Hospital OQR Program purposes. The NHSN is a Web-based reporting tool hosted by CDC and is provided free of charge to hospitals. Under the Hospital OQR Program requirements, hospitals must complete and submit a notice of participation form for the Hospital OQR Program if they have not already done so or have withdrawn from participation. By submitting this document, hospitals agree that they will allow CMS to publicly report the measures for which they have submitted data under the Hospital OQR Program.

For the CY 2014 payment determination, the burden associated with these requirements (including those previously adopted and those currently proposed) is the time and effort associated with completing the notice of participation form, collecting and submitting the data on the 32 measures. For the chart-abstracted measures where data is submitted directly to CMS, we estimate that there will be approximately 3,200 respondents per year. For hospitals to collect and submit the information on the chart-abstracted measures (including the OP–22 measure for which we are proposing that data be submitted via a Web-based tool rather than via an electronic file) we estimate it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 payment determination and our estimates for the additional proposed measures, we estimate there will be a total of 1,307,510 cases per year, approximately 409 cases per year per respondent. The estimated annual burden associated with the submission requirements for these chart-abstracted

measures is 762,278 hours (1,307,510 cases per year × 0.583 hours per case).

For the structural measures, excluding the proposed all-patient volume for selected surgical procedures measure, we estimate that each participating hospital will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 1,603 hours (3,200 hospitals × 0.167 hours per hospital × 3 structural measures per hospital).

For the collection of data for the proposed HAI Surgical Site Infection measure, we estimate that approximately 1,200 hospitals are participating in the Hospital OQR Program, but are not currently submitting HAI data to the NHSN. Based upon burden estimates associated with the collection of NHSN data currently approved under OCN: 0920–0666, we estimate that additional annual burden associated with this proposed measure will be 17,269 hours (0.533 hr per response × estimated 27 responses per hospital × 1,200 hospitals).

For the proposed collection of all-patient volume for selected outpatient surgical procedures, because hospitals must determine their populations for data reporting purposes and most hospitals are voluntarily reporting population and sampling data for Hospital OQR Program purposes, we believe the only additional burden associated with this proposed requirement would be the reporting of the data using the Web-based tool. We estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with this measure 534 hours (3,200 hospitals × 0.167 hours per hospital).

c. Proposed Hospital OQR Program Measures for CY 2015

For the CY 2015 payment determination, we are proposing to retain the requirement that hospitals must complete and submit a notice of participation form for the Hospital OQR Program. For the CY 2015 payment determination, we also are proposing to retain the measures used for CY 2014 payment determination (including, if adopted, the measures proposed in this proposed rule) and to add one additional HAI measure, Healthcare Personnel (HCP) Influenza Vaccination. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients and reduce disease burden and healthcare costs.

For the CY 2015 payment determination, the burden associated with these proposed requirements is the time and effort associated with completing the notice of participation form, collecting and submitting the data on the proposed measures, and collecting and submitting proposed all-patient volume data for selected outpatient surgical procedures. For the proposed chart-abstracted measures, we estimate that there will be approximately 3,200 respondents per year. For hospitals to collect and submit the information on the proposed chart-abstracted measures where data is submitted directly to CMS, we estimate it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 payment determination and our estimates for the additional proposed measures, we estimate there will be a total of 1,307,510 cases per year, approximately 409 cases per year per respondent. The estimated annual burden associated with the aforementioned proposed submission requirements for the proposed chart-abstracted data is 762,278 hours (1,307,510 cases per year × 0.583 hours per case). For the proposed structural measures, we estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with this proposed measure 1,603 hours (3,200 hospitals × 0.167 hours per hospital × 3 structural measures per hospital).

For the proposed collection of HAI data, we estimate that approximately 1,200 hospitals are participating in the Hospital OQR Program, but are not currently submitting HAI data to the NHSN. We base our burden estimates upon burden estimates associated with the collection of NHSN data currently approved under OCN: 0920–0666. For the proposed Surgical Site Infection HAI measure, we estimate that hospitals will incur an additional burden of 17,269 hours (0.533 hours per response × an estimated 27 responses per hospital × 1,200 hospitals).

For the proposed collection of HCP Influenza Vaccination HAI measure data, we estimate that hospitals will incur an additional burden of 14,400 hours (2.0 hours per response × an estimated 6 responses per hospital × 1,200 hospitals).

For the proposed collection of all-patient volume data for selected outpatient surgical procedures, because hospitals must determine their populations for data reporting purposes and most hospitals are voluntarily reporting population and sampling data for Hospital OQR purposes, we believe the only additional burden associated with this proposed requirement will be the reporting of the data using the Web-based tool. We estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with this proposed measure 534 hours (3,200 hospitals × 0.167 hours per hospital).

We invite public comment on the burden associated with these proposed information collection requirements.

3. Proposed Hospital OQR Program Validation Requirements for CY 2013

In this proposed rule, we are proposing to retain most of the requirements related to data validation for CY 2013 that we adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103 through 72106) for CY 2012, with some revisions. While these requirements are subject to the PRA, they are currently approved under OCN: 0938–1109 and expire October 31, 2013.

Similar to our approach for the CY 2012 Hospital IQR Program payment determination (75 FR 72103 through 72106), we are proposing to validate data from randomly selected hospitals for the CY 2013 payment determination, but we are proposing to reduce the number of hospitals from 800 to 450. We note that, because hospitals would be selected randomly, every hospital participating in the Hospital OQR Program would be eligible each year for validation selection.

In the CY 2011 OPPS/ASC proposed rule and final rule with comment period (75 FR 46381 and 72106, respectively), we discussed additional data validation conditions under consideration for CY 2013 and subsequent years. In this proposed rule, we are proposing to select for validation, up to 50 additional hospitals based upon targeting criteria.

For each selected hospital, we would randomly select up to 48 patient episodes of care per year (12 per quarter) for validation purposes from the total number of cases that the hospital successfully submitted to the OPPS Clinical Warehouse during the applicable time period. However, if a selected hospital submitted less than 12 cases in one or more quarters, only those cases available would be validated.

The burden associated with the proposed CY 2013 requirement is the time and effort necessary to submit validation data to a CMS contractor. We estimate that it would take each of the sampled hospitals approximately 12 hours to comply with these proposed data submission requirements. To

comply with the proposed requirements, we estimate each hospital must submit up to 48 cases for the affected year for review. We are proposing that selected hospitals comply with these requirements per year, which would result in a total of up to 24,000 charts being submitted by the sampled hospitals. The estimated annual burden associated with the proposed data validation process for CY 2013 is approximately 6,000 hours.

We also are proposing to reduce the deadline from 45 days to 30 days for hospitals to submit requested medical record documentation to a CMS contractor to support our validation process. This proposal may create an additional administrative burden for hospitals selected for validation. However, this proposed deadline is in line with our QIO regulations at § 476.78 and the total burden would be the time required to comply with the requirements for copying and mailing in a 30-day period 12 charts for each of four quarters for CY 2013.

We invite public comment on the burden associated with these proposed information collection requirements.

4. Proposed Hospital OQR Program Reconsideration and Appeals Procedures

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a mandatory reconsideration process that applied to the CY 2010 payment decisions. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60654 through 60655), we continued this process for the CY 2011 payment update. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106 through 72108), we continued this process for the CY 2012 payment update with some modifications. We eliminated the requirement that the reconsideration request form be signed by the hospital CEO to facilitate electronic submission of the form and reduce hospital burden. We are proposing to continue this process for the CY 2013 payment determination. While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 regulations excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals.

5. ASC Quality Reporting Program

In this proposed rule, we are proposing to adopt seven claims-based measures for collection beginning in CY 2012 and one NHSN HAI measure of Surgical Site Infection for collection beginning in CY 2013. These measures would be used for the CY 2014 payment determination. We are proposing to collect quality measure data for the seven claims-based measures by using Quality Data Codes (QDCs) placed on submitted claims beginning with services furnished from January 1, 2012 through December 31, 2012. Data collection for the HAI measure would begin with infection events occurring on or after January 1, 2013 through June 30, 2013. The eight proposed measures are:

- Patient Burns (NQF #0263)
- Patient Falls (NQF #0266)
- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)
- Hospital Transfer/Admission (NQF #0265)
- Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)
- Ambulatory Surgery Patients with Appropriate Method of Hair Removal (NQF #0515)
- Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin (NQF #0268)
- Surgical Site Infection Rate (NQF #0299)

Approximately 71 percent of ASCs participate in Medical Event Reporting, which includes reporting on the first four proposed claims-based measures listed above. Between January 1995 and December 2007, ASCs reported 126 events, an average of 8.4 events per year (Florida Medical Quality Assurance, Inc. and Health Services Advisory Group. Ambulatory Surgery Center Environmental Scan (July 2008) (Contract No. GS–10F–0096T).). Thus, we estimate the burden to report QDCs on this number of claims per year for the first four claims-based measures to be nominal due to the small number of cases (less than 1 case per month per ASC).

The remaining proposed claims-based measures concern surgical procedures. We estimate the burden associated with submitting QDCs for these measures to be 465,703 hours (5,577,280 claims per year × 50 percent of claims requiring quality data code information × 0.167 hours per claim). We refer readers to the HHS Report to Congress: Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan, available at the Web site: *https://www.cms.gov/ASCPayment/downloads/C_ASC_RTC%202011.pdf* as the source for the number of ASCs and number of claims per year to calculate ASC burden estimates.

For the collection of the Surgical Site Infection HAI data, we are proposing that ASCs would use the NHSN infrastructure and protocol to report the measure for ASC Quality Reporting Program purposes discussed above.

For the Surgical Site Infection HAI measure, we estimate that it will require ASCs an additional 8,275 hours (0.533 hours per response x an estimated 3 responses per ASC × 5,175 ASCs). We base the time per response for our burden estimate on burden estimates associated with the collection of NHSN data currently approved under OCN: 0920–0666, and the number of ASCs from the HHS Report to Congress: Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan, available at the Web site: *https://www.cms.gov/ASCPayment/downloads/C_ASC_RTC%202011.pdf*.

For CY 2015 payment determination, we are proposing to retain the eight measures we are proposing to adopt for CY 2014 payment determination (if they are adopted) and we are proposing to add two structural measures.

For the structural measures, we are proposing that ASCs would enter required information using a Web-based collection tool between July 1, 2013 and August 15, 2013. For the Safe Surgery Checklist Use structural measure, we estimate that each participating ASC will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 864 hours (5,175 ASCs × 0.167 hours per ASC).

For the ASC Facility Volume Data on Selected ASC Surgical Procedures structural measure, we estimate that each participating ASC will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure, 864 hours (5,175 ASCs × 0.167 hours per ASC).

For the CY 2016 payment determination, we are proposing to retain the ten measures we are proposing to adopt for the CY 2015 payment determination (if they are adopted), and are proposing to add one structural measure, Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

We estimate that each participating ASC will spend 10 minutes per year to collect and submit the data via a Web-based tool, making the estimated annual burden associated with this proposed measure 864 hours (5,175 ASCs × 0.167 hours per ASC).

6. Proposed 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs

Under 42 CFR 495.6(f)(9), we require eligible hospitals and CAHs participating in the Medicare EHR

Incentive Program (which would include those participating in the proposed 2012 Medicare EHR Incentive Program Electronic Reporting Pilot) to successfully report hospital clinical quality measures (CQMs) to CMS in the manner specified by CMS. Although we are proposing that eligible hospitals and CAHs may continue to attest CQMs in 2012, they may also choose to participate in the proposed 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs. We are proposing that eligible hospitals and CAHs participating in the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot must submit CQM data on all 15 CQMs (listed in Table 10 of the final rule (75 FR 44418 through 44420) for the Medicare and Medicaid EHR Incentive Program) to CMS, via a secure portal based on data obtained from the eligible hospital's or CAH's certified EHR technology.

Eligible hospitals and CAHs are required to report on core and menu set criteria for Stage 1 meaningful use. The reporting of clinical quality measures is part of the core set. We estimate that it would take an eligible hospital or CAH 0.5 hour to submit the required CQM information via the proposed 2012 Medicare EHR Incentive Program Electronic Reporting Pilot. Therefore, the estimated total burden for all 4,922 Medicare eligible hospitals and CAHs participating in the reporting Pilot (3,620 acute care hospitals and 1,302 CAHs) is 2,461 hours.

We believe that an eligible hospital or CAH might assign a Computer and Information Systems Managers to submit the CQM information on their behalf. We estimate the cost burden for an eligible hospital or CAH to submit the CQMs and hospital quality requirements is $29.64 (0.5 hour × $59.27 (mean hourly rate for computer and information systems managers based on the 2010 Bureau of Labor Statistics)) and the total estimated annual cost burden for all eligible hospitals and CAHs to submit the required CQMs is $145,889 ($29.64 × 4,922 hospitals and CAHs). We are soliciting public comments on the estimated numbers of eligible hospitals and CAHs that may registered for the Medicare EHR Incentive Program Electronic Reporting Pilot that would submit the CQM information via the proposed Electronic Reporting Pilot in FY 2012. We also invite public comments on the type of personnel or staff that would mostly likely submit on behalf of eligible hospitals and CAHs.

7. Additional Topics

In addition to seeking OMB approval for the proposed information collection requirements associated with the Hospital OQR Program, we are seeking public comment on several issues that may ultimately affect the burden associated with the Hospital OQR Program. Specifically, in this proposed rule, we are proposing to retain measures for the CY 2015 payment determinations, adopt new measures for the CY 2014 and CY 2015 payment determinations, and we are seeking comments on other possible measures under consideration for adoption into the Hospital OQR Program. We also are soliciting public comments on collecting chart-abstracted data for one measure for the CY 2013 payment determination via a Web-based tool, and on the continued use of an extraordinary circumstance extension or waiver for reporting quality data, and additional data validation conditions that we are considering adopting beginning with the CY 2014 payment determination.

We also are seeking public comment on our proposals for an ASC Quality Reporting Program for the ASC payment determinations for CYs 2014, 2015 and 2016.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.hhs.gov/Paperwork@cms.hhs.gov*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, (CMS–1525–P)

Fax: (202) 395–6974; or

E-mail: *OIRA_submission@omb.eop.gov*.

XIX. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XX. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated as an ''economically'' significant rule under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. We have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of the proposed rule. We are soliciting public comments on the Regulatory Impact Analysis provided.

2. Statement of Need

This proposed rule requests public comment on the CMS proposal to update the Medicare hospital outpatient prospective payment rates and the ambulatory surgical center prospective payment rates for CY 2012. The proposed rule is necessary to enable CMS to acquire and consider the public comments on the proposed changes to payment policies and payment rates for services furnished by hospitals and CMHCs to outpatients for CY 2012. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor

used to determine the APC payment rates. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. In addition, we must review the clinical integrity of payment groups and weights at least annually.

This proposed rule also requests public comment on the CMS proposal to update the ASC payment rates for CY 2012. The proposed rule is necessary to enable CMS to acquire and consider public comments on the proposed changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC for CY 2012. Because the ASC payment rates are based on the OPPS relative weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS weights. In addition, because the services provided in ASCs are identified by HCPCS codes which are reviewed and revised either quarterly or annually, depending on the HCPCS codes, it is necessary to update the ASC payment rates annually to reflect these changes to HCPCS codes. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC not less often than every 2 years.

Section 1833(t)(17) of the Act requires that subsection (d) hospitals that fail to meet quality reporting requirements under the Hospital OQR Program to incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor. In section XIV. of this proposed rule, we are proposing additional policies affecting the Hospital OQR Program for CY 2013, CY 2014, and CY 2015 that hospitals would have to meet in order to receive the full OPD fee schedule increase factor. We are soliciting public comments on these proposed additional policies.

In this proposed rule, to further implement section 6001(a)(3) of the Affordable Care Act, we set forth the proposed process for a hospital to request an exception to the prohibition on expansion of facility capacity under the whole hospital and rural provider exceptions to the physician self-referral prohibition. We also set forth a related proposal for amendments to the patient safety requirements in the provider agreement regulations. We are soliciting public comments on these proposed changes.

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals for discharges occurring on or after October 1, 2012. In this proposed rule, we are proposing to add one chart-abstracted measure for the FY 2014 payment determination under the Hospital Inpatient VBP Program. We are soliciting public comments on this proposed additional measure.

Section 109(b) of the MIEA TRHCA states that the Secretary may implement a quality reporting system for ASCs in a manner so as to provide for a reduction of 2.0 percentage point s in any annual update with respect to the year involved, for failure to report on quality measures. In this proposed rule, we are proposing to establish an ASC Quality Reporting Program with the collection of seven quality measures beginning in CY 2012.

3. Overall Impacts for Proposed OPPS and ASC Provisions

We estimate that the effects of the proposed OPPS provisions that would be implemented by this proposed rule would result in expenditures exceeding $100 million in any 1 year. We estimate the total increase (from proposed changes in this proposed rule as well as enrollment, utilization, and case-mix changes) in expenditures under the OPPS for CY 2012 compared to CY 2011 to be approximately $3.285 billion. Because this proposed rule for the OPPS is ''economically significant'' as measured by the $100 million threshold and also a major rule under the Congressional Review Act, we have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this rulemaking. Table 51 of this proposed rule displays the redistributional impact of the proposed CY 2012 changes on OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the effects of the proposed ASC provisions that would be implemented by this proposed rule for the ASC payment system would result in expenditures exceeding $100 million in any one year. We estimate the total increase (from proposed changes in this proposed rule as well as enrollment, utilization, and case-mix changes) in expenditures under the ASC payment system for CY 2012 compared to CY 2011 to be approximately $224 million. Because this proposed rule for the ASC payment system is ''economically significant'' as measured by the $100 million threshold and also a major rule under the Congressional Review Act, we have prepared a regulatory impact analysis of changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this rulemaking. Table 52 and Table 53 of this proposed rule display the redistributional impact of the CY 2012 proposed changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Effects of Proposed OPPS Changes in This Proposed Rule

We are proposing to update the OPPS payment rates and to revise several OPPS payment policies for CY 2012. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the conversion factor used to determine the APC payment rates. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. In addition, we must review the clinical integrity of payment groups and weights at least annually. Consistent with our historical proactice in this proposed rule, we are proposing to update the conversion factor and the wage index adjustment for hospital outpatient services furnished beginning January 1, 2012, as we discuss in sections II.B. and II.C., respectively, of this proposed rule. We discuss our implementation of section 10324 of the Affordable Care Act, as amended by HCERA, authorizing a wage index of 1.00 for certain frontier States. We also are proposing to revise the relative APC payment weights using claims data for services furnished on and after January 1, 2010, through and including December 31, 2010, and updated cost report information. We are proposing to continue the current payment adjustment for rural SCHs, including EACHs. Finally, we list the 19 drugs and biologicals in Table 26 of this proposed rule that we are proposing to remove from pass-through payment status for CY 2012.

Under this proposed rule, we estimate that the update change to the conversion factor and other adjustments (but not including the effects of outlier payments, pass-through estimates, and the application of the frontier State wage adjustment for CY 2012), would increase total OPPS payments by 1.5 percent in CY 2012. The proposed changes to the APC weights, the changes to the wage indices, the continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed

payment adjustment for cancer hospitals would not increase OPPS payments because these changes to the OPPS are budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system as shown in Table 51 below and described in more detail in this section. We also estimate that the total proposed change in payments between CY 2011 and CY 2012, considering all payments, including proposed changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the proposed OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F) and 1833(t)(3)(G) of the Act, would increase total estimated OPPS payments by 1.5 percent.

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2012 policy changes on various hospital groups. We post on the CMS Web site our hospital-specific estimated payments for CY 2012 with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/.* At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1525–P'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 51 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A.2. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service mix, or number of encounters. As we have done in previous rules, we are soliciting public comment and information about the anticipated effects of our proposed changes on providers and our methodology for estimating them.

(2) Estimated Effects of This Proposed Rule on Hospitals

Table 51 below shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the proposed change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers because we include CMHCs in our weight scalar estimate. As discussed in section II.F. of this proposed rule, we are proposing to extend an adjustment to certain cancer hospitals under section 3138 of the Affordable Care Act. Because these hospitals would continue to be eligible to receive hold harmless payments (under our standard policy), we now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs, and we also include a column that shows the impact on other hospitals of the proposed budget neutral cancer adjustment.

We present separate impacts for CMHCs in Table 51 because CMHCs are paid only for partial hospitalization services and CMHCs are a different provider type from hospitals. In CY 2011, we are paying CMHCs under APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), and we are paying hospitals for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). For CY 2012, we are proposing to continue this APC payment structure and to base payment fully on the median costs calculated using claims and cost report data for the type of provider for which rates are being set, that is, hospital or CMHC. We display the impact on CMHCs of this proposed policy below, and we discuss the impact on hospitals as part of our discussion of the impact of proposed changes on hospitals for CY 2012.

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor set under the methodology in the statute. The distributional impacts presented do not include assumptions about changes in volume and service mix. Section 1833(t)(3)(C)(iv) of the Act provides that, for purposes of this subparagraph subject to paragraph (17) and subparagraph (F) of this paragraph, the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act. The proposed market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket in this discussion, is 2.8 percent. However, section 1833(t)(3)(F)(i) of the Act reduces that 2.8 percent by the proposed productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act which we propose to be 1.2 percentage points (which is the MFP adjustment for FY 2012 as proposed in the FY 2012 IPPS/LTCH proposed rule), and section 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act further reduce the amount by 0.1 percentage point, resulting in the OPD fee schedule increase factor of 1.5 percent, which we are proposing to use in the calculation of the CY 2012 OPPS proposed conversion factor. We refer readers to section II.B. of this proposed rule for a detailed discussion of the calculation of the conversion factor and the source of its components. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index of 1.00. The amounts attributable to this frontier State wage index adjustment are incorporated into the CY 2012 estimates in Table 51.

Table 51 shows the estimated redistribution of hospital and CMHC payments among providers as a result of APC reconfiguration and recalibration; wage indices and the rural adjustment; the combined impact of the APC recalibration, wage and rural adjustment effects, and the OPD fee schedule increase factor update to the conversion factor; the effect of the proposed budget neutral adjustment to payments made to the 11 cancer hospitals that meet the classification criteria in section 1886(d)(1)(B)(v) of the Act; the frontier State wage index adjustment; and, finally, estimated redistribution considering all proposed payments for CY 2012 relative to all payments for CY 2011, including the impact of changes in estimated outlier payments, and changes to the pass-through payment estimate. We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are not proposing to make any changes to the policy for CY 2012. Because the proposed updates to the conversion factor (including the update of the OPD fee schedule increase factor, that is, the proposed IPPS market basket amount

less the productivity adjustment required by section 1833(t)(3)(F)(i) of the Act and less the adjustment required by sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act; the subtraction of the estimated cost of the cancer adjustment; the subtraction of the estimated cost of the rural adjustment; and the subtraction of the estimated cost of projected pass-through payment for CY 2012), are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also would depend on changes in volume, practice patterns, and the mix of services billed between CY 2011 and CY 2012 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed OPPS rates for CY 2012 would have a positive effect for providers paid under the OPPS, resulting in a 1.5 percent estimated increase in Medicare payments. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs suggest that these proposed changes would result in a 1.1 percent estimated increase in Medicare payments to all other hospitals.

To illustrate the impact of the proposed CY 2012 changes, our analysis begins with a baseline simulation model that uses the final CY 2011 weights, the FY 2011 final IPPS wage indices that include reclassifications, and the final CY 2011 conversion factor. Column 2 in Table 51 shows the independent effect of the proposed changes resulting from the reclassification of services among APC groups and the recalibration of APC weights, based on 12 months of CY 2010 OPPS hospital claims data and the most recent cost report data. We modeled the effect of the proposed APC recalibration changes for CY 2012 by varying only the weights (the final CY 2011 weights versus the proposed CY 2012 weights calculated using the service mix and volume in the CY 2010 claims used for this proposed rule) and calculating the percent difference in weight. Column 2 also reflects the effect of the proposed changes resulting from the APC reclassification and recalibration changes and any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the proposed changes in the relative magnitude of payment weights.

Column 3 reflects the independent effects of the proposed updated wage indices, including the proposed application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the frontier State wage index adjustment, which is not budget neutral and is included in Column 6. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are not proposing to make any changes to the policy for CY 2012. We modeled the independent effect of updating the wage indices by varying only the wage indices, holding APC relative weights, service mix, and the rural adjustment constant and using the proposed CY 2012 scaled weights and a CY 2011 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indices between CY 2011 and CY 2012.

Column 4 demonstrates the independent effect of the proposed cancer hospital payment adjustment. For CY 2012 we are proposing to make additional payment to raise each cancer hospital's payment to cost ratio (PCR) to the weighted average PCR for all other hospitals paid under the OPPS. We are proposing to accomplish this by adjusting each cancer hospital's OPPS payment by the percentage difference between their individual PCR (without TOPs) and the weighted average PCR of the other hospitals paid under the OPPS. This results in an increase in estimated payments to cancer hospitals of 38.8 percent compared to the estimated payment that would have been made under the OPPS to these hospitals as a class in CY 2011, but does not represent the estimated net increase in payment to cancer hospitals for CY 2012. After accounting for TOPs that we estimate cancer hospitals would no longer receive as a result of increased payment under the OPPS, the net increase in estimated payment to cancer hospitals for CY 2012 would be approximately 9 percent.

Column 5 demonstrates the combined ''budget neutral'' impact of proposed APC recalibration (that is, Column 2), the wage index update (that is, Column 3), as well as the impact of updating the conversion factor with the OPD fee schedule increase factor, the proposed 2.8 percent hospital market basket update less the multifactor productivity adjustment required by section 1833(t)(3)(F)(i) of the Act which we are proposing to be 1.2 percentage points, and less the 0.1 percentage point reduction required by sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act, which resulted in an OPD fee schedule increase factor of 1.5 percent). We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the weights and wage indices for each year, and using a CY 2011 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indices.

Column 6 demonstrates the cumulative impact of the proposed budget neutral adjustments from Columns 2 through 4, and the OPD fee schedule increase factor of 1.5 percent reflected in Column 5, combined with the non-budget neutral frontier State wage index adjustment, discussed in section II.C.1. of this proposed rule. This differs from Column 5 solely based on application of the proposed nonbudget neutral frontier Stage wage index adjustment.

Column 7 depicts the full impact of the proposed CY 2012 policies on each hospital group by including the effect of all the proposed changes for CY 2012 (including the APC reconfiguration and recalibration shown in Column 2) and comparing them to all estimated payments in CY 2011. Column 7 shows the combined budget neutral effects of Columns 2 through 4, plus the impact of the frontier State wage index adjustment; the proposed change to the fixed-dollar outlier threshold from $2,025 to $2,100 as discussed in section II.G. of this proposed rule; the change in the hospital OQR payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV.E. of this proposed rule); and the impact of increasing the estimate of the percentage of total OPPS payments dedicated to transitional pass-through payments. Of the 107 hospitals that failed to meet the OQR reporting requirements for the full CY 2011 update (and assumed, for modeling purposes, to be the same number for CY 2012), we included 30 hospitals in our model because they had both CY 2010 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2012 would increase payments to all providers by 1.5 percent for CY 2012. We modeled the independent effect of all changes in Column 7 using the final weights for CY 2011 and the proposed weights for CY 2012. We used the final conversion factor for CY 2011 of $68.876 and the proposed CY 2012 conversion factor of $69.420 discussed

in section II.B. of this proposed rule in this model.

Column 7 also contains simulated outlier payments for each year. We used the charge inflation factor used in the FY 2012 IPPS/LTCH PPS proposed rule of 9.08 percent (1.0908) to increase individual costs on the CY 2010 claims, and we used the most recent overall CCR in the April 2011 Outpatient Provider-Specific File (OPSF) (76 FR 26025). Using the CY 2010 claims and a 4.44 percent charge inflation factor, we currently estimate that outlier payments for CY 2011, using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,025 should be approximately 1.1 percent of total payments. Outlier payments of 1.1 percent are incorporated in the CY 2011 comparison in Column 6. We used the same set of claims and a charge inflation factor of 9.08 percent (1.0908) and the CCRs in the April 2011 OPSF, with an adjustment of 0.9850, to reflect relative changes in cost and charge inflation between CY 2010 and CY 2012, to model the CY 2012 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,100.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 51 shows the total number of facilities (4,141), including designated cancer and children's hospitals and CMHCs for which we were able to use CY 2010 hospital outpatient and CMHC claims to model CY 2011 and CY 2012 payments, by classes of hospitals. We excluded all hospitals for which we could not accurately estimate CY 2011 or CY 2012 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a disproportionate share (DSH) variable for hospitals not participating in the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number (3,879) of OPPS hospitals, excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute and, therefore, we removed them from our impact analyses. We show the isolated impact on 200 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: Proposed APC Changes Due to Reassignment and Recalibration

This column shows the combined effects of the proposed reconfiguration, recalibration, and other policies (such as setting payment for separately payable drugs and biologicals at ASP+4 percent with an accompanying reduction in the amount of cost associated with packaged drugs and biologicals and changes in payment for PHP services). Overall, we estimate that proposed changes in APC reassignment and recalibration across all services paid under the OPPS would increase payments to urban hospitals by 0.2 percent. We estimate that both large and other urban hospitals would experience an increase of 0.2 percent, all attributable to recalibration. We estimate that urban hospitals billing fewer than 21,000 lines for OPPS services would experience decreases ranging from 0.2 percent to 5.5 percent. The decrease of 5.5 percent for urban hospitals billing fewer than 5,000 lines per year is attributable to the decline in the proposed payment for APC 0034 (Mental Health Services Composite), for which the payment rate is proposed to be set at the payment rate for APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). Urban hospitals billing 21,000 or more lines for OPPS services would experience increases of 0.1 to 0.5 percent.

Overall, we estimate that rural hospitals would experience an increase of 0.2 percent as a result of changes to the APC structure. We estimate that rural hospitals of all bed sizes would experience increases of 0.1 to 0.5 percent as a result of the proposed APC recalibration. We estimate that rural hospitals that report fewer than 5,000 lines for OPPS services would experience a decrease of 1.2 percent, while rural hospitals that report 5,000 or more lines for OPPS services would experience an increase of 0.1 to 0.9 percent in payment as a result of proposed APC recalibration.

Among teaching hospitals, we estimate that the impact resulting from APC recalibration would include a decrease of 0.1 percent for major teaching hospitals and an increase of 0.3 for minor teaching hospitals and nonteaching hospitals.

Classifying hospitals by type of ownership suggests that voluntary, proprietary, and governmental hospitals would experience no change or estimated increases of 0.1 to 0.3 percent as a result of the proposed APC recalibration. Finally, we estimate that hospitals for which DSH payments are not available would experience a decrease of 7.5 to 7.7 percent. Hospitals for which DSH is not available furnish a large number of psychiatric services and we believe that the proposed decline in payment for APC 0176 is the cause for this estimated decline in payment.

Column 3: Proposed New Wage Indices and the Effect of the Rural Adjustment

This column estimates the impact of applying the proposed FY 2012 IPPS wage indices for the CY 2012 OPPS without the influence of the frontier State wage index adjustment which is not budget neutral. The frontier State wage index adjustment is reflected in the combined impact shown in Columns 6 and 7. We are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2012, as described in section II.E.2. of this proposed rule. We estimate that the combination of updated wage data and nationwide application of rural floor budget neutrality would redistribute payment among regions. We also updated the list of counties qualifying for the section 505 out-migration adjustment. Overall, we estimate that urban hospitals would experience no change from CY 2011 to CY 2012, and that rural hospitals would experience decreases of 0.2 to 0.4 percent as a result of the updated wage indices. We estimate that hospitals located in urban New England, Middle Atlantic, West North Central, West South Central, and Puerto Rico regions would experience increases of 0.1 to 0.5 percent while other urban regions would experience no change or decreases of 0.2 to 0.7 percent. Hospitals in urban New England are expected to see an increase of 3.8 percent as a result of the implementation of the rural floor. See section II.C. for more information. We estimate that hospitals in rural West North Central, West South Central, and Pacific States would experience increases of 0.1 to 0.5 percent, respectively, while other rural regions would experience decreases from 0.2 to 0.7 percent.

Column 4: Proposed Cancer Hospital Payment Adjustment

This column estimates the budget neutral impact of applying the proposed hospital-specific CY 2012 cancer adjustment authorized by section 3138 of the Affordable Care Act, which would

result in an estimated aggregate increase in OPPS payments to dedicated cancer hospitals of 38.8 percent for the CY 2012 OPPS. After accounting for TOPs that we estimate would no longer be made, the net impact would result in an increase in payment to these hospitals of approximately 9 percent. We estimate that all other hospitals would experience a decrease of 0.6 to 0.7 percent in CY 2012 as result of the adjustment to payments to the cancer hospitals under this proposed payment adjustment.

Column 5: All Proposed Budget Neutrality Changes Combined With the Proposed OPD Fee Schedule Increase

We estimate that, for most classes of hospitals, the addition of the proposed OPD fee schedule increase factor of 1.5 percent would mitigate the negative impacts created by the budget neutrality adjustments made in Columns 2 and 3. While all other classes of hospitals would receive an increase after the update is applied to the budget neutrality adjustments, urban hospitals that bill fewer than 11,000 lines and rural hospitals that report fewer than 5,000 lines would experience decreases. In particular, urban hospitals that report fewer than 5,000 lines would experience a cumulative decrease, after application of the proposed OPD fee schedule increase factor and the budget neutrality adjustments, of 4.3 percent, largely as a result of the proposed decrease in payment for APC 0034 (Mental Health Services Composite). OPPS payment for APC 0034 is proposed to continue being set to the payment rate of APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs), which experienced a decline based on updated cost report and hospital claims data.

Overall, we estimate that these proposed changes would increase payments to urban hospitals by 1.1 percent. We estimate that large urban hospitals and ''other'' urban hospitals would also experience an increase of 1.1 percent. We estimate that rural hospitals would experience a 0.8 percent increase as a result of the proposed OPD fee schedule increase factor and other budget neutrality adjustments.

Among teaching hospitals, we estimate that the observed impacts resulting from the proposed OPD fee schedule increase factor and other budget neutrality adjustments would include an increase of 1.2 percent for major teaching hospitals and an increase of 1.0 percent for minor teaching hospitals.

Classifying hospitals by type of ownership suggests that proprietary hospitals would experience an estimated increase of 0.7 percent, while voluntary hospitals would experience an estimated increase of 1.2 percent and government hospitals would experience an estimated increase of 0.6 percent.

Column 6: Proposed Frontier State Wage Index Adjustment

This column shows the impact of all budget neutrality adjustments, application of the proposed 1.5 percent OPD fee schedule increase factor, and the non-budget neutral impact of applying the proposed frontier State wage adjustment (that is, the proposed frontier State wage index change in addition to all changes reflected in Column 4). In general, we estimate that all facilities would experience a combined increase of 1.6 percent and that all hospitals would experience a combined increase of 1.1 percent. Hospitals in the rural Mountain region would experience an increase of 2.3 percent, most of which is attributable to the proposed frontier State wage adjustment. Similarly, hospitals in both the urban and rural West North Central region would experience an increase of 1.8 percent, most of which is attributable to the proposed frontier State wage adjustment.

Column 7: All Proposed Changes for CY 2012

Column 7 compares all proposed changes for CY 2012 to estimated final payment for CY 2011, including the proposed changes in the outlier threshold, payment reductions for hospitals that failed to meet the OQR reporting requirements, and the difference in pass-through estimates that are not included in the combined percentages shown in Column 5. This column includes estimated payment for a few hospitals receiving reduced payment because they did not meet their hospital outpatient quality measure reporting requirements; however, we estimate that the anticipated change in payment between CY 2011 and CY 2012 for these hospitals would be negligible. (We further discuss the estimated impacts of hospitals' failure to meet these requirements below in section XX.A.4.d. of this proposed rule.) Overall, we estimate that facilities would experience an increase of 1.5 percent under this proposed rule in CY 2012 relative to total spending in CY 2011. The projected 1.5 percent increase for all facilities in Column 7 of Table 51 reflects the proposed 1.5 percent OPD fee schedule increase factor, less 0.00 percent for the change in the pass-through estimate between CY 2011 and CY 2012, less 0.06 percent for the difference in estimated outlier payments between CY 2011 (1.06 percent) and CY 2012 (1.0 percent), less 0.09 percent due to the section 508 wage adjustment, plus 0.10 percent due to the frontier State wage index adjustment. When we exclude cancer and children's hospitals (which are held harmless to their pre-BBA amount) and CMHCs, the estimated increase is 1.5 percent after rounding.

We estimate that the combined effect of all proposed changes for CY 2012 would increase payments to urban hospitals by 1.2 percent. We estimate that large urban hospitals would experience a 1.1 percent increase, while ''other'' urban hospitals would experience an increase of 1.2 percent. We estimate that urban hospitals that bill less than 5,000 lines of OPPS services would experience a decrease of 4.2 percent, largely attributable to the proposed decline in payment for APC 0034 (Mental Health Services Composite). We estimate that urban hospitals that bill 11,000 or more lines of OPPS services would experience increases between 0.6 percent and 1.5 percent, while urban hospitals that report between 5,000 and 10,999 lines would experience a decrease of 0.8 percent.

Overall, we estimate that rural hospitals would experience a 0.9 percent increase as a result of the combined effects of all proposed changes for CY 2012. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services would experience a decrease of 0.7 percent and that rural hospitals that bill 5,000 or more lines of OPPS services would experience increases ranging from 0.8 to 1.7 percent.

Among teaching hospitals, we estimate that the impacts resulting from the combined effects of all proposed changes would include an increase of 1.2 percent for major teaching hospitals and 1.1 percent for minor teaching hospitals and non-teaching hospitals.

In our analysis, we have also stratified hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would receive an increase of 1.3 percent, proprietary hospitals would receive an increase of 0.8 percent, and governmental hospitals would experience an increase of 0.7 percent.

(3) Estimated Effects of This Proposed Rule on CMHCs

The last line of Table 51 demonstrates the isolated impact on CMHCs. In CY 2011, CMHCs are paid under four APCs for services under the OPPS: APC 0172

(Level I Partial Hospitalization (3 services) for CMHCs); APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs); APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs); and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). We implemented these four APCs for CY 2011. We adopted payment rates for each APC based on the cost data derived from claims and cost reports for the provider type to which the APC is specific and provided a transition to CMHC rates based solely on CMHC data for the two CMHC PHP per diem rates. For CY 2012, we are proposing to continue the four APC provider-specific structure we adopted for CY 2011 and to base payment fully on the cost data for the type of provider furnishing the service. We modeled the impact of this APC policy assuming that CMHCs would continue to provide the same number of days of PHP care, with each day having either 3 services or 4 or more services, as seen in the CY 2010 claims data used for this CY 2012 OPPS/ASC proposed rule. We excluded days with one or two services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. Because the relative payment weights for APC 0172 and APC 0173 for CMHCs both decline in CY 2012 due to CMHC cost data for partial hospitalization services provided by CMHCs, we estimate that there would be a 34.2 percent decrease in payments to CMHCs due to these APC policy changes (shown in Column 2).

Column 3 shows that the estimated impact of adopting the proposed CY 2012 wage index values have no influence on payments to CMHCs. Column 4 shows that CMHCs would receive a 0.7 percent reduction as a result of the proposed cancer hospital adjustment. We note that all providers paid under the OPPS, including CMHCs, would receive a proposed 1.5 percent OPD fee schedule increase factor. Column 5 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2012 and the proposed CY 2012 wage index updates, results in an estimated decrease of 33.2 percent. Column 6 shows that adding the frontier State wage adjustment results in no change to the cumulative 33.2 percent decrease. Column 7 shows that adding the proposed changes in outlier and pass-though payments would result in a 33.1 percent decrease in payment for CMHCs that reflects all proposed changes for CY 2012.

The impact of the changes to hospital payment rates for partial hospitalization services is reflected in the impact of all proposed changes on hospitals. The impact of the decline in payment for APC 0034 appears most notably in small urban hospitals that furnish primarily outpatient psychiatric services.

All providers paid under the OPPS would receive a proposed 1.5 percent OPD fee schedule increase factor under this policy. Combining this proposed OPD fee schedule increase factor with proposed changes in APC policy for CY 2012, the proposed CY 2012 wage index updates, and with proposed changes in outlier and pass-through payments, we estimate that the combined impact on hospitals within the OPPS system would be a 1.5 percent increase in total payment for CY 2012. Table 51 presents the estimated impact of the proposed changes to the OPPS for CY 2012.

TABLE 51—ESTIMATED IMPACT OF THE CY 2012 PROPOSED CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Number of hospitals	APC Recalibration	New wage index and rural adjustment	New cancer hospital payment adjustment	Comb (cols 2, 3,4) with market basket update	Comb (col 5) with frontier wage index adjustment	All changes
ALL FACILITIES *	4,141	0.0	0.0	0.0	1.5	1.6	1.5
ALL HOSPITALS	3,879	0.2	0.0	−0.6	1.0	1.1	1.1
(Excludes hospitals permanently held harmless and CMHCs)							
URBAN HOSPITALS	2,928	0.2	0.0	−0.6	1.1	1.2	1.2
LARGE URBAN (GT 1 MILL.)	1,592	0.2	0.0	−0.7	1.1	1.1	1.1
OTHER URBAN (LE 1 MILL.)	1,336	0.2	0.0	−0.6	1.1	1.3	1.2
RURAL HOSPITALS	951	0.2	−0.3	−0.7	0.8	1.0	0.9
SOLE COMMUNITY	385	0.1	−0.2	−0.6	0.8	1.3	0.9
OTHER RURAL	566	0.3	−0.4	−0.7	0.8	0.8	0.9
BEDS (URBAN):							
0–99 BEDS	1,007	−0.1	0.1	−0.7	0.8	0.9	0.8
100–199 BEDS	856	0.4	0.1	−0.7	1.3	1.4	1.3
200–299 BEDS	445	0.4	0.1	−0.7	1.3	1.5	1.4
300–499 BEDS	417	0.2	−0.1	−0.6	1.0	1.0	1.0
500 + BEDS	203	0.0	0.1	−0.6	1.0	1.0	1.1
BEDS (RURAL):							
0–49 BEDS	340	0.2	−0.1	−0.7	0.9	1.1	1.0
50–100 BEDS	364	0.1	−0.3	−0.6	0.6	0.9	0.7
101–149 BEDS	140	0.5	−0.2	−0.7	1.1	1.3	1.2
150–199 BEDS	60	0.2	−0.4	−0.7	0.6	1.2	0.7
200 + BEDS	47	0.1	−0.3	−0.6	0.8	0.8	0.8
VOLUME (URBAN):							
LT 5,000 Lines	611	−5.5	0.4	−0.7	−4.3	−4.2	−4.2
5,000–10,999 Lines	146	−1.5	−0.1	−0.7	−0.8	−0.6	−0.8
11,000–20,999 Lines	255	−0.2	−0.1	−0.7	0.6	0.6	0.6
21,000–42,999 Lines	490	0.5	−0.1	−0.7	1.2	1.2	1.2
42,999–89,999 Lines	738	0.5	0.1	−0.7	1.5	1.5	1.5
GT 89,999 Lines	688	0.1	0.0	−0.6	1.0	1.1	1.1

TABLE 51—ESTIMATED IMPACT OF THE CY 2012 PROPOSED CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM—Continued

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Number of hospitals	APC Recalibration	New wage index and rural adjustment	New cancer hospital payment adjustment	Comb (cols 2, 3,4) with market basket update	Comb (col 5) with frontier wage index adjustment	All changes
VOLUME (RURAL):							
LT 5,000 Lines	71	−1.2	−0.2	−0.7	−0.7	1.4	−0.7
5,000–10,999 Lines	81	0.9	0.1	−0.7	1.8	1.9	1.7
11,000–20,999 Lines	184	0.3	−0.3	−0.7	0.8	1.0	0.8
21,000–42,999 Lines	286	0.4	−0.3	−0.7	0.9	1.2	1.0
GT 42,999 Lines	329	0.1	−0.3	−0.6	0.7	0.9	0.8
REGION (URBAN):							
NEW ENGLAND	150	0.0	3.8	−0.6	4.6	4.6	4.4
MIDDLE ATLANTIC	351	0.1	0.1	−0.6	1.1	1.1	1.0
SOUTH ATLANTIC	452	0.3	−0.6	−0.7	0.6	0.6	0.7
EAST NORTH CENT	469	0.3	−0.6	−0.6	0.6	0.6	0.6
EAST SOUTH CENT	184	0.4	−0.7	−0.6	0.5	0.5	0.7
WEST NORTH CENT	193	0.1	0.1	−0.6	1.1	1.8	1.3
WEST SOUTH CENT	489	0.3	0.3	−0.7	1.4	1.4	1.5
MOUNTAIN	202	0.2	0.0	−0.6	1.0	1.4	1.2
PACIFIC	390	0.0	−0.2	−0.7	0.7	0.7	0.8
PUERTO RICO	48	0.3	0.5	−0.7	1.6	1.6	1.7
REGION (RURAL):							
NEW ENGLAND	26	−0.5	−0.5	−0.6	−0.1	−0.1	0.1
MIDDLE ATLANTIC	68	0.2	−0.2	−0.6	0.9	0.9	1.0
SOUTH ATLANTIC	162	0.4	−0.2	−0.7	1.0	1.0	1.1
EAST NORTH CENT	126	0.2	−0.7	−0.7	0.4	0.4	0.3
EAST SOUTH CENT	172	0.6	−0.6	−0.7	0.8	0.8	0.9
WEST NORTH CENT	101	−0.4	0.2	−0.6	0.7	1.8	1.0
WEST SOUTH CENT	201	0.4	0.1	−0.7	1.3	1.3	1.3
MOUNTAIN	66	0.2	−0.6	−0.6	0.5	2.3	0.5
PACIFIC	29	0.1	0.5	−0.6	1.5	1.5	1.7
TEACHING STATUS:							
NON-TEACHING	2,891	0.3	−0.1	−0.7	1.0	1.1	1.1
MINOR	699	0.3	−0.1	−0.6	1.0	1.2	1.1
MAJOR	289	−0.1	0.4	−0.6	1.2	1.2	1.2
DSH PATIENT PERCENT:							
0	7	−0.7	0.0	−0.7	0.1	0.1	0.3
GT 0–0.10	343	0.2	0.2	−0.7	1.2	1.3	1.3
0.10–0.16	359	0.4	−0.4	−0.7	0.8	0.9	0.8
0.16–0.23	733	0.3	0.0	−0.7	1.1	1.3	1.1
0.23–0.35	1,037	0.3	0.0	−0.6	1.2	1.3	1.2
GE 0.35	789	0.1	0.1	−0.6	1.0	1.0	1.2
DSH NOT AVAILABLE**	611	−7.5	0.5	−0.7	−6.2	−6.2	−6.1
URBAN TEACHING/DSH:							
TEACHING & DSH	901	0.2	0.1	−0.6	1.1	1.2	1.2
NO TEACHING/DSH	1,446	0.4	−0.1	−0.7	1.2	1.2	1.3
NO TEACHING/NO DSH	6	−0.7	0.0	−0.7	0.1	0.1	0.3
DSH NOT AVAILABLE**	575	−7.7	0.6	−0.7	−6.3	−6.3	−6.2
TYPE OF OWNERSHIP:.							
VOLUNTARY	2,060	0.3	0.1	−0.6	1.2	1.3	1.3
PROPRIETARY	1,259	0.0	−0.1	−0.7	0.7	0.8	0.8
GOVERNMENT	560	0.1	−0.4	−0.6	0.6	0.6	0.7
CMHCs	200	−34.2	0.0	−0.7	−33.2	−33.2	−33.1
Cancer Hospitals	11	0.2	0.6	38.8	41.5	41.5	37.8

Column (1) shows total hospitals and/or CMHCs.

Column (2) shows the impact of proposed changes resulting from the reclassification of HCPCS codes among APC groups and the proposed recalibration of APC weights based on CY 2010 hospital claims data.

Column (3) shows the proposed budget neutral impact of updating the wage index by applying the FY 2012 hospital inpatient wage index. See section II.C. for discussion of the estimated increase in payments to urban New England hospitals.

Column (4) shows the proposed budget neutral estimated impact within the OPPS of applying a proposed cancer hospital adjustment to all OPPS services. However, we note that after accounting for the TOPs that we estimate cancer hospitals would no longer receive, the proposed net increase in payment to cancer hospitals would be approximately 9 percent.

Column (5) shows the impact of all proposed budget neutrality adjustments and the proposed addition of the 1.5 percent OPD fee schedule increase factor (2.8 percent reduced by 1.2 percentage points for the proposed productivity adjustment and further reduced by 0.1 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (6) shows the proposed non-budget neutral impact of applying the frontier State wage adjustment, after application of the CY 2012 proposed OPD fee schedule increase factor.

Column (7) shows the proposed additional adjustments to the conversion factor resulting from a proposed change in the pass-through estimate and adds proposed outlier payments. This column also shows the expiration of section 508 wages on September 30, 2011 and the application of the proposed frontier State wage adjustment for CY 2012.

* These 4,141 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

(4) Estimated Effect of This Proposed Rule on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary share of payment would increase for services for which the OPPS payments would rise and would decrease for services for which the OPPS payments would fall. For example, for a service assigned to Level IV Needle Biopsy/Aspiration Except Bone Marrow (APC 0037) in the CY 2011 OPPS, the national unadjusted copayment is $228.76, and the minimum unadjusted copayment is $215.24, 20 percent of the national unadjusted payment rate of $1,076.14. For CY 2012, the proposed national unadjusted copayment for APC 0037 is $225.55, a decline from the copayment in effect for CY 2011. The proposed minimum unadjusted copayment for APC 0037 is $213.25 or 20 percent of the proposed CY 2012 national unadjusted payment rate for APC 0037 of $1,066.25. The proposed minimum unadjusted copayment would decline because the CY 2011 payment rate for APC 0037 would decline for CY 2012. For further discussion on the calculation of the proposed national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this proposed rule. We note that the proposed rural hospital and cancer hospital payment adjustments would result in corresponding increases in the beneficiary copayment, where those payment adjustments are applied. In all cases, the statute limits beneficiary liability for copayment for a procedure to the hospital inpatient deductible for the applicable year. The CY 2011 hospital inpatient deductible is $1,132 (75 FR 68799 through 68800). The CY 2012 hospital inpatient deductible was not known at the time this proposed rule was developed.

In order to better understand the impact of changes in copayment on beneficiaries, we modeled the percent change in total copayment liability using CY 2010 claims. We estimate, using the claims of the 4,141 hospitals and CMHCs on which our modeling is based, that total beneficiary liability for copayments would increase as an overall percentage of total payments, from 22.0 percent in CY 2011 to 22.1 percent in CY 2012 due largely to changes in service mix.

(5) Effects on Other Providers

The relative weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XIII. of this proposed rule. No types of providers other than hospitals and ASCs are affected by the changes we are proposing in this proposed rule.

(6) Effects on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be $3.285 billion in additional program payments for OPPS services furnished in CY 2012. The effect on the Medicaid program is expected to be limited to increased copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We refer readers to our discussion of the impact on beneficiaries under section XX.A.4.a.(4). of this proposed rule.

(7) Alternatives Considered

Alternatives to the changes we are proposing to make and the reasons for our selected alternatives are discussed throughout this proposed rule. Some of the major issues discussed in this proposed rule and the alternatives considered are discussed below.

• Alternatives Considered for Payment of the Acquisition and Pharmacy Overhead Costs of Drugs and Biologicals That Do Not Have Pass-Through Status

We are proposing that, for CY 2012, the OPPS would make payment for separately payable drugs and biologicals at ASP+4 percent, and this payment would continue to represent combined payment for both the acquisition and pharmacy overhead costs of separately payable drugs and biologicals. In addition, because we are proposing to continue to make a pharmacy overhead adjustment for CY 2012, we believe it is appropriate to account for inflation that has occurred since the overhead redistribution amount of $200 million was applied in CY 2011. Therefore, as discussed in further detail in section V.B.3. of this proposed rule, we believe that approximately $161 million of the estimated $705 million in pharmacy overhead cost currently attributed to coded packaged drugs and biologicals with an ASP and $54 million of the estimated $502 million in pharmacy overhead cost currently attributed to coded and uncoded packaged drugs and biologicals without an ASP should, instead, be attributed to separately payable drugs and biologicals to provide an adjustment for the pharmacy overhead costs of these separately payable products. As a result, we also are proposing to reduce the cost of packaged drugs and biologicals that is included in the payment for procedural APCs to offset the proposed $215 million adjustment to payment for separately payable drugs and biologicals. We are proposing that any redistribution of pharmacy overhead cost that may arise from CY 2012 final rule claims data would occur only from some drugs and biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals under the OPPS.

We considered two alternatives for payment of the acquisition and pharmacy overhead costs of drugs and biologicals that do not have pass-through status for CY 2012. The first alternative we considered, but are not proposing, is to compare the estimated aggregate cost of separately payable drugs and biologicals in our claims data to the estimated aggregate ASP dollars for separately payable drugs and biologicals, using the ASP as a proxy for average acquisition cost, to calculate the estimated percent of ASP that would serve as the best proxy for the combined acquisition and pharmacy overhead costs of separately payable drugs and biologicals (70 FR 68642), but without redistribution of estimated pharmacy overhead costs. Under this methodology without redistribution, using April 2011 ASP information and costs derived from CY 2010 OPPS claims data, we estimated the combined acquisition and overhead costs of separately payable drugs and biologicals to be ASP–2 percent. As discussed in section V.B.3. of this proposed rule, we also determined that the combined acquisition and overhead costs of packaged drugs are 188 percent of ASP. We did not choose this alternative because we believe that this analysis indicates that our standard drug payment methodology has the potential to ''compress'' the calculated costs of separately payable drugs and biologicals to some degree when there is no redistribution of estimated pharmacy overhead costs. Further, we recognize that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for

acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. Changes to the packaging threshold may result in changes to payment for the overhead cost of drugs and biologicals that do not reflect actual changes in hospital pharmacy overhead cost for those products.

The second alternative we considered and the one we are proposing for CY 2012 is to continue our pharmacy overhead redistribution methodology and proposing to apply an inflation allowance and redistribute $215 million in overhead costs from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals which would result in a payment for non-pass-through separately payable drugs and biologicals at ASP+4 percent, which would continue to represent a combined payment for both the acquisition costs of separately payable drugs and biologicals and the pharmacy overhead costs applicable to these products. We also are proposing to reduce the cost of packaged drugs and biologicals that is included in the payment for procedural APCs to offset the $215 million adjustment to payment for separately payable drugs and biologicals, resulting in payment for packaged drugs and biologicals of ASP+123 percent under our proposal.

We chose this alternative because we believe that it provides the most appropriate redistribution of pharmacy overhead costs associated with drugs and biologicals, based on the analyses discussed in section V.B.3. of this proposed rule.

• Proposed OPPS Payment Adjustment for Certain Cancer Hospitals

Section 3138 of the Affordable Care Act instructs the Secretary to conduct a study to determine if outpatient costs, including the cost of drugs and biologicals, incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to ambulatory classification groups exceed the costs incurred by other hospitals furnishing services under this subsection (section 1833(t) of the Act). Further, section 3138 of the Affordable Care Act provides that if the cancer hospitals' costs with respect to APC groups are determined to be greater than the costs of other hospitals paid under the OPPS, the Secretary shall provide an appropriate budget neutral payment adjustment to reflect these higher costs.

As discussed in detail in section II. F. of this proposed rule, using the claims and cost report data that we used under the modeled proposed CY 2011 OPPS, we constructed our traditional provider-level database of costs, modeled payments, units, service mix, wage index and other provider information that we typically use to establish class adjustments under the OPPS. We observed that cancer hospitals were more costly with respect to APC groups than other hospitals paid under the OPPS, having a standardized cost per discounted unit of $150.12 compared to a standardized cost per discounted unit of $94.14 for all other hospitals.

Having reviewed the cost data from the standard analytic database and determined that cancer hospitals are more costly with respect to APC groups than other hospitals within the OPPS system, we are proposing a payment adjustment for cancer hospitals for CY 2012 based on a comparison of costliness relative to payments using cost report data. Specifically, our proposed adjustment is as follows: If a hospital described in section 1886(d)(1)(B)(v) of the Act has a PCR (as determined by the Secretary) that is less than the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary) (Target PCR) for covered hospital outpatient department services (except pass-through devices defined in section 419.66), the payment adjustment is the percentage difference between the PCR of the hospital and the Target PCR. The CY 2012 proposed rule cost report data indicated a cancer hospital weighted average PCR of 0.647 (range = 0.56 to 0.82) and a weighted average PCR for all other hospitals equal to 0.901. Our proposed adjustment would result in an estimated 39.3 percent aggregate increase in budget neutral payments to cancer hospitals. For a cancer hospital with an individual PCR that is above the weighted average PCR of other hospitals furnishing services under the OPPS, we are proposing a zero percent adjustment for services furnished on and after January 1, 2012.

We considered three alternatives for the proposed OPPS payment adjustment for certain cancer hospitals. The first alternative we considered, but are not proposing, is to use our standard payment regression model instead of cost report data to identify an appropriate payment adjustment for cancer hospitals. We used this approach in our CY 2006 OPPS final rule with comment period to establish the 7.1 percent payment adjustment for rural SCHs (70 FR 68556 through 68561). However, in constructing our analysis of cancer hospitals' costs relative to other hospitals, we considered whether our standard analytical approach would lead to valid results. The analyses presented in the CY 2006 OPPS proposed and final rules were designed to establish an adjustment for a large class of rural hospitals. In contrast, section 3138 of the Affordable Care Act is specifically limited to identifying an adjustment for 11 cancer hospitals to the extent that their costs with respect to APC groups exceeded the costs incurred by other hospitals furnishing services under section 1833(t) of the Act. With such a small sample size (11 out of approximately 4,000 hospitals paid under the OPPS), we were concerned that the standard explanatory and payment regression models used to establish the rural hospital adjustment would lead to imprecise estimates of payment adjustments for this small group of hospitals. Further, section 3138 of the Affordable Care Act specifies explicitly that cost comparisons between classes of hospitals must include the cost of drugs and biologicals. In our CY 2006 analysis of rural hospitals, we excluded the cost of drugs and biologicals in our model because the extreme units associated with proper billing for some drugs and biologicals can bias the calculation of a service mix index, or volume weighted average APC relative weight, for each hospital (70 FR 42698). Therefore, we chose not to pursue our standard combination of explanatory and payment regression modeling to determine a cancer hospital adjustment.

The second alternative we considered, but are not proposing, is to provide the same adjustment to all cancer hospitals based on the difference between the weighted average PCR for all cancer hospitals (0.647) and the weighted average PCR for all other hospitals (0.901). This class adjustment, instead of a hospital specific adjustment, would provide a 39.3 percent payment increase for each cancer hospital. Because this alternative did not seem equitable to other hospitals furnishing services under OPPS as it would result in a PCR for most cancer hospitals that is higher the weighted average PCR of other hospitals furnishing services under OPPS and a much larger budget neutrality adjustment, we did not propose this alternative.

The third alternative we considered, and the one we are proposing for CY 2012, is to provide a hospital specific payment adjustment to cancer hospitals that have a PCR that is less than the weighted average PCR of other hospitals furnishing services under the OPPS, for covered hospital outpatient department services (except pass-through devices) furnished on and after January 1, 2012, based on the percent difference between

each cancer hospital's PCR and the weighted average PCR of other OPPS hospitals using the most recent cost report data. For cancer hospitals with an individual PCR that is above the weighted average PCR of other hospitals furnishing services under the OPPS, we are proposing a zero percent adjustment for services furnished on and after January 1, 2012. For purposes of calculating a proposed adjustment, we chose to rely on this straightforward assessment of payments and costs from the cost report data because of the concerns outlined above with respect to the small number of hospitals, and because of the challenges associated with accurately including drug and biological costs in our standard regression models. We believe that an appropriate adjustment would redistribute enough payments from other hospitals paid under the OPPS to the cancer hospitals to give cancer hospitals a PCR that is comparable to the average PCR for other hospitals paid under the OPPS.

• Alternatives Considered for the Supervision of Hospital Outpatient Therapeutic Services

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72012), we stated our intent to develop through our CY 2012 rulemaking an independent review process that enables the agency to request, with stakeholder input, advisory recommendations regarding the appropriate supervision level for individual outpatient therapeutic services. We considered three alternatives with regard to the nature of the advisory recommendations regarding the appropriate supervision level for individual outpatient therapeutic services.

The first alternative we considered but are not proposing is to use an existing body other than the APC Panel such as the Relative Value Scale Update Committee to make recommendations to CMS with regard to the level of supervision that would be required for outpatient therapeutic services. We did not choose a different existing body because we did not believe there was an alternative that had an appropriate balance of subject matter expertise or that would be able to furnish the appropriate advice.

The second alternative we considered but are not proposing is to establish a new non-advisory body such as a Technical Expert Panel. We did not propose to establish a new entity because currently we have no funding to do so. Moreover, it is not clear that the resources of a new body are necessary for the supervision deliberations, especially once initial determinations are made regarding key services. Also, we believe it is important to obtain advice that carries the weight of a Federal advisory recommendation.

The third alternative we considered, and the one we selected, is to propose to establish the Federal Advisory APC Panel as an independent review body that would evaluate individual outpatient therapeutic services for potential assignment by CMS of general (lower) or personal (higher) supervision. We are proposing to amend the APC Panel charter to render the Panel more appropriate for this task by expanding its scope to include the topic of supervision. We also are proposing to add two to four members to the Panel who would be representative of CAHs, so that all types of hospitals who are subject to the supervision rules for payment would be represented in developing the Panel's recommendations. We are proposing to use the standard APC Panel protocols with respect to frequency of meetings and receiving requests for evaluation of services. We believe it is important to obtain advice that carries the weight of a Federal advisory recommendation, because it may have greater legitimacy both with stakeholders and with CMS compared to the opinions of other types of groups. The APC Panel has a long and excellent history of providing valuable advice to CMS with regard to the clinical issues associated with the APC groupings of hospital outpatient therapeutic services under the OPPS, and we believe that extension of the function of the Panel to providing advice on supervision of individual hospital outpatient therapeutic services will result in both full consideration of the views of all types of hospitals and the best possible clinical decisions with respect to the level of supervision that should be required as a condition of Medicare payment.

b. Effects of Proposed ASC Payment System Changes in This Proposed Rule

On August 2, 2007, we published in the **Federal Register** the final rule for the revised ASC payment system, effective January 1, 2008 (72 FR 42470). In that final rule, we adopted the methodologies to set payment rates for covered ASC services to implement the revised payment system so that it would be designed to result in budget neutrality as required by section 626 of Pub. L. 108–173; established that the OPPS relative payment weights would be the basis for payment and that we would update the system annually as part of the OPPS rulemaking cycle; and provided that the revised ASC payment rates would be phased in over 4 years. During the 4-year transition to full implementation of the ASC payment rates, payments for surgical procedures performed in ASCs that were on the CY 2007 ASC list of covered surgical procedures were made using a blend of the CY 2007 ASC payment rate and the ASC payment rate calculated according to the ASC standard ratesetting methodology for the applicable transitional year. In CY 2009, we paid ASCs using a 50/50 blend, in which payment was calculated by adding 50 percent of the CY 2007 ASC rate for a surgical procedure on the CY 2007 ASC list of covered surgical procedures and 50 percent of the CY 2009 ASC rate calculated according to the ASC standard ratesetting methodology for the same procedure. For CY 2010, we transitioned the blend to a 25/75 blend of the CY 2007 ASC rate and the CY 2010 ASC payment rate calculated according to the ASC standard ratesetting methodology. In CY 2011, we are paying ASCs for all covered surgical procedures, including those on the CY 2007 ASC list, at the ASC payment rates calculated according to the ASC standard ratesetting methodology.

ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this proposed rule, we set the proposed CY 2012 ASC relative payment weights by scaling CY 2012 ASC relative payment weights by the ASC scalar of 0.9373. The estimated effects of the updated relative payment weights on payment rates during this second year of full implementation of the ASC payment rates calculated according to the ASC standard ratesetting methodology are varied and are reflected in the estimated payments displayed in Tables 52 and 53 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system, which is the consumer price index for all urban consumers (CPI–U), be reduced by the productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). We calculated the proposed CY 2012 ASC conversion factor by adjusting the CY 2011 ASC conversion factor by 1.0003 to account for changes in the pre-floor and pre-reclassified hospital wage indices between CY 2011 and CY 2012

and by applying the proposed CY 2012 MFP-adjusted CPI–U of 0.9 percent (2.3 percent CPI–U minus a productivity adjustment of 1.4 percent percentage points). The proposed CY 2012 ASC conversion factor is $42.329.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2012 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service mix between CY 2010 and CY 2012 with precision. We believe that the net effect on Medicare expenditures resulting from the proposed CY 2012 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of This Proposed Rule on Payments to ASCs

Some ASCs are multispecialty facilities that perform the gamut of surgical procedures, from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the proposed update to the CY 2012 payments would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 2012 update to the revised ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2010 claims data. Table 52 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2011 payments to estimated CY 2012 payments, and Table 53 shows a comparison of estimated CY 2011 payments to estimated CY 2012 payments for procedures that we estimate would receive the most Medicare payment in CY 2012.

Table 52 shows the estimated effects on aggregate proposed Medicare payments under the revised ASC payment system by surgical specialty or ancillary items and services group. We have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 52.

- Column 1—*Surgical Specialty or Ancillary Items and Services Group* indicates the surgical specialty into which ASC procedures are grouped or the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—*Estimated CY 2011 ASC Payments* were calculated using CY 2010 ASC utilization (the most recent full year of ASC utilization) and CY 2011 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2011 ASC payments.
- Column 3—*Estimated CY 2012 Percent Change* is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that would be attributable to updates to proposed ASC payment rates for CY 2012 compared to CY 2011.

As seen in Table 52, we estimate that the proposed update to ASC rates for CY 2012 would result in a 0 percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, a 1 percent increase in aggregate payment amounts for digestive system procedures, and a 2 percent increase in aggregate payment amounts for nervous system procedures.

Generally, for the surgical specialty groups that account for less ASC utilization and spending, we estimate that the payment effects of the CY 2012 update are variable. For instance, we estimate that, in the aggregate, payment for genitourinary system procedures and hemic & lymphatic systems procedures would increase by 5 percent and 4 percent, respectively, whereas auditory system procedures and cardiovascular system procedures would decrease by 5 percent and 4 percent, respectively, under the proposed CY 2012 rates.

An estimated increase in aggregate payment for the specialty group does not mean that all procedures in the group would experience increased payment rates. For example, the estimated modest increase for CY 2012 for genitourinary system procedures is likely due to an increase in the ASC payment weight for some of the high volume procedures, such as CPT code 50590 (Fragmenting of kidney stone) where estimated payment would increase by 25 percent for CY 2012.

Also displayed in Table 52 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. Payment for New Technology Intraocular Lenses (NTIOLs) is captured under this category. Because the NTIOL class for reduced spherical aberration expired on February 26, 2011, and a new NTIOL class was not approved during CY 2011 rulemaking, we redistributed the estimated payment dedicated to separately paid NTIOLs in CY 2011 while the NTIOL class was active to other services for CY 2012. Therefore, we estimate that aggregate payments for these items and services would decrease by 30 percent for CY 2012.

TABLE 52—ESTIMATED IMPACT OF THE PROPOSED CY 2012 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2012 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group	Estimated CY 2011 ASC payments (in millions)	Estimated CY 2012 percent change (3)
(1)	(2)	(3)
Total	$3,400	1
Eye and ocular adnexa	1,435	0
Digestive system	689	1
Nervous system	454	2
Musculoskeletal system	420	2
Genitourinary system	150	5
Integumentary system	132	1
Respiratory system	43	0
Cardiovascular system	32	−4
Ancillary items and services	29	−30
Auditory system	11	−5
Hematologic & lymphatic systems	5	4

Table 53 below shows the estimated impact of the proposed updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2012. The table displays 30 of the procedures receiving the greatest estimated CY 2011 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2011 program payment.

- Column 1–*HCPCS code*.
- Column 2—*Short Descriptor* of the HCPCS code.
- Column 3—*Estimated CY 2011 ASC Payments* were calculated using CY 2010 ASC utilization (the most recent full year of ASC utilization) and the CY 2011 ASC payment rates. The estimated CY 2011 payments are expressed in millions of dollars.
- Column 4—*Estimated CY 2012 Percent Change* reflects the percent differences between the estimated ASC payment for CY 2011 and the estimated payment for CY 2012 based on the proposed update.

As displayed in Table 53, 21 of the 30 procedures with the greatest estimated aggregate CY 2011 Medicare payment are included in the 3 surgical specialty groups that are estimated to account for the most Medicare payment to ASCs in CY 2011, specifically eye and ocular adnexa, digestive system, and nervous system surgical groups. Consistent with the estimated payment effects on the surgical specialty groups displayed in Table 52 the estimated effects of the proposed CY 2012 update on ASC payment for individual procedures shown in Table 53 are varied.

The ASC procedure for which the most Medicare payment is estimated to be made in CY 2011 is the cataract removal procedure reported with CPT code 66984 (Cataract surg w/iol 1 stage). We estimate that the proposed update to the ASC rates would result in a 0 percent change for this procedure in CY 2012. The estimated payment effects on two of the other three eye and ocular adnexa procedures included in Table 53 are slightly more significant. We estimate that the payment rate for CPT code 66821 (After cataract laser surgery) would increase by 2 percent and payment for CPT code 67042 (Vit for macular hole) would increase by 3 percent.

We estimate that the proposed payment rates for all of the digestive system procedures included in Table 53 would change by -3 to +3 percent in CY 2012. During the previous 4-year transition to the revised ASC payment system, payment for most of the high volume digestive system procedures decreased each year because, under the previous ASC payment system, the payment rates for many high volume endoscopy procedures were almost the same as the payments for the procedures under the OPPS.

The estimated effects of the proposed CY 2012 update on the nine nervous system procedures for which the most Medicare ASC payment is estimated to be made in CY 2011 would be variable. Our estimates indicate that the proposed CY 2012 update would result in payment increases of 2 to 3 percent for 6 of the 9 procedures and result in a 1 to 5 percent decrease for the other 3 nervous system procedures. The nervous system procedure for which we estimate a negative effect on CY 2012 payments is CPT code 63650 (Implant neuroelectrodes) which is expected to have payment decrease of 5 percent.

The estimated payment effects for most of the remaining procedures listed in Table 53 would be positive. For example, the payment rate for musculoskeletal CPT codes 26055 (Incise finger tendon sheath) is estimated to increase 4 percent over the CY 2011 payment rates. Musculoskeletal procedures are expected to account for a greater percentage of CY 2012 Medicare ASC spending as we estimate that payment for procedures in that surgical specialty group would increase under the revised payment system in CY 2012.

TABLE 53—ESTIMATED IMPACT OF THE PROPOSED CY 2012 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code *	Short descriptor	Estimated CY 2011 ASC payments (in millions)	Estimated CY 2012 percent change
(1)	(2)	(3)	(4)
66984	Cataract surg w/iol, 1 stage	$1,083	0
43239	Upper GI endoscopy, biopsy	158	−3

TABLE 53—ESTIMATED IMPACT OF THE PROPOSED CY 2012 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES—Continued

CPT/HCPCS Code *	Short descriptor	Estimated CY 2011 ASC payments (in millions)	Estimated CY 2012 percent change
(1)	(2)	(3)	(4)
45380	Colonoscopy and biopsy	133	2
45378	Diagnostic colonoscopy	100	2
45385	Lesion removal colonoscopy	87	2
66982	Cataract surgery, complex	79	0
62311	Inject spine l/s (cd)	66	2
64483	Inj foramen epidural l/s	66	2
66821	After cataract laser surgery	56	2
15823	Revision of upper eyelid	41	0
64493	Inj paravert f jnt l/s 1 lev	40	2
63650	Implant neuroelectrodes	38	−5
G0105	Colorectal scrn; hi risk ind	32	3
29881	Knee arthroscopy/surgery	31	0
29826	Shoulder arthroscopy/surgery	31	2
64721	Carpal tunnel surgery	30	2
29827	Arthroscop rotator cuf repr	27	2
29880	Knee arthroscopy/surgery	26	0
63685	Insrt/redo spine n generator	26	−1
G0121	Colon ca scrn not hi rsk ind	25	3
45384	Lesion remove colonoscopy	24	2
43235	Uppr gi endoscopy, diagnosis	23	−3
52000	Cystoscopy	20	1
28285	Repair of hammertoe	19	0
64622	Destr paravertebrl nerve l/s	19	3
64590	Insrt/redo pn/gastr stimul	16	−1
62310	Inject spine c/t	16	2
26055	Incise finger tendon sheath	16	4
50590	Fragmenting of kidney stone	15	25
67042	Vit for macular hole	14	3

* Note that HCPCS codes proposed for deletion for CY 2012 are not displayed in this table.

The previous ASC payment system served as an incentive to ASCs to focus on providing procedures for which they determined Medicare payments would support their continued operation. We note that, historically, the ASC payment rates for many of the most frequently performed procedures in ASCs were similar to the OPPS payment rates for the same procedures. Conversely, procedures with ASC payment rates that were substantially lower than the OPPS rates were performed least often in ASCs. We believed that the revised ASC payment system would encourage greater efficiency in ASCs and would promote significant increases in the breadth of surgical procedures performed in ASCs because it distributes payments across the entire spectrum of covered surgical procedures based on a coherent system of relative weights that are related to the clinical and facility resource requirements of those procedures.

The CY 2010 claims data that we used to develop the proposed CY 2012 ASC payment system relative payment weights and rates reflect the third year of utilization under the revised payment system. Although the changes in the claims data are not large, the data reflect increased Medicare ASC spending for procedures that were newly added to the ASC list in CY 2008. Our estimates based on CY 2010 data indicate that for CY 2012 there would be especially noticeable increases in spending for the hematologic and lymphatic systems compared to the previous ASC payment system.

(3) Estimated Effects of This Proposed Rule on Beneficiaries

We estimate that the proposed CY 2012 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures that we are adding to the ASC list of covered surgical procedures and for those that we are designating as office-based for CY 2012. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment. Second, ASC payment rates under the revised payment system are lower than payment rates for the same procedures under the OPPS; therefore, the beneficiary coinsurance amount under the ASC payment system almost always would be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Furthermore, the additions to the ASC list of covered surgical procedures would provide beneficiaries access to more surgical procedures in ASCs. Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts for that service in the physician's office compared to the ASC. However, for those additional procedures that we are proposing to designate as office-based in CY 2012, the beneficiary coinsurance amount would be no greater than the beneficiary coinsurance in the physician's office.

(4) Alternatives Considered

Alternatives to the changes we are proposing to make and the reasons that we have chosen specific options are discussed throughout this proposed rule. Some of the major ASC issues discussed in this proposed rule and the options considered are discussed below.

• Alternatives Considered for Office-Based Procedures

According to our final policy for the revised ASC payment system, we designate as office-based those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years and that we determine are predominantly performed in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure HCPCS code and, if appropriate, the clinical characteristics, utilization, and volume of related HCPCS codes. We establish payment for procedures designated as office-based at the lesser of the MPFS nonfacility practice expense payment amount or the ASC rate developed according to the standard methodology of the revised ASC payment system.

In developing this proposed rule, we reviewed CY 2010 utilization data for all surgical procedures added to the ASC list of covered surgical procedures in CY 2008 or later years and for those procedures for which the office-based designation is temporary in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72036 through 72038). Based on that review, and as discussed in section XIII.C.1.b. of this proposed rule, we are proposing to newly designate 10 surgical procedures as permanently office-based and proposing to make temporary office-based designations for 8 procedures in CY 2012 that were designated as temporarily office-based for CY 2011. We considered two alternatives in developing this policy.

The first alternative we considered was to make no change to the procedure payment designations. This would mean that we would pay for the ten procedures we are proposing to designate as permanently office-based and the eight procedures we are proposing to designate as temporarily office-based at an ASC payment rate calculated according to the standard ratesetting methodology of the revised ASC payment system. We did not select this alternative because our analysis of the data and our clinical review indicated that all 10 procedures we are proposing to designate as permanently office-based, as well as the 8 procedures that we are proposing to designate temporarily as office-based, are considered to be predominantly performed in physicians' offices. Consistent with our final policy adopted in the August 2, 2007 final rule (72 FR 42509 through 42513), we were concerned that making payments at the standard ASC payment rate for the 10 procedures we are proposing to designate as permanently office-based and the 8 procedures we are proposing to designate as temporarily office-based could create financial incentives for the procedures to shift from physicians' offices to ASCs for reasons unrelated to clinical decisions regarding the most appropriate setting for surgical care. Further, consistent with our policy, we believe that when adequate data become available to make permanent determinations about procedures with temporary office-based designations, maintaining the temporary designation is no longer appropriate.

The second alternative we considered and the one we are proposing for CY 2012 is to designate 10 additional procedures as permanently office-based for CY 2012 and to designate 8 procedures as temporarily office-based in CY 2012 that were designated as temporarily office-based for CY 2011. We chose this alternative because our claims data and clinical review indicate that these procedures could be considered to be predominantly performed in physicians' offices. We believe that designating these procedures as office-based, which results in the CY 2012 ASC payment rate for these procedures potentially being capped at the CY 2012 physicians' office rate (that is, the MPFS nonfacility practice expense payment amount), if applicable, is an appropriate step to ensure that Medicare payment policy does not create financial incentives for such procedures to shift unnecessarily from physicians' offices to ASCs, consistent with our final policy adopted in the August 2, 2007 final rule.

c. Accounting Statements and Tables

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), we have prepared two accounting statements to illustrate the impacts of this proposed rule. The first accounting statement, Table 54 below, illustrates the classification of expenditures for the CY 2012 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2012 OPD fee schedule increase shown in this proposed rule, based on the FY 2012 President's Budget. The second accounting statement, Table 55 below, illustrates the classification of expenditures associated with the 0.9 percent proposed CY 2011 update to the revised ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the FY 2012 President's Budget. Lastly, both tables classify all estimated impacts as transfers.

TABLE 54—ACCOUNTING STATEMENT: CY 2012 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2011 TO CY 2012 ASSOCIATED WITH THE PROPOSED CY 2012 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$0.5 billion.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who received payment under the hospital OPPS.
Total	$0.5 billion.

TABLE 55—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2011 TO CY 2012 AS A RESULT OF THE PROPOSED CY 2012 UPDATE TO THE REVISED ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$26 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.

TABLE 55—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2011 TO CY 2012 AS A RESULT OF THE PROPOSED CY 2012 UPDATE TO THE REVISED ASC PAYMENT SYSTEM—Continued

Category	Transfers
Total	$26 million.

d. Effect of Proposed Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

In section XVI. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68758 through 68781), section XVI. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60629 through 60655), and section XVI. of the CY 2011 OPPS/ASC final rule with comment period (75 FR72064 through 72110), we discussed our requirements for subsection (d) hospitals to report quality data under the Hospital OQR Program in order to receive the full OPD fee schedule increase factor for CY 2010, CY 2011, and CY 2012–2014, respectively. In section XIV. of this proposed rule, we are proposing additional policies affecting the Hospital OQR Program for CY 2013, CY 2014, and CY 2015.

We determined that 107 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor for CY 2011. Most of these hospitals (over 90 of the 107) received little or no OPPS payment on an annual basis and did not participate in the Hospital OQR Program. We estimate that 120 hospitals may not receive the full OPD fee schedule increase factor in CY 2012. We are unable at this time to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2013, CY 2014 and CY 2015.

In section XVI.E.3.a. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60647 through 60650), for the CY 2011 payment update, as part of the validation process, we required hospitals to submit paper copies of requested medical records to a designated contractor within the required timeframe. Failure to submit requested documentation could result in a 2 percentage point reduction to a hospital's CY 2011 OPD fee schedule increase factor, but the failure to attain a validation score threshold would not.

In section XVI.D.3.b of the CY 2011 OPPS/ASC final rule with comment period, we finalized our proposal to validate data submitted by 800 hospitals of the approximately 3,200 participating hospitals for purposes of the CY 2012 Hospital OQR Program payment determination. We stated our belief that this approach was suitable for the CY Hospital OQR Program because it would: Produce a more reliable estimate of whether a hospital's submitted data have been abstracted accurately; provide more statistically reliable estimates of the quality of care delivered in each selected hospital as well as at the national level; and reduce overall hospital burden because most hospitals would not be selected to undergo validation each year. We adopted a threshold of 75 percent as the threshold for the validation score because we believed this level was reasonable for hospitals to achieve while still ensuring accuracy of the data. Additionally, this level is consistent with what we adopted in the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program)) (75 FR 50225 through 50229). As a result, we believed that the effect of our validation process for CY 2012 would be minimal in terms of the number of hospitals that would not meet all program requirements.

In this proposed rule, we are proposing to validate data submitted by up to 500 of the approximately 3,200 participating hospitals for purposes of the CY 2013 Hospital OQR Program payment determination. Under our policy for the CY 2011 and CY 2012 payment determinations, and under our proposal for CY 2013, we stated that we would conduct a measure level validation by assessing whether the measure data submitted by the hospital matches the independently reabstracted measure data.

As stated above, we are unable to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2013. Therefore, we are unable to estimate the number of hospitals that would fail the validation documentation submission requirement for the proposed CY 2013 payment update.

The validation requirements for CY 2011, CY 2012, and the validation requirement proposed for CY 2013 would result in result in medical record documentation for approximately 7,300 cases for CY 2011, 9,600 cases per quarter for CY 2012, and approximately 6,000 cases per quarter for CY 2013, respectively, being submitted to a designated CMS contractor. We would pay for the cost of sending this medical record documentation to the designated CMS contractor at the rate of 12 cents per page for copying and approximately $1.00 per case for postage. We have found that an outpatient medical chart is generally up to 10 pages. Thus, as a result of validation requirements effective for the CY 2011 and CY 2012 payment determinations, and proposed for the CY 2013 payment determination, respectively, we would have expenditures of approximately $16,060 for CY 2011, $21,120 per quarter for CY 2012, and approximately $13,200 per quarter for CY 2013. Again, as we would pay for the data collection effort, we believe that a requirement for medical record documentation for 7,300 total cases for CY 2011, a maximum of 12 cases per quarter for 800 hospitals for CY 2012, and a maximum of 12 cases per quarter for up to 500 hospitals for CY 2013 represents a minimal burden to Hospital OQR Program participating hospitals.

In previous years, medical record documentation was requested by a CMS contractor and hospitals were given 45 days from the date of the request to submit the requested documentation. In section XIV.G.3.d. of this proposed rule, for the CY 2013 payment determination, we are proposing to reduce the time from 45 days to 30 days for hospitals to submit requested medical record documentation to meet our validation requirement; this may create an additional administrative burden. The total burden would be a maximum of 12 charts for each of the four quarters that must be copied and mailed within a 30-day period after the end of each quarter. We are proposing this deadline of 30 days to align the process with requirements in 42 CFR 476.78(b)(2), which allows 30 days for chart submission in the context of QIO review and to reduce the time for data validation completion to increase timeliness of providing hospitals feedback on their abstraction accuracy.

e. Effects of Proposed Changes to Physician Self-Referral Regulations

Section 6001(a) of the Affordable Care Act amended the whole hospital and rural provider exceptions (sections 1877(d)(2) and (d)(3) of the Act,

respectively) to impose additional restrictions on physician ownership or investment in hospitals. The amended whole hospital and rural provider exceptions provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act to set forth that the Secretary shall establish and implement an exception process to the prohibition on expansion of facility capacity.

Most physician-owned hospitals are unable to qualify for the ownership and investment exception at section 1877(d)(1) of the Act. Section 1877(d)(1) of the Act provides an exception for ownership or investment in publicly traded securities in a corporation where there is stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years; or the ownership involves mutual funds in a company that has assets greater than $75 million. Studies by the OIG and GAO have concluded that physician-owned hospitals tend to be smaller and are unable to meet the $75 million threshold.

The proposed regulations at § 411.362(c) set forth the proposed process for a hospital to request an exception to the prohibition on expansion of facility capacity. Proposed new § 411.362(c)(2) outlines the requirements for an applicable hospital request and § 411.362(c)(3) outlines the requirements for a high Medicaid facility request. Our proposed regulations would require each hospital desiring an exception to access certain data and make estimates based on that data to determine if the hospital meets the relevant criteria. For example, a hospital would be required to access data furnished by the CMS Healthcare Cost Report Information System (HCRIS) and by the Bureau of the Census, in addition to referencing data from the hospital's individual cost reports and making certain estimates on the basis of its cost report data. We believe the impact of these requirements on affected hospitals would be minimal.

Our proposed regulations would require each hospital requesting an exception to provide documentation supporting its calculations to demonstrate that it satisfies the relevant criteria. Our proposed regulations would further require each hospital to provide documentation to support information related to its number of operating rooms, procedure rooms, and beds. This information would include, for example, the number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits a request for an exception. Each hospital would also be required to provide a detailed explanation regarding whether and how it satisfies each of the relevant criteria. We believe physician-owned hospitals would be minimally affected by these requirements.

Our proposed regulations would require each hospital requesting an exception to disclose on a public Web site for the hospital that it is requesting an exception. Our proposed regulations would require each hospital to certify that it does not discriminate and does not permit physicians to discriminate against beneficiaries of Federal health care programs. In addition, under our proposed regulations, if CMS were to receive input from the community related to a particular hospital's request for an exception, the hospital may submit a rebuttal statement in response to input from the community. We believe the impact of these requirements on physician-owned hospitals would be minimal.

We believe our proposals would affect a relatively small number of physician-owned hospitals. We estimate that 265 physician-owned hospitals are eligible to apply for an exception. We believe accurately estimating the number of hospitals choosing to request an exception would be impracticable. Further, we are not aware of any existing data or projections that may produce an estimate with reasonable certainty. As a result, we are choosing to estimate that each of the 265 eligible hospitals will request an exception in order to avoid underestimating the potential impact. We are not aware of any data that may indicate the potential increase in operation rooms, procedure rooms, or beds pursuant to exceptions potentially approved. We also have no data or projections that may help estimate the number of physicians that would be affected by this proposed rule as a result of their ownership interests in hospitals.

The proposed requirements concerning the criteria and process for hospitals seeking an exception to the prohibition on expansion of facility capacity are consistent with the physician self-referral statute and regulations and the current practices of most hospitals. Thus, our proposed requirements would present a negligible impact on physician-owned hospitals. Physician-owned hospitals would bear costs associated with requesting an exception to the prohibition on facility expansion. In part because hospitals are currently undertaking the costs of producing a cost report, we believe that the cost of referencing the required data and making the required estimates would be negligible. In addition, we believe the costs of providing supporting documentation, certifying nondiscrimination against beneficiaries of Federal health care programs, and submitting other required information necessary to request an exception to CMS would be minimal.

We believe that beneficiaries may be positively impacted by these proposed provisions. Specifically, an increase in operating rooms, procedure rooms, and beds may augment the volume or nature of services offered by physician-owned hospitals. An expansion in the number of hospital beds may also permit additional inpatient admissions and overnight stays. Increased operating rooms, procedure rooms, and beds may result in improved access to health care facilities and services. We believe that our proposals are necessary to conform our regulations to the amendments to section 1877 of the Act. We also believe the proposed regulations would help minimize anticompetitive behavior that can affect the decision as to where a beneficiary receives health care services and would possibly enhance the services furnished.

In this proposed rule, we are soliciting public comments on each of the issues outlined above that contain estimates of the costs and benefits of the proposed rule.

f. Effects of Proposed Changes to Provider Agreement Regulations on Patient Notification Requirements

In section XV.D. of this proposed rule, we discuss our proposal concerning the requirement that all hospitals and critical access hospitals must furnish written notice to their patients at the beginning of their hospital stay or outpatient visit if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, and that the notice must indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition at a time when there is no physician present in the hospital. In this proposed rule, we are proposing to modify the provider agreement regulations to reduce the categories of outpatients who must be notified if hospital does not have a doctor of medicine or doctor of osteopathy on site

24 hours per days/7 days per week. We are proposing that only those outpatients who receive observation services, surgery, or services involving anesthesia must receive written notice. We are not making any changes to our patient safety requirements for physician-owned hospitals at § 411.362(b)(5)(i). We continue to believe that patients should be made aware of whether or not a doctor of medicine or a doctor of osteopathy is present in the hospital at all times, and the hospital's plans to address patient's emergency medical conditions when a doctor of medicine or a doctor of osteopathy is not present.

We believe our proposed changes to the provider agreement regulations would result in only a minor change in the number of hospitals that are subject to the disclosure requirements, specifically those multicampus hospitals that currently have 24 hour per day, seven day per week presence of a doctor of medicine or a doctor of osteopathy on one, but not all of their campuses with inpatient services. We anticipate that very few multicampus hospitals would fall into this category. Rather, the primary impact of the proposed regulation would be to change the number of annual written disclosures given by hospitals to patients. We believe the cost of implementing these provisions borne by hospitals would be limited to a one-time cost associated with completing minor revisions to portions of the hospitals, policies and procedures related to patient admission and registration, as well as providing written notification to patients and affected staff. Therefore, we do not believe that these proposed changes will have any significant economic impact on hospitals.

We do not anticipate that our proposals will have a significant economic impact on a substantial number of physicians, other health care providers and suppliers, or the Medicare or Medicaid programs and their beneficiaries. Specifically, we believe that this proposed rule will affect mostly hospitals, physicians, and beneficiaries. The proposed changes concerning the disclosure of the presence of a doctor of medicine or a doctor of osteopathy in hospitals is consistent with the physician self-referral statute and regulations as well as the current practices of most hospitals. Thus, our physician presence disclosure proposal would present a negligible economic impact on the hospital.

Overall, we believe that beneficiaries will be positively impacted by these provisions. Specifically, disclosure of physician presence equips patients to make informed decisions about where they elect to receive care. Our proposal makes no significant change that has the potential to impede patient access to health care facilities and services. In fact, we believe that our proposal will help minimize anti-competitive behavior that can affect the decision as to where a beneficiary receives health care services and possibly the quality of the services furnished.

g. Effects of Additional Proposed Hospital VBP Program Requirements

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to the FY 2013 base operating MS–DRG payment amount for each discharge of 1 percent, as required by section 1886(o)(7)(B)(i) of the Act. The applicable percentage for FY 2014 is 1.25 percent, for FY 2015 is 1.5 percent, for FY 2016 is 1.75 percent, and for FY 2017 and subsequent years is 2 percent. In section XVI.A.3. of this proposed rule, we are proposing additional requirements for the FY 2014 Hospital VBP Program. Specifically, we are proposing to add one chart-abstracted measure to the Hospital VBP measure set for the FY 2014 payment determination. Because this additional measure is chart-abstracted and is required for the Hospital IQR Program, its inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

h. Effects of the Proposed EHR Reporting Pilot

Under section XIV.J. of this proposed rule, we are proposing to allow eligible hospitals and CAHs that are participating in the EHR Incentive Program to meet the CQM reporting requirement of the program for payment year 2012 by participating in the Medicare EHR Incentive Program Electronic Reporting Pilot. This proposal would facilitate the use of an electronic infrastructure that supports the use of EHRs by hospitals and CAHs to meet the requirements in various CMS programs and reduce reporting burden simultaneously. Through this pilot, we have encouraged hospitals to take steps toward the adoption of EHRs that will allow for reporting of clinical quality data from EHRs to a CMS data repository. We expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS, in the future, to receive, quality measures via hospital EHRs for the Hospital IQR Program's measures. Hospitals that choose to participate in the EHR Incentive Program by means of this pilot for the purpose of meeting the CQM reporting requirement of Meaningful Use will be taking those first steps toward reporting clinical quality data in such a way.

B. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $34.5 million or less in any single year. Most ASCs and most CMHCs are considered small businesses with total revenues of $10 million or less in any single year. For details, see the Small Business Administration's Web site at *http://sba.gov;* choose ''Contracting'' and select ''Table of Small Business Size Standards'' in PDF or Excel.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We estimate that this proposed rule may have a significant impact on approximately 704 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a Regulatory Flexibility Analysis and a Regulatory Impact Analysis.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $135 million. This proposed rule would not mandate any requirements for State,

local, or tribal governments, nor would it affect private sector costs.

D. Conclusion

The changes we are proposing would affect all classes of hospitals paid under the OPPS and would affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2012. Table 51 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.5 percent increase in payments for all services paid under the OPPS in CY 2012, after considering all proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, wage index changes, including the proposed frontier State wage index adjustment, estimated payment for outliers, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience significant gains and others would experience modest losses in OPPS payments in CY 2012. Specifically, we estimate that the 11 dedicated cancer hospitals that met the classification criteria in section 1883(d)(1)(B)(v) of the Act, as a class, would receive an increase in payments under the OPPS of 38.8 percent for CY 2012, although after accounting for the TOPs that we estimate they would no longer receive due to increased payments under the OPPS, the net increase in payment to these hospitals would be approximately 9 percent. In contrast, we estimate that CMHCs would see an overall decrease in payment of 33.1 percent as a result of the proposed full transition in CY 2012 to payment rates for partial hospitalization services at CMHCs based on cost report and claims data submitted by CMHCs.

The proposed updates to the ASC payment system for CY 2012 would affect each of the approximately 5,000 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients that are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the revised payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 52 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI–U update of 0.9 percent proposed for CY 2012.

XXI. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they would not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 51 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 1.5 percent under this proposed rule. While we do not know the number of ASCs with government ownership, we anticipate that it is small. We believe that the proposed provisions related to payments to ASCs in CY 2012 would not affect payments to any ASCs owned by government entities.

The analyses we have provided in section XX.A. of this proposed rule, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Computer technology, Electronic health records, Electronic transactions, Health, Health care. Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR Chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for Part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 410.27 is amended by—

a. Revising the section heading.

b. Revising paragraph (a).

c. In paragraph (b), removing the cross-reference ''§ 410.168'' and adding in its place the cross-reference ''§ 410.29''.

d. In paragraph (c), removing the cross-reference ''§ 410.168'' and adding in its place the cross-reference ''subpart G of Part 424 of this chapter''.

e. Redesignating paragraphs (d) through (f) as paragraphs (e) through (g), respectively.

f. Adding a new paragraph (d).

The revisions and addition read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals that cannot be self-administered, if—

(1) They are furnished—

(i) By or under arrangements made by the participating hospital or CAH, except in the case of a SNF resident as provided in § 411.15(p) of this subchapter;

(ii) As an integral although incidental part of a physician's or nonphysician practitioner's services;

(iii) In the hospital or CAH or in a department of the hospital or CAH, as defined in § 413.65 of this subchapter; and

(iv) Under the direct supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner as specified in paragraph (g) of this section, subject to the following requirements:

(A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this subchapter, ''direct supervision'' means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed;

(B) Certain therapeutic services and supplies may be assigned either general supervision or personal supervision. When such assignment is made, *general supervision* means the definition specified at § 410.32(b)(3)(i), and *personal supervision* means the definition specified at § 410.32(b)(3)(iii);

(C) Nonphysician practitioners may directly supervise services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§ 410.71, 410.73, 410.74, 410.75, 410.76, and 410.77;

(D) For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively; and

(E) For *nonsurgical extended duration therapeutic services (extended duration services),* which are hospital or CAH outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate nonphysician practitioner's immediate availability after the initiation of the service, and are not primarily surgical in nature, Medicare requires a minimum of direct supervision during the initiation of the service which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner. ''Initiation'' means the beginning portion of the nonsurgical extended duration therapeutic service which ends when the patient is stable and the supervising physician or the appropriate nonphysician practitioner determines that the remainder of the service can be delivered safely under general supervision.

(2) In the case of partial hospitalization services, also meet the conditions of paragraph (e) of this section.

* * * * *

(d) Rules on emergency services furnished to outpatients in a foreign country are specified in subpart H of Part 424 of this chapter.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

3. The authority citation for Part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh and 1395nn).

4. Section 411.362 is amended by—

a. Adding in paragraph (a) definitions of ''baseline number of operating rooms, procedure rooms, and beds'' and ''main campus of the hospital'' in alphabetical order.

b. Revising paragraph (b)(2).

c. Adding paragraph (c).

The revision and additions read as follows:

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) * * *

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement).

Main campus of the hospital means ''campus'' as defined at § 413.65(a)(2).

* * * * *

(b) * * *

(2) *Prohibition on facility expansion.* The hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital is licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless an exception is granted pursuant to paragraph (c) of this section.

* * * * *

(c) Criteria for an individual hospital seeking an exception to the prohibition on facility expansion.

(1) *General.* An applicable hospital or high Medicaid facility may request an exception from the prohibition on facility expansion up to once every 2 years from the date of a CMS decision on the hospital's most recent request.

(2) *Criteria for applicable hospital.* An applicable hospital is a hospital that satisfies all of the following criteria:

(i) *Population increase.* Is located in a county that has a percentage increase in population that is at least 150 percent of the percentage increase in population of the State in which the hospital is located during the most recent 5-year period for which data are available as of the date that the hospital submits its request. To calculate State and county population growth, a hospital must use Bureau of the Census estimates.

(ii) *Medicaid inpatient admissions.* Has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located for each of the 3 most recent fiscal years for which data are available as of the date that the hospital submits its request. A hospital must use filed hospital cost report discharge data to estimate its annual percent of total inpatient admissions under Medicaid.

(iii) *Nondiscrimination.* Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(iv) *Average bed capacity.* Is located in a State in which the average bed capacity in the State is less than the national average bed capacity for each of the 3 most recent fiscal years for which data are available as of the date that the hospital submits its request.

(v) *Average bed occupancy.* Has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located for each of the 3 most recent fiscal years for which data are available as of the date that the hospital submits its request. A hospital must use filed hospital cost report data to determine its average bed occupancy rate.

(3) *Criteria for high Medicaid facility.* A high Medicaid facility is a hospital that satisfies all of the following criteria:

(i) *Sole hospital.* Is not the sole hospital in the county in which the hospital is located.

(ii) *Medicaid inpatient admissions.* With respect to each of the 3 most recent fiscal years for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located. A hospital must use filed hospital cost report discharge data to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

(iii) *Nondiscrimination.* Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(4) *Procedure for submitting a request.* (i) A hospital must either mail an original and one copy of the written request to CMS or submit the request electronically to CMS. If a hospital submits the request electronically, the hospital must mail an original hard copy of the signed certification set forth in paragraph (c)(4)(iii) of this section to CMS.

(ii) A request must include the following information:

(A) The name, address, National Provider Identification number(s) (NPI), Tax Identification Number(s) (TIN), and CMS Certification Number(s) (CCN) of the hospital requesting an exception.

(B) The county in which the hospital requesting an exception is located.

(C) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the hospital.

(D) A statement identifying the hospital as an applicable hospital or high Medicaid facility and a detailed explanation with supporting documentation regarding whether and how the hospital satisfies each of the criteria for an applicable hospital or high Medicaid facility. The request must state that the hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(E) Documentation supporting the hospital's calculations of its baseline number of operating rooms, procedure rooms, and beds; the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits a request for an exception; and the additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

(iii) A request must include the following certification signed by an authorized representative of the hospital: ''With knowledge of the penalties for false statements provided by 18 U.S.C. 1001, I certify that all of the information provided in the request and all of the documentation provided with the request is true and correct to the best of my knowledge and belief.'' An authorized representative is the chief executive officer, chief financial officer, or other comparable officer of the hospital.

(5) *Community input and timing of complete request.* Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public Web site for the hospital that it is requesting an exception. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the **Federal Register**. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS.

(i) If CMS does not receive written comments from the community, a request will be deemed complete at the end of the 30-day period.

(ii) If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement. A request will be deemed complete at the end of this 30-day period regardless of whether the hospital submits a rebuttal statement.

(6) A permitted increase under this section—

(i) May not exceed 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and

(ii) May occur only in facilities on the hospital's main campus.

(7) *Publication of final decisions.* Not later than 60 days after receiving a complete request, CMS will publish the final decision in the **Federal Register**.

(8) *Limitation on review.* There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the process under this section (including the establishment of such process).

PART 416—AMBULATORY SURGICAL SERVICES

5. The citation for Part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

6. Section 416.166 is amended by revising paragraph (b) to read as follows:

§ 416.166 Covered surgical procedures.

* * * * *

(b) *General standards.* Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the Internet on the CMS Web site that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

* * * * *

7. Section 416.171 is amended by revising paragraphs (b) and (d) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) *Exception.* The national ASC payment rates for the following items and services are not determined in accordance with paragraph (a) of this section but are paid an amount derived from the payment rate for the equivalent item or service set under the payment system established in part 419 of this subchapter as updated annually in the **Federal Register** and/or via the Internet on the CMS Web site.

* * * * *

(d) *Limitation on payment rates for office-based surgical procedures and covered ancillary radiology services.* Notwithstanding the provisions of paragraph (a) of this section, for any covered surgical procedure under § 416.166 that CMS determines is commonly performed in physicians' offices or for any covered ancillary radiology service, excluding those listed in paragraphs (d)(1) and (2) of this section, the national unadjusted ASC payment rates for these procedures and services will be the lesser of the amount determined under paragraph (a) of this section or the amount calculated at the nonfacility practice expense relative value units under § 414.22(b)(5)(i)(B) of this subchapter multiplied by the

conversion factor described in § 414.20(a)(3) of this subchapter.

(1) The national unadjusted ASC payment rate for covered ancillary radiology services that involve certain nuclear medicine procedures will be the amount determined under paragraph (a) of this section.

(2) The national unadjusted ASC payment rate for covered ancillary radiology services that use contrast agents will be the amount determined under paragraph (a) of this section.

* * * * *

8. Section 416.173 is revised to read as follows:

§ 416.173 Publication of revised payment methodologies and payment rates.

CMS publishes annually, through notice and comment rulemaking in the **Federal Register** and/or via the Internet on the CMS Web site, the payment methodologies and payment rates for ASC services and designates the covered surgical procedures and covered ancillary services for which CMS will make an ASC payment and other revisions as appropriate.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

9. The authority citation for Part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395(t), and1395hh).

10. Section 419.32 is amended by:

a. Revising paragraph (b)(1)(iv)(A).

b. Removing the word ''and'' that appears at the end of paragraph (b)(1)(iv)(B)(*1*).

c. Removing the period and adding ''; and'' in its place at the end of paragraph (b)(1)(iv)(B)(*2*).

d. Adding a new paragraph (b)(1)(iv)(B)(*3*).

The revision and addition read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv)(A) For calendar year 2003 and subsequent years, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, reduced by the factor(s) specified in paragraph (b)(1)(iv)(B) of this section.

(B) * * *

(*3*) For calendar year 2012, a multifactor productivity adjustment (as determined by CMS) and 0.1 percentage point.

* * * * *

11. Section 419.43 is amended by adding paragraph (i) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(i) *Payment adjustment for certain cancer hospitals.*—(1) *General rule.* CMS provides for a payment adjustment for covered hospital outpatient department services furnished on or after January 1, 2012, by a hospital described in section 1886(d)(1)(B)(v) of the Act.

(2) *Amount of payment adjustment.* The amount of the payment adjustment under paragraph (i)(1) of this section is determined by the Secretary as follows:

(i) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (as determined by the Secretary) that is less than the weighted average payment-to-cost ratio of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary) (referred to as the target payment-to-cost ratio), for covered hospital outpatient department services except pass-through devices as defined in § 419.66, the payment adjustment is the percentage difference between the payment-to-cost ratio of the hospital and the target payment-to-cost ratio.

(ii) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (as determined by the Secretary) that is less than the weighted average payment-to-cost ratio of other hospitals furnishing services under section 1866(t) of the Act (as determined by the Secretary) (referred to as the target payment-to-cost ratio), for pass-through devices as defined in § 419.66, the payment adjustment is zero percent.

(iii) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (as determined by the Secretary) that is greater than the target payment-to-cost ratio (as determined by the Secretary), for covered hospital outpatient department services, the payment adjustment is zero percent.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (i)(1) of this section in a budget neutral manner.

12. Section 419.70 is amended by revising paragraphs (d)(2) introductory text and (d)(6) to read as follows:

§ 419.70 Transitional adjustments to limit decline in payments.

* * * * *

(d) * * *

(2) *Temporary treatment for small rural hospitals on or after January 1, 2006.* For covered hospital outpatient services furnished in a calendar year from January 1, 2006, through December 31, 2011, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 95 percent of that difference for services furnished during CY 2006, 90 percent of that difference for services furnished during CY 2007, and 85 percent of that difference for services furnished during CYs 2008, 2009, 2010, and 2011 if the hospital—

* * * * *

(6) *Temporary treatment for sole community hospitals on or after January 1, 2010, and through December 31, 2011.* For covered hospital outpatient services furnished on or after January 1, 2010, through December 31, 2011, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

13. The authority citation for Part 489 continues to read as follows:

Authority: Secs. 1102, 1819, 1820(e), 1861, 1864(m), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh).

14. Section 489.20 is amended by revising paragraph (w) to read as follows:

§ 489.20 Basic commitments.

* * * * *

(w)(1) In the case of a hospital as defined in § 489.24(b), to furnish written notice to all patients at the beginning of their planned or unplanned inpatient hospital stay or at the beginning of any planned or unplanned outpatient visit for observation, surgery or any other procedure requiring anesthesia, if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, in order to assist the patients in making informed decisions regarding their care, in accordance with § 482.13(b)(2) of this subchapter. For purposes of this paragraph, a planned hospital stay or

outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or outpatient service. An unplanned hospital stay or outpatient visit begins at the earliest point at which the patient presents to the hospital.

(2) In the case of a hospital that is a main provider and has one or more remote locations of a hospital or one or more satellites, as these terms are defined in § 413.65(a)(2), § 412.22(h), or § 412.25(e) of this chapter, as applicable, the determination is made separately for the main provider and each remote location or satellite whether notice to patients is required. Notice is required at each location at which inpatient services are furnished at which a doctor of medicine or doctor of osteopathy is not present 24 hours per day, 7 days per week.

(3) The written notice must state that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition, as defined in § 489.24(b), at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital.

(4) Before admitting a patient or providing an outpatient service to outpatients for whom a notice is required, the hospital must receive a signed acknowledgment from the patient stating that the patient understands that a doctor of medicine or doctor of osteopathy may not be present during all hours services are furnished to the patient.

(5) Each dedicated emergency department, as that term is defined in § 489.24(b), in a hospital in which a doctor of medicine or doctor of osteopathy is not present 24 hours per day, 7 days per week must post a notice conspicuously in a place or places likely to be noticed by all individuals entering the dedicated emergency department. The posted notice must state that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs of any patient with an emergency medical condition, as defined in § 489.24(b), at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

15. The authority citation for Part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

16. Section 495.8 is amended by revising paragraph (b)(2)(ii) and adding paragraph (b)(2)(vi) to read as follows:

§ 495.8 Demonstration of meaningful use criteria.

* * * * *

(b) * * *

(2) * * *

(ii) *Reporting clinical quality information.* For § 495.6(f)(9) ''Reporting hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States,'' report the hospital quality measures selected by CMS to CMS (or in the case of Medicaid eligible hospitals, the States) in the form and manner specified by CMS (or in the case of Medicaid eligible hospitals, the States).

* * * * *

(vi) *Exception for Medicare eligible hospitals and CAHs for FY 2012—Participation in the Medicare EHR Incentive Program Electronic Reporting Pilot.* In order to satisfy the clinical quality measure reporting objective in § 495.6(f)(9), aside from attestation, a Medicare eligible hospital or CAH may participate in the Medicare EHR Incentive Program Electronic Reporting Pilot.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778 (Medical Assistance)

Dated: June 24, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 28, 2011.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–16949 Filed 7–1–11; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 76 Monday,
No. 137 July 18, 2011

Part III

Securities and Exchange Commission

17 CFR Part 240
Business Conduct Standards for Security-Based Swap Dealers and Major Security-Based Swap Participants; Proposed Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34–64766; File No. S7–25–11]

RIN 3235–AL10

Business Conduct Standards for Security-Based Swap Dealers and Major Security-Based Swap Participants

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') is proposing for comment new rules under the Securities Exchange Act of 1934 (''Exchange Act'') that are intended to implement provisions of Title VII (''Title VII'') of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (''Dodd-Frank Act'') relating to external business conduct standards for security-based swap dealers (''SBS Dealers'') and major security-based swap participants (''Major SBS Participants'').

DATES: Comments should be received on or before August 29, 2011.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/proposed.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number S7–25–11 on the subject line; or
- Use the Federal eRulemaking Portal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number S7–25–11. This file number should be included on the subject line if e-mail is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/proposed.shtml*). Comments are also available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Lourdes Gonzalez, Acting Co-Chief Counsel, Joanne Rutkowski, Branch Chief, Cindy Oh, Special Counsel, Office of Chief Counsel, Division of Trading and Markets, at (202) 551–5550, at the Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Commission is proposing Rules 15Fh–1 to 15Fh–6 and 15Fk–1 under the Exchange Act governing certain business conduct requirements for SBS Dealers and Major SBS Participants. The Commission is soliciting comments on all aspects of the proposed rules and will carefully consider any comments received.

Table of Contents

I. Introduction

A. Statutory Framework

On July 21, 2010, the President signed the Dodd-Frank Act into law.[1] Title VII of the Dodd-Frank Act generally provides the Commission with authority to regulate ''security-based swaps,'' the Commodity Futures Trading Commission (''CFTC'') with authority to regulate ''swaps,'' and both the CFTC and the Commission with authority to regulate ''mixed swaps.'' [2]

Section 764 of the Dodd-Frank Act amends the Exchange Act by adding new Section 15F.[3] Paragraph (h) of the new section authorizes and requires the Commission to adopt rules specifying business conduct standards for SBS Dealers [4] and Major SBS Participants [5] in their dealings with counterparties, including counterparties that are ''special entities.'' ''Special entities'' are generally defined to include federal agencies, states and their political subdivisions, employee benefit plans as defined under the Employee Retirement Income Security Act of 1974 (''ERISA''), governmental plans as defined under ERISA, and endowments.[6] Congress granted the Commission broad authority to promulgate business conduct requirements, as appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Exchange Act.[7]

Section 15F(h)(6) of the Exchange Act directs the Commission to prescribe rules governing business conduct standards for SBS Dealers and Major SBS Participants (collectively, ''SBS Entities''). These standards, as described in Exchange Act Section 15F(h)(3), must require an SBS Entity to: verify that a counterparty meets the eligibility standards for an ''eligible contract participant'' (''ECP''); disclose to the counterparty material information about the security-based swap, including material risks and characteristics of the security-based swap, and material incentives and conflicts of interest of the SBS Entity in connection with the security-based swap; and provide the counterparty with information concerning the daily mark for the security-based swap. Section 15F(h)(3) also directs the Commission to establish a duty for SBS Entities to communicate in a fair and balanced manner based on principles of fair dealing and good faith. Section 15F(h)(1) of the Exchange Act grants the Commission authority to promulgate rules applicable to SBS Entities that relate to, among other things, fraud, manipulation and abusive practices involving security-based swaps (including security-based swaps that are offered but not entered into),

[1] Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[2] Section 712(d) of the Dodd-Frank Act provides that the Commission and the CFTC, in consultation with the Board of Governors of the Federal Reserve System (''Federal Reserve''), shall jointly further define the terms ''swap,'' ''security-based swap,'' ''swap dealer,'' ''security-based swap dealer,'' ''major swap participant,'' ''major security-based swap participant,'' ''eligible contract participant,'' and ''security-based swap agreement.'' Public Law 111–203, 124 Stat. 1376, 1644–1646 (2010). These terms are defined in Sections 721 and 761 of the Dodd-Frank Act and, with respect to the term ''eligible contract participant,'' in Section 1a(18) of the Commodity Exchange Act, 7 U.S.C. 1a(18), as re-designated and amended by Section 721 of the Dodd-Frank Act. Section 721(c) of the Dodd-Frank Act also requires the CFTC to adopt a rule to further define the terms ''swap,'' ''swap dealer,'' ''major swap participant,'' and ''eligible contract participant,'' and Section 761(b) of the Dodd-Frank Act permits the Commission to adopt a rule to further define the terms ''security-based swap,'' ''security-based swap dealer,'' ''major security-based swap participant,'' and ''eligible contract participant,'' with regard to security-based swaps, for the purpose of including transactions and entities that have been structured to evade Title VII. Public Law 111–203, 124 Stat. 1376, 1658–1672, 1754, 1759 (2010). Finally, Section 712(a) of the Dodd-Frank Act provides that the Commission and CFTC, after consultation with the Federal Reserve, shall jointly prescribe regulations regarding ''mixed swaps,'' as may be necessary to carry out the purposes of Title VII. Public Law 111–203, 124 Stat. 1376, 1642 (2010).

[3] *See* Public Law 111–203, 124 Stat. 1376, 1789–1792, § 764(a) (adding Exchange Act Section 15F). All references to the Exchange Act are to the Exchange Act, as amended by the Dodd-Frank Act.

[4] Section 761 of the Dodd-Frank Act amends Section 3(a) of the Exchange Act to add new Exchange Act Section 3(a)(71)(A), which generally defines ''security-based swap dealer'' as ''any person who: (i) holds themself [sic] out as a dealer in security-based swaps; (ii) makes a market in security-based swaps; (iii) regularly enters into security-based swaps with counterparties as an ordinary course of business for its own account; or (iv) engages in any activity causing it to be commonly known in the trade as a dealer or market maker in security-based swaps.'' Public Law 111–203, 124 Stat. 1376, 1758, § 761.

The Commission and the CFTC are jointly proposing rules and interpretive guidance under the Exchange Act and the Commodity Exchange Act to further define the terms ''swap dealer,'' ''security-based swap dealer,'' ''major swap participant,'' ''major security-based swap participant,'' and ''eligible contract participant.'' *See* Further Definition of ''Swap Dealer,'' ''Security-Based Swap Dealer,'' ''Major Swap Participant,'' ''Major Security-Based Swap Participant'' and ''Eligible Contract Participant,'' Exchange Act Release No. 63452 (Dec. 7, 2010), 75 FR 80174 (Dec. 21, 2010) (''Definitions Release'').

[5] Section 761 of the Dodd-Frank Act amends Section 3(a) of the Exchange Act to add new Exchange Act Section 3(a)(67)(A), which defines ''major security-based swap participant'' as ''any person: (i) Who is not a security-based swap dealer; and (ii)(I) who maintains a substantial position in security-based swaps for any of the major security-based swap categories, as such categories are determined by the Commission, excluding both positions held for hedging or mitigating commercial risk and positions maintained by any employee benefit plan (or any contract held by such a plan) as defined in paragraphs (3) and (32) of Section 3 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002) for the primary purpose of hedging or mitigating any risk directly associated with the operation of the plan; (II) whose outstanding security-based swaps create substantial counterparty exposure that could have serious adverse effects on the financial stability of the United States banking system or financial markets; or (III) that is a financial entity that (aa) is highly leveraged relative to the amount of capital such entity holds and that is not subject to capital requirements established by an appropriate Federal banking regulator; and (bb) maintains a substantial position in outstanding security-based swaps in any major security-based swap category, as such categories are determined by the Commission.'' Public Law 111–203, 124 Stat. 1376, 1755–1756, § 761(a) (to be codified at 15 U.S.C. 78c(a)(67)(A)).

See also Definitions Release, *supra* note 4.

[6] Public Law 111–203, 124 Stat. 1376, 1789–1790, § 764(a) (to be codified at 15 U.S.C. 78o–10(h)(2)(C)).

[7] *See* Public Law 111–203, 124 Stat. 1376, 1790 (to be codified at 15 U.S.C. 78o–10(h)(3)(D)) (''[b]usiness conduct requirements adopted by the Commission shall establish such other standards and requirements as the Commission may determine are appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of this Act''). *See also* Public Law 111–203, 124 Stat. 1376, 1789 (to be codified at 15 U.S.C. 78o–10(h)(1)(D)) (requiring that SBS Entities comply as well with ''such business conduct standards * * * as may be prescribed by the Commission by rule or regulation that relate to such other matters as the Commission determines to be appropriate'').

diligent supervision of SBS Entities and adherence to all applicable position limits.[8]

Section 15F(h)(4) of the Exchange Act requires that an SBS Dealer that ''acts as an advisor to a special entity'' must act in the ''best interests'' of the special entity and undertake ''reasonable efforts to obtain such information as is necessary to make a reasonable determination'' that a recommended security-based swap is in the best interests of the special entity. Section 15F(h)(5) requires that SBS Entities that offer to or enter into a security-based swap with a special entity comply with any duty established by the Commission that requires an SBS Entity to have a ''reasonable basis'' for believing that the special entity has an ''independent representative'' that meets certain criteria and undertakes a duty to act in the ''best interests'' of the special entity.[9] This provision also requires that an SBS Entity disclose in writing the capacity in which it is acting (*e.g.*, as principal) before initiating a transaction with a special entity.[10]

Section 15F(k) of the Exchange Act requires each SBS Entity to designate a chief compliance officer and imposes certain duties on that person.

B. Consultations

In developing the rules proposed herein, the Commission staff has, in compliance with Sections 712(a)(2)[11] and 752(a)[12] of the Dodd-Frank Act, consulted and coordinated with the CFTC and the prudential regulators.[13] Commission staff also met with persons representing a broad spectrum of views on the proposed rules.[14] These meetings were conducted jointly with CFTC staff. Among the persons who participated in the meetings were other regulators, broker-dealers, consumer and investor advocates, endowments, end-users, financial institutions, futures commission merchants, industry trade groups, investment fund managers, labor unions, pension fund managers, self-regulatory organizations (''SROs''), state and local governments, and swap dealers. We have considered standards or guidance issued by prudential regulators and international organizations, requirements applicable under foreign regulatory regimes, and recommendations for industry ''best practices.''[15] We have also taken into account the more than 70 comments received by the CFTC on its proposed business conduct rules for swap dealers and major swap entities.[16]

The staffs of the Commission and the CFTC have been consulting with the staff of the Department of Labor, and will continue to do so, concerning the potential interface between ERISA and the business conduct requirements of the Dodd-Frank Act. We recognize the importance of the ability of SBS Dealers to offer security-based swaps to special entities that are subject to ERISA, both for dealers and for the pension plans that may rely on security-based swaps to manage risk and reduce volatility.

C. Approach to Drafting the Proposed Rules

1. General Objectives

Section 15F(h) of the Exchange Act provides the Commission with both mandatory and discretionary rulemaking authority. Our intent, in exercising this authority, is to establish a regulatory framework that both protects investors and promotes efficiency, competition, and capital formation.[17] The Commission staff has worked closely with CFTC staff in consulting with the public and in developing the proposed rules, with a view to establishing consistent and comparable requirements for our respective registrants, to the extent possible.[18]

The Commission understands that the proposed rules discussed herein, as well as other proposals that the Commission is considering to implement the Dodd-Frank Act, if adopted, could significantly affect—and be significantly affected by—the development of the security-based swaps market in a number of ways. If the Commission adopts rules that are too permissive, for example, they may not adequately protect investor interests or promote the purposes of the Dodd-Frank Act. If, however, the Commission adopts measures that are too onerous, they could unduly limit hedging and other legitimate activities by discouraging participation in security-based swap markets. We are aware that the further development of the security-based swaps market, including in response to rules adopted by the Commission under the Dodd-Frank Act, may alter the calculus for regulation of business conduct of SBS Entities. We urge commenters, as they review the proposed rules, to consider generally the role that regulation may play in the development of the market for security-

---

[8] The Commission has proposed for comment a new Rule 9j–1 under the Exchange Act, which is intended to prevent fraud, manipulation, and deception in connection with the offer, purchase or sale of any security-based swap, the exercise of any right or performance of any obligation under a security-based swap, or the avoidance of such exercise or performance. Prohibition against Fraud, Manipulation, and Deception in Connection with Security-Based Swaps, Exchange Act Release No. 63236 (Nov. 3, 2010), 75 FR 68560 (Nov. 8, 2010). The Commission is separately considering the matter of position limits, and would propose any position limits in a separate rulemaking, as necessary.

[9] Pub. L. 111–203, 124 Stat. 1376, 1791 (to be codified at 15 U.S.C. 78o–10(h)(5)).

[10] *Id.*

[11] Section 712(a)(2) of the Dodd-Frank Act states in part, ''the Securities and Exchange Commission shall consult and coordinate to the extent possible with the Commodity Futures Trading Commission and the prudential regulators for the purposes of assuring regulatory consistency and comparability, to the extent possible.'' Public Law 111–203, 124 Stat. 1376, 1641–1642 (to be codified at 15 U.S.C. 8302(a)(2)).

[12] Section 752(a) of the Dodd-Frank Act states in part that, ''[i]n order to promote effective and consistent global regulation of swaps and security-based swaps, the Commodity Futures Trading Commission, the Securities and Exchange Commission, and the prudential regulators (as that term is defined in Section 1a(39) of the Commodity Exchange Act), as appropriate, shall consult and coordinate with foreign regulatory authorities on the establishment of consistent international standards with respect to the regulation (including fees) of swaps.'' Public Law 111–203, 124 Stat. 1376, 1749–1750 (to be codified at 15 U.S.C. 8325(a)).

[13] ''Prudential regulator,'' as explained in Section 711 of the Dodd-Frank Act, has the meaning given to it in section 1a of the Commodity Exchange Act (7 U.S.C. 1a), including any modification thereof under section 721(b) of the Dodd-Frank Act. Public Law 111–203, 124 Stat. 1376, 1641 (to be codified at 15 U.S.C. 8301).

[14] A list of Commission staff meetings in connection with this rulemaking is available on the Commission's website under ''Meetings with SEC Officials'' at *http://www.sec.gov/comments/df-title-vii/swap/swap.shtml.* In addition, the Commission received several letters from the public, available at *http://www.sec.gov/comments/df-title-vii/swap/swap.shtml.*

[15] *See, e.g.,* Int'l Org. of Securities Commissions, *Operational and Financial Risk Management Control Mechanisms for Over-the-Counter Derivatives Activities of Regulated Securities Firms,* (July 1994) (''IOSCO Report''); Bank for Int'l Settlements, Basel Committee on Banking Supervision, Risk Management Guidelines for Derivatives (July 1994) (''BIS Report''); Derivatives Policy Group, *Framework for Voluntary Oversight* (Mar. 1995), *http://www.riskinstitute.ch/137790.htm;* The Counterparty Risk Management Group, *Improving Counterparty Risk Management Practices* (June 1999) (''CRMPG I Report''); The Counterparty Risk Management Group, *Toward Greater Financial Stability: A Private Sector Perspective. The Report of the Counterparty Risk Management Policy Group II* (July 27, 2005) (''CRMPG II Report''); The Counterparty Risk Management Group, *Containing Systemic Risk: The Road to Reform, The Report of the CRMPG III* (Aug. 6, 2008) (''CRMPG III Report''). In considering industry voluntary best practices, the Commission acknowledges that such best practices were not necessarily intended to establish or guide regulatory standards for which market participants would have legal liability if violated.

[16] *See* Business Conduct Standards for Swap Dealers and Major Swap Participants with Counterparties, 75 FR 80638 (Dec. 22, 2010) (''CFTC External Business Conduct Release''). Comments received by the CFTC are available at *http://comments.cftc.gov/PublicComments/CommentList.aspx?id=935.*

[17] *See* Section 3(f) of the Exchange Act, 15 U.S.C. 78c(f).

[18] *See* Section I.B, *supra.*

based swaps, as well as the role that market developments may play in changing the nature and implications of regulation, and to focus in particular on this issue with respect to the proposed business conduct standards for SBS Entities.

2. SRO Rules as a Potential Point of Reference

Under the framework established in the Dodd-Frank Act, SBS Entities are not required to be members of SROs, and no SRO has authority to regulate the activities of an SBS Entity, unless the SBS Entity is otherwise a member of that SRO. Nevertheless, we preliminarily believe that SRO business conduct rules provide a potential point of reference to inform our development of business conduct rules for SBS Entities, for several reasons.[19]

First, a number of the business conduct standards in Section 15F(h) of the Exchange Act, including those regarding fair and balanced communications,[20] supervision,[21] and designation of a chief compliance officer,[22] appear to be patterned on and are consistent with standards that have been established by SROs for their members, with Commission approval.[23]

Second, business conduct standards under SRO rules have been developed over the course of many decades with input from market participants. Many market participants are familiar with these standards and are experienced with implementing them through existing compliance and supervisory controls and procedures. Indeed, if the Commission were to promulgate completely new business conduct standards that deviate in approach from established SRO rules in the same areas, our actions could increase uncertainty and impose burdens on the many market participants already familiar with SRO business conduct standards by requiring them to adapt to and implement a new and different business conduct regime for security based swap transactions.

Third, to the extent that certain SBS Entities may also be registered as broker-dealers, they would be subject to the full panoply of SRO rules, including SRO business conduct rules, with respect to their activities related to security-based swaps.[24] If the Commission were to adopt business conduct standards that differ materially from those imposed by SRO rules, these firms could be required to comply with two different, and potentially inconsistent, business conduct regimes—the Commission's and the SRO's—for the same transaction. Conversely, consistency between the business conduct requirements could reduce potential competitive disparities between SBS Entities that are SRO members and those that are not. Consistent regulatory requirements could also potentially benefit counterparties to SBS Entities, by providing a more uniform level of protection and limiting the confusion or uncertainty that might otherwise arise if substantially different rules were to apply to the same type of transaction based solely on whether the SBS Entity is an SRO member.

At the same time, in considering the business conduct standards that have been developed by SROs, we are mindful that the security-based swap market historically has been primarily an institutional market in which transactions are typically negotiated on a principal-to-principal basis. While there is a wide range of counterparty sophistication within this market, the greater participation of institutional investors in the security-based swap market suggests a potentially different dynamic in the nature of the interactions between SBS Entities and their counterparties. Accordingly, it may be appropriate, for example, for the business conduct requirements applicable to SBS Entities to diverge to some extent from the requirements generally applicable to broker-dealers, whose activities may range from principal trading with institutional counterparties to retail brokerage on behalf of individual investors.

In light of these considerations, the Commission is seeking to strike a balance in its use of SRO business conduct standards as a point of reference for the proposed rules. As noted above, one potential benefit of this approach would be to provide greater legal certainty and promote consistent requirements across different types of SBS Entities. That potential benefit would not be achieved if the Commission were to implement, interpret and enforce its business conduct standards in a manner that differs substantially from that of the SROs without grounding such actions in functional differences between the security-based swap market and other securities markets. Thus, absent such functional differences, when a business conduct standard in these proposed rules is based on a similar SRO standard, we would expect—at least as an initial matter—to take into account the SRO's interpretation and enforcement of its standard when we interpret and enforce our rule. At the same time, as noted above, we are not bound by an SRO's interpretation and enforcement of an SRO rule, and our policy objectives and judgments may diverge from those of a particular SRO. Accordingly, we would also expect to take into account such differences in interpreting and enforcing our rules.

We request comment on all aspects of our approach to using business conduct requirements applicable to market professionals (such as broker-dealers and futures commission merchants) under existing SRO rules as a point of reference in developing the business conduct requirements applicable to SBS Entities.

3. Business Conduct Rules Not Expressly Addressed by the Dodd-Frank Act

In addition to business conduct requirements expressly addressed by Title VII of the Dodd-Frank Act, we are proposing for comment certain other business conduct requirements for SBS Dealers that we preliminarily believe would further the principles that underlie the Dodd-Frank Act. These rules would, among other things, impose certain ''know your counterparty'' and suitability obligations on SBS Dealers, and restrict SBS Dealers from engaging in certain ''pay to play'' activities.[25]

Know Your Counterparty—Broker-dealers are subject to ''know your customer'' standards that help to ensure investor protection and fair dealing in securities transactions, both for retail

[19] We have looked, in particular, to the requirements imposed by the Financial Industry Regulatory Authority, Inc., the Municipal Securities Rulemaking Board, and the National Futures Association.

[20] Section 15F(h)(3)C) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1790 (to be codified at 15 U.S.C. 78o–10(h)(3)(C)). *Cf.* NASD Rule 2210(d)(1)(A).

[21] Section 15F(h)(1)(B) of the Exchange Act, Pub. L. 111–203, 124 Stat. 1376, 1789 (to be codified at 15 U.S.C. 78o–10(h)(1)(B)). *Cf.* NASD Rules 3010 and 3012.

[22] Section 15F(k) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1793—1794 (to be codified at 15 U.S.C. 78o–10(k)). *Cf.* FINRA Rule 3130.

[23] The Commission exercises oversight over SROs with respect to their interpretive, rulemaking and enforcement activities. *See* Section 19 of the Exchange Act, 15 U.S.C. 78s.

[24] Because security-based swap transactions are ''securities'' within the meaning of Section 3(a)(10) of the Exchange Act, broker-dealers would be subject to SRO business conduct and other rules applicable to such transactions. Public Law 111–203, 124 Stat. 1376, 1755, § 761(a)(2) (to be codified at 15 U.S.C. 78c(a)(10)).

[25] The CFTC has recently proposed rules that would impose similar requirements for swap dealers and major swap participants. *See* CFTC External Business Conduct Release, *supra,* note 16.

and institutional investors.[26] We preliminarily believe that a ''know your counterparty'' standard would be consistent with the principles underlying the Dodd-Frank Act. Accordingly, we are proposing, in addition to the rules expressly addressed by Section 15F(h) of the Exchange Act, certain ''know your counterparty'' requirements for SBS Dealers.[27]

Suitability—Broker-dealers are subject to suitability standards that help to ensure investor protection and fair dealing in securities transactions, both for retail and institutional investors.[28] In addition, the Dodd-Frank Act effectively imposes a suitability requirement on SBS Dealers that, when acting as advisors, make recommendations to special entities.[29] We preliminarily believe that it would be appropriate to extend these protections to certain situations in which an SBS Dealer is entering into a security-based swap with a counterparty that is not a special entity. Accordingly, we are proposing certain suitability requirements for SBS Dealers when making recommendations to counterparties.[30]

Pay to Play—We are also proposing pay to play restrictions for SBS Dealers that are intended to complement the restrictions applicable to other market intermediaries seeking to engage in securities transactions with municipal entities. As explained more fully in Section II.D.5, pay to play practices, in which elected officials may allow political contributions to play a role in the selection of financial services providers, distort the process by which public contracts are awarded. Concerns about pay to play practices in the municipal securities and investment adviser contexts have prompted the promulgation of pay to play restrictions for those market professionals.[31] We are concerned that similar pay to play practices could distort the market for securities-based swap transactions.[32] These abuses encourage corrupt market practices, and can harm municipal entities that subsequently enter into inappropriate security-based swaps.[33] Because certain SBS Dealers may not be covered by other pay to play rules already in effect, we are proposing for comment here pay to play rules intended to create a comparable regulatory framework with respect to those SBS Dealers. Given the similarity of pay to play practices across various contexts, and to facilitate compliance, we are proposing pay to play rules that are intended to be consistent with existing pay to play rules, to the extent practicable.

We request comment on all aspects of our proposal to impose certain limited business conduct requirements not expressly addressed by the Dodd-Frank Act.

4. Differences Between SBS Dealers and Major SBS Participants

We have also considered how the differences between the definitions of SBS Dealer and Major SBS Participant may be relevant in formulating the business conduct standards applicable to these entities. The Dodd-Frank Act defines ''security-based swap dealer'' in a functional manner, by reference to the way a person holds itself out in the market and the nature of the conduct engaged in by that person, and how the market perceives the person's activities.[34] As described in our joint proposal with the CFTC regarding this definition:

> [S]wap dealers can often be identified by their relationships with counterparties. Swap dealers tend to enter into swaps with more counterparties than do non-dealers, and in some markets, non-dealers tend to constitute a large portion of swap dealers' counterparties. In contrast, non-dealers tend to enter into swaps with swap dealers more often than with other non-dealers. The Commissions can most efficiently achieve the purposes underlying Title VII of the Dodd-Frank Act—to reduce risk and to enhance operational standards and fair dealing in the swap markets—by focusing their attention on those persons whose function is to serve as the points of connection in those markets. The definition of swap dealer, construed functionally in the manner set forth above, will help to identify those persons.[35]

The definition of ''major security-based swap participant,'' in contrast, focuses on the market impacts and risks associated with an entity's security-based swap positions.[36] Despite the differences in focus, the Dodd-Frank Act applies substantially the same statutory standards to SBS Dealers and Major SBS Participants.[37] We have attempted to

[26] *See* Notice of Filing of Amendment No. 1 to a Proposed Rule Change and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, to Adopt FINRA Rules 2090 (Know Your Customer) and 2111 (Suitability) in the Consolidated FINRA Rulebook, Exchange Act Release No. 63325 (Nov. 17, 2010), 75 FR 71479 (Nov 23, 2010) (effective July 9, 2012) (''Suitability Order'').

[27] Proposed Rule 15Fh–3(e), discussed in Section II.C.3, *infra.*

[28] *See* Suitability Order, *supra.*

[29] Section 15F(h)(4)(C) of the Exchange Act (''Any security-based swap dealer that acts as an advisor to a special entity shall make reasonable efforts to obtain such information as is necessary to make a reasonable determination that any security-based swap recommended by the security-based swap dealer is in the best interests of the special entity''). Pub. L. 111–203, 124 Stat. 1376, 1790–1791 (to be codified at 15 U.S.C. 78o–10(h)(4)(C)).

[30] Proposed Rule 15Fh–3(f), discussed in Section II.C.4, *infra.* The suitability obligation would not apply if the counterparty is an SBS Entity or a swap dealer or major swap participant. In addition, the proposed rule would include an alternative similar to the FINRA ''institutional suitability'' exemption, as described more fully below.

[31] *See* Rule 205(4)–5 under the Investment Advisers Act of 1940 (applying pay to play restrictions to investment advisers), and MSRB Rule G–37 (which seeks to eliminate pay to play practices in the municipal securities market through restrictions on political contributions and prohibitions on municipal securities business).

[32] For example, the Commission has brought a number of actions in connection with payments by J.P. Morgan Securities Inc. to local firms whose principals or employees were friends of Jefferson County, Alabama public officials in connection with $5 billion in County bond underwriting and interest rate swap agreement business awarded to the broker-dealer. The Commission has alleged that J.P. Morgan Securities engaged in pay to play practices in connection with obtaining municipal security underwriting and interest swap agreement business from municipalities. The Commission has alleged that J.P. Morgan Securities incorporated certain of the costs of these payments into higher swap interest rates it charged the County, directly increasing the swap transaction costs to the County and its taxpayers. *See SEC* v. *Larry P. Langford,* Litigation Release No. 20545 (Apr. 30, 2008) and *SEC* v. *Charles E. LeCroy,* Litigation Release No. 21280 (Nov. 4, 2009) (charging Alabama local government officials and J.P. Morgan employees with undisclosed payments made to obtain municipal bond offering and swap agreement business from Jefferson County, Alabama). *See also J.P. Morgan Securities Inc.*, File No. 3–13673 (Nov. 4, 2009) (instituting administrative and cease-and-desist proceedings against a broker-dealer that allegedly was awarded bond underwriting and interest rate swap agreement business by Jefferson County in connection with undisclosed payments by employees of the firm).

[33] *See also* Political Contributions by Certain Investment Advisers, Investment Advisers Act Release No. 3043 (July 1, 2010), 75 FR 41018 (July 14, 2010) (describing concerns that led to adoption of Advisers Act Rule 206(4)–5); Alexander W. Butler, Larry Fauver, and Sandra Mortal, *Corruption, Political Connections, and Municipal Finance,* 22 The Review of Financial Studies 2873 (2009) (describing effect of pay to play practices on greater credit risk, higher bond yields and underwriting premium fees in municipal bond sales and underwriting).

[34] *See* note 4, *supra* (definition of ''security-based swap dealer'').

[35] Definitions Release (using ''swap dealer'' to refer both to security-based swap dealer and to swap dealer).

[36] As explained in the Definitions Release, the ''major security-based swap participant'' definition uses terms—particularly ''systemically important,'' ''significantly impact the financial system,'' and ''create substantial counterparty exposure''—that denote a focus on entities that pose a high degree of risk through their security-based swap activities. In addition, the link between the ''major participant'' definition and risk was highlighted during the Congressional debate on the statute. *See* 156 Cong. Rec. S5907 (daily ed. July 15, 2010) (dialogue between Senators Hagen and Lincoln, discussing how the goal of the major participant definition was to ''focus on risk factors that contributed to the recent financial crisis, such as excessive leverage, under-collateralization of swap positions, and a lack of information about the aggregate size of positions'').

[37] In particular, under Section 15F of the Exchange Act, SBS Dealers and Major SBS Participants generally are subject to the same types of margin, capital, business conduct and certain other requirements, unless an exclusion applies. In this way, the statute applies comprehensive

take into account these differing definitions and regulatory concerns in considering whether the business conduct requirements that we are proposing for SBS Dealers that are not expressly addressed by the statute should or should not apply to Major SBS Participants as well.[38] In general, where the Dodd-Frank Act imposes a business conduct requirement on both SBS Dealers and Major SBS Participants, we have proposed rules that would apply equally to SBS Dealers and Major SBS Participants. Where, however, a business conduct requirement is not expressly addressed by the Dodd-Frank Act, the proposed rules generally would not apply to Major SBS Participants.[39]

We request comment on whether this approach is appropriate. Where the Dodd-Frank Act requires that a business conduct rule apply to all SBS Entities, should the rule impose the same requirements on Major SBS Participants as on SBS Dealers? Where we are proposing rules for SBS Dealers that are not expressly addressed by the Dodd-Frank Act, should any of these rules apply as well to Major SBS Participants? If so, which rules and why?

5. Treatment of Special Entities

Congress has provided certain additional protections in the Dodd-Frank Act for ''special entities''—including certain municipalities, pension plans, and endowments—in connection with security-based swaps. In particular, as described in Section II.D below, Sections 15F(h)(4) and (5) of the Exchange Act, as amended by the Dodd Frank Act, establish a set of additional provisions addressed solely to the interactions between SBS Entities and special entities in connection with security-based swaps.

Some commenters have noted that special entities, like other market participants, may use swaps and security-based swaps for a variety of beneficial purposes, including risk management and portfolio adjustment.[40] For example, we understand that pension plans can be authorized to use such instruments in order to meet the investment objectives of their members.[41] At the same time, some commenters have also noted that the financial sophistication of these entities can vary greatly.[42] Such variation in sophistication, among other factors, has raised concerns about potential abuses in connection with security-based swap transactions with special entities.[43]

In implementing the special entity provisions of the Dodd-Frank Act, we have sought to give full effect to the additional protections for these entities contemplated by the statute, while not imposing restrictions on SBS Entities that would unduly limit their willingness or ability to provide special entities with the access to security-based swaps that special entities may need for risk management and other beneficial purposes. We request comment on all aspects of the approach to special entities described in this release.

II. Discussion of Proposed Rules Governing Business Conduct

The proposed rules would implement the requirements of the Dodd-Frank Act relating to business conduct standards for SBS Entities.

A. Scope: Proposed Rule 15Fh–1

Proposed Rule 15Fh–1 provides that proposed Rules 15Fh–1 through 15Fh–6 and Rule 15Fk–1 are not intended to limit, or restrict, the applicability of other provisions of the federal securities laws, including but not limited to Section 17(a) of the Securities Act of 1933 (''Securities Act''), Sections 9 and 10(b) of the Exchange Act, and the rules and regulations thereunder.[44] It also provides that proposed Rules 15Fh–1 through 15Fh–6 and Rule 15Fk–1 would not only apply in connection with entering into security-based swaps but also would continue to apply, as relevant, over the term of executed security-based swaps. Specifically, as discussed more fully herein, an SBS Entity's obligations under proposed Rules 15Fh–3(c) (daily mark) and 15Fh–3(g) (fair and balanced communications) would continue to apply over the life of a security-based swap. In addition, SBS Entities would be subject to ongoing obligations under proposed Rules 15Fh–3(h) (supervision) and 15Fk–1 (chief compliance officer). The proposed rules would not, however, apply to security-based swaps executed prior to the compliance date of these rules.

Request for Comments

The Commission requests comments generally on all aspects of proposed Rule 15Fh–1 and the scope of the proposed business conduct rules. In addition, we request comment on the following specific issues:

- Should any rule proposed by this release specify in greater detail the manner in which its disclosure or other requirements apply to associated persons?[45] If so, for which rules would such clarification be helpful? How should the Commission apply the requirements of such rules to the associated person?
- Should the proposed rules apply to transactions between an SBS Entity and

regulation to entities (*i.e.,* Major SBS Participants) whose security-based swap activities do not cause them to be dealers, but nonetheless could pose a high degree of risk to the U.S. financial system generally. *See* Public Law 111–203, 124 Stat. 1376, 1785–1796 (to be codified at 15 U.S.C. 78o–10).

[38] *See* Section I.C.4, *infra*.

[39] There are exceptions to this principle. We are proposing that all SBS Entities be required to determine if a counterparty is a special entity. In addition, Section 3C(g)(5) of the Exchange Act creates certain rights with respect to clearing for counterparties entering into security-based swaps with SBS Entities but does not require disclosure. We are proposing a rule that would require an SBS Entity to disclose to a counterparty certain information relating to these rights. *See* Public Law 111–203, 124 Stat. 1376, 1766–1767 (to be codified at 15 U.S.C. 78c–3(g)(5)). The proposed rule is intended to further the purposes of the Dodd-Frank Act to ensure that, wherever possible and appropriate, derivatives contracts formerly traded exclusively in the OTC market are cleared through a regulated clearing agency.

[40] As explained by one commenter:

''Swaps permit [pension] plans to hedge against market fluctuations, interest rate changes, and other factors that create volatility and uncertainty with respect to plan funding. Swaps also help plans rebalance their investment portfolios, diversify their investments, and gain exposure to particular asset classes without direct investments. By helping to protect plan assets as part of a prudent long-term investment strategy, swaps benefit the millions of participants who rely on these plans for retirement income, health care, and other important benefits.''

Letter from Mark J. Ugoretz, President and CEO, The ERISA Industry Committee to David A. Stawick, Secretary, CFTC (Feb. 22, 2011).

[41] *See, e.g.,* Letter from Joseph A. Dear, Chief Investment Officer, California Public Employees' Retirement System *et al.* to David A. Stawick, Secretary, CFTC (Feb. 18, 2011) (the ''Public Pension Funds Letter''):

To fulfill obligations to our members, we invest in a wide variety of assets classes, including alternative investment management, global equity, global fixed income, inflation-linked assets, and real estate. As part of our investment and risk management policies, we have authorized the use of certain derivates. The authorized derivatives include futures, forward, swaps, structured notes and options.

[42] *See, e.g.,* Letter from Barbara Roper, Director of Investor Protection, Consumer Federation of America, Lisa Donner, Executive Director, Americans for Financial Reform, Michael Greenberger, J.D., Founder and Director of University of Maryland Center for Health and Homeland Security, and Damon Silvers, Director of Policy and Special Counsel, AFL–CIO to David A. Stawick, Secretary, CFTC (Feb. 22, 2011).

[43] *See, e.g.,* 156 Cong. Rec. S5903 (daily ed. Jul. 15, 2010) (statement of Sen. Lincoln) (discussing how ''pension plans, governmental investors, and charitable endowments were falling victim to swap dealers marketing swaps and security-based swaps that they knew or should have known to be inappropriate or unsuitable for their clients. Jefferson County, AL, is probably the most infamous example, but there are many others in Pennsylvania and across the country.'').

[44] Section 15F(h) of the Exchange Act does not, by its terms, create a new private right of action or right of rescission, nor do we anticipate that the proposed rules would create any new private right of action or right of rescission.

[45] As described below, proposed Rule 15Fh–2(d) would provide that the term ''security-based swap dealer or major security-based swap participant'' would include, ''where relevant,'' an associated person of the SBS Entity in question.

its affiliates? If so, which rules? Why or why not?

• Should any rules proposed by this release, such as those relating to the daily mark or fair and balanced communications, apply to security-based swaps that were entered into prior to the effective date of these rules? If so, which rules and why?

• Should any of the proposed rules apply to amendments, made after the effective date of these rules, to security-based swaps that were entered into prior to the effective date of the rules? If so, which rules and why?

• Are there any specific interactions or relationships between the proposed rules and existing federal securities laws that should be addressed? Are there any specific interactions or relationships between the proposed rules and other regulatory requirements, such as SRO rules, that should be addressed? Are there any specific interactions or relationships between the proposed rules and other existing non-securities statutes and regulations (*e.g.,* ERISA) that should be addressed? If so, how should those interactions or relationships be clarified?

• To the extent any of the rules proposed herein are intended to provide additional protections for a particular counterparty, should the counterparty be able to opt out of those protections? Should the ability to opt out be limited to certain types of counterparties? Why or why not? What criteria should determine or inform the decision to permit a counterparty to opt out? For example, should opt out be permitted when a counterparty is a regulated entity such as a registered broker-dealer? A registered futures commission merchant? A bank? Should opt out be permitted when a counterparty meets certain objective standards, such as being a ''qualified institutional buyer'' within the meaning of Rule 144A under the Securities Act?[46] Why or why not? What other standards, if any, should the Commission consider? What would be the advantages and disadvantages of permitting a counterparty to opt out? What are the reasons that a counterparty might want to opt out of protections provided by the proposed business conduct standards? For example, would permitting counterparties to opt out lower costs? Would these reasons vary among different types of counterparties? Would counterparties have a meaningful opportunity to elect whether or not to opt out of these protections, or would they face commercial or other pressure from SBS Entities that could curtail their choice? How would permitting counterparties to opt out affect the protections otherwise afforded by the proposed rules to the counterparties of SBS Entities? How would the overall effectiveness of a proposed rule be affected if a substantial population of counterparties opts out of that rule?

• As discussed below in Section II.E, proposed Rule 15Fk–1 would require an SBS Entity to have policies and procedures reasonably designed to achieve compliance with Section 15F and the rules and regulations thereunder. Should an SBS Entity be deemed to have complied with a requirement under the proposed rules if: (i) The SBS Entity has established and maintained written policies and procedures, and a documented system for applying those policies and procedures, that are reasonably designed to achieve compliance with the requirement; and (ii) the SBS Entity has reasonably discharged the duties and obligations required by the written policies and procedures and documented system and did not have a reasonable basis to believe that the written policies and procedures and documented system were not being followed? Why or why not? Please explain the advantages or disadvantages of this approach to the extent it results in rules that effectively require SBS Entities to maintain and enforce specified policies and procedures regarding certain conduct, rather than rules that directly require, or prohibit, that conduct. Would this approach be appropriate for certain specific requirements of the rules but not for others? Why or why not? Would such an approach encourage or discourage compliance with the requirements under the proposed rules? Would the behavior of SBS Entities or the way in which they design their compliance programs be different under this approach than it would be under the rules as proposed? How would the effectiveness of such an approach compare to the effectiveness of the rules as proposed in implementing the requirements of the Dodd-Frank Act regarding the business conduct of SBS Entities, especially with respect to special entities? Would such an approach affect the ability of the Commission to inspect for compliance with the rules or to bring enforcement actions regarding violations? If so, how?

• As discussed herein, we preliminarily believe that, absent special circumstances, it would be appropriate for SBS Entities to rely on counterparty representations in connection with certain specific requirements under the proposed rules. To solicit input on when it would no longer be appropriate for an SBS Entity to rely on such representations without further inquiry, the Commission is proposing for comment two alternative approaches. One approach would permit an SBS Entity to rely on a representation from a counterparty unless it knows that the representation is not accurate. The second would permit an SBS Entity to rely on a representation unless the SBS Entity has information that would cause a reasonable person to question the accuracy of the representation. Should the rules that the Commission ultimately adopts include a standard addressing the circumstances in which an SBS Entity may rely on representations to establish compliance with the proposed rules? Why or why not?

B. Definitions: Proposed Rule 15Fh–2

Proposed Rule 15Fh–2(a), as discussed in Section II.D.3 below, would define ''act as an advisor'' for purposes of Section 15F(h)(4) of the Exchange Act and proposed Rule 15Fh–4(b).

Proposed Rule 15Fh–2(b) would define ''eligible contract participant'' to mean any person defined in Section 3(a)(66) of the Exchange Act.

Proposed Rule 15Fh–2(c), as discussed in Section II.D.4.b. below, would define ''independent representative of a special entity'' for purposes of Section 15F(h)(5) of the Exchange Act and proposed Rule 15Fh–5.

Proposed Rule 15Fh–2(d) would provide that ''security-based swap dealer or major security-based swap participant'' would include, where relevant, an associated person of the SBS Dealer or Major SBS Participant.[47] To the extent that an SBS Entity acts through, or by means of, an associated person of that SBS Entity, the associated person must comply as well with the

[46] *See* Rule 144A(a), 17 CFR 230.144A(a) (defining ''qualified institutional buyer''). *See* Letter from Kenneth E. Bensten, Jr., Executive Vice President, Public Policy and Advocacy, SIFMA, and Robert C. Pickel, Executive Vice Chairman, ISDA to David A. Stawick, Secretary, CFTC (Feb. 17, 2011) (on file with Commission) (''SIFMA/ISDA 2011 Letter'') (recommending that Commission permit opt out by ''sophisticated counterparties,'' including '' 'qualified institutional buyers' as defined in Rule 144A * * * and corporations having total assets of $100 million or more'').

[47] *See* Section 3(a)(70) of the Exchange Act, Pub. L. 111–203, 124 Stat. 1376, 1757–1758 (to be codified at 15 U.S.C. 78c(a)(70)) (defining ''Person Associated with a Security-Based Swap Dealer or Major Security-Based Swap Participant'').

applicable business conduct standards.[48]

Proposed Rule 15Fh–2(e), as discussed in Section II.D.1 below, would define ''special entity.''

Proposed Rule 15Fh–2(f), as discussed in Section II.D.4.e below, would define a person that is ''subject to a statutory disqualification'' to mean a person that would be subject to a statutory disqualification under the provisions of Section 3(a)(39) of the Exchange Act.

Request for Comments

The Commission requests comments generally on all aspects of proposed Rule 15Fh–2. In addition, we request comments on the following specific issues:

- Are there additional terms that should be defined by the Commission; if so, how should such terms be defined and why?[49]
- Should the proposed rules expressly identify the requirements that apply to associated persons of an SBS Entity? If so, which rules and why?
- Is it possible that an associated person that is an entity (*i.e.,* not a natural person) that effects or is involved in effecting security-based swaps on behalf of an SBS Entity would be subject to a statutory disqualification? If so, should the Commission consider excepting any such persons from the prohibition in Section 15F(b)(6)? Under what circumstances and why? Should the Commission except such persons globally or on an individual basis?
- Are there certain statutorily disqualified persons who should not be permitted to remain associated with an SBS Entity based upon the nature of the disqualification?
- Should there be any differentiation in relief based upon the nature of the person, *e.g.,* a natural person or an entity? If so, when and why?

C. Business Conduct Requirements: Proposed Rule 15Fh–3

1. Counterparty Status

Proposed Rule 15Fh–3(a)(1) would require an SBS Entity, as provided by Section 15F(h)(3)(A) of the Exchange Act, to verify that a counterparty whose identity is known to an SBS Entity prior to the execution of the transaction meets the eligibility standards for an ECP before entering into a security-based swap with that counterparty other than on a registered national securities exchange.[50] Although the statute is silent concerning the timing of the verification, we believe it is important for an SBS Entity to verify ECP status before entering into a security-based swap because, among other things, Section 6(l) of the Exchange Act makes it unlawful to effect a transaction in a security-based swap with or for a person that is not an ECP, unless the transaction is effected on a registered national securities exchange.[51] In addition, proposed Rule 15Fh–3(a)(1) would not require an SBS Entity to verify the ECP status of a counterparty in a transaction executed on a registered national securities exchange or a registered security-based swap execution facility (''SEF''). Such verification would not be necessary because, under proposed Rule 809, SEFs may not provide access to entities that are not ECPs, and thus an SBS Entity could effectively rely on the verification of ECP status by a SEF or any broker or SBS Dealer indirectly providing access.[52]

Proposed Rule 15Fh–3(a)(2) would require an SBS Entity to verify whether a counterparty whose identity is known to an SBS Entity prior to the execution of the transaction is a special entity before entering into a security-based swap with that counterparty.[53] Although the Dodd-Frank Act does not specifically require an SBS Entity to verify whether a counterparty is a special entity, we preliminarily believe that such verification would facilitate the implementation of the special business conduct rules under the Dodd-Frank Act that apply to SBS Entities dealing with special entities.[54]

We believe that SBS Entities may satisfy these proposed verification requirements through any reasonable means.[55] For example, an SBS Entity could verify that a counterparty is an ECP by obtaining a written representation from the counterparty. We preliminarily believe that it would not be reasonable for an SBS Entity to rely on a representation that merely states that the counterparty is an ECP because the counterparty may not be familiar with the definitions of the term under the federal securities laws. However, it would be reasonable for an SBS Entity to rely on a written representation as to specific facts about the counterparty (e.g., that it has $10 million in assets) in order to conclude that the counterparty is an ECP.

Similarly, we preliminarily believe that it would not be reasonable for an SBS Entity to rely on a representation that merely states that the counterparty is not a ''special entity'' because the counterparty may not be familiar with the definition of the term under the federal securities laws. However, an

[48] *See* Section 20(b) of the Exchange Act, 15 U.S.C. 78t(b) (''It shall be unlawful for any person, directly or indirectly, to do any act or thing which it would be unlawful for such person to do under the provisions of this title or any rule or regulation thereunder through or by means of any other person.'').

[49] The Commission is proposing to define certain additional terms solely for purposes of proposed Rules 15Fh–6 and 15Fk–1. *See* proposed Rules 15Fh–6(a) and 15Fk–1(e).

[50] *See* Section 15F(h)(3)(A) of the Exchange Act (requiring the Commission to establish a duty for an SBS Entity to verify that its counterparty meets the eligibility requirements of an ECP). Public Law 111–203, 124 Stat. 1376, 1790 (to be codified at 15 U.S.C. 78o–10(h)(3)(A). Under Exchange Act Section 3(a)(65), the term ''eligible contract participant'' has the same meaning as in Section 1a of the Commodity Exchange Act (7 U.S.C. 1a). Public Law 111–203, 124 Stat. 1376, 1755 (to be codified at 15 U.S.C. 78c(a)(65)). *See also* Definitions Release (proposing to further define ''eligible contract participant'' to include, among others, swap dealers, major swap participants, security-based swap dealers and major security-based swap participants).

[51] Public Law 111–203, 124 Stat. 1376, 1777, § 764(e) (to be codified at 15 U.S.C. 78f(l)) (''[i]t shall be unlawful for any person to effect a transaction in a security-based swap with or for a person that is not an eligible contract participant, unless such transaction is effected on a [registered] national securities exchange''). *See also* Public Law 111–203, 124 Stat. 1376, 1801, § 768(b) (to be codified at 15 U.S.C. 77e(d)) (''unless a registration statement meeting the requirements of section 10(a) [of the Securities Act] is in effect as to a security-based swap, it shall be unlawful for any person * * * to offer to sell, offer to buy or purchase or sell a security-based swap to any person who is not an eligible contract participant'').

[52] Registration and Regulation of Security-Based Swap Execution Facilities, Exchange Act Release No. 63825 (Feb. 2, 2011), 76 FR 10948 (Feb. 28, 2011) (proposed Rule 809 would permit, but not require SEF participation ''only if such person is registered with the Commission as a security-based swap dealer, major security-based swap participant, or broker (as defined in section 3(a)(4) of the Act, 15 U.S.C. 78c(a)(4)), or if such person is an eligible contract participant (as defined in section 3(a)(65) of the Act, 15 U.S.C. 78c(a)(65)).'').

[53] *See generally* Section 15F(h)(1)(D) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1789 (to be codified at 15 U.S.C. 78o–10(h)(1)(D)) (authorizing the Commission to prescribe business conduct standards that relate to ''such other matters as the Commission determines to be appropriate'').

[54] *See* Section II.D, *infra.* Because proposed Rule 15Fh–3(a)(2) would only apply when an SBS Entity knows the identity of its counterparty prior to the execution of a transaction, it is consistent with Section 15F(h)(7) of the Exchange Act, which contemplates an exception to all of the various business conduct requirements of Section 15F(h) for any transaction that is initiated by a special entity on an exchange or SEF, where the SBS Entity does not know the identity of the counterparty to the transaction.

[55] The SBS Entity must keep records of its verification. *See* proposed Rule 15Fk–1, discussed *infra* at Section II.E, which would require an SBS Entity to have written policies and procedures and maintain records sufficient to enable its chief compliance office to verify compliance with the requirements of the proposed rules. In addition, the Commission is required to propose a rule regarding reporting and recordkeeping requirements for SBS Entities. *See* Section 15F(f)(2) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1788 (to be codified at 15 U.S.C. 78o–10(f)(2)) (''The Commission shall adopt rules governing reporting and recordkeeping for security-based swap dealers and major security-based swap participants'').

SBS Entity could verify that a counterparty is not a special entity by obtaining a written representation from the counterparty that it does not fall within any of the enumerated categories of persons that are ''special entities'' for purposes of Section 15F of the Exchange Act (*e.g.,* that the counterparty is not a municipality, pension plan, etc.). In the context of either the ECP or the special entity verification, an SBS Entity would be entitled to rely on a counterparty's written representation for purposes of compliance with Rule 15Fh–3(a) without further inquiry, absent special circumstances described below.[56]

To solicit input on when it would no longer be appropriate for an SBS Entity to rely on such representations without further inquiry, the Commission is proposing for comment two alternative approaches. One approach would permit an SBS Entity to rely on a representation from a special entity for purposes of Rule 15Fh–3(a) unless it knows that the representation is not accurate. The second would permit an SBS Entity to rely on a representation unless the SBS Entity has information that would cause a reasonable person to question the accuracy of the representation.

Under either approach, an SBS Entity could not ignore information in its possession as a result of which the SBS Entity would know that a representation is inaccurate.[57] In addition, under the second approach, an SBS Entity also could not ignore information that would cause a reasonable person to question the accuracy of a representation and, if the SBS Entity had such information, it would need to make further reasonable inquiry to verify the accuracy of the representation.[58]

An SBS Entity that has complied with the requirements of proposed Rule 15Fh–3(a)(1) concerning a counterparty's eligibility for a particular security-based swap would fulfill its obligations under the proposed rule for that security-based swap, even if the counterparty subsequently ceases to meet the eligibility standards for an ECP during the term of that security-based swap. However, verification of a counterparty's status as an ECP (and, as applicable, as a special entity) for one security-based swap would not necessarily satisfy the SBS Entity's obligation with respect to other security-based swaps executed with that counterparty in the future. An SBS Entity would need to verify the counterparty's status for each subsequent security-based swap (which it could do by relying on written representations from the counterparty, as described above). An SBS Entity could satisfy this obligation by relying on a representation in a master or other agreement that is deemed to be repeated and incorporated into each security-based swap under that agreement as of the date on which each security-based swap is executed.[59]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

• Although we are proposing to require that an SBS Entity verify that a counterparty is an ECP, we are not proposing at this time to require that the SBS Entity otherwise determine that a potential counterparty is ''qualified'' to engage in security-based swaps before entering into a security-based swap with that person.[60] Given that the Dodd-Frank Act permits any ECP to engage in security-based swaps, would it be appropriate for the Commission to limit which ECPs may engage in security-based swaps? Should the Commission impose an additional requirement that an SBS Entity determine that an ECP is otherwise ''qualified'' before the SBS Entity can enter into security-based swaps with such ECP? If so, what qualifications should be applied, and to which types of ECPs? For example, the definition of ECP includes persons with $5 million or more invested on a discretionary basis that enter into the security-based swap ''to manage risks.'' [61] In contrast, under FINRA rules, ''retail customers'' would include persons (whether a natural person, corporation, partnership, trust, or otherwise) with total assets of up to $50 million.[62] To what extent do natural persons and institutions with assets of less than $50 million engage in security-based swap transactions? Would the ''know your counterparty'' and suitability obligations of an SBS Dealer under proposed Rule15Fh–3(e) and (f), as described more fully below, help to

[56] An SBS Entity would not be required to obtain a representation from the counterparty and so could elect to verify the counterparty's status through any other reasonable means.

[57] As described *infra,* proposed Rule 15Fh–3(e) would require an SBS Dealer to have policies and procedures reasonably designed to obtain and retain certain essential facts regarding a counterparty. As a result, information in the SBS Entity's possession would include information gathered by an SBS Dealer through compliance with the ''know your counterparty'' provisions of proposed Rule 15Fh–3(e), as well as any other information the SBS Entity has acquired through its interactions with the counterparty including other representations obtained from the counterparty by the SBS Entity.

[58] *Cf.* Rule 144A(d)(1)(iv) under the Securities Act, 17 CFR 230.144A(d)(1)(iv) (providing that in determining whether a prospective purchaser is a qualified institutional buyer, a seller of securities is entitled to rely on a certification by an executive officer of the purchaser with respect to the amount of securities owned and invested on a discretionary basis). The Commission, in its release adopting Rule 144A, explained that ''[u]nless circumstances exist giving a seller reason to question the veracity of the certification, the seller would not have a duty of inquiry to verify the certification.'' Private Resales of Securities to Institutions, Securities Act Release No. 6862 (April 27, 1990), 55 FR 17933 (Apr. 30, 1990). *Cf. also* Short Sales, Exchange Act Release No. 50103 (July 28, 2004), 69 FR 48008 (Aug. 6, 2004) at n. 58 (explaining that a broker-dealer can rely on a customer's assurance to establish the ''reasonable grounds'' required by Rule 203(b)(1)(ii) unless the broker-dealer ''knows or has reason to know'' that a customer's prior assurances resulted in failures to deliver).

Under Regulation R, a bank or a broker-dealer satisfies its customer eligibility requirements if the bank or broker-dealer ''has a reasonable basis to believe that the customer'' is an institutional customer or high net worth customer before the time specified in the rule. When adopting Regulation R, the Commission stated that a bank or broker-dealer would have a ''reasonable basis to believe'' if it obtains a signed acknowledgment that the customer met the applicable standards, unless it had information that would cause it to believe that the information provided by the customer was or was likely to be false. Definitions of Terms and Exemptions Relating to the ''Broker'' Exceptions for Banks, Exchange Act Release No. 56501 (Sep. 28, 2007), 72 FR 56514 (Oct. 3, 2007).

Commenters have suggested a similar approach. *See* SIFMA/ISDA 2011 Letter (suggesting that an SBS Entity should be able to rely on written representations by the counterparty ''absent actual notice of countervailing facts (or facts that reasonably should have put the [SBS Entity] on notice)'').

We note that Congress used similar language in the statutory provisions governing registration of SBS Entities. *See* Section 15F(b)(6) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1785 (to be codified at 15 U.S.C. 78o–10(b)(6)) (generally making it unlawful for an SBS Entity to permit an associated person that is subject to a statutory disqualification to effect or participate in effecting security-based swaps on behalf of the SBS Entity if the SBS Entity ''knew, or in the exercise of reasonable care should have known,'' of the statutory disqualification).

[59] *See, e.g.,* SIFMA/ISDA 2011 Letter (suggesting that an SBS Entity should be able to rely on a master agreement that contains (1) a counterparty eligibility representation that is deemed to be made at the inception of each transaction and (2) a covenant that the counterparty will notify the SBS Entity if it ceases to be an ECP).

[60] *Cf.* FINRA Rule 2360(16)(A) (providing that no member or person associated with a member shall accept an order from a customer to purchase or write an option contract unless, among other things, the customer's account has been approved for options trading).

[61] A natural person with $5 million or more invested on a discretionary basis would qualify as an ECP if he or she entered into a security-based swap ''to manage risks.'' *See* Section 1a(18)(A)(xi) of the Commodity Exchange Act.

[62] Under FINRA rules, unless a person had total assets of at least $50 million, a broker-dealer engaging in transactions with that person would be subject to retail suitability obligations. *See* FINRA Rule 2111(b) (referring to NASD Rule 3110(c)(4)).

mitigate concerns regarding these persons?

• Are there alternative approaches that would be feasible in terms of market practice for determining ECP and special entity status? If so, what would be the advantages and disadvantages of these approaches for SBS Entities and counterparties? Should the Commission, for example, establish specific documentation requirements or procedures that could be used to verify ECP or special entity status? Should specific types of documentation be required? If so, what types of documentation (*e.g.,* bank or brokerage statements, legal entity filings)?

• Should the Commission otherwise specify the means by which SBS Entities should verify the status of a counterparty? If so, what means should it require?

• What are the advantages and disadvantages of the two alternative proposed approaches for determining when an SBS Entity may no longer rely on counterparty representations? Which alternative would strike the better balance among the regulatory interest in the verification of ECP and special entity status, the sound functioning of the security-based swap market, and the potential compliance costs for market participants? What, if any, other alternatives should the Commission consider (*e.g.,* a recklessness standard) and why?

• In light of the additional protections that are afforded special entities under the Dodd-Frank Act described in Section I.C.5 above, should an SBS Entity be required to undertake diligence or further inquiry in ascertaining the special entity status of a potential counterparty before it can rely on any representation as to such status from the counterparty? Why or why not? If such diligence or inquiry is not required, should an SBS Entity be permitted to rely on representations as to special entity status from a counterparty only where the SBS Entity does not have information that would cause a reasonable person to question the accuracy of the representation? Why or why not? Would requiring such diligence or further inquiry—or allowing reliance on representations only in such a manner—unduly limit the willingness or ability of SBS Entities to provide special entities with the access to security-based swaps for the purposes described in Section I.C.5 above? Why or why not? What, if any, other measures should be required in connection with an SBS Entity's verification of a counterparty's special entity status?

• Are there particular classes of ECPs or special entities for which an SBS Entity should be required to undertake further review or inquiry, rather than rely on written representations to verify status? Should further review or inquiry be required when, for example, a potential counterparty is a natural person or a special entity? If so, what review or inquiry should be required and, in what circumstances?

• Are there other potentially reasonable means or procedures that an SBS Entity might use to verify ECP or special entity status, other than through written representations, as to which the Commission should consider providing guidance? If so, what means or procedures should such guidance address, and how?

2. Disclosure

Section 15F(h)(3)(B) of the Exchange Act broadly requires the Commission to adopt rules requiring disclosures by SBS Entities to counterparties of information related to ''material risks and characteristics'' of the security-based swap, ''material incentives or conflicts of interest'' that an SBS Entity may have in connection with the security-based swap, and the ''daily mark'' of a security-based swap.

a. Disclosure Not Required When the Counterparty Is an SBS Entity or a Swap Dealer or a Major Swap Participant

Section 15F(h)(3)(B) further provides that disclosures under that section are not required when the counterparty is ''a security-based swap dealer, major security-based swap participant, security-based swap dealer, or major security-based swap participant.'' [63] We believe that the repetition of the terms ''security-based swap dealer and major security-based swap participant'' in this Exchange Act provision is a drafting error, and that Congress instead intended an exclusion identical to that found in the Commodity Exchange Act, which provides that these general disclosures are not required when the counterparty is ''a swap dealer, major swap participant, security-based swap dealer, or major security-based swap participant.'' [64] Accordingly, we are proposing that the disclosure requirements under Rule 15Fh–3(b) (information about material risks and characteristics, and material incentives or conflicts of interests), Rule 15Fh–3(c) (the daily mark), and Rule 15Fh–3(d) (clearing rights) not apply whenever the counterparty is an SBS Dealer, a Major SBS Participant, a swap dealer or a major swap participant.[65]

Request for Comments

The Commission requests comments generally on all aspects of this exception. In addition, we request comments on the following specific issues:

• Should some or all of the disclosure requirements under proposed Rule 15Fh–3(b) (information about material risks and characteristics, material incentives or conflicts of interests), Rule 15Fh–3(c) (the daily mark), and Rule 15Fh–3(d) (clearing rights) apply when the counterparty is an SBS Entity, swap dealer or major swap participant? Why or why not? For example, we are not proposing to require that an SBS Entity provide a daily mark to a counterparty that is an SBS Entity, swap dealer or major swap participant, because we preliminarily believe that a counterparty that falls into one of these categories would be able to perform the function on its own. Nevertheless, would there be some advantage in requiring such counterparties to exchange their respective marks, on a daily basis, so that any discrepancies are more transparent and can be identified and addressed promptly? Why or why not? Would there be disadvantages to this approach? Why or why not? Similarly, would there be any advantage in requiring any of the other disclosures to be made to a counterparty that is an SBS Entity, swap dealer or major swap participant? Why or why not? Would there be disadvantages? Why or why not?

• Should the Commission instead require that disclosures be made upon request by a counterparty that is an SBS Entity, swap dealer or major swap participant? Why or why not?

• Should the Commission require a different type or amount of disclosure for categories of counterparties that are market professionals such as broker-dealers, futures commission merchants and banks? What criteria should determine or inform the type or amount of disclosure? For example, should an SBS Entity be permitted to provide different or less detailed disclosure to a counterparty that is a registered broker-dealer? A registered futures commission merchant? A bank?

[63] Public Law 111–203, 124 Stat. 1376, 1790 (to be codified at 15 U.S.C. 78o–10(h)(3)(B)).

[64] Public Law 111–203, 124 Stat. 1376, 1708 (to be codified at 7 U.S.C. 6s(h)(3)(B)).

[65] *But see* proposed Rule 15Fh–1 (the proposed rules ''are not intended to limit, or restrict, the applicability of other provisions of the federal securities laws, including but not limited to, Section 17(a) of the Securities Act of 1933 and Sections 9 and 10(b) of the Securities Exchange Act of 1934.'').

b. Timing and Manner of Certain Disclosures

Proposed Rule 15Fh–3(b) would require that disclosures regarding material risks and characteristics and material incentives or conflicts of interest be made to potential counterparties before entering into a security-based swap, but would not mandate the manner in which those disclosures are made.[66] Proposed Rule 15Fh–3(d) similarly would require that disclosures regarding certain clearing rights be made before entering into a security-based swap, but also would not mandate the manner of disclosure. To the extent such disclosures were not otherwise provided to the counterparty in writing prior to entering into a security-based swap, proposed Rules 15Fh–3(b)(3) and 15Fh–3(d)(3) would require an SBS Entity to make a contemporaneous record of the non-written disclosures made pursuant to proposed Rules15Fh–3(b) and 15Fh–3(d), respectively, and provide a written version of these disclosures to the counterparty in a timely manner, but in any case no later than the delivery of the trade acknowledgement[67] of the particular transaction.[68]

Because disclosures of material risks and characteristics, material incentives or conflicts of interests, and clearing rights include information that the counterparty should consider in deciding whether to enter into the security-based swap, we are proposing to require that these disclosures be provided before entry into a security-based swap.

Concerning the manner of disclosure, however, we preliminarily believe that parties should have flexibility to make disclosures by various means, provided that the SBS Entity (1) makes an appropriate record of such disclosures and (2) supplies its counterparty with a written version of any disclosure required under these rules that was not made in writing prior to the transaction. Means of disclosure may include master agreements and related documentation, telephone calls, emails, instant messages, and electronic platforms.[69] Proposed Rule 15Fh–3(b) would require that the required disclosures regarding material risks and characteristics and material incentives or conflicts of interest be made ''in a manner reasonably designed to allow the counterparty to assess'' the information being provided. This provision is intended to require that disclosures be reasonably clear and informative as to the relevant material risks or conflicts that are the subject of the disclosure. This provision is not intended to impose a requirement that disclosures be tailored to a particular counterparty or to the financial, commercial or other status of that counterparty.[70]

We understand that security-based swaps generally are executed under master agreements, with much of the transaction-specific disclosure provided over the telephone, in instant messages or in confirmations. We anticipate that SBS Entities may elect to make certain required disclosures of material information to their counterparties in a master agreement or other written document accompanying such agreement.[71]

Commenters have asked that we clarify the applicability of these disclosure requirements to SEF- and exchange-traded security-based swaps in which the SBS Entity may not know the identity of the counterparty until immediately prior to (or after) execution of a transaction. The Dodd-Frank Act only addresses this issue in the context of special entities. Specifically, Section 15F(h)(7) provides an exception to the requirements of Section 15F(h) for a transaction that is ''initiated'' by a special entity on a SEF or an exchange and for which the SBS Entity does not know the identity of the counterparty to the transaction.[72]

We are seeking comment, therefore, on whether and how the proposed disclosure requirements should be satisfied for security-based swap transactions that are executed on a SEF or exchange and for which the SBS Entity does not know the identity of the counterparty until immediately prior to (or after) the execution of the transaction. In particular, we seek comment on how the disclosure obligations discussed below under proposed Rule 15Fh–3(b) (concerning material risks and characteristics, and material incentives or conflicts of interest) and proposed Rule 15Fh–3(d) (regarding clearing rights) could be met.

The statute requires rules adopted by the Commission to require the SBS Entity to make these disclosures. We believe that SBS Entities generally should be able to rely on means reasonably designed to achieve timely delivery of the required disclosures. In particular, an SBS Entity could cause

---

[66] Section 15F(h)(3)(B) of the Exchange Act is silent regarding both form and timing of disclosure. *See* Public Law 111–203, 124 Stat. 1376, 1790 (to be codified at 15 U.S.C. 78o–10(h)(3)(B)).

[67] *See* Trade Acknowledgement and Verification of Security-Based Swap Transactions, Exchange Act Release No. 63727 (Jan. 14, 2011), 76 FR 3859 (Jan. 21, 2011) (proposing Rule 15Fi–1(c)(1), which would require a trade acknowledgement to be provided within 15 minutes of execution for a transaction that has been executed and processed electronically; within 30 minutes of execution for a transaction that is not electronically executed, but that will be processed electronically; and within 24 hours of execution for a transaction that the SBS Entity cannot process electronically).

[68] *See also* Section 15F(g) of the Exchange Act (requiring the Commission to adopt rules governing daily trading records, including recordings of telephone calls):

(g) DAILY TRADING RECORDS.—

(1) IN GENERAL.—Each registered security-based swap dealer and major security-based swap participant shall maintain daily trading records of the security-based swaps of the registered security-based swap dealer and major security-based swap participant and all related records (including related cash or forward transactions) and recorded communications, including electronic mail, instant messages, and recordings of telephone calls, for such period as may be required by the Commission by rule or regulation.

(2) INFORMATION REQUIREMENTS.—The daily trading records shall include such information as the Commission shall require by rule or regulation.

(3) COUNTERPARTY RECORDS.—Each registered security-based swap dealer and major security-based swap participant shall maintain daily trading records for each counterparty in a manner and form that is identifiable with each security-based swap transaction.

Public Law 111–203, 124 Stat. 1376, 1788–1789 (to be codified at 15 U.S.C. 78o–10(g)).

[69] For SBS Entities to rely on electronic media, however, their counterparties must have the capability to effectively access all of the information required by Rule 15Fh–3(b)(3) in a format that is understandable but not unduly burdensome for the counterparty. *See* Use of Electronic Media by Broker-Dealers, Transfer Agents and Investment Advisers for Delivery of Electronic Information, Securities Act Release No. 7288 (May 9, 1996), 61 FR 24644 (May 15, 1996). *See also* Use of Electronic Media, Exchange Act Release No. 42728 (Apr. 28, 2000), 65 FR 25843 (May 4, 2000).

[70] SBS Entities would, of course, have an on-going obligation to communicate with counterparties in a fair and balanced manner based on principles of fair dealing and good faith. *See* proposed Rule 15Fh–3(g) (discussed *infra* at Section II.C.5).

[71] While certain forms of disclosure may be highly standardized, the Commission anticipates that even such forms of disclosures will require certain provisions to be tailored to the particular transaction, most notably pricing and other transaction-specific commercial terms. We believe the proposed approach is generally consistent with the use of standardized disclosures suggested by industry groups and commenters. *See* CRMPG III Report (suggesting that standardized risk disclosures should be viewed as a supplement to, rather than a substitute for, more detailed disclosures); and Letter from Kenneth E. Bentsen, Jr., Executive Vice President, Public Policy and Advocacy, SIFMA and Robert G. Pickel, Executive Vice Chairman, ISDA to Elizabeth M. Murphy, Secretary, Commission and David A. Stawick, Secretary, Commodity Futures Trading Commission (Oct. 22, 2010) (on file with Commission) (''SIFMA/ISDA 2010 Letter'') (recommending the use of standard disclosure templates that could be adopted on an industry-wide basis, and noting that ''the process of developing standardized disclosure materials would * * * provide a means for identifying circumstances in which more tailored disclosure might be appropriate'').

[72] Public Law. 111–203, 124 Stat. 1376, 1792 (to be codified at 15 U.S.C. 78o–10(h)(7). *See* Section II.D, *infra.*

the required disclosures to be delivered through a third party or other indirect means (such as by contracting with a SEF to deliver the disclosure electronically) in circumstances in which it may not be practicable for an SBS Entity to directly provide the disclosures in a timely manner.

Commenters have suggested that SBS Entities should be able to rely on trade acknowledgements to satisfy certain disclosure requirements.[73] Because proposed Rule 15Fh–3(b) would require that disclosures be made before ''entering into'' a security-based swap, SBS Entities generally would not be able to rely on trade acknowledgements and other documents that are provided after the transaction is executed to satisfy the rule's disclosure obligations. SBS Entities could, however, rely on trade acknowledgements to memorialize disclosures they made, whether orally or by other means, prior to entering into the proposed transaction.[74]

Finally, although we are proposing to permit disclosure by a range of means, both oral and written, we may revisit whether Congress's objectives under Section 15F(h) and the focus here on supervision and compliance require some further specific obligations concerning the manner in which disclosures are made.

Request for Comments

The Commission requests comments generally on all aspects of this approach to the timing and manner of disclosure. In addition, we request comments on the following specific issues:

- Should the Commission impose more specific requirements concerning the timing and manner of disclosures? If so, what additional requirements should the Commission impose, and why?
- Commenters have urged the Commission to encourage the use of standardized disclosure templates.[75] Who would develop those templates? What would the content be? What disclosures do or do not lend themselves to a standardized template? How would the templates be updated or supplemented to respond to market developments or account for the characteristics of a specific transaction?
- Should the Commission require that all material disclosures be provided in writing prior to the execution of the transaction? If not, does the option to memorialize the disclosure and provide a written version of the disclosure to the counterparty provide adequate safeguards to ensure that parties are complying with the disclosure, supervision and compliance requirements discussed more fully below, as well as the provisions intended to increase the protection of special entities? Are there any other safeguards the Commission should consider? How do such safeguards provide the same or better protection or information for counterparties than written disclosures in advance of a transaction?
- Should the Commission require disclosures to be made a certain period of time before execution of a transaction? If so, what would be the advantages and disadvantages of various periods?
- Should the Commission impose specific requirements concerning the timing and manner in which disclosures are made to certain counterparties, such as special entities or categories of special entities? If so, which counterparties, and why? What requirements would be appropriate for which counterparties?
- Should the Commission require that disclosures be made in writing prior to the execution of the transaction when the counterparty is a special entity? Why or why not? If so, should this requirement apply with respect to all special entities? If not, how should the Commission distinguish among special entities?
- Should the Commission permit SBS Entities to rely on information in trade acknowledgements to satisfy certain disclosure requirements? Why or why not? Are there other approaches that would be more effective or efficient than the Commission's proposed approach to disclosure?
- In which situations (or under what circumstances) would the SBS Entity not know the identity of the counterparty prior to execution of the transaction on a SEF or exchange? If the SBS Entity subsequently learns the identity of the counterparty, when would such identity typically be ascertained (*e.g.,* before, at the time of, or after the execution of the transaction)? In such situations, how should material information be disclosed?
- The Dodd-Frank Act and the Commission's proposal with respect to SEFs contemplate that SEFs and exchanges will promulgate detailed standards for the listing and trading of security-based swaps that may be transacted on their markets. Should SEFs and exchanges also be required to provide a means to deliver the disclosures to counterparties required under proposed Rules 15Fh–3(b) and (d)? Would SEF and exchange listing and trading rules provide an adequate alternative means for providing the required disclosures? Why or why not? How would differences in rules across markets for similar products be addressed? What other issues may arise in connection with this approach and how could they be addressed?
- Should disclosures by means of a SEF or exchange require a standardized format? Are there specific transactions, classes of transactions, or types of counterparties for which this approach would or would not be appropriate? Are there other means by which SBS entities could satisfy their disclosure obligations in this context?
- Should an SBS Entity be permitted to reference publicly available information to comply with its disclosure requirements to its counterparty without having the information deemed to be adopted or affirmed by the SBS Entity? For example, should an SBS Entity be permitted to direct its counterparty to reports filed under the Exchange Act and publicly available on EDGAR without being considered to affirm or adopt the disclosure? Should an SBS Entity be permitted to satisfy the disclosure requirements by directing its counterparty to the Web site of a company underlying a credit default swap regarding disclosures of material risks without being considered to affirm or adopt the disclosure?

c. Material Risks and Characteristics of the Security-Based Swap

Section 15F(h)(3)(B) of the Exchange Act provides that business conduct requirements adopted by the Commission shall require disclosure by the SBS Entity of information about the material risks and characteristics of the security-based swap.[76] A fact is material if there is a substantial likelihood that a reasonable investor would consider the information to be important in making an investment decision.[77] Disclosures should include a clear explanation of the material economic

[73] *See* SIFMA/ISDA 2010 Letter (''We recommend that the Commissions clarify that, to the extent that a counterparty is in possession of the master documentation and confirmation specifying the economic and other material terms of a specific transaction, registrant counterparties will have satisfied this requirement.'').

[74] Proposed Rule 15Fk–1, discussed *infra* at Section II. E, would require an SBS Entity to have reasonable written policies and procedures concerning the timing and form of disclosure, and maintain records sufficient to enable its chief compliance officer to verify compliance with the disclosure requirements under the proposed rules.

[75] *See, e.g.,* SIFMA/ISDA 2010 Letter at 3.

[76] We read this provision to require disclosure about the material risks and characteristics of the security-based swap itself and not of the underlying reference security or index.

[77] *Basic Inc.* v. *Levinson,* 485 U.S. 224, 231–32 (1988).

characteristics of the security-based swap, including a discussion of the key assumptions that give rise to the expected pay-offs.[78] The SBS Entity should consider, among other things, the complexity of each of the characteristics of the security-based swap in determining the materiality of the characteristic, as well as the related material risks to be disclosed.[79]

We understand that there are certain general types of risks, including credit risk,[80] settlement risk,[81] market risk,[82] liquidity risk,[83] operational risk,[84] and legal risk [85] that are commonly associated with securities-based swaps.[86] Proposed Rule 15Fh–3(b)(1) would require an SBS Entity to disclose the material factors that influence the day-to-day changes in valuation, the factors or events that might lead to significant losses, the sensitivities of the security-based swap to those factors and conditions, and the approximate magnitude of the gains or losses the security-based swap would experience under specified circumstances.[87] SBS Entities should also consider the unique risks and characteristics associated with a particular security-based swap, class of security-based swap or trading venue, and tailor their disclosures accordingly.[88]

An SBS Entity also should consider risks that may be associated specifically with uncleared security-based swaps. Among other things, the absence of a credit support agreement in an uncleared security-based swap could create risks associated with the absence of a bilateral obligation to post initial and variation margin.[89] An SBS Entity should consider whether the absence of provisions that would typically be associated with a cleared security-based swap, for example, could create a material risk that would need to be disclosed in connection with a transaction involving a security-based swap that is not submitted for clearing.[90]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- The documentation governing a security-based swap transaction should include all of the terms agreed by the parties that could affect the economic and other risks of the transaction. Should the requirements for disclosure of material characteristics of a security-based swap be deemed satisfied if the SBS Entity has entered into a master agreement with and provided a trade acknowledgement (or draft trade acknowledgement) or other documentation governing the particular security-based swap to the counterparty? Why or why not? How would such an approach provide meaningful disclosure to counterparties regarding the risks of the transactions they are entering into? What types of risks might not be readily apparent to a counterparty from a review of the governing documentation for a transaction? Would the timeliness of such disclosure be a problem if information on a trade acknowledgement, for example, is not provided to a counterparty until after the parties have entered into a security-based swap?
- Are there particular material risks or characteristics that the Commission should specifically require an SBS Entity to disclose to a counterparty? If so, which ones and why?
- Are there specific material risks or characteristics that should be disclosed with respect to swaps that are not cleared, or are not SEF- or exchange-traded? If so, which ones and why?
- Are there particular material risks or characteristics that the Commission should specifically require an SBS Entity to disclose when the counterparty is a special entity or a particular category of special entity? If so, which ones and why? Should any such special disclosure requirements apply to any categories of counterparties other than special entities?
- Should the Commission require an SBS Entity to disclose its anticipated profit for the security-based swap? If so, how should an SBS Entity be required to compute profitability for purposes of the rule? [91] If the Commission were to adopt such a requirement, should it be limited to transactions in which the counterparty is a special entity, a particular category of special entity, or another type of counterparty?
- Should the SBS Entity disclose or identify for the counterparty information regarding the issuer of the underlying security that is publicly available, such as whether the issuer of an underlying security is subject to the

[78] *See* CRMPG III Report at 61. *See also* SIFMA/ISDA 2010 Letter (stating that ''[t]here is no better description of the characteristics of a transaction than the contract provisions expressly defining its economic terms.'').

[79] The adequacy of such disclosures will be determined by reference to the ''reasonable investor'' standard above.

[80] By ''credit risk,'' we mean the risk that a party to a security-based swap will fail to perform on an obligation under the security-based swap. IOSCO Report at 3; BIS Report at 11.

[81] By ''settlement risk,'' we mean the risk that a party will not receive funds or instruments from its counterparty at the expected time, either as a result of a failure of the counterparty to perform or a failure of the clearing agency to perform. *See* IOSCO Report at 3.

[82] By ''market risk,'' we mean the risk to the value of a security-based swap resulting from adverse movements in the level or volatility of market prices. *See* BIS Report at 12.

[83] By ''liquidity risk,'' we mean the risk that a counterparty may not be able to, or cannot easily, unwind or offset a particular position at or near the previous market price because of inadequate market depth or because of disruptions in the marketplace. *See* BIS Report at 13.

[84] By ''operational risk,'' we mean the risk that deficiencies in information systems or internal controls, including human error, will result in unexpected loss. *See* IOSCO Report at p. 3; BIS Report at 14.

[85] By ''legal risk,'' we mean the risk that agreements are unenforceable or incorrectly or inadequately documented. *See* IOSCO Report at p. 4; BIS Report at 16.

[86] *See generally* IOSCO Report; BIS Report.

[87] *See* CRMPG III Report at 60. These disclosures are intended to be disclosures concerning the material risks and characteristics of the security-based swap itself, not the material risks and characteristics of the security-based swap with respect to a particular counterparty. In other words, the proposed rule would not require an SBS Entity to disclose different material risks and characteristics to different counterparties solely because of the identity or nature of the counterparty. As noted previously, proposed Rule 15Fh–3(b) would require disclosures to be made in a manner reasonably designed to allow the counterparty to assess the material risks and characteristics. In addition, SBS Entities would have an on-going obligation to communicate with counterparties in a fair and balanced manner based on principles of fair dealing and good faith. *See* proposed Rule 15Fh–3(g) (discussed *infra* at Section II.C.5).

[88] We anticipate that SBS Entities may provide these disclosures through various means, including scenario analysis. *See, e.g.,* CRMPG III Report at 60 (recommending that disclosure include ''rigorous scenario analyses and stress tests that prominently illustrate how the instrument will perform in extreme scenarios, in addition to more probable scenarios'').

[89] We note that currently market participants often choose to use a credit support agreement or annex specifying the applicable valuation methodologies for the calculation of margin or collateral and the mechanics for the exchange of margin or collateral in connection with a security-based swap.

[90] With respect to uncleared security-based swaps, the Commission expects to propose rules regarding a counterparty's right to have any of its property received by an SBS Entity to margin, guarantee, or secure the obligations of the counterparty in an uncleared security-based swap segregated from the funds of the SBS Entity. *See* Section 3E(f)(1)(A) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1775–1776 (to be codified at 15 U.S.C. 78c–5(f)(1)(A)) (requiring an SBS Entity to notify a counterparty at the beginning of a security-based transaction that the counterparty has the right to require segregation of the funds or other property supplied to margin, guarantee, or secure the obligations of the counterparty).

[91] *See* Swap Financial Group, Dodd-Frank Title VII: Business Conduct and Special Entities Briefing for SEC/CFTC Joint Working Group (Aug. 9, 2010) (on file with the Commission) (''Swap Financial Group Presentation'') at 55 (describing profit as the ''[m]ark-up or 'spread' between price charged to the client and cost of dealer's hedge'').

periodic reporting requirements of the Exchange Act?

• Is there a basis for distinguishing between the types of disclosures that should be required to be provided by an SBS Dealer and those that should be required to be provided by a Major SBS Participant? If so, how should the types of disclosures required to be provided by a Major SBS Participant differ from those that have been proposed?

• Should the Commission specifically require scenario analysis disclosure? Why or why not? If such analysis should be required, should the Commission require the disclosure for uncleared security-based swaps? Should the Commission limit the scenario analysis disclosure requirement to ''high-risk complex security-based swaps,'' as described in the CRMPG III Report? If so, how should the definitional hurdles outlined in the CRMPG III Report be addressed? [92] If not, why? Is there another standard the Commission should consider for requiring scenario analysis?

• Should an SBS Entity be required to provide a scenario analysis for any security-based swap, upon reasonable request by any counterparty? What are the advantages and disadvantages to SBS Entities and counterparties associated with such an analysis? If the cost varies by type of security-based swap, please provide an average cost by category of security-based swap.

• Should a scenario analysis provided by an SBS Entity to a counterparty be required to be consistent with similar analyses prepared by the SBS Entity for its own internal purposes (*e.g.,* risk management)? If not, how would they differ and why?

• We do not intend that the proposed rule require an SBS Entity to disclose any information considered proprietary in nature. Would disclosure of proprietary information be a concern under the current formulation of the rule? If so, what types of proprietary information might be subject to disclosure under the proposed rule? Is there other information that could adequately substitute for purposes of meaningful disclosure? What methods, if any, could be applied to transform specific types of proprietary information into comparable information suitable for a counterparty (*e.g.,* aggregation, averaging)? What other mechanisms, if any, could be used to protect proprietary information while providing adequate disclosure to counterparties?

• As noted above, we understand that security-based swaps are often entered into under a master agreement that governs the relationship between the SBS Entity and its counterparty.[93] In particular, master agreements generally contain terms that govern all succeeding security-based swaps and other derivatives between the counterparties, and include provisions such as events of default, cross-default provisions, additional termination events, payment netting and close-out netting, and information regarding rights and obligations as a result of particular events.[94] Should the Commission require the use of a master agreement for security-based swaps? If a master agreement is required when parties enter into a security-based swap, what particular issues should be addressed in the master agreement? For example, should the master agreement be required to address whether payment netting or close-out netting rights exist? If the Commission does not require the use of a master agreement, should it require that all security-based swaps include certain provisions typically included in master agreements? If so, which provisions?

• Should an SBS Entity be required to disclose the absence of certain material provisions typically contained in master agreements for security-based swap transactions? [95] Similarly, should an SBS Entity be required to disclose if the documentation includes material provisions that are unusual in light of typical master agreements? In either case, how should the ''normal'' or ''typical'' master agreement be defined? By reference to particular types of standardized master agreements? If so, which ones? To what extent would a requirement to provide a disclosure separate from a master agreement regarding the material terms of the master agreement have the effect of incentivizing counterparties to review their agreements less carefully (and instead rely on the disclosure)? To what extent might disclosures regarding the documentation between the parties potentially affect any interpretation of the terms agreed by the parties in the event of a subsequent dispute over such terms? How might that in turn affect the nature or usefulness of the disclosures that SBS Entities might provide regarding their documentation?

• Should the Commission establish certain minimum standards for the agreements governing security-based swaps? If so, what standards and why?

d. Material Incentives or Conflicts of Interest

Proposed Rule 15Fh–3(b)(2) would require that an SBS Entity disclose all material incentives or conflicts it may have in connection with a security-based swap.[96] We preliminarily believe that the term ''incentives''—which is used in Section 15F(h)(3)(b)(ii) of the Dodd-Frank Act—refers not to any profit or return that the SBS Entity would expect to earn from the security-based swap itself, or from any related hedging or trading activities of the SBS Entity, but rather to any other financial arrangements pursuant to which an SBS Entity may have an incentive to encourage the counterparty to enter into the transaction. This disclosure would include, among other things, information concerning any compensation (*e.g.,* under revenue-sharing arrangements) or other incentives the SBS Entity receives from any source other than the counterparty in connection with the security-based swap to be entered into with the counterparty, but would not include, for

[92] *See* CRMPG III Report at 54–56 (''The definition of a high-risk complex financial instrument is itself a complex subject. * * * [T]he definitional challenge is better framed by identifying the key characteristics of classes of high-risk complex financial instruments that warrant special treatment in terms of sales and marketing practices, disclosure practices, diligence standards, and, more broadly, the level of sophistication required for all market participants. * * * While issues surrounding leverage, market liquidity, and price transparency are the key characteristics in identifying high-risk complex financial instruments, other factors have contributed to the problems witnessed during the credit market crisis.'').

[93] *See, e.g., Thrifty Oil Co.* v. *Bank of America Nat'l Trust and Sav. Ass'n,* 322 F.3d 139, 143 (9th Cir. 2003) (describing use of master agreements). We note that market participants may already look to certain master agreements that are generally considered covered by the swap safe harbors in the U.S. Bankruptcy Code (''Bankruptcy Code''). Sections 362(b)(17) and 560 of the Bankruptcy Code provide an exception to the automatic stay and *ipso facto* prohibitions in the Bankruptcy Code to allow for the exercise of any contractual right of any swap participant or financial participant to cause the liquidation, termination, or acceleration of one or more swap agreements, including netting and set-off rights. *See* 11 U.S.C. 362(b)(27) and 560. The definition of ''swap agreement'' under Section 101(53B)(v) of the Bankruptcy Code specifically contemplates master agreements. *See* 11 U.S.C. 101(53B)(v).

[94] Parties may also choose to use a credit support agreement or annex specifying the applicable valuation methodologies for the calculation of margin or collateral and the mechanics for the exchange of margin or collateral in connection with a security-based swap.

[95] For example, absent provisions for payment netting or close-out netting, questions may arise as to whether all of the counterparty's trades with the particular SBS Entity would be taken into account in calculating (1) net periodic payments, (2) one net close-out amount in respect of a default by either party, and (3) net margin obligations.

[96] *See* Section 15F(h)(3)(B)(ii) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1790 (to be codified at 15 U.S.C. 78o–10(h)(3)(B)(ii)) (providing that business conduct requirements adopted by the Commission shall require disclosure by an SBS Entity of ''any material incentives or conflicts of interest'' that the SBS Entity may have in connection with the security-based swap).

example, expected cash flows received from a transaction to hedge the security-based swap or that the security-based swap is intended to hedge.[97]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Are there specific material incentives or conflicts that the Commission should require an SBS Entity to disclose to a counterparty? Are there specific material incentives or conflicts that should be disclosed with respect to security-based swaps that are not cleared, or are not SEF- or exchange-traded?
- Should we require an SBS Entity to disclose affiliations or material business relationships with a SEF or exchange? Why or why not?
- Should we require an SBS Entity to disclose affiliations or material business relationships with a clearing agency? Why or why not?
- Should the Commission impose other more specific requirements concerning the content of the required disclosures when the counterparty is a special entity? If so, which ones and why? Should such specific requirements apply only to certain categories of special entities?
- Should the Commission impose other more specific requirements concerning the content of the required disclosures when an SBS Dealer is acting as an advisor to a special entity? If so, which ones and why? Should such specific requirements apply only to certain categories of special entities?
- Is there a basis for distinguishing between the types of conflicts disclosures required to be provided by an SBS Dealer and those required to be provided by a Major SBS Participant? If so, how should the types of conflicts disclosures required to be provided by a Major SBS Participant differ from those that have been proposed?
- We do not intend to require the disclosure of information considered proprietary in nature in order for an SBS Entity to discharge its obligation under the proposed rule. Is such disclosure a concern under the current formulation of the rule? If so, what types of proprietary information might be subject to disclosure under the proposed rule? Is there other information that could adequately substitute for purposes of meaningful disclosure? What other mechanisms, if any, could be used to protect proprietary information while providing adequate disclosure to counterparties?

e. Daily Mark

Exchange Act Section 15F(h)(3)(B)(iii) directs the Commission to adopt rules that require an SBS Entity to disclose: (i) for cleared security-based swaps, upon request of the counterparty, the daily mark from the appropriate derivatives clearing organization; [98] and (ii) for uncleared security-based swaps, the daily mark of the transaction.[99] We preliminarily believe that the daily mark, as proposed for the purposes of this rule, would provide helpful transparency to counterparties during the lifecycle of a security-based swap. As explained below, the daily mark under the proposed rule is intended to provide a counterparty with a useful and meaningful reference point against which to assess, among other things, the calculation of variation margin for a security-based swap or portfolio of security-based swaps, and otherwise inform the counterparty's understanding of its financial relationship with the SBS Entity.[100]

The term ''daily mark'' is not defined in the statute and, as explained below, we are proposing that the term have analogous meanings for cleared and uncleared security-based swaps. For cleared security-based swaps, proposed Rule 15Fh–3(c)(1) would require an SBS Entity, upon the request of the counterparty, to disclose to the counterparty in writing the daily end-of-day settlement price received by the SBS Entity from the appropriate clearing agency. ''End-of-day settlement price'' in this context refers to the value for any given security-based swap used by the clearing agency that forms the basis of subsequent margin calculations for clearing participants.[101]

We are not proposing to require that clearing agencies use a particular calculation methodology for purposes of the proposed rule.[102] We understand

[97] If an SBS Entity is also registered as a broker-dealer, it would be subject to similar disclosure requirements under FINRA rules in certain circumstances. *See, e.g.,* FINRA Rule 2269, Disclosure of Participation or Interest in Primary or Secondary Distribution (''A member who is acting as a broker for a customer or for both such customer and some other person, or a member who is acting as a dealer and who receives or has promise of receiving a fee from a customer for advising such customer with respect to securities, shall, at or before the completion of any transaction for or with such customer in any security in the primary or secondary distribution of which such member is participating or is otherwise financially interested, give such customer written notification of the existence of such participation or interest.'').

[98] Although Section 15F(h)(3)(B)(iii) of the Exchange Act refers to a ''derivatives clearing organization,'' the Commission believes that this was a drafting error and that Congress intended to refer to a ''clearing agency'' because the Dodd-Frank Act elsewhere requires security-based swaps to be cleared at registered clearing agencies, not derivatives clearing organizations. *See* Section 17A(g) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1768 (to be codified at 15 U.S.C. 78q–1(g)).

[99] We note that various market participants have expressed concerns that the statutory requirement to provide a daily mark to a pension plan would necessarily include an SBS Entity within the definition of ''fiduciary'' for ERISA purposes under a current Department of Labor proposal, which may then cause the security-based swap to be a prohibited transaction under ERISA, unless it qualifies for a Prohibited Transaction Exemption. *See* Definition of the Term ''Fiduciary,'' 75 FR 65263 (Oct. 22, 2010); SIFMA/ISDA Letter; Joint Letter from American Bankers Association, American Benefits Council, Committee on Investment of Employee Benefit Assets, The ERISA Industry Committee, Financial Executives International's Committee on Corporate Treasury, Financial Services Roundtable, Insured Retirement Institute, National Association of Insurance and Financial Advisors, National Association of Manufacturers, Securities Industry and Financial Markets Association to David A. Stawick, Secretary, CFTC (Feb. 22, 2011); Letter from Sandra Haas, Managing Director, Head of Pensions, Endowment and Foundation Coverage, Morgan Stanley & Co., Incorporated, and Jim McCarthy, Managing Director, Head of Retirement Services and Client Advisory, Morgan Stanley Smith Barney LLC to Office of Regulations and Interpretations, Employee Benefits Security Admin., Dep't of Labor (Feb. 2, 2011); Letter from Don Thompson, Managing Director and Assistant General Counsel, JPMorgan Chase & Co. to Office of Regulations and Interpretations, Employee Benefits Security Admin., Dep't of Labor (Feb. 3, 2011). As noted in Section I.B., the staffs of the Commission, DoL and CFTC have been consulting and will continue to do so in order to address these concerns. See Letter from Phyllis C. Borzi, Assistant Secretary, Employee Benefits Security Administration, Department of Labor, to Gary Gensler, Chairman, CFTC (April 28, 2011) (''In DOL's view, a swap dealer or major swap participant that is acting as a plan's counterparty in an arm's length bilateral transaction with a plan represented by a knowledgeable independent fiduciary would not fail to meet the terms of the counterparty exception [to the proposed revised definition of ERISA fiduciary] solely because it complied with the business conduct standards set forth in the CFTC's proposed regulation.''). The Commission also solicits comments with respect to alternatives for addressing this issue.

In addition, as discussed infra in Section II.C.4, we do not believe that disclosure of the daily mark would in and of itself constitute a recommendation under proposed Rule 15Fh–3(f).

[100] As explained below, the daily mark under the proposed rule would not necessarily represent the last price at which a security-based swap traded, or a price that is executable.

[101] For example, ICE Trust, a clearing agency for credit default swaps, indicates that it ''establishes a daily settlement price for all cleared CDS instruments, using a pricing process developed specifically for the CDS market by ICE Trust. ICE Trust clearing participants are required to submit prices on a daily basis. ICE Trust conducts an auction process daily which results in periodic trade executions between its clearing participants. This process determines the daily settlement prices, which are validated by the ICE Trust Chief Risk Officer and used for the daily mark-to-market valuations.'' ICE Trust, *https://www.theice.com/ice_trust.jhtml* (March 14, 2011).

[102] The Commission understands that the particular methodologies used by clearing agencies to produce the end of day settlement price may vary. We understand that there are various means

that, for a given security-based swap, a clearing agency uses the same end-of-day settlement price for the daily valuation of positions held by all clearing members regardless of position direction or size, and independent of any member-specific attribute, such as credit quality, other portfolio holdings, or concentration of positions. Accordingly, the prices do not necessarily represent the last price at which the security-based swap traded, or a price that is executable.

Because the term ''daily mark'' is used both in the context of cleared and uncleared security-based swaps, the Commission preliminarily believes that the meaning of ''daily mark'' for uncleared swaps should be analogous to that for cleared swaps, and that the attributes of daily marks produced by clearing agencies for cleared security-based swaps under proposed Rule 15Fh–3(c)(1) should be equally applicable to, and provide guidance for the computation of, the daily mark required to be provided with respect to uncleared security-based swaps. To ensure a degree of uniformity in market practices among SBS Entities, proposed Rule 15Fh–3(c)(2) would require an SBS Entity to disclose the midpoint between the bid and offer prices for a particular uncleared security-based swap, or the calculated equivalent thereof, as of the close of business unless the parties agree in writing otherwise.[103] We preliminarily believe that the proposed rule would result in a daily mark that reflects daily changes in valuation that is: (a) The same for all counterparties of the SBS Entity that have a position in the uncleared security-based swap, (b) not adjusted to account for holding-specific attributes such as position direction, size, or liquidity, and (c) not adjusted to account for counterparty-specific attributes such as credit quality, other counterparty portfolio holdings, or concentration of positions.[104]

For actively traded security-based swaps that have sufficient liquidity, computing a daily mark as the midpoint between the bid and offer prices for a particular security-based swap, known as a ''midmarket value,'' would be consistent with the proposed Rule 15Fh–3(c)(2). For security-based swaps that are not actively traded, or do not have up-to-date bid and offer quotes, the SBS Entity may calculate an equivalent to a midmarket value using mathematical models, quotes and prices of other comparable securities, security-based swaps, or derivatives, or any combination thereof, provided that these calculations produce a daily mark that is consistent with the attributes described above.[105] Again, the daily mark is not intended to represent the value that either an SBS Entity or its counterparty would use for its own, internal valuation, or fair value for financial reporting purposes for the particular security-based swap. Nor would the daily mark necessarily represent a price at which the SBS Entity would be willing to execute a trade.[106]

Furthermore, though the daily mark may be used as an input to compute the variation margin between an SBS Entity and its counterparty, it is not necessarily the sole determinant of how such margin is computed. Differences between the daily mark and computations for variation margin result from adjustments for position size, position direction, credit reserve, hedging, funding, liquidity, counterparty credit quality, portfolio concentration, bid-ask spreads, or other costs, that may be included as part of the margin computations. Nonetheless, the Commission believes the daily mark, as proposed for the purposes of this rule, would provide a useful and meaningful reference point, similar to that for cleared security-based swaps, for counterparties holding positions in uncleared security-based swaps.[107]

Proposed Rule 15Fh–3(c)(2) would also require that, at or before delivery of the first disclosure of the daily mark, an SBS Entity disclose to the counterparty its data sources and a description of the methodology and assumptions to be used to prepare the daily mark for an uncleared security-based swap.[108] We preliminarily believe that such disclosure would provide the counterparty a useful context with which it can assess the quality of the mark received.[109] In addition, proposed Rule 15Fh–3(c) would also require that an SBS Entity promptly disclose any

by which security-based swap clearing agencies calculate end-of-day settlement prices for each product in which they hold a cleared interest each business day. In the credit default swap context, for example, end-of-day settlement prices may be determined each business day for each eligible product based upon pricing data from one or more of various sources, including prices of over-the-counter transactions submitted for clearing; indicative settlement prices contributed by clearing members; and pricing information licensed from other third-party sources. *See, e.g.,* Letter from Ann K. Shuman, Managing Director and Deputy General Counsel, Chicago Mercantile Exchange Inc., to Elizabeth Murphy, Secretary, Commission (Dec. 14, 2009) (File No. S7–06–09); Letter from Kevin McClear, General Counsel, ICE Trust, to Elizabeth Murphy, Secretary, Commission (Dec. 4, 2009) (File No. S7–05–09).

[103] Parties could agree that the daily mark would be computed as of a time other than the close of business but could not agree to waive the requirement that the daily mark be provided on a daily basis, as required by the statute.

[104] SIFMA and ISDA have suggested that ''[b]y market convention and often by contract, parties generally agree to utilize a mid-market level for margin purposes. Counterparties understand that this level does not represent a valuation at which a transaction may be entered into or terminated and accordingly may differ from actual market prices. We recommend that the Commissions endorse this use of mid-market levels for margin purposes as a uniform market practice.'' SIFMA/ISDA 2010 Letter at 17. For a discussion of midmarket value and adjustments, see ISDA Research Notes, The Value of a New Swap, Issue 3, 2010, available at *http://www.isda.org/researchnotes/pdf/NewSwapRN.pdf* (''ISDA Note'') (describing midmarket value as ''the net present value of the transaction assuming it is priced at mid-market'').

[105] *See* ISDA Note.

[106] As discussed in Section II.C.4, *infra,* we do not believe that compliance with the requirements of proposed Rule 15Fh–3(c), in and of itself, should cause an SBS Dealer to be deemed to have made a recommendation under proposed Rule 15Fh–3(f).

[107] *See* ISDA Note (''even though market participants do not actually transact at the midmarket rate, it is nonetheless useful because it is an objective, transparent rate that might be used as a basis for actual pricing'').

[108] *Cf.* Trading & Capital-Markets Manual § 2150 (Bd. of Gov. Fed. Reserve Sys. Jan. 2009), *available at http://www.federalreserve.gov/boarddocs/supmanual/trading/200901/0901trading.pdf:*

When observable market prices are available for a transaction, two pricing methodologies are primarily used—bid/offer or midmarket. Bid/offer pricing involves assigning the lower of bid or offer prices to a long position and the higher of bid or offer prices to short positions. Midmarket pricing involves assigning the price that is midway between bid and offer prices. Most institutions use midmarket pricing schemes, although some firms may still use bid/offer pricing for some products or types of trading. Midmarket pricing is the method recommended by the accounting and reporting subcommittee of the Group of Thirty's Global Derivatives Study Group, and it is the method market practitioners currently consider the most sound. * * *

For many illiquid or customized transactions, such as highly structured or leveraged instruments and more complex, nonstandard notes or securities, reliable independent market quotes are usually not available, even infrequently. In such instances, other valuation techniques must be used to determine a theoretical, end-of-day market value. These techniques may involve assuming a constant spread over a reference rate or comparing the transaction in question with similar transactions that have readily available prices (for example, comparable or similar transactions with different counterparties). More likely, though, pricing models will be used to price these types of customized transactions.

[109] The Commission recognizes that different SBS Entities may produce somewhat different marks for similar security-based swaps, depending on the respective data sources, methodologies and assumptions used to calculate the marks. Thus, the data sources, methodologies and assumptions would provide a context in which the quality of the mark could be evaluated. See Disclosure of Accounting Policies for Derivative Financial Instruments and Derivative Commodity Instruments and Disclosure of Quantitative and Qualitative Information about Market Risk Inherent in Derivative Financial Instruments, Other Financial Instruments and Derivative Commodity Instruments, Securities Act Release No. 7386 (Jan. 31, 1997), 62 FR 6044 (Feb. 10, 1997). We understand that currently, industry practice is often to include similar disclosures for margin calls in swap documentation, such as a credit support annex.

material changes to the data sources, methodology, or assumptions over the term of the security-based swap. An SBS Entity would not be required to disclose the data sources or a description of the methodology and assumptions more than once unless it materially changes the data sources, methodology or assumptions used to calculate the daily mark. For the purposes of this rule, a material change would include any change that has a material impact on the daily mark provided. We understand that the daily mark for illiquid security-based swaps may be generated using models that may or may not be proprietary. The required disclosure of the data sources or description of the methodology and assumptions used to prepare the daily mark is not intended to require so much detail as to result in disclosure of an SBS Entity's proprietary information.

We preliminarily believe that, for the disclosure to the counterparty to be meaningful, the daily mark for both cleared and uncleared security-based swaps should be provided without charge and with no restrictions on internal use by the recipient, although restrictions on dissemination to third parties are permissible. The rule would not, however, mandate the means by which an SBS Entity makes the required disclosures. Commenters have asked if SBS Entities may satisfy their obligations in this regard by making the relevant information available to counterparties through password-protected access to a website containing the relevant information.[110] The Commission preliminarily believes that such a method would be an appropriate way for SBS Entities to discharge their obligations with respect to daily marks, subject to compliance with the Commission's guidance on the use of electronic media.[111] In particular, the use of electronic media should not be so burdensome that intended recipients cannot effectively access the information provided. Further, persons to whom information is sent or provided electronically must have the opportunity to download directly the information, or otherwise have an opportunity to retain and analyze the information through the selected medium or have ongoing access equivalent to personal retention.[112] Information of this kind is directly relevant to a counterparty's understanding of its financial relationship under a security-based swap and so, we preliminarily believe that access to the information as described above is necessary to ensure a counterparty's ability to monitor that relationship over the life of the transaction.[113]

SBS Entities also should consider the need to provide appropriate clarifying statements or disclosures relating to the daily mark. Such statements or disclosures may include, as appropriate, that the daily mark may not be a price at which the SBS Entity would agree to replace or terminate the security-based swap, nor the value at which the security-based swap is recorded in the books of the SBS Entity.[114]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Is the end-of-day settlement price an appropriate ''daily mark'' for cleared security-based swaps for purposes of this rule? If not, how should the Commission define ''daily mark'' in this context?
- Should the Commission prescribe a method for determining the end-of-day settlement price for cleared security-based swaps for purposes of this rule? If so, what method and why?
- Is the midpoint between the bid and offer prices for a particular uncleared security-based swap, or the calculated equivalent thereof, as of the close of business unless the parties agree in writing otherwise, an appropriate ''daily mark'' for uncleared security-based swaps? If not, how should the Commission define ''daily mark'' in this context, and why?
- Should the Commission prescribe a different method for calculating the daily mark for uncleared security-based swaps for purposes of this rule? If so, what method and why? Should valuations of equivalent positions used by the SBS Entity for other purposes, such as collateral valuation or the preparation of financial statements, be taken into consideration? Why or why not, and how?
- Are there requirements under proposed Rule 15Fh–3(c) that would cause an SBS Entity to be a fiduciary for ERISA purposes? If so, which requirements, and is there an alternate method for calculating the daily mark that would not cause an SBS Entity to be a fiduciary for ERISA purposes?
- In calculating the midmarket value, should the Commission require an SBS Entity to use third-party market quotations (*i.e.,* should the Commission allow an SBS Entity to use its own market quotations)? Why or why not? Should there be constraints or conditions on such use? Why or why not?
- Should the Commission require an SBS Entity to provide an executable quote or the price at which the SBS Entity would terminate the security-based swap, in addition to the daily mark, for purposes of comparison or other reasons? If so, should this additional information always be required or is there a stronger rationale for the additional information to be required for certain identifiable types of security-based swap positions, such as security-based swaps that are highly customized to a counterparty's requirements, or otherwise illiquid, and for which the daily mark may be significantly different from an executable quote?
- Should the Commission require an SBS Entity to provide a value that would be used for purposes of variation margin, in addition to the daily mark, for purposes of comparison or other reasons? If so, should this additional information always be required or is there a stronger rationale for the additional information to be required for certain identifiable types of security-based swap positions, such as security-based swaps that are highly customized to a counterparty's requirements, or otherwise illiquid, and for which the daily mark may be significantly different from a value used for variation margin?
- If the SBS Entity and a particular counterparty are parties to more than

[110] SIFMA/ISDA 2010 Letter at p. 17.

[111] *See* Use of Electronic Media by Broker-Dealers, Transfer Agents and Investment Advisers for Delivery of Electronic Information, Securities Act Release No. 7288 (May 9, 1996), 61 FR 24644 (May 15, 1996) (''Electronic Media Release''). *See also* Use of Electronic Media, Exchange Act Release No. 42728 (Apr. 28, 2000), 65 FR 25843 (May 4, 2000).

[112] *See* Electronic Media Release.

[113] A counterparty may also require continuing access to satisfy recordkeeping requirements to which it may be subject.

The Commission has proposed to require clearing agencies to make available to the public, on terms that are fair and reasonable and not unreasonably discriminatory, all end-of-day settlement prices and any other prices with respect to security-based swaps that the clearing agency may establish to calculate mark-to-market margin requirements for its participants and any other pricing or valuation information with respect to security-based swaps as is published or distributed by the clearing agency to is participants. *See* Clearing Agency Standards for Operation and Governance, Exchange Act Release No. 64017 (March 2, 2011), 76 FR 14472 (March 16, 2011) (proposed Rule 17Aj–1). As we explained in proposing Rule 17Aj–1, we preliminarily believe that public availability of this information would help to improve fairness, efficiency, and market competition by making available to all market participants data that may otherwise be available only to a limited subset of market participants. *See id.*

[114] *Cf.* CFTC External Business Conduct Release (proposed Rule 17 CFR 23.431(c)).

one security-based swap transaction with one another, should the SBS Entity be permitted to provide a single aggregate daily mark for all of the security-based swaps, allowing for netting between the parties? Why or why not?

• Should the Commission require an SBS Entity to provide additional disclosures including, as appropriate: (1) That the daily mark may not necessarily be a price at which either the counterparty or the SBS Entity would agree to replace or terminate the security-based swap; (2) that, depending upon the agreement of the parties, calls for margin may be based on considerations other than the daily mark provided to the counterparty; and (3) that the daily mark may not necessarily be the value of the security-based swap that is recorded in the books of the SBS Entity? [115] In addition to disclosing any material changes to data sources, methodology or assumptions used, should an SBS Entity be required to disclose the impacts of these material changes? Are there any other disclosures that the Commission should require the SBS Entity to provide in connection with the daily mark?

• We do not intend the proposed disclosures regarding the data sources and description of the methodologies and assumptions used to prepare the daily marks to require the disclosure of information considered proprietary in nature in order for an SBS Entity to discharge its obligations. Is such disclosure a concern under the current formulation of the rule? If so, what types of proprietary information might be subject to disclosure under the proposed rule? Is there other information that could adequately substitute for purposes of meaningful disclosure? What mechanisms, if any, could be used to protect proprietary information implicated by the daily mark requirement while providing adequate disclosure to counterparties?

• Should access to a Web site or electronic platform be considered sufficient for disclosure of the daily mark? Why or why not? Should other forms of Internet-based or electronic disclosure be addressed, and if so, how?

• Should we require that the daily mark for both cleared and uncleared security-based swaps should be provided without charge and with no restrictions on internal use by the recipient, although restrictions on dissemination to third parties are permissible? Why or why not?

[115] *Cf.* CFTC External Business Conduct Release (proposed § 23.431(c)).

f. Clearing Rights

Proposed Rule 15Fh–3(d) would require an SBS Entity, before entering into a security-based swap with a counterparty, to disclose to the counterparty its rights under Section 3C(g) of the Exchange Act concerning submission of a security-based swap to a clearing agency for clearing.[116] Although they are not required by the Dodd-Frank Act, we preliminarily believe that such disclosures would promote the objectives of Section 3C(g).

The counterparty's rights, and thus the proposed disclosure obligations, would differ depending on whether the clearing requirement of Section 3C(a) applies to the relevant transaction.[117] When the clearing requirements of Section 3C(a)(1) apply to a security-based swap, proposed Rule 15Fh–3(d)(1)(i) would require the SBS Entity to disclose to the counterparty the clearing agencies that accept the security-based swap for clearing and through which of those clearing agencies the SBS Entity is authorized or permitted, directly or through a designated clearing member, to clear the security-based swap. The SBS Entity would also be required to notify the counterparty of the counterparty's sole right to select which clearing agency is to be used to clear the security-based swap, provided it is a clearing agency at which the SBS Entity is authorized or permitted, directly or through a designated clearing member, to clear the security-based swap.[118] We note that, while proposed Rule 15Fh–3(d) would not require an SBS Entity to become a member or participant of a specific clearing agency, an SBS Entity could not enter into security-based swaps that are subject to a mandatory clearing requirement without having some arrangement in place to clear the transaction.[119]

For security-based swaps that are not subject to the clearing requirement under Exchange Act Section 3C(a)(1), proposed Rule 15Fh–3(d)(2) would require the SBS Entity to determine whether the security-based swap is accepted for clearing by one or more clearing agencies and, if so, to disclose to the counterparty the counterparty's right to elect clearing of the security-based swap.[120] Proposed Rule 15Fh–3(d)(2)(ii) would require the SBS Entity to disclose to the counterparty the clearing agencies that accept the type, category, or class of security-based swap transacted and whether the SBS Entity is authorized or permitted, directly or through a designated clearing member, to clear the security-based swap through such clearing agencies. Proposed Rule 15Fh–3(d)(2)(iii) would require the SBS Entity to notify the counterparty of the counterparty's sole right to select the clearing agency at which the security-based swap would be cleared, provided it is a clearing agency at which the SBS Entity is authorized or permitted, directly or through a designated clearing member, to clear the security-based swap. Once again, the proposed rule would not require an SBS Entity to become a member or participant of a particular clearing agency, notwithstanding the election of the counterparty to clear the transaction.

The proposed rule would require that disclosure be made before a transaction occurs. The Commission believes that it would be appropriate for a counterparty to exercise its statutory right to select the clearing agency at which its security-based swaps would be cleared (as provided above) on a transaction-by-transaction basis, on an asset-class-by-asset-class basis, or in terms of all

[116] *See* Section 15F(h)(1)(D) of the Exchange Act (authorizing the Commission to prescribe business conduct standards that relate to ''such other matters as the Commission determines to be appropriate''); *see also* Dodd-Lincoln Letter (describing anticipated benefits of clearing as a means of ''bringing transactions and counterparties into a sound, conservative and transparent risk management framework''). Public Law 111–203, 124 Stat. 1376, 1789 (to be codified at 15 U.S.C. 78o–10(h)(1)(D)).

[117] Section 3C(a)(1) of the Exchange Act provides that: ''It shall be unlawful for any person to engage in a security-based swap unless that person submits such security-based swap for clearing to a clearing agency that is registered under this Act or a clearing agency that is exempt from registration under this Act if the security-based swap is required to be cleared.'' Public Law 111–203, 124 Stat. 1376, 1762 (to be codified at 15 U.S.C. 78c–3(a)(1)).

[118] Proposed Rule 15Fh–3(d)(1)(ii). *See* Exchange Act 3C(g)(5)(A), Public Law 111–203, 124 Stat. 1376, 1766–1777 (to be codified at 15 U.S.C. 78c–3(g)(5)(A)):

With respect to any security-based swap that is subject to the mandatory clearing requirement under subsection (a) and entered into by a security-based swap dealer or a major security-based swap participant with a counterparty that is not a swap dealer, major swap participant, security-based swap dealer, or major security-based swap participant, the counterparty shall have the sole right to select the clearing agency at which the security-based swap will be cleared.

[119] *See* Exchange Act Section 3C(a), Public Law 111–203, 124 Stat. 1376, 1762, § 763(a) (to be codified at 15 U.S.C. 78c–3(a)).

[120] *See* Exchange Act Section 3C(g)(5)(B), Public Law 111–203, 124 Stat. 1376, 1767, (to be codified at 15 U.S.C. 78c–3(g)(5)(B)):

With respect to any security-based swap that is not subject to the mandatory clearing requirement under subsection (a) and entered into by a security-based swap dealer or a major security-based swap participant with a counterparty that is not a swap dealer, major swap participant, security-based swap dealer, or major security-based swap participant, the counterparty—(i) may elect to require clearing of the security-based swap; and (ii) shall have the sole right to select the clearing agency at which the security-based swap will be cleared.

potential transactions the counterparty may execute with the SBS Entity.

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Should the Commission require SBS Entities to disclose a counterparty's rights to select a clearing agency, as provided above? What benefits would this requirement provide? Would the proposed disclosure requirement impose an undue burden on SBS Entities? If so, what would the burden be, and are there other ways to ensure that a counterparty is aware of its rights with respect to clearing?
- Would the SBS Entity be in a position to know, in all cases, the information that would be required to be disclosed under proposed Rule 15Fh–3(d)? If not, why? Would the time needed to gather the required information affect the transaction process for security-based swaps to any material extent? If so, how?
- Should the Commission require SBS Entities to disclose any other information to counterparties regarding their rights or obligations in connection with the clearing of security-based swap transactions? For example, under Section 3C(g) of the Exchange Act, certain ''end users'' have the option not to have their security-based swaps cleared, even if those security-based swaps have been made subject to a mandatory clearing requirement.[121] Should an SBS Entity be required to disclose to such end users that they may elect not to have their security-based swaps cleared under these circumstances? Why or why not?
- Should an SBS Entity be permitted to allow its counterparties to elect the clearing agency at which its security-based swaps would be cleared on a transaction-by-transaction basis, on an asset-class-by-asset-class basis, or in terms of all potential transactions? If not, what restrictions should apply to the SBS Entity in this context?

3. Know Your Counterparty

Proposed Rule 15Fh–3(e) would establish a ''know your counterparty'' requirement for SBS Dealers.[122] The proposed rule would require an SBS Dealer to have policies and procedures reasonably designed to obtain and retain a record of the essential facts that are necessary for conducting business with each counterparty that is known to the SBS Dealer.[123] For purposes of the proposed rule, ''essential facts'' would be: (i) Facts necessary to comply with applicable laws, regulations and rules, (ii) facts necessary to effectuate the SBS Dealer's credit and operational risk management policies in connection with transactions entered into with such counterparty, (iii) information regarding the authority of any person acting for such counterparty, and (iv) if the counterparty is a special entity, such background information regarding the independent representative as the SBS Dealer reasonably deems appropriate.[124]

The ''know your counterparty'' obligations under the proposed rule are a modified version of the ''know your customer'' obligations imposed on other market professionals, such as broker-dealers, when dealing with customers.[125] Although the statute does not require the Commission to adopt a ''know your counterparty'' standard, we preliminarily believe that such a standard would be consistent with basic principles of legal and regulatory compliance, operational and credit risk management, and authority. Further, we preliminarily believe that entities that currently operate as SBS Dealers typically would already have in place, as a matter of their normal business practices, ''know your counterparty'' policies and procedures that could potentially satisfy the requirements of the proposed rule. We are proposing to apply the requirement in proposed Rule 15Fh–3(e) to SBS Dealers but not to Major SBS Participants because we do not anticipate that Major SBS Participants would serve a dealer-type role in the market.

Request for Comments

The Commission requests comments generally on all aspects of proposed 15Fh–3(e). In addition, we request comments on the following specific issues:

- Should the Commission impose a ''know your counterparty'' requirement? If not, why not? Does the Commission need to clarify any of the proposed requirements? If so, how? Are there any specific categories of information that an SBS Dealer should be required to obtain from a counterparty? Should the Commission specify how any such information should be obtained from the counterparty?
- Should the ''know your counterparty'' obligations apply to Major SBS Participants, as well as to SBS Dealers? If so, why?
- To what extent would the current business practices of SBS Dealers, including their compliance procedures and their credit and operational risk management procedures, comply with the proposed ''know your counterparty'' requirements? To what extent would the proposed rule require SBS Dealers to change their current business practices? Would the proposed requirements impose any particular burdens on market participants?
- Should SBS Dealers be required to obtain any particular or additional information regarding their counterparty beyond what would be required under the proposed rule? If so, what specific information should SBS Dealers be required to obtain?
- Should the proposed requirement track more closely the ''know your customer'' requirement imposed under SRO rules? In particular, should the proposed rule require an SBS Dealer to obtain information necessary to effectively ''service the counterparty,'' to implement a counterparty's ''special instructions,'' or to evaluate the counterparty's security-based swaps experience, financial wherewithal and

[121] Exchange Act Section 3C(g), Public Law 111–203, 124 Stat. 1376, 1767, § 763(a) (to be codified at 15 U.S.C. 78c–3(g)). *See* End-User Exception to Mandatory Clearing of Security-Based Swaps, Exchange Act Release No. 63556 (Dec. 15, 2010), 75 FR 79992 (Dec. 21, 2010) (proposing new Rule 3Cg–1 under the Exchange Act governing the exception to mandatory clearing of security-based swaps available for counterparties meeting certain conditions).

[122] *See* Section 15F(h)(1)(D) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1789, (to be codified at 15 U.S.C. 78o–10(h)(1)(D)) (authorizing, but not explicitly mandating, the Commission to prescribe business conduct standards that relate to ''such other matters as the Commission determines to be appropriate'').

[123] The proposed rule would not apply to security-based swaps for which the SBS Dealer does not know the identity of the counterparty, as is the case, for example, for many security-based swaps traded on a SEF or an exchange.

[124] The Commission is considering the minimum requirements for an SBS Dealer's operational and credit risk management practices and expects to address any such matters in a separate rulemaking.

[125] *Cf.* FINRA Rule 2090 (''Every member shall use reasonable diligence, in regard to the opening and maintenance of every account, to know (and retain) the essential facts concerning every customer and concerning the authority of each person acting on behalf of such customer''). Supplementary Material .01 to FINRA Rule 2090 defines the ''essential facts'' for purposes of the FINRA rule to include certain information not required by our proposed rule. For purposes of FINRA Rule 2090, facts ''essential'' to ''knowing the customer'' are those required to (a) effectively service the customer's account, (b) act in accordance with any special handling instructions for the account, (c) understand the authority of each person acting on behalf of the customer, and (d) comply with applicable laws, regulations, and rules. *See also* 14 CFR 13.5 (requiring a bank that is a government securities broker or dealer to make reasonable efforts to obtain information concerning the customer's financial status, tax status and investment objectives, and such other information used or considered to be reasonable by the bank in making recommendations to the customer).

trading objectives? [126] If so, how should such terms be interpreted in the context of SBS Dealers and the security-based swap market?

• Are there any circumstances in which it would not be appropriate to apply a ''know your counterparty'' obligation? What circumstances and why?

• Should ''know your counterparty'' requirements apply differently with respect to cleared and uncleared swaps? If so, how and why?

4. Recommendations by SBS Dealers

Proposed Rule 15Fh–3(f) would generally require an SBS Dealer that makes a ''recommendation'' to a counterparty to have a reasonable basis for believing that the recommended security-based swap or trading strategy involving security-based swaps is suitable for the counterparty.

In determining whether to propose Rule 15Fh–3(f), a business conduct requirement not expressly addressed by the statute, the Commission considered the suitability obligations imposed when other market professionals recommend a security or trading strategy to customers, including institutional customers.[127] The obligation to make only suitable recommendations is a core business conduct requirement for broker-dealers.[128] Municipal securities dealers also have a suitability obligation when recommending municipal securities transactions to a customer.[129] Federally regulated banks have a suitability obligation as well when acting as a broker or dealer in connection with the purchase or sale of government securities.[130] Depending on the scope of its activities, an SBS Dealer may be subject to one of these other suitability obligations, in addition to those under our proposed rule. In particular, if an SBS Dealer is also a registered broker-dealer and a FINRA member, it would be subject as well to FINRA suitability requirements in connection with the recommendation of a security-based swap or trading strategy involving a security-based swap, as well as the anti-fraud provisions of the Exchange Act.[131] Proposed Rule 15Fh–3(f) is intended to ensure that all SBS Dealers that make recommendations are subject to this obligation, tailored as appropriate in light of the nature of the security-based swap markets.[132]

Proposed Rule 15Fh–3(f) would only apply when an SBS Dealer makes a ''recommendation'' to a counterparty. The Commission preliminarily believes that the determination of whether an SBS Dealer has made a recommendation that triggers a suitability obligation should turn on the facts and circumstances of the particular situation and, therefore, whether a recommendation has taken place is not susceptible to a bright line definition. This is consistent with the FINRA approach to what constitutes a recommendation. In the context of the FINRA suitability standard, factors considered in determining whether a recommendation has taken place include whether the communication ''reasonably could be viewed as a 'call to action' '' and ''reasonably would influence an investor to trade a particular security or group of securities.'' [133] The more individually tailored the communication to a specific customer or a targeted group of customers about a security or group of securities, the greater the likelihood that the communication may be viewed as a ''recommendation.'' The Commission preliminarily believes that this approach should apply in the context of proposed Rule 15Fh–3(e) as well.

An SBS Dealer typically would not be deemed to be making a recommendation solely by reason of providing general financial or market information, or transaction terms in response to a request for competitive bids.[134] Furthermore, compliance with the requirements of the proposed rules, in particular, Rule 15Fh–3(a) (verification of counterparty status), 15Fh–3(b) (disclosures of material risks and characteristics, and material incentives or conflicts of interest), 15Fh–3(c) (disclosures of daily mark), and 15Fh–3(d) (disclosures regarding clearing rights) would not, in and of itself, result in an SBS Dealer being deemed to be making a ''recommendation.''

When the suitability obligation of proposed Rule 15Fh–3(f) applies, the SBS Dealer must, as a threshold matter, understand the security-based swap or trading strategy that it is recommending. Proposed Rule 15Fh–3(f)(1)(i) would require an SBS Dealer to have a reasonable basis to believe, based on reasonable diligence, that the recommendation is suitable for at least some counterparties. In general, what constitutes reasonable diligence will vary depending on, among other things, the complexity of and risks associated with the security-based swap or trading strategy and the SBS Dealer's familiarity with the security-based swap or trading strategy. An SBS Dealer's reasonable diligence must provide it with an understanding of the potential risks and rewards associated with the recommended security-based swap or trading strategy. An SBS Dealer that lacks this understanding would not be able to meet its obligations under the proposed rule.[135] In addition, under

[126] *Cf.* Supplementary Material .01 to FINRA Rule 2090 (''For purposes of this Rule, facts 'essential' to 'knowing the customer' are those required to (a) Effectively service the customer's account, (b) act in accordance with any special handling instructions for the account, (c) understand the authority of each person acting on behalf of the customer, and (d) comply with applicable laws, regulations, and rules.'').

[127] *See* Section 15F(h)(1)(D) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1789 (to be codified at 15 U.S.C. 78o–10(h)(1)(D)) (authorizing, but not explicitly requiring, the Commission to prescribe business conduct standards that relate to ''such other matters as the Commission determines to be appropriate''), and Section 15F(h)(3)(D) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1790 (to be codified at 15U.S.C. 78o–10(h)(3)(D)) (authorizing the Commission to establish ''such other standards and requirements as the Commission may determine are appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of this Act'').

[128] *See, e.g.*, FINRA Rules 2090 and 2111 (effective July 9, 2012). *See also Charles Hughes & Co.* v. *SEC*, 139 F.2d 434 (2d Cir. 1943) (enforcing suitability obligations under the antifraud provisions of the Exchange Act).

[129] MSRB Rule G–19(c) provides that:

In recommending to a customer any municipal security transaction, a broker, dealer, or municipal securities dealer shall have reasonable grounds: (i) Based upon information available from the issuer of the security or otherwise, and (ii) based upon the facts disclosed by such customer or otherwise known about such customer, for believing that the recommendation is suitable.

[130] *See* Trading & Capital-Markets Manual § 2150 (imposing a suitability obligation on federally regulated banks acting as a government securities broker or government securities dealer); Government Securities Sales Practices, 62 FR 13276 (Mar. 19, 1997) (codified at 12 CFR parts 13, 208, 211, and 368).

[131] *See* Section II.A, *supra*. *See also* FINRA Rule 2111 (effective July 9, 2012). Under FINRA rules, unless a counterparty had total assets of at least $50 million, he or she would be entitled to the protections provided by retail suitability obligations in the broker-dealer context. *See* FINRA Rule 2111(b) (referring to NASD Rule 3110(c)(4)).

[132] Some dealers have indicated that they already apply ''institutional suitability'' principles to their swap business. *See, e.g.,* Letter from Richard Ostrander, Managing Director and Counsel, Morgan Stanley, to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, and David A. Stawick, Secretary, Commodity Futures Trading Commission (Dec. 3, 2010) at 5; Report of the Business Standards Committee, Goldman Sachs (Jan. 2011), *http://www2.goldmansachs.com/our-firm/business-standards-committee/report.pdf.*

[133] *See* FINRA Notice to Members 01–23 (Mar. 19, 2001), and Notice of Filing of Proposed Rule Change to Adopt FINRA Rules 2090 (Know Your Customer) and 2111 (Suitability) in the Consolidated FINRA Rulebook, Exchange Act Release No. 62718 (Aug. 13, 2010), 75 FR 51310 (Aug. 19, 2010), as amended, Exchange Act Release No. 62718A (Aug. 20, 2010), 75 FR 52562 (Aug. 26, 2010) (discussing what it means to make a ''recommendation'').

[134] *Cf.* Supplementary Material .03 to FINRA Rule 2090.

[135] *See, e.g., Michael F. Siegel*, 2007 NASD Discip. LEXIS 20 (2007), *aff'd,* Exchange Act

Continued

proposed Rule 15Fh–3(f)(1), in order to establish a reasonable basis for a recommendation to a particular counterparty, the SBS Dealer would need to have or obtain relevant information regarding the counterparty, including the counterparty's investment profile (including trading objectives) and its ability to absorb potential losses associated with the recommended security-based swap or trading strategy.[136]

Proposed Rule 15Fh–3(f)(2) would provide an alternative to the general suitability requirement, under which an SBS Dealer could fulfill its obligations with respect to a particular counterparty if: (1) The SBS Dealer reasonably determines that the counterparty (or its agent) is capable of independently evaluating investment risks with regard to the relevant security-based swap or trading strategy involving a security-based swap; (2) the counterparty (or its agent) affirmatively represents in writing that it is exercising independent judgment in evaluating the recommendations by the SBS Dealer; and (3) the SBS Dealer discloses that it is acting in the capacity of a counterparty, and is not undertaking to assess the suitability of the security-based swap or trading strategy.[137] We preliminarily believe that parties should be able to make these disclosures on a transaction-by-transaction basis, on an asset-class-by-asset-class basis, or in terms of all potential transactions between the parties.[138]

If an SBS Dealer cannot rely on the alternative provided by proposed Rule 15Fh–3(f)(2), it would need to make an independent determination that the recommended security-based swap or trading strategy involving security-based swaps is suitable for the counterparty.[139]

We preliminarily believe that an SBS Dealer, for purposes of Rule 15Fh–3(f)(2), reasonably could determine that the counterparty (or its agent) is capable of independently evaluating investment risks with regard to the relevant security-based swap (or trading strategy involving a security-based swap) through a variety of means, including the use of written representations from its counterparty. For example, absent special circumstances described below, we preliminarily believe it would be reasonable for an SBS Dealer to rely on written representations by its counterparty that the counterparty (or its agent) is capable of independently evaluating investment risks with regard to any security-based swap (or trading strategy involving a security-based swap). Upon receiving such a representation (or the representation required by Rule 15Fh–3(f)(2)(ii) with respect to the counterparty's exercise of independent judgment), the SBS Dealer would be entitled to rely on the representation without further inquiry, absent special circumstances described below.

To solicit input on when it would no longer be appropriate for an SBS Dealer to rely on such representations without further inquiry, the Commission is proposing for comment two alternative approaches. One approach would permit an SBS Dealer to rely on a representation from a counterparty for purposes of Rule 15Fh–3(f)(2)(i) or (ii) unless it knows that the representation is not accurate. The second would permit an SBS Dealer to rely on a representation unless the SBS Dealer has information that would cause a reasonable person to question the accuracy of the representation.

Under either approach, an SBS Dealer could not ignore information in its possession as a result of which the SBS Dealer would know that a representation is inaccurate. In addition, under the second approach, an SBS Dealer also could not ignore information that would cause a reasonable person to question the accuracy of a representation and, if the SBS Dealer had such information, it would need to make further reasonable inquiry to verify the accuracy of the representation.

We are proposing to apply the requirement in proposed Rule 15Fh–3(f) to SBS Dealers but not to Major SBS Participants because we do not anticipate that Major SBS Participants will serve a dealer-type role in the market.[140] Further, under the proposed rule, the obligation would not apply to an SBS Dealer in dealings with an SBS Entity, swap dealer, or major swap participant.[141] We preliminarily believe that these types of counterparties, which are professional intermediaries or major participants in the swaps or security-based swap markets, would not need the protections that would be afforded by this rule.

In addition, when an SBS Dealer is acting as an advisor to a special entity, we are proposing that the suitability requirement will be deemed satisfied by compliance with the requirements of Rule 15Fh–4(b). Under Section 15F(h)(4), an SBS Dealer that acts as an advisor to a special entity is required to make a reasonable determination that its recommendations are in the best interests of the counterparty.[142] The statute and proposed Rule 15Fh–4(b)(2) set forth specific information that an SBS Dealer must make reasonable efforts to obtain as necessary when making that determination. As explained more fully in Section II.D.3, *infra,* the proposed rule would further

---

Release No. 58737 (Oct. 6, 2008), *vacated in part and remanded on other grounds*, 592 F.3d 147 (10th Cir. 2010) (finding that registered representative lacked any reasonable basis for recommending securities because he did not have sufficient understanding of what he was recommending). *See also* Distribution by Broker-Dealers of Unregistered Securities, Exchange Act Release No. 6721 (Feb. 2, 1962) (''the making of recommendations for the purchase of a security implies that the dealer has a reasonable basis for such recommendations which, in turn, requires that, as a prerequisite, he shall have made a reasonable investigation''). *Cf.* Supplementary Material .03 to FINRA Rule 2090.

[136] Under FINRA Rule 2111(a) (effective July 9, 2012), a customer's investment profile includes, but is not limited to, the customer's age, other investments, financial situation and needs, tax status, investment objectives, investment experience, investment time horizon, liquidity needs, risk tolerance, and any other information the customer may disclose to the member or associated person in connection with such recommendation. *See also* FINRA Rule 2360(b)(19)(B) (''No member or person associated with a member shall recommend to a customer an opening transaction in any option contract unless the person making the recommendation has a reasonable basis for believing, at the time of making the recommendation, that the customer * * * is financially able to bear the risks of the recommended position in the option contract.'').

[137] As discussed in Section II.D.3, the standards for determining that an SBS Dealer is not acting as an advisor under proposed Rule 15Fh–2(a) would be substantially the same as the standards that an SBS Dealer must satisfy to qualify for the alternative to the general suitability standard under proposed Rule 15Fh–3(f). Accordingly, as described more fully below, we are also proposing that the general suitability requirement be deemed satisfied if an SBS Dealer is deemed not to be acting as an advisor to a special entity in accordance with proposed Rule 15Fh–2(a).

[138] This approach is consistent with FINRA's approach to institutional suitability. *See* Supplementary Material .07 to FINRA Rule 2111 (effective July 9, 2012) (''With respect to having to indicate affirmatively that it is exercising independent judgment in evaluating the member's or associated person's recommendations, an institutional customer may indicate that it is exercising independent judgment on a trade-by-trade basis, on an asset-class-by-asset-class basis, or in terms of all potential transactions for its account.'').

[139] This also is consistent with FINRA's approach to institutional suitability. *See id.*

[140] *See* discussion in Section I.C.4, *supra.* If a Major SBS Participant is, in fact, recommending security-based swaps to counterparties, we believe it is likely that person is engaged in other activities that would cause it to come within the definition of an SBS Dealer (and therefore no longer able to qualify as a Major SBS Participant) or other regulated entity that historically has been subject to a suitability obligation.

[141] *See* proposed Rule 15Fh–3(f).

[142] Section 15F(h)(4)(C) (''Any security-based swap dealer that acts as an advisor to a special entity shall make reasonable efforts to obtain such information as is necessary to make a reasonable determination that any security-based swap recommended by the security-based swap dealer is in the best interests of the special entity''). Public Law 111–203, 124 Stat. 1376, 1790–1791 (to be codified at 15 U.S.C. 78o–10(h)(4)(C)).

require that the SBS Dealer act in the ''best interests'' of the special entity, which goes beyond and encompasses the general suitability requirements of proposed Rule 15Fh–3(f). Accordingly, we preliminarily believe that the general suitability requirement of proposed Rule 15Fh–3(f) should be deemed satisfied by compliance with the requirements of proposed Rule 15Fh–4(b).

Request for Comments

The Commission requests comments generally on all aspects of proposed Rule 15Fh–3(f). In addition, we request comments on the following specific issues:

• As noted above, the term ''recommendation'' has been interpreted in the context of the FINRA suitability requirement. Should the Commission define or describe more fully what is a ''recommendation'' in this context, and if so, what should the definition or description be and why? In what specific circumstances, if any, would additional guidance as to the meaning of a ''recommendation'' be useful? Does the existing FINRA guidance provide sufficient clarity in this regard? Why or why not? Would a different approach be appropriate given the differences in the market for security-based swaps? Why or why not? Should the Commission expressly address the application of any part of the FINRA guidance in this context? If so, how?

• Should the Commission permit an SBS Dealer to rely on the institutional suitability alternative that would be available under proposed Rule 15Fh–3(f)(2)? Why or why not? Should additional or different requirements be placed upon an SBS Dealer's use of this alternative? If so, what requirements should be added or changed and why?

• Is FINRA's guidance regarding the customer information a broker-dealer should have available in order to make a suitability determination an appropriate model for security-based swap markets? How, if at all, should that guidance be modified? Should the SBS Dealer be required to obtain different or additional information regarding the counterparty?

• Should the suitability obligations apply to Major SBS Participants, as well as to SBS Dealers? Why or why not?

• Should the suitability obligations apply to recommendations made to SBS Entities, swap dealers and major swap participants? Why or why not?

• Should the suitability obligations apply when recommendations are made to a counterparty that is a broker-dealer?[143] Another type of market intermediary? Why or why not? Are there any other circumstances in which the proposed suitability requirement should not apply, or should apply in a different way?

• Are there any particular types of security-based swap transactions for which heightened or otherwise modified suitability requirements should apply? If so, what types of transactions? What requirements should apply to these transactions?

• Should different categories of ECPs be treated differently under the proposed rules for purposes of suitability determinations? If so, how? For example, under our proposed rules an SBS Entity would be subject to the suitability requirement of proposed Rule 15F–3(f)(2) when entering into security-based swaps with any person that qualified as an ECP, a category that includes persons with $5 million or more invested on a discretionary basis that enter into the security-based swap ''to manage risks.''[144] In contrast, under FINRA rules, in order to apply an analogous suitability standard, a broker-dealer must be dealing with an entity (whether a natural person, corporation, partnership, trust, or otherwise) with total assets of at least $50 million.[145] Should the Commission apply a different standard of suitability depending on whether the counterparty would be protected as a retail investor under FINRA rules when the SBS Dealer is also a registered broker-dealer?[146] If so, what should the standard be and to whom should it apply? In what ways should the similarities and differences between security-based swaps and the types of securities transactions otherwise subject to FINRA rules inform the standard applied by the Commission in this context?

• Is it appropriate for the Commission to exclude from the scope of the proposed rule situations in which an SBS Dealer is making recommendations to a special entity, since recommendations to those entities are subject to separate and heightened suitability requirements? Why or why not?

• Should the proposed alternative available under proposed Rule 15Fh-3(f)(2) be limited to counterparties that would not be protected as retail investors under FINRA rules or another category of counterparties?[147] If not, should we require that the proposed alternative be addressed on a transaction-by-transaction basis (*i.e.,* not generally on a relationship basis or asset-class-by-asset-class) for counterparties that would otherwise be protected as retail investors under FINRA rules or another category of counterparties? Why or why not?

• Should the suitability obligation be limited to recommendations to counterparties that would be protected as retail investors under FINRA rules or another subset of counterparties? If so, should these counterparties be covered by a suitability rule similar to FINRA Rule 2360 regarding options suitability? Should this requirement be limited to another category of counterparties?[148] Why or why not?

• Should the Commission provide guidance on other methods by which an SBS Dealer can assess a counterparty's capability to independently evaluate investment risks and exercise independent judgment? If so, what alternative approaches, and what would be the advantages and disadvantages for SBS Dealers and counterparties?

---

[143] FINRA ''know your customer'' obligations do not apply to a broker-dealer's dealings with another broker or dealer. *See* NASD Rule 0120(g) (''[t]he term 'customer' shall not include a broker or dealer'').

[144] *See* Section 1a(18)(A)(xi) of the Commodity Exchange Act, as amended by the Dodd-Frank Act.

[145] *See* FINRA Rule 2111(b) (referring to NASD Rule 3110(c)(4)).

[146] Under FINRA rules, a retail customer would generally be an entity (whether a natural person, corporation, partnership, trust, or otherwise) with total assets of less than $50 million). *See* NASD Rule 3110(c)(4). An SBS Dealer that is also a broker-dealer would need to have a reasonable basis to believe that any recommendation of security-based swap or trading strategy to such a person is suitable for that person, based on the information obtained through the reasonable diligence of the member or associated person to ascertain the counterparty's investment profile. This general suitability obligation under current FINRA rules would apply regardless of whether the SBS Dealer could otherwise rely on the alternative under proposed Rule 15Fh–3(f)(2).

[147] *See id.*

[148] FINRA Rule 2360(b)(19) (Suitability) provides that:

(A) No member or person associated with a member shall recommend to any customer any transaction for the purchase or sale of an option contract unless such member or person associated therewith has reasonable grounds to believe upon the basis of information furnished by such customer after reasonable inquiry by the member or person associated therewith concerning the customer's investment objectives, financial situation and needs, and any other information known by such member or associated person, that the recommended transaction is not unsuitable for such customer.

(B) No member or person associated with a member shall recommend to a customer an opening transaction in any option contract unless the person making the recommendation has a reasonable basis for believing, at the time of making the recommendation, that the customer has such knowledge and experience in financial matters that he may reasonably be expected to be capable of evaluating the risks of the recommended transaction, and is financially able to bear the risks of the recommended position in the option contract.

• Should the Commission impose specific requirements with respect to the level of detail that should be required for representations? If so, what requirements and why?

• Should the Commission permit SBS Dealers to rely on disclosures made by counterparties for purposes of proposed Rule 15Fh–3(f)(2) on a transaction-by-transaction basis, on an asset-class-by-asset-class basis, or in terms of all potential transactions between the parties? Why or why not? What are the potential advantages and disadvantages of such an approach?

• What are the advantages and disadvantages of the two alternative proposed approaches to guidance on when an SBS Dealer may not rely on a representation? Which alternative would strike the best balance among the potential disadvantages to market participants, the regulatory interest (including protecting counterparties in security-based swap transactions) and promoting the sound functioning of the security-based swap market? What, if any, other alternatives should the Commission consider (*e.g.,* a recklessness standard) and why?

• Are there particular categories of counterparties for which an SBS Dealer should be required to undertake further review or inquiry to establish a counterparty's capability? Should additional information be required when, for example, a potential counterparty is a natural person? If so, what review or inquiry should be required in what circumstances?

• Are there other potential reasonable methods of establishing a counterparty's capability to independently evaluate investment risks and exercise independent judgment besides written representations? Should the Commission consider providing guidance regarding these other methods? If so, what methods should such guidance address and how?

5. Fair and Balanced Communications

Proposed Rule 15Fh–3(g) would implement the statutory requirement that SBS Entities communicate with counterparties in a fair and balanced manner based on principles of fair dealing and good faith.[149] This obligation would apply in connection with entering into security-based swaps, and would continue to apply over the term of a security-based swap.[150] The standard is consistent with the similarly worded requirement in the FINRA customer communications rule, which is designed to ensure that any customer communications reflect a balanced treatment of potential benefits and risks.[151] As we explained in Section I.C.2, *supra,* when a business conduct standard is based on a similar SRO standard, we generally expect to interpret our standard consistently with SRO interpretations of their rules, recognizing that we may need to account for functional differences between the security-based swap market and other securities markets. Accordingly, we are proposing three additional standards, drawn from FINRA regulation, to clarify the statutory requirement.[152] These standards do not represent an exclusive list of considerations that an SBS Entity must make in determining whether a communication with a counterparty is fair and balanced.

We propose to require that communications must provide a sound basis for evaluating the facts with respect to any security-based swap or trading strategy involving a security-based swap that the communication is designed to cover.[153] In addition, we propose to prohibit communications that imply that past performance would recur, or that make any exaggerated or unwarranted claim, opinion, or forecast.[154] Finally, we propose to require that any statement referring to the potential opportunities or advantages presented by a security-based swap or trading strategy involving a security-based swap be balanced by a statement of the corresponding risks having the same degree of specificity as the statement of opportunities.[155] SBS Entities should also avoid broad generalities in their communications, to the extent appropriate and practicable under the circumstances.

We note that, regardless of the scope of the rules proposed herein, all communications by SBS Entities will be subject to the specific anti-fraud provisions added to the Exchange Act under Title VII of the Dodd-Frank Act, [156] as well as general anti-fraud provisions under the federal securities laws.[157]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

• Should the Commission further clarify any proposed requirements to engage in fair and balanced communications? If so, how? Are there specific circumstances regarding the application of the proposed requirements that the Commission should address? If so, which circumstances, and what guidance is required?

• Should the Commission specify any additional requirements for the duty to engage in fair and balanced communications? If so, what requirements and why?

• Should an SBS Entity be able to rely on SRO guidance with respect to communications for purposes of compliance with the proposed rule? If so, how would such reliance function as both the security-based swap market and the broader securities markets continue to evolve?

• Should the Commission provide additional guidance with respect to the nature of fair and balanced communications for purposes of furthering compliance with the proposed rule and providing greater

[149] *See* Exchange Act Section 15F(h)(3)(C), Pub. L. 111–203, 124 Stat. 1376, 1790 (to be codified at 15 U.S.C. 78o–10(h)(3)(C)).

[150] *See* proposed Rule 15Fh–1.

[151] NASD Rule 2210(d). *See* IM–2210–1(1), Guidelines to Ensure That Communications with the Public Are Not Misleading (''Members must ensure that statements are not misleading within the context in which they are made. A statement made in one context may be misleading even though such a statement could be appropriate in another context. An essential test in this regard is the balanced treatment of risks and potential benefits.'').

[152] *Cf.* SIFMA/ISDA 2010 Letter at 4 (requesting the Commission clarify the standards for fair and balanced communication by reference to the existing FINRA standards for customer communication, subject to appropriate modifications to reflect the heightened standards for participation in the swap markets).

[153] Proposed Rule 15Fh–3(g)(1). *Cf.* NASD Rule 2210(d)(1)(A) (''All member communications with the public shall be based on principles of fair dealing and good faith, must be fair and balanced, and must provide a sound basis for evaluating the facts in regard to any particular security or type of security, industry, or service.'').

[154] Proposed Rule 15Fh–3(g)(2). *Cf.* NASD Rule 2201(d)(1)(D) (''Communications with the public may not predict or project performance, imply that past performance will recur or make any exaggerated or unwarranted claim, opinion or forecast. A hypothetical illustration of mathematical principles is permitted, provided that it does not predict or project the performance of an investment or investment strategy.''). Proposed Rule 15Fh–3(e)(4) does not constitute a blanket prohibition of communications such as scenario or profitability analyses that are required or advisable under other provisions of these rules.

[155] Proposed Rule 15Fh–3(g)(3). *Cf.* NASD IM–2210–1(1) (''An essential test in this regard is the balanced treatment of risks and potential benefits.'').

[156] *See* Sections 9(j) and 15F(h)(4)(A) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1777–1778 and 1790 (to be codified at 15 U.S.C. 78i(j) and 15 U.S.C. 78o–10(h)(4)(A)). *See also* Prohibition Against Fraud, Manipulation, and Deception in Connection with Security-Based Swaps, Exchange Act Release No. 63236 (Nov. 3, 2010), 75 FR 68560 (Nov. 8, 2010) (proposing Rule 9j–1 to implement the anti-fraud prohibitions of Section 9(j) of the Exchange Act).

[157] *See, e.g.,* 15 U.S.C. 77q and 78i, and, if the SBS Entity is registered as a broker-dealer, 15 U.S.C. 78o.

legal certainty to market participants? If so, what guidance and why?

• What are the specific practical effects, advantages and disadvantages that market participants identify in considering how to comply with the proposed rules? Are there modifications or clarifications to the proposed rules that would better balance the advantages and disadvantages of the statutory requirement while furthering the Commission's regulatory objectives?

• Are there any particular differences between the traditional securities markets and the markets for security-based swaps that need to be taken into account in clarifying the statutory requirement to communicate in a fair and balanced manner based on principles of fair dealing and good faith? If so, what are these differences, and how should the Commission's proposal be modified to take them into account?

• Should we distinguish between the fair and balanced communication requirements applicable to an SBS Dealer and those applicable to a Major SBS Participant? If so, how should the requirements applicable to a Major SBS Participant differ from those that are being proposed?

• Are there any circumstances in which the fair and balanced communications requirements should not apply? Which circumstances, and why?

• We preliminarily believe that proposed Rule 15F–3(g) would provide additional investor protection beyond what would otherwise arise by virtue of applicable anti-fraud rules. Will the proposed communications requirements have the effect of reducing communications between SBS Entities and their counterparties? In what respects, and why? What alternative approaches might the Commission consider to effectively implement the statutory requirement without unduly discouraging effective communication between market participants?

6. Obligation Regarding Diligent Supervision

Exchange Act Section 15F(h)(1)(B) authorizes the Commission to adopt rules for the diligent supervision of the business of SBS Entities. Proposed Rule 15Fh–3(h) would establish supervisory obligations that incorporate principles from both Exchange Act Section 15(b) and existing SRO rules.[158] As we discussed earlier, the concept of diligent supervision is consistent with business conduct standards for broker-dealers that have historically been established by SROs for their members, subject to Commission approval. We anticipate that certain SBS Entities may also be registered broker-dealers and thus subject to substantially similar requirements under SRO rules.[159] More generally, we believe that the SRO requirements provide a useful point of reference that has been implemented by a wide range of firms in the U.S. financial services industry.

Under proposed Rule 15Fh–3(h)(1), each SBS Entity would be required to establish, maintain and enforce a system to supervise, and would be required to supervise diligently, the business of the SBS Entity involving security-based swaps.[160]This system would be required to be reasonably designed to achieve compliance with applicable federal securities laws and the rules and regulations thereunder.[161] Proposed Rule 15Fh–3(h) would provide a baseline requirement for an effective supervisory system, although a particular system may need additional elements in order to be effective. For that reason, proposed Rule 15Fh–3(h)(2) would state that it establishes only minimum requirements; by implication, the list would not be exhaustive. These obligations are based on SRO standards and we generally expect to interpret these obligations taking into account SRO interpretations of their rules, recognizing that we are not bound by SRO interpretations and may need to account for functional differences between the security-based swap market and other securities markets.

Proposed Rule 15Fh–3(h)(2)(i) would require an SBS Entity to designate at least one qualified person with supervisory responsibility for security-based swap transactions.[162] Proposed Rule 15Fh–3(h)(2)(ii) would require an SBS Entity to use reasonable efforts to determine that all supervisors are qualified and have sufficient training, experience, and competence to adequately discharge their responsibilities.[163] Proposed Rule 15Fh–3(h)(2)(iii) would require an SBS Entity to adopt written policies and procedures addressing the types of security-based swap business in which the SBS Entity is engaged. The policies and procedures would need to be reasonably designed to achieve compliance with applicable securities laws and the rules and regulations thereunder,[164] and include, at a minimum: (1) Procedures for the review by a supervisor of all transactions for which registration as an SBS Entity is required; [165] (2) procedures for the

[158] The Commission's policy regarding failure to supervise is well established. 15 U.S.C. 78o(b)(4)(E) and 15 U.S.C. 78o(b)(6)(A). As we have explained in other contexts:

The Commission has long emphasized that the responsibility of broker-dealers to supervise their employees is a critical component of the federal regulatory scheme. * * * In large organizations it is especially imperative that those in authority exercise particular vigilance when indications of irregularity reach their attention. The supervisory obligations imposed by the federal securities laws require a vigorous response even to indications of wrongdoing. Many of the Commission's cases involving a failure to supervise arise from situations where supervisors were aware only of ''red flags'' or ''suggestions'' of irregularity, rather than situations where, as here, supervisors were explicitly informed of an illegal act.

Even where the knowledge of supervisors is limited to ''red flags'' or ''suggestions'' of irregularity, they cannot discharge their supervisory obligations simply by relying on the unverified representations of employees. Instead, as the Commission has repeatedly emphasized, ''[t]here must be adequate follow-up and review when a firm's own procedures detect irregularities or unusual trading activity. * * *'' Moreover, if more than one supervisor is involved in considering the actions to be taken in response to possible misconduct, there must be a clear definition of the efforts to be taken and a clear assignment of those responsibilities to specific individuals within the firm.

John H. Gutfreund, Exchange Act Release No. 31554 (Dec. 3, 1992) (report pursuant to Section 21(a) of the Exchange Act) (footnotes omitted).

[159] *See, e.g.,* NASD Rules 3010 and 3012.

[160] We will consider consolidating any recordkeeping obligations proposed as part of this rule into a separate recordkeeping rule that we are required to adopt under the Dodd-Frank Act. *See* Section 15F(f)(2) of the Exchange Act, 15 U.S.C. 78o–10(f)(2) (''The Commission shall adopt rules governing reporting and recordkeeping for security-based swap dealers and major security-based swap participants.'').

[161] Proposed Rule 15Fh–3(h)(2). *See* NASD Rule 3010(a) (''Each member shall establish and maintain a system to supervise the activities of each registered representative, registered principal, and other associated person that is reasonably designed to achieve compliance with applicable securities laws and regulations, and with applicable NASD Rules.'').

[162] *Cf.* NASD Rule 3010(a)(2) (requiring ''[t]he designation, where applicable, of an appropriately registered principal(s) with authority to carry out the supervisory responsibilities of the member for each type of business in which it engages for which registration as a broker/dealer is required'').

[163] *Cf.* NASD Rule 3010(a)(6) (requiring members to use ''[r]easonable efforts to determine that all supervisory personnel are qualified by virtue of experience or training to carry out their assigned responsibilities'').

[164] *Cf.* NASD Rule 3010(b)(1) (''Each member shall establish, maintain, and enforce written procedures to supervise the types of business in which it engages and to supervise the activities of registered representatives, registered principals, and other associated persons that are reasonably designed to achieve compliance with applicable securities laws and regulations, and with the applicable Rules of NASD.'').

[165] Proposed Rule 15Fh–3(h)(2)(iii)(A). *Cf.* NASD Rule 3010 (d)(1) (''Each member shall establish procedures for the review and endorsement by a registered principal in writing, on an internal record, of all transactions and for the review by a registered principal of incoming and outgoing written and electronic correspondence of its registered representatives with the public relating to the investment banking or securities business of such member. Such procedures should be in writing and be designed to reasonably supervise each registered representative.'').

review by a supervisor of written correspondence with counterparties and potential counterparties and internal written (including electronic) communications relating to the securities-based swap business; [166] (3) procedures for a periodic review of the security-based swap business in which it engages; [167] (4) procedures to conduct reasonable investigation into the background of associated persons; [168] (5) procedures to monitor employee personal accounts held at another SBS Dealer, broker, dealer, investment adviser, or other financial institution; [169] (6) a description of the supervisory system, including identification of the supervisory personnel; [170] (7) procedures prohibiting supervisors from supervising their own activities or reporting to, or having their compensation or continued employment determined by, a person or persons they are supervising; [171] and (8) procedures preventing the standards of supervision from being reduced due to any conflicts of interest that may be present with respect to the associated person being supervised.[172] Proposed Rule 15Fh–3(h)(4) would require SBS Entities to promptly update their supervisory procedures as legal or regulatory changes warrant. Proposed Rule 15Fh–3(h)(2)(iii)(F) would require SBS Entities to maintain records identifying supervisory personnel.

As part of the required system reasonably designed to achieve compliance with applicable federal securities laws and regulations, proposed Rule 15Fh–3(h)(2)(iv) would require an SBS Entity to adopt written policies and procedures reasonably designed, taking into consideration the nature of such SBS Entity's business, to comply with the duties set forth in Section 15F(j) of the Exchange Act.[173] Section 15F(j) of the Exchange Act requires an SBS Entity to comply with obligations concerning: (1) Monitoring of trading to prevent violations of applicable position limits; (2) establishing sound and professional risk management systems; (3) disclosing to regulators information concerning its trading in security-based swaps; (4) establishing and enforcing internal systems and procedures to obtain any necessary information to perform any of the functions described in Section 15F of the Exchange Act, and providing the information to regulators, on request; (5) implementing conflict-of-interest systems and procedures that establish structural and institutional safeguards to ensure that the activities of any person within the firm relating to research or analysis of the price or market for any security-based swap, or acting in the role of providing clearing activities, or making determinations as to accepting clearing customers are separated by appropriate informational partitions within the firm from the review, pressure, or oversight of persons whose involvement in pricing, trading, or clearing activities might potentially bias their judgment or supervision and contravene the core principles of open access and the business conduct standards addressed in Title VII of the Dodd-Frank Act; and (6) addressing antitrust considerations such that the SBS Entity does not adopt any process or take any action that results in any unreasonable restraint of trade or impose any material anticompetitive burden on trading or clearing.

Under proposed Rule 15Fh–3(h)(3), an SBS Entity or associated person would not have failed diligently to supervise a person that is subject to the supervision of that SBS Entity or associated person, if two conditions are met. First, the SBS Entity must have established policies and procedures, and a system for applying those policies and procedures, which would reasonably be expected to prevent and detect, to the extent practicable, any violation of the federal securities laws and the rules thereunder related to security-based swaps. Second, such person must have reasonably discharged the duties and obligations incumbent on it by reason of such procedures and system without a reasonable basis to believe that such procedures were not being followed. However, the absence of either or both of these conditions would not necessarily mean that an SBS Entity or associated person failed to diligently supervise any other person.

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Should supervisory requirements be imposed on Major SBS Participants? Why or why not?
- Should different supervisory requirements apply to SBS Dealers and Major SBS Participants? If so, how should the requirements differ, and why?
- Should we require a specific means by which an SBS Entity must determine whether a supervisor is qualified and has sufficient training, experience, and competence to adequately discharge his or her responsibilities? If so, what means? For example, should we require that supervisors pass exams comparable to FINRA Series 24? Should any such requirement apply to supervisors at Major SBS Participants as well, or only to supervisors at SBS Dealers?
- Should the Commission consider imposing a testing requirement comparable to FINRA Series 7 for all associated persons of an SBS Dealer or Major SBS Participant? Why or why not? Are there other models the Commission should consider? Which models, and why?

[166] Proposed Rule 15Fh–3(h)(2)(iii)(B). *Cf.* NASD Rule 3010(d)(2) (which provides in part that ''[e]ach member shall develop written procedures that are appropriate to its business, size, structure, and customers for the review of incoming and outgoing written (*i.e.,* non-electronic) and electronic correspondence with the public relating to its investment banking or securities business, including procedures to review incoming, written correspondence directed to registered representatives and related to the member's investment banking or securities business to properly identify and handle customer complaints and to ensure that customer funds and securities are handled in accordance with firm procedures'').

[167] Proposed Rule 15Fh–3(h)(2)(iii)(C). *Cf.* NASD Rule 3010(c)(1) (''Each member shall conduct a review, at least annually, of the businesses in which it engages, which review shall be reasonably designed to assist in detecting and preventing violations of, and achieving compliance with, applicable securities laws and regulations, and with applicable NASD rules.'').

[168] Proposed Rule 15Fh–3(h)(2)(iii)(D). *Cf.* NASD Rule 3010(e) (''Each member shall have the responsibility and duty to ascertain by investigation the good character, business repute, qualifications, and experience of any person prior to making such a certification in the application of such person for registration with this Association.'').

[169] Proposed Rule 15Fh–3(h)(2)(iii)(E).

[170] Proposed Rule 15Fh–3(h)(2)(iii)(F). *Cf.* NASD Rule 3010(b)(3) (''The member's written supervisory procedures shall set forth the supervisory system established by the member pursuant to paragraph (a) above, and shall include the titles, registration status and locations of the required supervisory personnel and the responsibilities of each supervisory person as these relate to the types of business engaged in, applicable securities laws and regulations, and the Rules of this Association.'').

[171] Proposed Rule 15Fh–3(h)(2)(iii)(G). *Cf.* NASD Rule 3012(a)(2)(A)(i) (''General Supervisory Requirement. A person who is either senior to, or otherwise independent of, the producing manager must perform such supervisory reviews.'').

[172] Proposed Rule 15Fh–3(h)(2)(iii)(H). These conflicts could arise from the position of the associated person being supervised, the revenue that person generates for the SBS Entity, or any compensation that the person conducting the supervision may derive from the associated person being supervised. *Cf.* NASD Rule 3012(a)(2)(C) (requiring ''procedures that are reasonably designed to provide heightened supervision over the activities of each producing manager who is responsible for generating 20% or more of the revenue of the business units supervised by the producing manager's supervisor. For the purposes of this subsection only, the term 'heightened supervision' shall mean those supervisory procedures that evidence supervisory activities that are designed to avoid conflicts of interest that serve to undermine complete and effective supervision because of the economic, commercial, or financial interests that the supervisor holds in the associated persons and businesses being supervised.'').

[173] Public Law 111–203, 124 Stat. 1376, 1792–1793 (to be codified at 15 U.S.C. 78o–10(j)).

• Would any of these proposed supervisory requirements be more appropriately assigned to the chief compliance officer, and if so, which ones and why?
• Should certain obligations not be imposed on a supervisor of an SBS Entity? If so, which ones and why?
• Should an SBS Entity be able to rely on SRO guidance with respect to supervision for purposes of compliance with the proposed rule? Is that guidance sufficiently clear under the circumstances? Should that guidance be adopted or modified for purposes of its application to SBS Entities in the context of the security-based swap markets? If so, how and why?
• Do any of these proposed supervisory obligations conflict with current supervisory obligations, and if so, which ones and how?
• Should the Commission impose explicit supervision obligations with respect to the requirements of Section 15F(j), and if so, which ones and why? In particular, should the Commission impose explicit obligations with respect to the monitoring of trading to prevent violations of applicable position limits? Should the Commission impose explicit obligations with respect to establishing sound and professional risk management systems? Should the Commission impose explicit obligations to disclose to regulators information concerning trading in security-based swaps? Should the Commission impose explicit obligations with respect to establishing and enforcing internal systems and procedures to obtain any necessary information to perform any of the functions described in Section 15F of the Act? Should the Commission impose explicit obligations with respect to providing the information to regulators, on request? Should the Commission impose explicit obligations with respect to implementing conflict-of-interest systems and procedures to ensure that activities relating to research or analysis of the price or market for any security-based swap, clearing activities, and determinations as to accepting clearing customers are separated from the review, pressure, or oversight of persons whose involvement in pricing, trading, or clearing activities might potentially bias their judgment or supervision and contravene the core principles of open access and the business conduct standards addressed in the Act? Should the Commission impose explicit obligations with respect to addressing antitrust considerations such that the SBS Entity does not adopt any process or take any action that results in any unreasonable restraint of trade; or impose any material anticompetitive burden on trading or clearing?
• Should an SBS Entity be required to have policies and procedures reasonably designed to prevent the improper use or disclosure of counterparty information? [174]

D. Proposed Rules Applicable to Dealings With Special Entities

Congress has provided certain additional protections under Sections 15F(h)(4) and (5) of the Exchange Act for ''special entities'' in connection with security-based swaps.[175] Under the terms of Section 15F(h)(7) of the Exchange Act, Section 15F(h) would not apply to a transaction that is initiated by a special entity on an exchange or SEF and the SBS Entity does not know the identity of the counterparty to the transaction. The statute does not define the term ''initiated''. We preliminarily believe that there may be circumstances in which it may be unclear which party, in fact, ''initiated'' the communications that resulted in the parties entering into a security-based swap transaction. Accordingly, we are proposing to read Section 15F(h)(7) to apply to any transaction with a special entity on a SEF or an exchange where the SBS Entity does not know the identity of its counterparty. We recognize that, under this reading, the exemption under Section 15F(h)(7) would be available regardless of which side ''initiates'' a transaction, so long as the other conditions are met. We are seeking comment on whether this reading is appropriate or whether another possible reading of this provision should be made.

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

• Should the Commission adopt a different interpretation of Section 15F(h)(7)? If so, what interpretation and why?
• Should the exemption be limited to situations in which the special entity takes specific steps, such as submitting a request for quote or some other communication regarding a potential transaction on an exchange or SEF? Are there other communications or circumstances of entry into a security-based swap that should be regarded as the ''initiation'' of a transaction by a special entity? If so, which ones?
• Should the exemption continue to apply if the SBS Entity learns the identity of the special entity? If so, under what conditions and why?

1. Scope of the Definition of ''Special Entity''

Exchange Act Section 15F(h)(2)(C) defines a ''special entity'' as: (i) A Federal agency; [176] (ii) a State, State agency, city, county, municipality, or other political subdivision of a State; [177] (iii) any employee benefit plan, as defined in section 3 of ERISA; [178] (iv) any governmental plan, as defined in section 3 of ERISA; [179] or (v) any

[174] As noted above, proposed Rule 15Fh–3(h)(2)(iv) would require SBS Entities to adopt written policies and procedures reasonably designed, taking into consideration the nature of such SBS Entity's business, to comply with the duties set forth in Section 15F(j) of the Exchange Act, including implementing conflict-of-interest systems and procedures that establish structural and institutional safeguards to ensure that the activities of any person within the firm relating to research or analysis of the price or market for any security-based swap, or acting in the role of providing clearing activities, and or making determinations as to accepting clearing customers are separated by appropriate informational partitions within the firm from the review, pressure, or oversight of persons whose involvement in pricing, trading, or clearing activities might potentially bias their judgment or supervision and contravene the core principles of open access and the business conduct standards described in Title VII of the Dodd-Frank Act.

[175] *See* discussion in Section I.C.5, *supra.*

[176] The definition of ''security-based swap'' excludes an ''agreement, contract or transaction a counterparty of which is a Federal Reserve bank, the Federal Government, or a Federal agency that is expressly backed by the full faith and credit of the United States.'' Section 3(a)(68) of the Exchange Act, by reference to Section 1a of the Commodity Exchange Act. Accordingly, the Commission expects that special entities that are Federal agencies will be a narrow category for purposes of these rules.

[177] *Cf.* Exchange Act Section 15B(e)(8), Pub. L. 111–203, 124 Stat. 1376, 1790–1791 (to be codified at 15 U.S.C. 78o–4(e)(8)) (defining ''municipal entity'' to include ''any agency, authority, or instrumentality of the States, political subdivision, or municipal corporate entity''); 17 CFR 275.206(4)–(5) (defining ''governmental entity'' to include ''any agency, authority, or instrumentality of the state or political subdivision'').

[178] 29 U.S.C. 1002. The term ''special entity'' includes employee benefit plans defined in section 3 of ERISA. This class of employee benefit plans is broader than the category of plans that are ''subject to'' ERISA for purposes of Section 15F(h)(5)(A)(i)(VII) of the Exchange Act. Employee benefit plans not ''subject to'' regulation under ERISA include: (1) Governmental plans; (2) church plans; (3) plans maintained solely for the purpose of complying with applicable workmen's compensation laws or unemployment compensation or disability insurance laws; (4) plans maintained outside the U.S. primarily for the benefit for persons substantially all of whom are nonresident aliens; or (5) unfunded excess benefit plans. *See* 29 U.S.C. 1003(b).

[179] Section 3(32) of ERISA defines ''governmental plan'' as a ''plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision thereof, or by any agency or instrumentality of any of the foregoing.'' 29 U.S.C. 1002(32).

endowment, including an endowment that is an organization described in section 501(c)(3) of the Internal Revenue Code of 1986.[180] Commenters have raised a number of questions about the scope of the definition, as to which we are soliciting further comment below.[181]

Request for Comments

The Commission requests comment on all aspects of the definition of ''special entity.'' In particular, we are seeking comment as to what clarifications to the definition may be required and why. Commenters should also explain why any suggested clarification is consistent with both the express statutory language and the policies underlying Section 764 of the Dodd-Frank Act. In addition, the Commission requests comments on the following specific issues.

- Should the Commission interpret ''employee benefit plan, as defined in section 3'' of ERISA to mean a plan that is subject to regulation under ERISA? [182] Why or why not?
- Should the Commission interpret ''government plan'' to include government investment pools or other plans, programs or pools of assets? Why or why not?
- Should the Commission define ''endowment''? If so, how? What organizations should be included in or excluded from the definition, and why? [183] Should the Commission interpret ''endowment'' to include funds that are not separate legal entities? Why or why not? Should the term ''endowment'' include legal entities or funds that are not organized or located in the United States? Should the term ''endowment'' be limited to those organizations described in Section 501(c)(3) of the Internal Revenue Code?
- Should the Commission interpret ''endowment'' to include an organization that uses the assets of its endowment to pledge or maintain collateral obligations, or otherwise enhance or support the organization's obligations under a security-based swap? [184] Why or why not?
- Should the Commission interpret ''special entity'' to exclude a collective investment vehicle in which one or more special entities have invested? [185] Should a collective investment vehicle be considered a special entity if the fund manager, for example, becomes subject to fiduciary duties under ERISA with respect to plan assets in the fund? Why or why not?
- Should the Commission exclude from the definition of ''special entity'' any foreign entity?
- Should the Commission interpret ''special entity'' to include a master trust holding the assets of one or more funded plans of a single employer and its affiliates? [186] Why or why not?

2. Best Interests

Section 15F(h) of the Exchange Act uses the term ''best interests'' in several instances with respect to special entities. Section 15F(h)(4)(B) imposes on an SBS Dealer that ''acts as an advisor'' to a special entity a duty to act in the ''best interests'' of the special entity. In addition, Section 15F(h)(4)(C) requires the SBS Dealer that ''acts as an advisor'' to a special entity to make ''reasonable efforts to obtain such information as is necessary to make a reasonable determination'' that any swap recommended by the SBS Dealer is in the ''best interests'' of the special entity. Finally, Section 15F(h)(5) of the Exchange Act requires an SBS Entity that is a counterparty to a special entity to have a ''reasonable basis'' to believe that the special entity has an independent representative that undertakes to act in the best interests of the special entity.[187]

The term ''best interests'' is not defined in the Dodd-Frank Act. The Commission is not proposing to define ''best interests'' in this rulemaking. Instead we are seeking comment on whether we should define that term, and if so, whether such definition should use formulations based on the standards applied to investment advisers,[188] municipal advisors,[189] or ERISA fiduciaries,[190] or some other formulation.[191]

---

[180] The term ''endowment'' is not defined in the Dodd-Frank Act, or in the securities laws generally.

[181] *See, e.g.,* SIFMA/ISDA 2010 Letter at 2 (requesting confirmation that ''collective investment vehicles do not become 'Special Entities' merely as a result of the investment by Special Entities in such vehicles,'' and asserting that ''master trusts holding the assets of one or more funded plans of a single employer should be considered 'Special Entities' '').

[182] *See, e.g., id.* (requesting confirmation that ''plans not subject to the Employee Retirement Income Security Act of 1974 ('ERISA') (unless they are covered by another applicable prong of the ''Special Entity'' definition (*e.g.,* governmental plans)) are not 'Special Entities' ''). Section 4 of ERISA provides that the provisions of ERISA shall not apply to an employee benefit plan that is a governmental plan (as defined in section 1002(32) of ERISA); a church plan (as defined in section 1002(33) of ERISA) with respect to which no election has been made under 26 U.S.C. section 410(d); a plan that is maintained solely for the purpose of complying with applicable workmen's compensation laws or unemployment compensation or disability insurance laws; a plan that is maintained outside of the United States primarily for the benefit of persons substantially all of whom are nonresident aliens; or a plan that is an excess benefit plan (as defined in section 1002(36) of ERISA) and is unfunded.

See Letter from Daniel Crowley, Partner, K&L Gates on behalf of the Church Alliance, to David A. Stawick, Secretary, CFTC (Feb. 22, 2011) (on file with the CFTC), *http://comments.cftc.gov/PublicComments/CommentList.aspx?id=935* (requesting clarification that church plans be included in the definition of special entity).

[183] For accounting purposes, the term ''endowment'' is defined to mean ''[a]n established fund of cash, securities, or other assets to provide income for the maintenance of a not-for-profit organization. The use of the assets of the fund may be permanently restricted, temporarily restricted, or unrestricted. Endowment funds generally are established by donor-restricted gifts and bequests to provide a permanent endowment, which is to provide a permanent source of income, or a term endowment, which is to provide income for a specified period.'' Financial Accounting Standards Board ASC Section 958–205–20, Glossary, Non-for-Profit Entities.

[184] *See* Swap Financial Group Presentation at 8 (concerning the scope of this prong of the definition of ''special entity'').

[185] *See* note 181, *supra.*

[186] *See id.*

[187] Section 15F(h)(5)(A)(i)(IV) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1791 (to be codified at 15 U.S.C. 78o–10(h)(5)(A)(i)(IV)).

[188] We recently stated that, under the Advisers Act, an adviser is a fiduciary whose duty is to serve the best interests of its clients, which includes an obligation not to subordinate clients' interests to its own. An adviser must deal fairly with clients and prospective clients, seek to avoid conflicts with its clients and, at a minimum, make full disclosure of any material conflict or potential conflict. *See* Amendments to Form ADV, Investment Advisers Act Release No. 3060 (July 28, 2010), 75 FR 49234 (Aug. 12, 2010), *citing SEC* v. *Capital Gains Research Bureau, Inc.,* 375 U.S. 180, 191–194 (1963) (holding that investment advisers have a fiduciary duty enforceable under Section 206 of the Advisers Act, that imposes upon investment advisers the ''affirmative duty of 'utmost good faith, and full and fair disclosure of all material facts,' as well as an affirmative obligation to 'employ reasonable care to avoid misleading' '' their clients and prospective clients).

[189] *See, e.g.,* Exchange Act Section 15B(b)(2)(L), Public Law 111–203, 124 Stat. 1376, 1919 (to be codified at 15 U.S.C. 78o–4(b)(2)(L)) (requiring the MSRB to prescribe means reasonably designed to prevent acts, practices, and courses of conduct that are not consistent with a municipal advisor's fiduciary duty to its municipal entity clients). The MSRB requested comment on draft Rule G–36 concerning the fiduciary duty of municipal advisors, and a draft interpretive notice under Rule G–36. *See* MSRB Notice 2011–14 (Feb. 14, 2011).

[190] *See, e.g.,* 29 U.S.C. 1104(a)(1)(A) (''a fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and for the exclusive purpose of: (i) Providing benefits to participants and their beneficiaries; and (ii) defraying reasonable expenses of administering the plan'') and 29 U.S.C. 1104(a)(1)(B) (a fiduciary must act ''with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims'').

[191] We note that Section 913 of the Dodd-Frank Act authorizes the Commission to promulgate rules to provide that the standard of conduct for broker-dealers and investment advisers when providing personalized investment advice about securities to retail customers (and such other customers as the Commission may by rule provide) shall be to act in the best interest of the customer without regard to the financial or other interest of the intermediary providing the advice. Public Law 111–203, 124 Stat. 1376, 1827–1829.

Request for Comments

The Commission is seeking comment generally on whether and how it should clarify the meaning of the term ''best interests'' under Section 15F(h). In addition, we request comments on the following specific issues:

- Should the Commission define the term ''best interests'' in this context? If so, what definitions should the Commission consider and why? What are the advantages and drawbacks of particular definitions in this context? What factors should be included in the determination of a special entity's ''best interests''?
- Should the Commission adopt a definition of ''best interests'' that is based on the fiduciary duty applicable to investment advisers under the Investment Advisers Act of 1940 (''Advisers Act'')? [192] Why or why not?
- Should the Commission adopt a definition of ''best interests'' that is based on the fiduciary duty applicable to municipal advisors under the Exchange Act? [193] Why or why not?
- Should the Commission adopt a definition of ''best interests'' that is based on the fiduciary duty applicable to fiduciaries under ERISA? [194] Why or why not?
- Should the Commission define ''best interests'' in a manner consistent with how it may define ''best interests'' in any rulemaking it may choose to propose under Section 913 of the Dodd-Frank Act, if any? Why or why not?

3. Anti-Fraud Provisions: Proposed Rule 15Fh–4(a)

Section 15F(h)(4)(A) of the Exchange Act provides that it shall be unlawful for an SBS Entity to: (i) Employ any device, scheme, or artifice to defraud any special entity or prospective customer who is a special entity; (ii) engage in any transaction, practice, or course of business that operates as a fraud or deceit on any special entity or prospective customer who is a special entity; or (iii) to engage in any act, practice, or course of business that is fraudulent, deceptive, or manipulative. Consistent with the guidance in our previous order regarding the effective date of this provision, we are proposing a rule to render the statutory standard effective.[195]

4. Advisor to Special Entities: Proposed Rules 15Fh–2(a) and 15Fh–4(b)

Exchange Act Section 15F(h)(4) imposes a duty on an SBS Dealer that acts as an advisor to a special entity to act in the best interests of the special entity.[196] The Dodd-Frank Act does not define ''advisor.'' Commenters have urged us to establish a clear standard for determining when an SBS Dealer is acting as an advisor within the meaning of Section 15F(h)(4).[197] These commenters have expressed concern that compliance with the ''best interests'' standard applicable to advisors would create significant burdens and potential legal liability for SBS Dealers, and therefore SBS Dealers need certainty as to when they would or would not be acting as an advisor. For example, commenters have expressed concern that the business conduct obligations imposed by the Dodd-Frank Act might cause an SBS Dealer to be a ''fiduciary'' under ERISA, and therefore effectively prohibit SBS Dealers from entering into security-based swaps with pension plans that are subject to ERISA.[198] We recognize the importance of this issue, both for dealers and for the pension plans that may rely on security-based swaps to manage risk and reduce volatility. The determination whether an SBS Dealer is acting as an advisor for purposes of Section 15F(h)(4) and proposed Rule 15Fh–4(b) is not intended to prejudice the determination whether the SBS Entity is otherwise subject to regulation as an ERISA fiduciary.[199] Although each regulatory regime applies independently, we anticipate that Commission staff will continue to consult with representatives of the Department of Labor to facilitate a full understanding of how the regulatory regimes interact with one another, and to determine whether any modifications to our proposed rules may be necessary or appropriate in light of these interactions.

An SBS Dealer that is acting as an advisor must in any case comply with the requirements of the Dodd-Frank Act. If an SBS Dealer is acting as an advisor, then under Section 15F(h)(4) and proposed Rule 15Fh–4(b), it must act in the best interests of the special entity. As part of its duty to act in the best interests of the special entity, the SBS Dealer would be required to provide suitable advice.[200] Consistent with Section 15F(h)(4)(C), proposed Rule 15Fh-4(b)(2) would require an SBS Dealer in these circumstances to make reasonable efforts to obtain the information it considers necessary to make a reasonable determination that any recommended security-based swap or trading strategy involving a security-based swap is in the best interests of the special entity. The proposed rule would identify specific types of information that the SBS Dealer should take into account in making this determination. This information would include, but not be limited to, the authority of the special entity to enter into a security-based swap; the financial status of the

[192] *See supra* note 188.

[193] *See supra* note 189.

[194] *See supra* note 190.

[195] *See* Order Pursuant to Sections 15F(b)(6) and 36 of the Securities Exchange Act of 1934 Granting Temporary Exemptions and Other Temporary Relief, Together with Information on Compliance Dates for New Provisions of the Securities Exchange Act of 1934 Applicable to Security-Based Swaps, and Request for Comment, Securities Act Release No. 64678 (June 15, 2011), 76 FR 36287 (June 22, 2011) at note 192:

Section 15F(h)(6) of the Exchange Act, 15 U.S.C. 78o–10(h)(6), directs the Commission to ''prescribe rules under this subsection [(h) of the Exchange Act, 15 U.S.C. 78o–10(h),] governing business conduct standards.'' Accordingly, business conduct standards pursuant to section 15F(h) of the Exchange Act, 15 U.S.C. 78o–10(h), will be established by rule and compliance will be required on the compliance date of the Commission rule establishing these business conduct standards.

[196] Section 15F(h)(2)(A) of the Exchange Act requires all SBS Entities to comply with the requirements of Section 15F(h)(4). Public Law 111–203, 124 Stat. 1376, 1789 (to be codified at 15 U.S.C. 78o–10(h)(2)(A)). The anti-fraud prohibitions of Section 15F(h)(4)(A) apply by their terms to all SBS Entities. Sections 15F(h)(4)(B) and (C) impose certain ''best interests'' obligations on an SBS Dealer that acts as an advisor to a special entity. See also Section II.D.2, *infra.*

[197] *See, e.g.,* SIFMA/ISDA 2010 Letter at 2 (''It is essential that the Commissions articulate a clear standard for the circumstances that give rise to 'advisor' status and the corresponding imposition of the statutory 'fiduciary-like' duty to act in the best interests of a Special Entity.'')

[198] As discussed in note 99, *supra,* the Department of Labor is proposing amendments to the definition of a fiduciary under ERISA that would provide a limited exception for a person that renders ''investment advice'' for compensation if that person ''can demonstrate that the recipient of the advice knows or, under the circumstances, reasonably should know, that the person is providing the advice or making the recommendation in its capacity as a purchaser or seller of a security or other property, or as an agent of, or appraiser for, such a purchaser or seller, whose interests are adverse to the interests of the plan or its participants or beneficiaries, and that the person is not undertaking to provide impartial investment advice.'' The Department of Labor in its proposing release explained that it had determined that ''such communications ordinarily should not result in fiduciary status * * * if the purchaser knows of the person's status as a seller whose interests are adverse to those of the purchaser, and that the person is not undertaking to provide impartial investment advice.'' Definition of the Term ''Fiduciary,'' 75 FR 65263, 65267 (Oct. 22, 2010).

[199] *See* Letter from Phyllis C. Borzi, Assistant Secretary, Employee Benefits Security Administration, Department of Labor, to Gary Gensler, Chairman, CFTC (Apr. 28, 2011) (''In [the Department of Labor's] view, a swap dealer or major swap participant that is acting as a plan's counterparty in an arm's length bilateral transaction with a plan represented by a knowledgeable independent fiduciary would not fail to meet the terms of the counterparty exception solely because it complied with the business conduct standards set forth in the CFTC's proposed regulation.''), *http://comments.cftc.gov/PublicComments/CommentList.aspx?id=935.*

[200] *See* Section II.C.4, *infra* (discussing the interaction of the ''best interests'' and ''suitability'' standards).

special entity, as well as future funding needs; the tax status of the special entity; the investment or financing objectives of the special entity; the experience of the special entity with respect to entering into security-based swaps, generally, and security-based swaps of the type and complexity being recommended; whether the special entity has the financial capability to withstand changes in market conditions during the term of the security-based swap; and such other information as is relevant to the particular facts and circumstances of the special entity, market conditions and the type of security-based swap or trading strategy involving a security-based swap being recommended.

Proposed Rule 15Fh–2(a) would generally define ''act as an advisor'' in the context of an SBS Dealer to mean recommending a security-based swap or a trading strategy involving a security-based swap to a special entity.[201] For these purposes, ''recommending'' would have the same meaning as that discussed above in connection with proposed Rule 15Fh–3(f). An SBS Dealer would not be deemed an ''advisor'' to a special entity with a duty under Section 15F(h)(4) and proposed Rule 15Fh–4(b) to act in the ''best interests'' of the special entity if it did not make a ''recommendation'' to a special entity. Commenters have advised us that, in order to avoid making a ''recommendation'' and unintentionally becoming an ''advisor'' to a special entity SBS Dealers may simply refrain from interacting with special entities—particularly to the extent that they perceive any uncertainty in the determination of whether a particular communication would constitute a ''recommendation.'' [202]

It is important to note that the duties imposed on an SBS Dealer that is ''acting as an advisor''—as well as the definition of that phrase in proposed Rule 15Fh–2(a)—are specific to this advisory context, and are in addition to any duties that may be imposed under other applicable law. Among other things, an SBS Dealer that acts as an advisor to a special entity may fall within the definition of ''investment adviser'' under Section 202(a)(11) of the Advisers Act unless it can rely on the exclusion provided by Section 202(a)(11)(C) for a broker-dealer whose advice is ''solely incidental'' to the conduct of its business as a broker dealer and who receives no special compensation therefor, or other applicable exclusion.[203] An SBS Dealer that acts as an advisor to a municipal entity may also be a ''municipal advisor'' under Section 15B(e) of the Exchange Act.[204]

Commenters have suggested that the standard established by Section 15F(h)(4) for an SBS Dealer acting as an advisor to a special entity could ''have the effect of chilling a critical element of the customary commercial interactions'' with special entities, absent some greater legal certainty about when an SBS Dealer would, in fact, be deemed to be ''acting as advisor'' to a special entity.[205] Accordingly, proposed Rule 15Fh–2(a) would provide this legal certainty by permitting an SBS Dealer to establish that it is not acting as an advisor where certain conditions are met. Under the proposed rule, the special entity must represent, in writing, that it will not rely on recommendations provided by the SBS Dealer and that it instead will rely on advice from a ''qualified independent representative,'' as defined in proposed Rule 15Fh–5(a) and discussed more fully below in Section II.D.4.c. In addition, the SBS Dealer must disclose to the special entity that by obtaining the special entity's written representation as described above, the SBS Dealer is not undertaking to act in the best interests of the special entity, as would otherwise be required under Section 15F(h)(4).[206] Finally, the SBS Dealer must have a reasonable basis to conclude that the special entity has a qualified independent representative.[207]

The Commission believes that the SBS Dealer could form this reasonable basis through a variety of means, including relying on written representations from the special entity to the same extent as discussed below in connection with an SBS Dealer acting as a counterparty to a special entity.[208] Upon receiving such representations, the SBS Dealer would be entitled to rely on these representations without further inquiry, absent special circumstances described below.

To solicit input on when it would no longer be appropriate for an SBS Dealer to rely on such representations without further inquiry, the Commission is proposing for comment two alternative approaches. One approach would permit an SBS Dealer to rely on a representation from a special entity for purposes of Rule 15Fh–2(a) unless it knows that the representation is not accurate. The second would permit an SBS Dealer to rely on a representation unless the SBS Dealer has information that would cause a reasonable person to question the accuracy of the representation.

Under either approach, an SBS Dealer could not ignore information in its possession as a result of which the SBS Dealer would know that a representation is inaccurate. In addition, under the second approach, an SBS Dealer also could not ignore information that would cause a reasonable person to question the accuracy of a representation and, if the SBS Dealer had such information, it would need to make further reasonable inquiry to verify the accuracy of the representation.

While the Dodd-Frank Act does not preclude an SBS Dealer from acting as both advisor and counterparty, commenters have argued that it could be impracticable for an SBS Dealer that is acting as a counterparty to a special entity to meet the ''best interests'' standards that would be imposed by Section 15F(h)(4) if it were also acting as an advisor to the special entity.[209] We recognize the potential tension in the statute itself between the role of a party acting as a principal in a security-based swap transaction, and the obligation imposed by Section 15F(h)(4) for an advisor to determine that a transaction is in the ''best interests'' of the special entity. We are seeking comment on whether we should further clarify the obligations of an SBS Dealer that is seeking to act both as an advisor and a counterparty to a special entity. We also are seeking comment on the need to define ''best interests'' in this context. Finally, as noted above, we understand that there are concerns arising from the potential interaction between the requirements of the Dodd-Frank Act

[201] *See* Section II.C.4 regarding what would or would not generally be considered a recommendation.

[202] *See, e.g.,* SIFMA 2011 Letter.

[203] *See* 15 U.S.C. 80b–2(a)(11).

[204] *See* Public Law 111–203, 124 Stat. 1376, 1921–1922 (to be codified at 15 U.S.C. 78o–4).

[205] SIFMA/ISDA 2011 Letter at 33.

[206] Proposed Rule 15Fh–2(a).

[207] As noted above, an SBS Dealer in these circumstances must separately determine whether it is subject to regulation as an investment adviser, a municipal advisor or other regulated entity.

[208] *See* Section II.D.4.c, *infra.*

[209] *See* SIFMA/ISDA 2010 Letter at 8:

Dealers will almost certainly refuse to engage in any swap activity in which they could potentially be deemed an ''advisor.'' The actions that a Dealer acting as an ''advisor'' would be required to take pursuant to Dodd-Frank are the very actions that could lead the Dealer to be deemed a fiduciary under ERISA. The penalties that would result were the Dealer deemed a fiduciary under ERISA are draconian, including that a swap between the Dealer and the plan would be deemed a prohibited transaction in violation of ERISA and would be subject to rescission and an excise tax equal to 15% of the amount involved in the transaction for each year or part of a year that the transaction remains uncorrected (which, if not corrected upon notice, could escalate up to a 100% excise tax).

(and our rules thereunder) and the requirements of other applicable law, including ERISA.

Request for Comments

The Commission requests comments generally on all aspects of proposed Rules 15Fh–2(a) and 15Fh–4(b). In addition, we request comments on the following specific issues:

- Is the proposed definition of the term ''acts as an advisor'' appropriate? Why or why not? What, if any, material inconsistencies would the proposed definition create with respect to any other applicable laws? What specific practical effects, advantages or disadvantages may arise in connection with the proposed definition? How, if at all, should any definition or interpretation of ''recommendation'' in this context diverge from the meaning of the term for purposes of the suitability obligation under Proposed Rule 15Fh–3(f)?
- Should the Commission instead define ''advisor'' to mean ''any person who, for compensation, engages in the business of advising special entities, as to the value of security-based swaps or as to the advisability of security-based swaps or trading strategies involving security-based swaps,'' consistent with the definition of an investment adviser? [210] Why or why not?
- Should the Commission instead define ''act as an advisor'' as ''providing advice to or on behalf of a special entity with respect to a security-based swap or trading strategy involving a security-based swap,'' consistent with the definition of a municipal advisor? [211] Why or why not? What other definitions should be considered by the Commission and why?
- When, if at all, could an SBS Dealer, in fact, act as both an advisor and counterparty to a special entity in a securities-based swap transaction, consistent with the ''best interests'' requirements of Section 15F(h)(4) and proposed Rule 15Fh–4(b)? [212] In what way could disclosure help to address concerns about the potentially conflicting roles of an SBS Dealer in these circumstances? Should the Commission, for example, clarify that it would not be inconsistent with an SBS Dealer's duty to act in the best interests of the special entity if the SBS Dealer, as principal, were to earn a reasonable profit or fee from the transaction it enters into with the special entity?
- Should the Commission instead prohibit an SBS Dealer from acting as both an advisor and counterparty to a special entity? [213] Why or why not?
- Should the Commission define ''acts as an advisor'' to require an understanding among the parties that the SBS Dealer is undertaking to act as an advisor to the special entity? Why or why not? If such a definition should be contemplated, in what circumstances, if any, should such an understanding not be permitted? Should a written agreement be required to establish that the SBS Dealer is undertaking to ''act as an advisor''?
- How would the proposed rules with respect to acting as an advisor change current practice regarding recommending and entering into security-based swaps with special entities?
- Should the Commission impose specific requirements with respect to the level of detail that should be required for written representations? If so, what requirements and why?
- What are the advantages and disadvantages of the two alternative proposed approaches regarding when it would no longer be appropriate to rely on written representations? Which alternative would strike the best balance among the potential disadvantages to market participants, the regulatory interest in appropriate rules for advisory relationships, and the sound functioning of the security-based swap market? What, if any, other alternatives should the Commission consider (*e.g.,* a recklessness standard) and why?
- In light of the additional protections that are afforded special entities under the Dodd-Frank Act, as described in Section I.C.5 above, should an SBS Dealer be required to undertake diligence or further inquiry before it can rely on any representation from a special entity for purposes of Rules 15Fh–2(a) and 15Fh–4(b)? Why or why not? If such diligence or inquiry is not required, should an SBS Dealer be permitted to rely on representations from the special entity only where the SBS Dealer does not have information that would cause a reasonable person to question the accuracy of the representation? Why or why not? Would requiring such diligence or further inquiry—or allowing reliance on representations only in such a manner—unnecessarily limit the willingness or ability of SBS Dealers to provide special entities with the access to security-based swaps for the purposes described in Section I.C.5 above? Why or why not? What, if any, other measures should be required in connection with an SBS Dealer's satisfaction of the requirements of these rules?
- Are there particular circumstances under which an SBS Dealer should be required to obtain information or undertake further review or inquiry about a special entity's independent representative or other facts in addition to obtaining written representations from the special entity as described above? Are there particular categories of special entities for which an SBS Dealer should be required to undertake further review or inquiry? Which categories, and why? What review or inquiry should be required, and in what circumstances?
- Are there other potential reasonable methods of establishing the relationship between a special entity and an SBS Dealer, and if so, what guidance should the Commission consider providing with respect to such methods?

5. Counterparty to Special Entities: Proposed Rule 15Fh–5

Under Exchange Act Section 15F(h)(5)(A), any SBS Entity that offers to enter into or enters into a security-based swap with a special entity must comply with any duty established by the Commission requiring that SBS Entity to have a ''reasonable basis'' for believing that the special entity has an ''independent representative'' that meets certain requirements, including that it undertakes a duty to act in the best interests of the counterparty it represents. Proposed Rules 15Fh–2(c) and 15Fh–5(a) would implement this provision. In particular, proposed Rule 15Fh–2(c) would define an ''independent representative,'' and proposed Rule 15Fh–5(a) would require an SBS Entity to have a reasonable basis to believe that this independent representative is qualified to represent the special entity by virtue of satisfying certain specified requirements.

---

[210] *See* Advisers Act Section 202(a)(11) (definition of ''investment adviser'').

[211] *See* Exchange Act Section 15B(e)(4), Public Law 111–203, 124 Stat. 1376, 1921–1922 (to be codified at 15 U.S.C. 78o–4(e)(4)); *see generally* Registration of Municipal Advisors, Exchange Act Release No. 63579 (Dec. 20, 2011), 76 FR 824 (Jan. 6, 2011).

[212] Commenting on a parallel provision in the Commodity Exchange Act, Senator Lincoln stated that:

[N]othing in [Commodity Exchange Act Section 4s(h)] prohibits a swap dealer from entering into transactions with Special Entities. Indeed, we believe it will be quite common that swap dealers will both provide advice and offer to enter into or enter into a swap with a special entity. However, unlike the status quo, in this case, the swap dealer would be subject to both the acting as advisor and business conduct requirements under subsections (h)(4) and (h)(5).

156 Cong. Rec. S5923 (daily ed. Jul. 15, 2010) (statement of Sen. Lincoln).

[213] Recently approved amendments to MSRB Rule G–23 would prohibit dealer-financial advisers from switching roles and becoming underwriters in the same municipal securities transactions. *See also* MSRB Notice 2011–29 (May 31, 2011) (discussing rule amendment and interpretive notice).

Request for Comments

The Commission requests comments generally on all aspects of proposed Rule 15Fh–5. In addition, we request comments on the following specific issues:

- Is it sufficiently clear what is meant by ''offers to enter into'' a security-based swap? If not, how should the Commission clarify the requirement?
- Should the proposed rule apply to all transactions with all special entities? Why or why not? Which, if any, transactions or special entities should be excluded from the scope of the proposed rule, and why?

a. Scope of Qualified Independent Representative Requirement

We are proposing to apply the qualified independent representative requirements to Major SBS Participants as well as to SBS Dealers because, although Section 15F(h)(2)(B) addresses only the requirement for SBS Dealers to comply with the requirements of Section 15F(h)(5), the specific requirements under Section 15F(h)(5)(A) apply by their terms to both SBS Dealers and Major SBS Participants that offer to or enter into a security-based swap with a special entity.

We are further proposing to apply the qualified independent representative requirement under Section 15F(h)(5) to security-based swap transactions with all special entities. There is a statutory ambiguity concerning the scope of this requirement. Section 15F(h)(5)(A) provides broadly that ''[a]ny security-based swap dealer or major security-based swap participant that offers to [enter into] or enters into a security-based swap with a special entity shall'' comply with certain requirements. These requirements are defined in Section 15F(h)(5)(A)(i) to include ''any duty established by the Commission * * * with respect to a counterparty that is an eligible contract participant within the meaning of subclause (I) or (II) of clause (vii) of section 1a(18) of the Commodity Exchange Act [*i.e.,* governmental or multinational or supranational entities].'' We are proposing standards that would apply whenever an SBS Entity is acting as counterparty to *any* special entity as defined in Section 15F(h)(1)(C), including a special entity that is an ECP within the meaning of subclause (I) or (II) of clause (vii) of Commodity Exchange Act Section 1a(18). The proposed rule would be consistent with categories of special entities mentioned in the legislative history.[214] It also would give meaning to the requirement of Section 15F(h)(5)(A)(i)(VII) concerning ''employee benefit plans subject to ERISA,'' that are not ECPs within the meaning of subclause (I) or (II) of clause (vii) of section 1a(18) of the Commodity Exchange Act but are included in the category of retirement plans identified in the definition of special entity.[215]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Should proposed Rule 15Fh–5 apply to both SBS Dealers and Major SBS Participants? Why or why not?

b. Independent Representative—Proposed Rule 15Fh–2(c)

Proposed Rule 15Fh–5(a) would require that the SBS Entity have a reasonable basis to believe that a special entity has as qualified ''independent representative.'' Under proposed Rule 15Fh–2(c)(1), a representative of a special entity must be independent of the SBS Entity that is the counterparty to a proposed security-based swap. Proposed Rule 15Fh–2(c)(2) would provide that a representative of a special entity is ''independent'' of an SBS Entity if the representative does not have a relationship with the SBS Entity, whether compensatory or otherwise, that reasonably could affect the independent judgment or decision-making of the representative. This standard is similar to the ''no material relationship'' standard that is used or proposed in other contexts.[216] We preliminarily believe it would be an appropriate standard here because the SBS Entity would possess the necessary facts to determine if, in fact, there exists a relationship with the independent representative that would be likely to impair the independence of the independent representative in making decisions that may affect the SBS Entity.

Proposed Rule 15Fh–2(c)(3) would provide that a representative of a special entity will be deemed to be independent of an SBS Entity if two conditions are satisfied. First, the representative is not and, within one year, was not an associated person of the SBS Entity and second, the representative has not received more than ten percent of its gross revenues over the past year, directly or indirectly, from the SBS Entity. This latter restriction would apply, for example, with respect to revenues received as a result of referrals by the SBS Entity, and so is intended to address the situation in which a representative is hired by the special entity as a result of a recommendation by the SBS Entity. This restriction would apply as well to revenues received, directly or indirectly, from associated persons of the SBS Entity.

For the SBS Entity to form a reasonable basis to believe the percentage of the independent representative's gross revenues that is received directly or indirectly from the SBS Entity, the SBS Entity would likely need to obtain information regarding the independent representative's gross revenues from either the special entity or the independent representative. The Commission believes that an SBS Entity could use a variety of methods to gather this information. The SBS Entity may request the financial statements of the independent representative for the relevant periods. Another way to obtain this information would be to obtain written representations from the special entity or independent representative regarding the revenues received, directly or indirectly from the SBS Entity and that such revenues were less than ten percent of the independent representative's gross revenues. Upon receiving such representations, the SBS

---

[214] *See* H.R. Conf. Rep. 111–517 (June 29, 2010) (''When *acting as counterparties to a pension fund, endowment fund, or state or local government,* dealers are to have a reasonable basis to believe that the fund or governmental entity has an independent representative advising them.'') (emphasis added).

[215] *See* Section 15F(h)(1)(C)(iii) of the Exchange Act, Pub. L. 111–203, 124 Stat. 1376, 1789 (to be codified at 15 U.S.C. 78o–10(h)(1)(C)(iii)).

[216] Proposed Rules 15Fh–2(c)(1) and (2). This proposed alternative standard of independence would be consistent with the standard for existing and currently proposed director independence in other contexts. *See* Ownership Limitations and Governance Requirements for Security-Based Swap Clearing Agencies, Security-Based Swap Execution Facilities, and National Securities Exchanges with Respect to Security-Based Swaps under Regulation MC, Exchange Act Release No. 63107 (Oct. 14, 2010), 75 FR 65882, 65897 (Oct. 26, 2010) (proposed Rule 700(l)); Security-Based Swap Data Repository Registration, Duties, and Core Principles, Exchange Act Release No. 63347 (Nov. 19, 2010), 75 FR 77306, 77322 (Dec. 10, 2010); MSRB, Notice of Filing of Amendment No. 1 to and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, to Amend Rule A–3, on Membership on the Board, to Comply with the Dodd-Frank Wall Street Reform and Consumer Protection Act, Exchange Act Release No. 63025 (Sep. 30, 2010), 75 FR 61806, 61808 (Oct. 6, 2010). It also would be consistent with the NYSE standard for director independence and how public companies have addressed this standard in their policies to determine director independence. *See* NYSE Rule 303A.02(A) (''No director qualifies as 'independent' unless the board of directors affirmatively determines that the director has no material relationship with the listed company (either directly or as a partner, shareholder or officer of an organization that has a relationship with the company) .

Entity would be entitled to rely on them without further inquiry, absent special circumstances described below.

To solicit input on when it would no longer be appropriate for an SBS Entity to rely on such representations without further inquiry, the Commission is proposing for comment two alternative approaches. One approach would permit an SBS Entity to rely on a representation from a special entity for purposes of Rule 15Fh–2(c) unless it knows that the representation is not accurate. The second would permit an SBS Entity to rely on a representation unless the SBS Entity has information that would cause a reasonable person to question the accuracy of the representation.

Under either approach, an SBS Entity could not ignore information in its possession as a result of which the SBS Entity would know that a representation is inaccurate. In addition, under the second approach, an SBS Entity also could not ignore information that would cause a reasonable person to question the accuracy of a representation and, if the SBS Entity had such information, it would need to make further reasonable inquiry to verify the accuracy of the representation.

An SBS Entity may obtain information from the independent representative as part of its efforts to form a reasonable basis for its determination that it is independent of the independent representative. In order for the basis for its determination to be reasonable, however, the SBS Entity could not ignore information it possesses concerning whether the independent representative is or has been, an associated person of the SBS Entity, for example, if it were seeking to rely on the objective standard of proposed Rule 15Fh–2(c)(1), or whether there exists any other relationship with the SBS Entity that reasonably could affect the independent judgment or decision-making of the independent representative for purposes of proposed Rule 15Fh–2(c)(2).

A number of special entities have requested that the Commission confirm that the representative is only required to be independent of the SBS Entity and not independent of the special entity itself.[217] We preliminarily believe that Section 15F(h)(5)(A)(i)(III) requires only that the independent representative be independent of the SBS Entity. The Dodd-Frank Act is silent concerning the question of independence from the special entity, and nothing in the legislative history suggests that the Commission should preclude the use of a qualified independent representative that is affiliated with the special entity.[218]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Should the Commission adopt a different definition of ''independent representative of a special entity'' in proposed Rule 15Fh–2(c), and if so, why? Are there other standards of independence that we should consider, such as standards that would be relevant to determining the independence of a fiduciary for ERISA purposes? Which standards and why? How should such standards be modified to address the particular concerns of Section 15F(h)(5)? Should the Commission require consideration of other or additional factors in determining the independence of the independent representative of a special entity? Which factors and why? Should such factors include consideration of relationships the independent representative may have with an SBS Entity on behalf of multiple special entities? Should the Commission also consider relationships the independent representative has entered into with an SBS Entity on behalf of a special entity outside of the security-based swap transaction context?
- Should the definition of ''independent representative of a special entity'' exclude certain categories of associated persons of the SBS Entity? Of the independent representative? Which ones and why?
- Should the gross revenues in the definition exclude the revenues of affiliates of the independent representative?
- Is ten percent of gross revenues an appropriate measure of independence? Should the percentage be increased or decreased, and why? Should the Commission adopt a standard that is consistent with that used by the Department of Labor, for example, under which the general standard of independence for fiduciaries in connection with prohibited transaction exemptions under ERISA is that no more than 1% of an independent fiduciary's annual income is derived from or attributable to the party in interest and its affiliates? [219] Should another financial or other quantifiable standard be used in lieu of gross revenues? Why or why not?
- Should the Commission consider a timeframe other than one year to determine whether a representative is independent of the SBS Entity? Should the timeframe be two years, consistent with the pay to play provisions of proposed Rule 15Fh–6? Should some other timeframe be used? If so, what timeframe and why?
- Should the Commission consider a different approach to independence based on, for example, audit committee independence standards under Section 10A(m)(3) [220] and Rule 10A–3(b),[221] or the concept of an ''interested person'' under Section 2(a)(1) of the Investment Company Act of 1940? [222] Why or why not? Should we consider other approaches? If so, which approaches and why?
- Should the Commission permit an independent representative that receives compensation from the proceeds of a security-based swap so long as the compensation is authorized by, and paid at the written direction of, the special entity? Why or why not?
- Should the Commission adopt a different definition of ''independent representative of a special entity'' for different types of special entities? For example, are there certain types of special entities, *e.g.,* a State, State agency, city, county, municipality, or

[217] Letter from Lynn D. Dudley, Senior Vice President, Policy, American Benefits Council, to Elizabeth M. Murphy, Secretary, Commission and David A. Stawick, Secretary, CFTC (Sept. 8, 2010) (''American Benefits Council Letter'') at 6.

[218] *See also* 156 Cong. Rec. S5903 (daily ed. Jul. 15, 2010) (statements of Sens. Lincoln and Harkin):

Mrs. LINCOLN. Our intention in imposing the independent representative requirement was to ensure that there was always someone independent of the swap dealer or the security-based swap dealer reviewing and approving swap or security-based swap transactions. However, we did not intend to require that the special entity hire an investment manager independent of the special entity. Is that your understanding, Senator Harkin?

Mr. HARKIN. Yes, that is correct. We certainly understand that many special entities have internal managers that may meet the independent representative requirement. For example, many public electric and gas systems have employees whose job is to handle the day-to-day hedging operations of the system, and we intended to allow them to continue to rely on those in-house managers to evaluate and approve swap and security-based swap transactions, provided that the manager remained independent of the swap dealer or the security-based swap dealer and meet the other conditions of the provision. Similarly, the named fiduciary or in-house asset manager (''INHAM'') for a pension plan may continue to approve swap and security-based swap transactions.

[219] *See* Exemption Procedures under Federal Pension Law, *http://www.dol.gov/ebsa/publications/exemption_procedures.html* (''While in certain cases the department has permitted an independent fiduciary to receive as much as 5% of its annual income from the party in interest and its affiliates, these cases have involved unusual circumstances, and the general standard of independence remains a 1% test.'').

[220] 15 U.S.C. 78j–1(m)(3).

[221] 17 CFR 240.10A–3(b).

[222] 15 U.S.C. 80a–2(a)(19).

other political subdivision of a State, or a governmental plan as defined in Section 3 of ERISA, for which the Commission should define independence to require that the independent representative is not and has not been an associated person of the SBS Entity within the last two years and has not received any of its gross revenues, directly or indirectly from the SBS Entity or an associated person of the SBS Entity within the last two years? [223] What if the time period outlined in the prior sentence was limited to one year? Should this stricter standard apply only with respect to special entities defined in clause (ii)? Are there any other classes of special entities to which this stricter standard should apply?

• Are there other standards of independence that would be more appropriate for independent representatives for special entities defined in clauses (ii) and (iv) of Section 15F(h)(2)(C) of the Exchange Act? Which standards and why?

• Are there certain types of relationships that, so long as they have been fully disclosed to the special entity and the special entity has consented to any conflicts of interest related thereto, should not be deemed to affect the independence of the representative? What types of relationships, and why? Are there some conflicts that are so significant that a special entity should not be able to consent to them? If so, what types of conflicts, and why?

• Is the interpretation of Section 15F(h)(5)(A)(i)(III) appropriate? Can and should independent representatives be required to be independent of the special entity entering into the security-based swap as well as independent of the SBS Entity? Why or why not? If an SBS Entity is relying on written representations from a special entity that is represented by an internal ''independent representative,'' should the SBS Entity be required to also obtain such representations from someone other than the independent representative?

• How, if at all, should the recommendation by an SBS Entity of a particular independent representative or group of independent representatives be deemed to affect the independent judgment or decision-making of the representative? Please explain. If such a recommendation could be deemed to affect the independence of a special entity, are there appropriate safeguards that should be required if an SBS Entity maintains a ''preferred list'' of independent representatives? What safeguards, and why?

c. Reasonable Basis To Believe the Qualifications of the Independent Representative

As noted above, proposed Rule 15Fh–5 would require the SBS Entity to reasonably determine that a special entity's independent representative is a ''qualified independent representative.'' The requirements for being a ''qualified independent representative'' are drawn primarily from the statute and are described in the following sections. The Commission believes that an SBS Entity could use a variety of methods to establish a ''reasonable basis'' to believe that a special entity's ''independent representative'' is ''qualified'' for purposes of proposed Rule 15Fh–5.[224]

We preliminarily believe that, except as specifically noted below, an SBS Entity could rely on written representations regarding the various qualifications of the independent representative to form a reasonable basis to believe that the independent representative is ''qualified''.[225] Upon receiving such representations, the SBS Entity would be entitled to rely on them without further inquiry, absent special circumstances described below.

To solicit input on when it would no longer be appropriate for an SBS Entity to rely on such representations without further inquiry, the Commission is proposing for comment two alternative approaches. One approach would permit an SBS Entity to rely on a representation from a special entity for purposes of Rule 15Fh–5 unless it knows that the representation is not accurate. The second would permit an SBS Entity to rely on a representation unless the SBS Entity has information that would cause a reasonable person to question the accuracy of the representation.

Under either approach, an SBS Entity could not ignore information in its possession as a result of which the SBS Entity would know that a representation is inaccurate. In addition, under the second approach, an SBS Entity also could not ignore information that would cause a reasonable person to question the accuracy of a representation and, if the SBS Entity had such information, it would need to make further reasonable inquiry to verify the accuracy of the representation.

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

• Commenters have suggested that an independent representative should be deemed ''qualified'' if it is ''a sophisticated, professional adviser such as a bank, Commission-registered investment adviser, insurance company or other qualifying [Qualified Professional Asset Manager (''QPAM'')] or INHAM for Special Entities subject to ERISA, a registered municipal advisor, or a similar qualified professional''.[226] Should the Commission permit this presumption? If so, the Commission asks commenters to address specifically how regulated status would inform the determination as to whether an independent representative satisfies the qualification requirements of Section 15F(h)(5) and proposed Rule 15Fh–5. If the Commission were to adopt a presumption, should it apply equally for all regulated persons? Should the

[223] *See* Exchange Act Sections 15F(h)(2)(C)(ii) (defining ''special entity'' to include ''a State, State agency, city, county, municipality, or other political subdivision of a State'') and 15F(h)(2)(C)(iv) (a governmental plan as defined in Section 3 of ERISA), Pub. L. 111–203, 124 Stat. 1376, 1789.

[224] The SBS Entity may also be provided a copy of the representations that the independent representative provides to the special entity regarding its qualifications. In the absence of language precluding the SBS Entity from relying on the representations, the Commission preliminarily believes that the SBS Entity could rely on the representations to form a reasonable basis for its determinations to the same extent it could if the special entity had provided the representations to the SBS Entity. Furthermore, we do not believe that such reliance would constitute a ''material business relationship'' between the SBS Entity and independent representative.

[225] In particular, absent the special circumstances described above, an SBS Entity would be permitted to rely on a representation that stated the independent representative:

(1) Had sufficient knowledge to evaluate the transaction and risks;

(2) Would undertake a duty to act in the best interests of the special entity;

(3) Would make appropriate and timely disclosures to the special entity of material information concerning the security-based swap;

(4) Would provide written representations to the special entity regarding fair pricing and the appropriateness of the security-based swap; and

(5) In the case of employee benefit plans subject to the Employee Retirement Income Security Act of 1974, was a fiduciary as defined in section 3(21) of that Act (29 U.S.C. 1002(21)); and

(6) In the case of a special entity defined in §§ 240.15Fh–2(e)(2) or (4), was a person that is subject to rules of the Commission, the CFTC or a self-regulatory organization subject to the jurisdiction of the Commission or the CFTC prohibiting it from engaging in specified activities if certain political contributions have been made.

It would not be appropriate, however, for an SBS Entity to rely on a general representation that merely states that the counterparty has a ''qualified independent representative'' for purposes of proposed Rule 15Fh–5.

The SBS Entity could also obtain a representation that that the independent representative was not subject to a statutory disqualification. However, as discussed below, the SBS Entity would also be expected to search publicly available databases such as BrokerCheck.

[226] SIFMA/ISDA 2011 Letter.

presumption instead be limited to certain types of regulated persons, ERISA fiduciaries, for example? Why, or why not? If the Commission does not permit the presumption, how, if at all, should the status of an independent representative be taken into account for purposes of determining whether the requirements of the proposed rule are satisfied? [227]

• Are there other approaches that the Commission should consider in permitting an SBS Entity to rely on a special entity's written representation that it has a ''qualified independent representative''? If so, what alternative approaches, if any, would be feasible in terms of market practice and the advantages and disadvantages for SBS Entities and special entities?

• Should the Commission require that the SBS Entity obtain written representations regarding the qualifications of the independent representative directly from the independent representative? From both the independent representative and the special entity? Why or why not?

• Should the Commission allow an SBS Entity to rely on written representations the independent representative provides to the special entity? What constraints, if any, should be placed on such reliance? For example, should an explicit statement regarding the SBS Entity's use of the representations be required to be included in the documentation of the security-based swap? What are the respective advantages and disadvantages of the proposed approaches to guidance on when it would not be appropriate to rely on a special entity's written representations? Which alternative would strike the best balance among the potential disadvantages to market participants, the regulatory interest in appropriate independent representation for special entities, and the sound functioning of the security-based swap market? What, if any, other alternatives should the Commission consider and why?

• Should an SBS Entity be required to undertake further review or inquiry for particular categories of special entities? If so, what review or inquiry should be required in what circumstances?

• In light of the additional protections that are afforded special entities under the Dodd-Frank Act described in Section I.C.5 above, should an SBS Entity be required to undertake diligence or further inquiry before it can rely on any representation from a special entity concerning the qualifications of its representative? Why or why not? If such diligence or inquiry is not required, should an SBS Entity be permitted to rely on representations from the special entity only where the SBS Entity does not have information that would cause a reasonable person to question the accuracy of the representation? Why or why not? Would requiring such diligence or further inquiry—or allowing reliance on representations only in such a manner—unnecessarily limit the willingness or ability of SBS Entities to provide special entities with the access to security-based swaps for the purposes described in Section I.C.5 above? Why or why not? What, if any, other measures should be required in connection with an SBS Entity's satisfaction of the requirements of proposed Rule 15Fh–5?

• Are there other potential reasonable means of establishing that a special entity's independent representative has the requisite qualifications, other than written representations, for which the Commission should consider providing guidance? If so, what means should such guidance address and how?

i. Qualified Independent Representative—Sufficient Knowledge To Evaluate Transaction and Risks

Proposed Rule 15Fh–5(a)(1) would require that the SBS Entity have a reasonable basis to believe that the independent representative has sufficient knowledge to evaluate the transaction and risks.[228] Industry groups have recognized that intermediaries should assess the sophistication of a counterparty—or its agent—including the counterparty's capability to understand the risk and return characteristics of the instrument.[229] The independent representative will play an important role in assessing and advising the special entity in this regard.[230]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

• Should the Commission require the SBS Entity to reevaluate (or, as applicable require a new written representation regarding) the qualifications of the independent representative periodically? If so, how often? Should such reevaluation be required for specific types of security-based swaps or in certain circumstances? If so, with respect to which types and in what circumstances?

• Should the Commission specify particular facts or circumstances that might give rise to a requirement for further review or inquiry on the part of an SBS Entity, notwithstanding any representations from the counterparty? Why or why not? What facts or circumstances should be considered, if any?

• Should the Commission consider the development of a proficiency examination for independent representatives? [231] Should such testing requirement be mandatory? Should it apply to both in-house and third-party independent representatives? Why or why not?

• Should the Commission require that independent representatives be registered with the Commission as municipal advisors or investment advisers, or otherwise subject to regulation, such as banking regulation, for example?

ii. Qualified Independent Representative—No Statutory Disqualification

Proposed Rule 15Fh–5(a)(2) would require that the SBS Entity have a reasonable basis to believe that the independent representative is not subject to a statutory disqualification.[232] Although Exchange Act Section 15F(h) does not define ''subject to a statutory disqualification,'' the term has an established meaning under Section

[227] *See, e.g.,* Section II.D.4.c.iii (seeking comment on, among other things, whether an ERISA plan fiduciary should be deemed to act in the best interests of the special entity that is an employee benefit plan that is subject to regulation under ERISA).

[228] *See* Section 15F(h)(5)(A)(i)(I) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1791 (to be codified at 15 U.S.C. 78o–10(h)(5)(A)(i)(I)). As noted above, an SBS Entity could rely on representations from the special entity to form this reasonable basis, as discussed in note 213 and related text.

[229] *See* CRMPG III Report at 57–59 (describing standards of sophistication for investors of high-risk complex financial instruments).

[230] *See* note 225, *supra,* and related text regarding an SBS Entity's reliance on a representation from the special entity to form this reasonable basis.

[231] *See* Letter from Joseph A. Dear, Chief Investment Officer, California Public Employees' Retirement System *et al.,* to David A. Stawick, Secretary, CFTC (Feb. 18, 2011) (suggesting that the CFTC consider an approach that would involve passage of a proficiency examination by the independent representative); Letter from Peter A. Shapiro, Managing Director, Swap Financial Group to David A. Stawick, Secretary, CFTC (Feb. 22, 2011); Letter from Frank Iacono, Partner, Riverside Risk Advisors LLC to David A. Stawick, Secretary, CFTC (Feb. 22, 2011). Comments submitted to the CFTC are available at *http://comments.cftc.gov/PublicComments/CommentList.aspx?id=935t.*

[232] *See* Section 15F(h)(5)(A)(i)(II) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1791 (to be codified at 15 U.S.C. 78o–10(h)(5)(A)(i)(II)). As noted above, an SBS Entity could rely on representations from the special entity to form this reasonable basis, as discussed in note 213 and related text. See discussion above in Section II.B.

3(a)(39) of the Exchange Act,[233] which defines circumstances that would subject a person to a statutory disqualification with respect to membership or participation in, or association with a member of, an SRO. Although Section 3(a)(39) would not literally apply here, we are proposing to define ''subject to a statutory disqualification'' for purposes of proposed Rule 15Fh–5 by reference to Section 3(a)(39) of the Exchange Act.

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- What, if any, other ''statutory disqualification'' models or definitions should the Commission consider, and why?
- Should the Commission specify particular facts or circumstances that require further review or inquiry on the part of an SBS Entity, notwithstanding written representations received?
- Should the Commission require an SBS Entity to check publicly available databases, such as FINRA's BrokerCheck and the Commission's Investment Adviser Public Disclosure program, to determine whether an independent representative is subject to a statutory disqualification? [234] Why or why not? If so, which databases should be required to be consulted? Should such databases include sources outside the Commission and self-regulatory organizations, such as databases maintained by other regulators or federal or state officials? Why or why not? If so, which outside databases should be required to be consulted? Should the Commission require an SBS Entity to conduct any other type of inquiry to determine whether an independent representative is subject to a statutory disqualification? Why or why not?

iii. Qualified Independent Representative—Acting in the Best Interests of the Special Entity

Proposed Rule 15Fh–5(a)(3) would require that the SBS Entity have a reasonable basis to believe that the independent representative ''undertakes a duty to act in the best interests'' of the special entity.[235] As discussed above, we are not proposing to define ''best interests.'' We also note that an independent representative may be subject to similar or additional obligations under other applicable law with respect to its activities on behalf of the special entity.[236]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Should the independent representative be required to be subject to some form of regulation (*e.g.,* as an investment adviser or an ERISA plan fiduciary) under which the independent representative has a duty to act in the best interests of the special entity (or some similar requirement)?
- Should an in-house independent representative be deemed to act in the best interests of the special entity by virtue of its employment with the special entity? Why or why not?
- Should an ERISA plan fiduciary, as defined under Section 3(21) of ERISA, that meets the standards of ERISA be deemed to act in the best interests of a special entity that is an employee benefit plan subject to regulation under ERISA, for purposes of the proposed rule? Should a QPAM? [237] An INHAM? [238] Why or why not?

iv. Qualified Independent Representative—Appropriate Disclosures to Special Entity

Section 15F(h)(5)(A)(i)(V) requires that the SBS Entity comply with any rules promulgated by the Commission requiring the SBS Entity to have a reasonable basis to believe that the independent representative will make appropriate disclosures. The Dodd-Frank Act is silent concerning the content of these disclosures. Proposed Rule 15Fh–5(a)(4) would require that the SBS Entity have a reasonable basis to believe that the independent representative will make appropriate and timely disclosures to the special entity of material information regarding the security-based swap.[239]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Should the Commission impose specific requirements with respect to this obligation, such as the content of the disclosures that should be made by the independent representative? If so, what requirements and why? Should the ''appropriate disclosures'' include disclosures regarding the qualifications of the independent representative, in addition to disclosures regarding the security-based swap? Why or why not? Should such disclosures address other subjects not directly related to the security-based swap? Which ones and why?
- If the SBS Entity is not relying on written representations, should the Commission allow a presumption that an in-house independent representative, by virtue of its employment with the special entity, will make appropriate disclosures of material information to the special entity? Why or why not?
- Should the Commission also require that the SBS Entity have a reasonable basis to believe that the independent representative will make appropriate and timely disclosures to the special entity of any potential conflicts of interest that the representative may have in connection with the security-based swap transaction? Why or why not? Would such disclosures be considered part of the ''best interests'' undertaking of an independent representative? Why or why not?

v. Qualified Independent Representative—Written Representations

Proposed Rule 15Fh–5(a)(5) would require that the SBS Entity have a reasonable basis to believe that the independent representative will provide written representations to the special entity regarding fair pricing and the appropriateness of the security-based

[233] 15 U.S.C. 78c(a)(39).

[234] *See, e.g., http://www.finra.org/Investors/ToolsCalculators/BrokerCheck/index.htm,* and *http://www.adviserinfo.sec.gov/(S(b3d5ktvihzlhai45hknxzk45))/IAPD/Content/Search/iapd_Search.aspx.*

[235] *See* Section 15F(h)(5)(A)(i)(IV) of the Exchange Act, Pub. L. 111–203, 124 Stat. 1376, 1791 (to be codified at 15 U.S.C. 78o–10(h)(5)(A)(i)(IV)). *See* note 225, *supra,* and related text regarding an SBS Entity's reliance on a representation from the special entity to form this reasonable basis.

[236] As noted above, depending on the circumstances, an independent representative may be an ''investment adviser'' within the meaning of Section 202(a)(11) of the Advisers Act, a ''municipal advisor'' within the meaning of Section 15B(e) of the Exchange Act, or a fiduciary for purposes of ERISA. A municipal advisor, for example, ''shall be deemed to have a fiduciary duty to any municipal entity for whom such municipal advisor acts as a municipal advisor.'' 15 U.S.C. 78o–4(c)(1).

[237] *See* Department of Labor Prohibited Transaction Exemption (''PTE'') 84–14, 70 FR 49305 (Aug. 23, 2005); Amendment to PTE 84–14 for Plan Asset Transactions Determined by Independent Qualified Professional Asset Managers, 75 FR 38837 (July 6, 2010).

[238] *See* Department of Labor PTE 96–23, 61 FR 15975 (Apr. 10, 1996); Proposed Amendment to PTE 96–23 for Plan Asset Transactions Determined by In-House Asset Managers, 75 FR 33642 (proposed June 14, 2010).

[239] *See* note 225, *supra,* and related text regarding an SBS Entity's reliance on a representation from the special entity to form this reasonable basis.

swap.[240] Commenters have suggested that a written representation ''should be sufficient if the representation states that the representative is obligated, by law and/or contract, to review pricing and appropriateness with respect to any swap transaction in which the representative serves as such with respect to the plan''.[241] We are not proposing a specific means by which this standard must be satisfied. We preliminarily believe, however, the approach described above would be reasonable. Another way for an SBS Entity to form a reasonable basis for its determination would be relying on a written representation that the independent representative will document the basis for its conclusion that the transaction was fairly priced and appropriate for the plan, and that the independent representative or the special entity will maintain that documentation in its records for an appropriate period of time, and make such records available to the plan upon request.

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Should the Commission impose specific requirements with respect to this obligation? If so, what requirements and why?

vi. Qualified Independent Representative—ERISA Fiduciary

Proposed Rule 15Fh–5(a)(6) would require an SBS Entity to have a reasonable basis to believe that the independent representative, in the case of a special entity that is an employee benefit plan subject to ERISA, is a ''fiduciary'' as defined in section 3(21) of that Act (29 U.S.C. 1002).[242] None of the requirements set forth in the proposed rule is intended to limit, restrict, or otherwise affect the fiduciary's duties and obligations under ERISA.[243]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Should the Commission impose specific requirements with respect to this obligation? If so, what requirements and why?
- Should other independent representative qualifications under proposed Rule 15Fh–5(a)(1) be deemed satisfied if the independent representative in the case of employee benefit plans subject to ERISA, is a fiduciary as defined in section 3(21) of ERISA? If so, which requirements and why?

vii. Qualified Independent Representative—Subject to ''Pay To Play'' Prohibitions

We are proposing to include an additional requirement, not expressly addressed by the Dodd-Frank Act, that the SBS Entity have a reasonable basis for believing that the independent representative is subject to ''pay to play'' rules if the special entity is a State, State agency, city, county, municipality, or other political subdivision of a State, or a governmental plan, as defined in Section 3(32) of ERISA.[244] We believe that, unless exempted or excepted, an independent representative in these circumstances would likely be either a municipal advisor, or an investment adviser.[245] A registered municipal advisor would be subject to pay to play prohibitions under MSRB rules.[246] An investment adviser that is registered with the Commission would be subject to existing Commission rules regarding these practices.[247]

We do not, however, intend to prohibit other qualified persons from acting as independent representatives so long as those persons are similarly subject to pay to play restrictions. As discussed in Section II.D.5 below, pay to play practices may result in significant harm to these types of special entities in connection with security-based swap transactions.[248] The concern is heightened here because of the fiduciary role that Congress has envisaged for independent representatives to special entities. In the case of independent representatives, the concern would be that a person might make contributions in order to be chosen as an independent representative (and obtain the fees commensurate with that role), and then not act as an impartial advisor with respect to the transaction. The proposed rule is intended to deter SBS Entities from participating, even indirectly, in such practices. Accordingly, proposed Rule 15Fh–5(a)(7) would require an SBS Entity to have a reasonable basis for believing that the independent representative is a person that is subject to rules of the Commission, the CFTC or an SRO subject to the jurisdiction of the Commission or the CFTC prohibiting it from engaging in specified activities if certain political contributions have been made, unless the independent representative is an employee of the special entity.[249]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Are there circumstances in which an independent representative that is advising a special entity that is a State, State agency, city, county, municipality, or other political subdivision of a State, or a governmental plan, as defined in Section 3(32) of ERISA, other than an employee of the special entity, would not be subject to pay to play restrictions?
- Should the Commission consider a different requirement, for example, that the independent representative be

[240] *See* Section 15F(h)(5)(A)(i)(VI) of the Exchange Act, Pub. L. 111–203, 124 Stat. 1376, 1791 (to be codified at 15 U.S.C. 78o–10(h)(5)(A)(i)(VI)). *See* note 225, *supra,* and related text regarding an SBS Entity's reliance on a representation from the special entity to form this reasonable basis.

[241] American Benefits Council Letter at 9.

[242] *See* Section 15F(h)(5)(A)(i)(VII) of the Exchange Act, Pub. L. 111–203, 124 Stat. 1376, 1791 (to be codified at 15 U.S.C. 78o–10(h)(5)(A)(i)(VII)). *See* note 225, *supra,* and related text regarding an SBS Entity's reliance on a representation from the special entity to form this reasonable basis.

[243] *See* notes 99, 198 and 189, *supra,* regarding the Department of Labor's proposal to amend definition of ''fiduciary'' for purposes of ERISA.

[244] *See* Exchange Act Section 15F(h)(1)(C), Public Law 111–203, 124 Stat. 1376, 1789 (to be codified at 15 U.S.C. 78o–10(h)(1)(C)) (authorizing the Commission to prescribe business conduct standards that relate to ''such other matters as the Commission determines to be appropriate''). For a discussion of abuses associated with pay to play practices, see Section II.D.5 below. *See* note 213 above and related text regarding an SBS Entity's reliance on a representation from the special entity to form this reasonable basis.

[245] *See* 15 U.S.C. 80b–2(a)(11) (defining ''investment adviser''), and 15 U.S.C. 78o–4(3) (defining ''municipal advisor''). Exchange Act Section 15B(4)(C) excludes from the definition of ''municipal advisor'' any investment adviser that is registered under the Advisers Act, and persons associated with the investment adviser who are providing investment advice.'' 15 U.S.C. 78o–4(4)(C).

[246] *See, e.g.* MSRB Notice 2011–04, Request for Comment on Pay to Play Rules for Municipal Advisors (Jan. 14, 2011) (requesting comment on a draft proposal to establish ''pay to play'' and related rules relating to municipal advisors and to make certain conforming changes to existing pay to play rules for brokers, dealers and municipal securities dealers).

[247] *See, e.g.,* 17 CFR 275.206(4)–5 (prohibiting certain political contributions by investment advisers providing or seeking to provide investment advisory services to public pension plans and other government investors).

[248] *See* note 32, *supra.*

[249] *See* Exchange Act Section 15B(e)(4), Public Law 111–203, 124 Stat. 1376, 1921–1922 (to be codified at 15 U.S.C 78o–4(e)(4)) (defining ''municipal advisor'' as a person ''other than a municipal entity or an employee of a municipal entity'' that engages in the specified activities).

subject to specific prohibitions, such as those described in Advisers Act Rule 206(4)–5 (prohibiting investment advisers that are registered, or required to be registered with the Commission, from providing or seeking to provide investment advisory services to public pension plans and other government investors when certain political contributions have been made)?

• Should the Commission require that the independent representative be a registered municipal advisor or Commission registered investment adviser?

d. Disclosure of Capacity

Proposed Rule 15Fh–5(b) would require that, before initiation of a security-based swap with a special entity, an SBS Dealer must disclose in writing the capacity or capacities in which it is acting.[250] An SBS Dealer that is acting as a counterparty but not an advisor to a special entity, for example, would need to make clear to the special entity the capacity in which it is acting (*i.e.,* that it is acting as a counterparty, but not as an advisor).

Commenters have noted that a firm may be acting in multiple capacities in relation to a special entity, for example, as underwriter in a bond offering as well as counterparty to a security-based swap used to hedge the financing transaction.[251] In these circumstances, the SBS Dealer's duty to the special entity could vary depending upon the capacity in which it is acting, and so it is important for a special entity and its independent representative to understand the roles in which the SBS Dealer is acting.[252] The proposed rule, therefore, would require an SBS Dealer that engages in business, or has engaged in business within the last twelve months, with the counterparty in more than one capacity to disclose the material differences between such capacities in connection with the security-based swap and any other financial transaction or service involving the counterparty.[253]

We are proposing to apply the requirement in proposed Rule 15Fh–5(b) to SBS Dealers but not Major SBS Participants because the statutory requirement, by its terms, requires disclosure in writing of ''the capacity in which the security-based swap dealer is acting.'' [254]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

• Are there specific capacities in which an SBS Dealer may act that merit more detailed types of disclosures? If so, which capacities, and what types of disclosures should be required? Should the Commission define in further detail the specific categories of ''capacities'' in which SBS Dealers may act that would need to be disclosed under the proposed rule—*e.g.,* as advisor, counterparty, underwriter, etc? If so, which capacities should be identified and disclosed?

• Should the Commission require similar disclosures by Major SBS Participants? Why or why not?

• Are there certain capacities for which disclosures should not be required? If so, which capacities, and why?

• Should the required disclosure be limited to other ''capacities'' within a timeframe other than twelve months? If so, what would be the appropriate time frame? Why?

• Should there be a *de minimis* exclusion from the required disclosure? If so, what would be an appropriate threshold? Are there certain ''capacities'' that should be disclosed regardless of the dollar amount involved?

• We understand that some SBS Dealers may utilize a single relationship point of contact to manage the multiple capacities in which they may act with regard to a special entity. Does this relationship management model increase the likelihood that the special entity would be confused as to the standard of conduct with which each associated person is required to comply? Should the SBS Dealer be required to disclose the material differences in capacities that are managed separate and apart from this centralized relationship point? If an SBS Dealer has information barriers in place between certain associated persons or affiliates, should the SBS Dealer still be required to disclose to the special entity any material differences in the capacities in which these associated persons are acting? Would these types of information barriers impair the customer service that a special entity might otherwise receive?

• Are there any circumstances in which an affiliate of the SBS Dealer should be treated as an independent entity or third party, for the purposes of this disclosure rule?

6. Prohibition on Certain Political Contributions by SBS Dealers: Proposed Rule 15F–6

We are proposing a rule that would prohibit an SBS Dealer from engaging in security-based swap transactions with a ''municipal entity'' if certain political contributions have been made to officials of the municipal entity.[255] Pay to play occurs when persons seeking to do business with state and municipal governments make political contributions, or are solicited to make political contributions, to elected officials or candidates in order to influence the selection process.[256] In making such contributions, interested persons hope to benefit from officials who ''award the contracts on the basis of benefit to their campaign chests rather than to the governmental

[250] *See* Section 15F(h)(5)(A)(2)(i) of the Exchange Act, Pub. L. 111–203, 124 Stat. 1376, 1791 (to be codified at 15 U.S.C. 78o–10(h)(5)(A)(2)(i)).

[251] *See* Swap Financial Group Presentation at 55.

[252] In the case of special entities that are municipal entities, MSRB Rule G–23 generally prohibits dealer-financial advisors from acting in multiple capacities in the same municipal securities transactions. *See also* MSRB Notice 2011–29 (May 31, 2011) (discussing rule amendment and interpretive notice).

[253] *See* proposed Rule 15Fh–5(b).

[254] We making this statement because the introductory clause of Section 15F(h)(5) imposes disclosure obligations on both SBS Dealers and Major SBS Participants and thus could be read to impose the capacity disclosure obligation on all SBS Entities. *See* Section 15F(h)(5)(A)(2)(ii) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1791 (to be codified at15 U.S.C. 78o–10(h)(5)(A)(2)(ii)). We also note that the obligation in the text of the statute does not require Commission rulemaking.

[255] *See* Section 15F(h)(1)(D) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1789, 15 U.S.C. 78o–10(h)(1)(D) (authorizing the Commission to prescribe business conduct standards that relate to ''such other matters as the Commission determines to be appropriate'').

The proposed restrictions would apply to dealings with a ''municipal entity,'' which is defined in Exchange Act Section 15B(e)(8) (15 U.S.C. 78o–4(e)(8)) as: ''any State, political subdivision of a State, or municipal corporate instrumentality of a State, including—(A) any agency, authority, or instrumentality of the State, political subdivision, or municipal corporate instrumentality; (B) any plan, program, or pool of assets sponsored or established by the State, political subdivision, or municipal corporate instrumentality or any agency, authority, or instrumentality thereof; and (C) any other issuer of municipal securities.''

[256] *See, e.g., Blount* v. *SEC,* 61 F. 3d 938 (D.C. Cir. 1995), *cert. denied,* 116 S. Ct. 1351 (1996) (holding that ''underwriters' campaign contributions self-evidently create a conflict of interest in state and local officials who have power over municipal securities contracts and a risk that they will award the contracts on the basis of benefit to their campaign chests rather than to the governmental entity''); Testimony of Martha Mahan Haines before the U.S. Senate Committee on Banking, Housing, and Urban Affairs, Subcommittee on Securities, Insurance, and Investment (May 21, 2009) (stating that pay to play practices may result in an unqualified financial advisor being chosen because of his political contributions). *See also* Political Contributions by Certain Investment Advisers, *supra,* note 32 at notes 18 through 25, citing examples of more recent Commission and criminal actions against investment advisers and other parties for violations involving pay to play arrangements.

entity.'' [257] Pay to play practices may take a variety of forms, including an SBS Dealer's direct contributions to government officials, an SBS Dealer's solicitation of third parties to make contributions or payments to government officials or political parties in the state or locality where the SBS Dealer seeks to provide services, or an SBS Dealer's payments to third parties to solicit (or as a condition of obtaining) security-based swap business.

In the context of security-based swaps, pay to play practices may result in municipal entities entering into transactions not because of hedging needs or other legitimate purposes, but rather because of campaign contributions given to an official with influence over the selection process. Where pay to play exists, SBS Dealers may compete for security-based swap business based on their ability and willingness to make political contributions, rather than on their merit or the merit of a proposed transaction. We believe these practices may result in significant harm to municipalities and others in connection with security-based swap transactions, just as they do in connection with other municipal securities transactions.[258]

By its nature, pay to play is covert because participants do not broadcast that contributions or payments are made or accepted for the purpose of influencing the selection of a financial services provider. As one court noted, ''[w]hile the risk of corruption is obvious and substantial, actors in this field are presumably shrewd enough to structure their relations rather indirectly.'' [259] Consequently, pay to play practices are often hard to prove because it is difficult to prove that contributions were made for the purpose of obtaining government business, and that those contributions then drove the selection of a particular entity.

Absent implementation of specific rules prohibiting pay to play practices, it is likely such practices would continue undeterred, given that such practices pose a ''collective action'' problem.[260] That is, government officials who engage in pay to play practices may have an incentive to continue accepting contributions to support their campaigns, for fear of being disadvantaged relative to their opponents. In addition, SBS Dealers may have an incentive to participate out of concern that they may be overlooked if they fail to make contributions. Both the stealthy nature of these practices and the inability of markets to properly address them strongly support the need for a prophylactic measure to address them, such as proposed Rule 15Fh–6.[261]

Proposed Rule 15Fh–6 is modeled on, and intended to complement, existing restrictions on pay to play practices under Advisers Act Rule 206(4)–5, which imposes pay to play restrictions on investment advisers providing or seeking to provide investment advisory services to public pension plans and other government investors,[262] and under MSRB Rules G–37 and G–38, which impose pay to play restrictions on municipal securities dealers and broker-dealers engaging or seeking to engage in the municipal securities business. The proposed rule would create a comparable regulatory framework, as there are no existing federal pay to play restrictions that would apply to all SBS Dealers in their dealings with municipal entities. The proposed rule is intended to deter SBS Dealers from engaging in pay to play practices.

The proposed rule itself does not attempt to stamp out corruption by public officials or to regulate local elections, nor is it a ban on political contributions. Rather, the proposed rule would bar SBS Dealers from entering into contracts after they make contributions, with the aim of eliminating motivation to engage in pay to play.

We have closely drawn proposed Rule 15Fh–6 to accomplish its goal of preventing *quid pro quo* arrangements while avoiding unnecessary burdens on the protected speech and associational rights of SBS Dealers and their covered employees.[263] The proposed rule would address only direct contributions to officials—it is not intended in any way to impinge on a wide range of expressive conduct in connection with elections. It would be triggered only when a business relationship exists or will be established in the near future. It would target those employees of SBS Dealers whose contributions raise the greatest danger of *quid pro quo* exchanges, and it would cover only contributions to those government officials who would be the most likely targets of a *quid pro quo* because of their authority to influence the award of government contracts. Finally, the proposed rule would not prevent anyone from making contributions at or below a specified *de minimis* level.

We are proposing to apply the requirements in proposed Rule 15Fh–6 to SBS Dealers but not to Major SBS Participants because we do not anticipate that Major SBS Participants would serve a dealer-type role in the market.[264]

a. Prohibitions

Proposed Rule 15Fh–6(b)(1) would generally make it unlawful for an SBS Dealer to offer to enter or to enter into a security-based swap with a municipal entity for a two-year period after the SBS Dealer or any of its covered associates makes a contribution to an official of the municipal entity.[265]

Proposed Rule 15Fh–6(b)(3)(i) would prohibit an SBS Dealer from paying a third party to solicit municipal entities to enter into a security-based swap, unless the third party is a ''regulated person'' that is itself subject to a pay to

[257] *Blount,* 61 F.3d at 944–45.

[258] *See id. See SEC* v. *Larry P. Langford,* Litigation Release No. 20545 (Apr. 30, 2008) and *SEC* v. *Charles E. LeCroy,* Litigation Release No. 21280 (Nov. 4, 2009) (charging Alabama local government officials and J.P. Morgan employees with undisclosed payments made to obtain municipal bond offering and swap agreement business from Jefferson County, Alabama). *See also J.P. Morgan Securities Inc.,* Securities Act Release No. 9078 (Nov. 4, 2009) (instituting administrative and cease-and-desist proceedings against a broker-dealer that the Commission alleged was awarded bond underwriting and interest rate swap agreement business by Jefferson County in connection with undisclosed payments by employees of the firm).

[259] *Blount* v. *SEC,* 61 F.3d at 945.

[260] As we explained in our release adopting Advisers Act Rule 206(4)–5, a collective action problem exists when participants who prefer to abstain from pay to play nonetheless feel compelled to participate due to concern that they will be locked out of the market unless they take part. *See* Political Contributions by Certain Investment Advisers, note 33, *supra.*

[261] *Cf. Blount,* 61 F.3d at 945 (''no smoking gun is needed where, as here, the conflict of interest is apparent, the likelihood of stealth great, and the legislative purpose prophylactic'').

[262] 17 CFR 275.206(4)–5. *See* Political Contributions by Certain Investment Advisers, note 32, *supra.* (adopting Advisers Act Rule 206(4)–5). *See also* Rules Implementing Amendments to the Investment Advisers Act of 1940, Investment Advisers Act Release No. 3110 (Nov. 19, 2010), 75 FR 77052 (Dec. 10, 2010) (proposing amendments to Investment Advisers Act Rule 206(4)–5).

[263] The proposed rule is closely modeled on the MSRB Rule G–37 upheld by the Court of Appeals for the District of Columbia Circuit in *Blount* v. *SEC,* 61 F.3d at 947–48.

[264] *See* discussion in Section I.C.4, *supra.*

[265] Proposed Rule 15Fh–6(a)(5) would define the term ''official'' of a municipal entity for purposes of the proposed rule to mean:

A person (including any election committee for such person) who was, at the time of the contribution, an incumbent, candidate or successful candidate for elective office of a municipal entity, if the office:

(i) Is directly or indirectly responsible for, or can influence the outcome of, the selection of a security-based swap dealer or major security-based swap participant by a municipal entity; or

(ii) Has authority to appoint any person who is directly or indirectly responsible for, or can influence the outcome of, the selection of a security-based swap dealer or major security-based swap participant by a municipal entity.

play restriction under applicable law.[266] We are concerned that the adoption of a rule addressing pay to play practices by security-based swap dealers would lead to the use of solicitors by security-based swap dealers to circumvent the rule. Proposed Rule 15Fh–6(b)(3)(i) is intended to deter SBS Dealers from participating, even indirectly, in such practices.

Third, proposed Rule 15Fh–6(b)(3)(ii) would ban an SBS Dealer from soliciting or coordinating contributions to an official of a municipal entity with which the SBS Dealer is seeking to enter into, or has entered into a security-based swap, or payments to a political party of a state or locality with which the SBS Dealer is seeking to enter into, or has entered into, a security–based swap. These proposed prohibitions are similar to those contained in Advisers Act Rule 206(4)–5, and MSRB Rules G–37 and G–38.

Proposed Rule 15Fh–6(c) would make it unlawful for an SBS Dealer to do indirectly or through another person or means anything that would, if done directly, result in a violation of the prohibitions contained in the proposed rule.

b. Two-Year ''Time Out''

Proposed Rule 15Fh–6(b)(1) would prohibit an SBS Dealer from offering to enter into, or entering into, a security-based swap with a municipal entity within two years after a contribution to an official of such municipal entity has been made by the SBS Dealer or any of its covered associates. We believe the two-year time out requirement strikes an appropriate balance, as it is sufficiently long to act as a deterrent but not so long as to be unnecessarily onerous. The two-year time out is consistent with the time out provisions contained in Advisers Act Rule 206(4)–5 and MSRB Rule G–37.

c. Covered Associates

Political contributions made to influence the selection of a firm are typically made not by the firm itself, but by officers and employees of the firm who have a stake in the business relationship with the municipal entity.[267] For this reason, the restrictions under proposed Rule 15Fh–6(b)(1) would apply to contributions by any ''covered associate'' of an SBS Dealer, which is defined to include: (i) Any general partner, managing member or executive officer, or other person with a similar status or function; [268] (ii) any employee who solicits a municipal entity to enter into a security-based swap with the SBS Dealer and any person who supervises, directly or indirectly, such employee; and (iii) any political action committee controlled by the SBS Dealer or any of its covered associates.[269] This definition is consistent with a similar provision in Advisers Act Rule 206(4)–5.[270]

Because the proposed rule would attribute to a firm those contributions made by a person even prior to becoming a covered associate of the firm, SBS Dealers would need to ''look back'' in time to determine whether the time out applies when an employee becomes a covered associate. For example, if the contribution was made less than two years (or six months, as applicable) before an individual becomes a covered associate, the proposed rule would prohibit the firm from entering into a security-based swap with the relevant municipal entity until the two-year time out period has expired.

d. Officials

The restrictions would apply when contributions are made to an ''official'' of a municipal entity. Proposed Rule 15Fh–6(a)(5) would define ''official'' to mean any person (including any election committee for such person) who was, at the time of the contribution, an incumbent, candidate or successful candidate for elective office of a municipal entity, if the office is directly or indirectly responsible for, or can influence the outcome of, the selection of an SBS Dealer by a municipal entity; or has authority to appoint any person who is directly or indirectly responsible for, or can influence the outcome of, the selection of an SBS Dealer by a municipal entity.

e. Exceptions

i. De Minimis Contributions

The proposed rule would permit an individual who is a covered associate to make aggregate contributions without being subject to the two-year time out period, of up to $350 per election, for any one official for whom the individual is entitled to vote, and up to $150 per election, to an official for whom the individual is not entitled to vote.[271] We are proposing this two-tier approach because, while we recognize persons can have a legitimate interest in contributing to campaigns of people for whom they are unable to vote, we are concerned that contributions by covered associates living in distant jurisdictions may be less likely to be made for purely civic purposes. Accordingly, the proposed *de minimis* exception for contributions to candidates for whom a covered associate is not entitled to vote is lower than the *de minimis* exception for candidates for whom a covered associate is entitled to vote. We believe that the $150 exception for contributions to a candidate for whom the covered associate is not entitled to vote is appropriate because of the more remote interest a covered associate is likely to have in contributing to such a person.

ii. New Covered Associates

The prohibitions of the proposed rule would not apply to contributions by an individual made more than six months prior to becoming a covered associate of the SBS Dealer, unless such individual solicits the municipal entity after becoming a covered associate.[272]

iii. Exchange and SEF Transactions

The prohibitions of proposed Rule 15Fh–6 would not apply to a security-based swap that is initiated by a municipal entity on a registered national securities exchange or SEF, for which the SBS Dealer does not know the identity of the counterparty at any time up to and including the time of execution of the transaction.[273]

f. Exception and Exemptions

We are proposing a provision that would provide an SBS Dealer a limited ability to cure the consequences of an inadvertent political contribution to an official for whom the covered associate is not entitled to vote. The exception would apply to contributions that, in the aggregate, do not exceed $350 to any one official per election. The SBS Dealer

[266] Proposed Rule 15Fh–6(a)(7) would define ''regulated person,'' for purposes of the rule, to mean generally a person that is subject to rules of the Commission, the CFTC or an SRO subject to the jurisdiction of the Commission or the CFTC prohibiting it from engaging in specified activities if certain political contributions have been made, or its officers or employees.

[267] *See* Political Contributions by Certain Investment Advisers, *supra,* note 33.

[268] Proposed Rule 15Fh–6(a)(3) would define ''executive officer'' of an SBS Dealer to mean, for purposes of the rule:

- The president;
- Any vice president in charge of a principal business unit, division or function (such as sales, administration or finance);
- Any other officer of the SBS Dealer who performs a policy-making function; or
- Any other person who performs similar policy-making functions for the SBS Dealer.

[269] Proposed Rule 15Fh–6(a)(2).

[270] 17 CFR 275.206(4)–5(f)(2).

[271] Proposed Rule 15Fh–6(b)(2)(i).

[272] Proposed Rule 15Fh–6(b)(2)(ii).

[273] Proposed Rule 15Fh–6(a)(2)(iii).

must have discovered the contribution that resulted in the prohibition within four months of the date of the contribution, and obtained the return of the contribution to the contributor within 60 calendar days of the date of discovery. In addition, an SBS Dealer would not be able to rely on this exception more than twice in any 12-month period, or more than once for any covered associate, regardless of the time between contributions.[274] This automatic exception mirrors similar provisions contained in Advisers Act Rule 206(4)–5 and MSRB Rule G–37.

The scope of this exception would be limited to the types of contributions we believe are less likely to raise pay to play concerns. The prompt return of the contribution would provide an indication that the contribution would not affect an official's decision to enter into a transaction with the SBS Dealer. The relatively small amount of the contribution, in conjunction with the other conditions of the exception, should help to mitigate concerns that the contribution was made for purposes of influencing the municipal entity's selection process. The restrictions on repeated triggering contributions should reinforce the need for effective compliance controls. Because the proposed exception would operate automatically, we preliminarily believe that it should be subject to conditions that are objective and limited in order to capture only those contributions that are less likely to raise pay to play concerns.

In addition, we are proposing a provision under which an SBS Dealer may apply to the Commission for an exemption from the two-year ban. In determining whether to grant the exemption, the Commission would consider, among other factors: (i) Whether the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes of the Exchange Act; (ii) whether the SBS Dealer, (a) Before the contribution resulting the prohibition was made, had adopted and implemented policies and procedures reasonably designed to prevent violations of the proposed rule, (b) prior to or at the time the contribution, had any actual knowledge of the contribution, and (c) after learning of the contribution, had taken all available steps to cause the contributor to obtain return of the contribution and such other remedial or preventative measures as may be appropriate under the circumstances; (iii) whether, at the time of the contribution, the contributor was a covered associate or otherwise an employee of the SBS Dealer, or was seeking such employment; (iv) the timing and amount of the contribution; (v) the nature of the election (*e.g.,* state or local); and (vi) the contributor's intent or motive in making the contribution, as evidenced by the facts and circumstances surrounding the contribution.[275] This exemption is similar to the exemption-by-application provisions contained in Advisers Act Rule 206(4)–5 and MSRB Rule G–37.

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Do security-based swap transactions with municipal entities present the same risks of pay to play abuses as other securities transactions involving municipal securities dealers and investment advisers? If not, why not?
- Do the same risks of pay to play abuses exist when a Major SBS Participant, rather than an SBS Dealer, is seeking to enter into a security-based swap with a municipal entity? If not, why not? Should the proposed rule apply to Major SBS Participants, as well as to SBS Dealers? If so, why?
- Is the term ''municipal entity'' appropriately defined? If not, should the definition refer to ''a State, State agency, city, county, municipality, or other political subdivision of a State, or any governmental plan, as defined in section 3 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002)'' within the meaning of Exchange Act Section 15F(h)(2)(C)? Should the Commission use the definition of ''government entity'' from Advisers Act Rule 206(4)–5?[276] Should the Commission instead follow the approach of MSRB Rule G–37?[277]
- Should the requirements of proposed Rule 15Fh–6 be deemed satisfied if an SBS Dealer can establish that it is subject to other regulation that similarly prohibits it from engaging in security-based swap activities if certain political contributions have been made? Should an SBS Dealer's ability to rely on other regulation be conditioned on a Commission finding that the other regulation imposes substantially equivalent or more stringent restrictions than proposed Rule 15Fh–6 would impose on SBS Dealers, and that such other rules are consistent with the objectives of proposed Rule 15Fh–6? Why or why not?
- Proposed Rule 15Fh–6(b)(3)(i) is intended to prevent SBS Dealers from participating, even indirectly, in pay to play practices. What would be the advantages and disadvantages of such an approach? Is there another approach that the Commission should consider? Are there differences between the operations of SBS Dealers and other securities firms that would make the third-party solicitor provision unnecessary? If so, what are they? Would the provision impose any collection of information obligations? If so, what would they be? What would be the costs and benefits of this approach?

E. Chief Compliance Officer: Proposed Rule 15Fk–1

Section 15F(k) of the Exchange Act requires an SBS Entity to designate a chief compliance officer (''CCO''), and imposes certain duties and responsibilities on that CCO. Proposed Rule 15Fk–1 would codify the provisions of Exchange Act Section 15F(k) with some modifications based on the current compliance obligations applicable to CCOs of other Commission-regulated entities. The proposed requirements underscore the central role that sound compliance programs play to ensure compliance with the Exchange Act and rules and regulations thereunder applicable to security-based swaps.[278]

Proposed Rule 15Fk–1(a) would require an SBS Entity to designate a CCO on its registration form, and proposed Rule 15Fk–1(b) would impose certain duties on the CCO. Proposed Rule 15Fk–1(b)(1) would require that the CCO report directly to the board of directors, a body performing a function similar to the board, or to the senior

[274] Proposed Rule 15Fh–6(e)(1).

[275] Proposed Rule 15Fh–6(e).

[276] As used in 17 CFR 275.206(4)–5, the term ''government entity'' means any state or political subdivision of a state, including:

(i) Any agency, authority, or instrumentality of the state or political subdivision;

(ii) A pool of assets sponsored or established by the state or political subdivision or any agency, authority or instrumentality thereof, including, but not limited to a ''defined benefit plan'' as defined in section 414(j) of the Internal Revenue Code (26 U.S.C. 414(j)), or a state general fund;

(iii) A plan or program of a government entity; and

(iv) Officers, agents, or employees of the state or political subdivision or any agency, authority or instrumentality thereof, acting in their official capacity.

[277] MSRB Rule G–37 references ''the governmental issuer specified in [Section 3(a)(29) of the Exchange Act]'' which would include ''a State or any political subdivision thereof, or any municipal corporate instrumentality of one more States.''

[278] *See* FINRA Rule 3130.

officer of the SBS Entity.[279] Proposed Rule 15Fk–1(b)(2) would require the CCO to review the compliance of the SBS Entity with respect to the requirements in Section 15F of the Exchange Act and the rules and regulations thereunder.[280] Rule 15Fk–1(b)(2) would further require that, as part of the CCO's obligation to review compliance by the SBS Entity, the CCO establish, maintain, and review policies and procedures that are reasonably designed to achieve compliance by the SBS Entity with Section 15F of the Exchange Act and the rules and regulations thereunder.[281]

Proposed Rule 15Fk–1(b)(3) would require that the CCO, in consultation with the board of directors, a body performing a function similar to the board, or the senior officer of the organization, resolve conflicts of interest that may arise.[282] We understand that the primary responsibility for the resolution of conflicts generally lies with the business units within the SBS Entities. As a result, we would anticipate that the CCO's role with respect to such resolution and mitigation of conflicts of interest would include the recommendation of one or more actions, as well as the appropriate escalation and reporting with respect to any issues related to the proposed resolution of potential or actual conflicts of interest, rather than decisions relating to the ultimate final resolution of such conflicts. Under proposed Rule 15Fk–1(b)(4), the CCO would be responsible for administering each policy and procedure that is required to be established pursuant to Section 15F of the Act and the rules and regulations thereunder.[283] The Commission would expect that a CCO should be competent and knowledgeable regarding Section 15F of the Exchange Act and the rules and regulations thereunder, and should be empowered with full responsibility and authority to execute his or her responsibilities.

Proposed Rule 15Fk–1(b)(5) would require the CCO to establish, maintain and review policies and procedures reasonably designed to ensure compliance with the provisions of the Exchange Act and the rules and regulations thereunder relating to the SBS Entity's business as an SBS Entity.[284] The title of CCO does not, in and of itself, carry supervisory responsibilities. Consistent with current industry practice, we generally would not expect a CCO appointed in accordance with proposed Rule 15Fk–1 to have supervisory responsibilities outside of the compliance department. Accordingly, absent facts and circumstances that establish otherwise, we generally would not expect that a CCO would be subject to a sanction by the Commission for failure to supervise other SBS Entity personnel. Moreover, a CCO who does have supervisory responsibilities could rely on the provisions of proposed Rule 15Fh–3(h)(3), under which a person associated with an SBS Entity shall not be deemed to have failed to reasonably supervise another person if such other person is not subject to the CCO's supervision, or if: (i) the SBS Entity has established and maintained written policies and procedures, and a documented system for applying those policies and procedures, that would reasonably be expected to prevent and detect, insofar as practicable, any violation of the federal securities laws and the rules and regulations thereunder relating to its business as an SBS Entity; and (ii) the supervising person has reasonably discharged the duties and obligations required by the written policies and procedures and documented system, and did not have a reasonable basis to believe that the written policies and procedures and documented system were not being followed.[285]

Proposed Rule 15Fk–1(b)(6) would require the CCO to establish, maintain and review policies and procedures reasonably designed to remediate promptly non-compliance issues identified by the CCO.[286] Proposed Rule 15Fk–1(b)(7) would require the CCO to establish and follow procedures reasonably designed for management response and resolution of non-compliance issues.[287]

Proposed Rule 15Fk–1(c)(1) would require that the CCO annually prepare and sign a report describing the compliance policies and procedures (including the code of ethics and conflicts of interest policies) and compliance of the SBS Entity with the Exchange Act and rules and regulations thereunder relating to its business as an SBS Entity.[288] Proposed Rule 15Fk–1(c)(2) would require that each compliance report also contain, at a minimum: A description of the SBS Entity's enforcement of its policies and procedures relating to its business as an SBS Entity; any material changes to the policies and procedures since the date of the preceding compliance report; any recommendation for material changes to the policies and procedures as a result of the annual review, the rationale for such recommendation, and whether such policies and procedures were or will be modified by the SBS Entity to incorporate such recommendation; and any material compliance matters identified since the date of the preceding compliance report.[289] Proposed Rule 15Fk–1(e)(4) would define ''material compliance matter'' to mean any compliance matter about which the board of directors of the SBS Entity would reasonably need to know

[279] *See* Section 15F(k)(2)(A) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1793 (to be codified at 15 U.S.C. 78o–10(k)(2)(A)).

[280] *See* Section 15F(k)(2)(B) of the Exchange Act, Public Law. 111–203, 124 Stat. 1376, 1793 (to be codified at 15 U.S.C. 78o–10(k)(2)(B)).

[281] The requirement to establish, maintain and review policies and procedures reasonably designed to achieve compliance with Section 15F of the Exchange Act and the rules thereunder is based on FINRA Rule 3130, which requires certification that a member has in place processes to ''establish, maintain, and review policies and procedures reasonably designed to achieve compliance with applicable FINRA rules, MSRB rules and federal securities laws and regulations.'' Similar requirements appear in Rule 38a–1(a)(1) under the Investment Company Act of 1940, 17 CFR 270.38a–1(a)(1) (requiring registered investment companies to ''[a]dopt and implement written policies and procedures reasonably designed to prevent violation of the Federal Securities laws by the fund''); and Advisers Act Rule 206(4)–7(a), 17 CFR 275.206(4)–7(a) (requiring registered investment advisers to ''[a]dopt and implement written policies and procedures reasonably designed to prevent violation, by you and your supervised persons, of the [Advisers] Act, and the rules that the Commission has adopted under the [Advisers] Act'').

[282] *See* Section 15F(k)(2)(C) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1793 (to be codified at 15 U.S.C. 78o–10(k)(2)(C)).

[283] *See* Section 15F(k)(2)(D) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1793 (to be codified at 15 U.S.C. 78o–10(k)(2)(D)).

[284] *See* Section 15F(k)(2)(E) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1793 (to be codified at 15 U.S.C. 78o–10(k)(2)(E)).

[285] *Cf.* Compliance Programs of Investment Companies and Investment Advisers, Investment Advisers Act Release No. 2204 (Dec. 17, 2003), 68 FR 74714 (Dec. 24, 2003) at note 78.

[286] *See* Section 15F(k)(2)(F) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1793 (to be codified at 15 U.S.C. 78o–10(k)(2)(F)).

[287] *See* Section 15F(k)(2)(G) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1793 (to be codified at 15 U.S.C. 78o–10(k)(2)(G)).

[288] *See* Section 15F(k)(3)(A) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1794 (to be codified at 15 U.S.C. 78o–10(k)(3)(A)). We believe that there is a drafting error in the reference in Section 15F(k)(3)(A) of the Exchange Act to compliance of the ''major swap participant'' in this provision, and are proposing to apply the requirement with respect to the compliance of the ''major security-based swap participant.''

[289] This requirement is modeled on a similar requirement for chief compliance officers under Investment Company Act Rule 38a–1(4), 17 CFR 270.38a–1(a)(4). The report under the Investment Company Act, however, is not required to be filed with the Commission.

The Commission is proposing a similar requirement for chief compliance officers of security-based swap data repositories. *See* Security-Based Swap Data Repository Registration, Duties and Core Principles, Exchange Act Release No. 63347 (Nov. 19, 2010), 75 FR 77306 (Dec. 10, 2010) (''SDR Registration Release'') (proposing Exchange Act Rule 13n–11(d)(1)).

to oversee the compliance of the SBS Entity, and that involves, without limitation, a violation of the federal securities laws relating to its business as an SBS Entity by the SBS Entity or its officers, directors, employees or agents; a violation of the policies and procedures of the SBS Entity relating to its business as an SBS Entity; or a weakness in the design or implementation of the policies and procedures of the SBS Entity relating to its business as an SBS Entity.[290]

Proposed Rule 15Fk–1(c)(2)(ii)(D) would require the CCO to certify, under penalty of law, the accuracy and completeness of the report.[291] Proposed Rule 15Fk–1(c)(2)(ii)(A) would require that the CCO's annual report accompany each appropriate financial report of the SBS Entity that is required to be furnished or filed with the Commission.[292] To allow the annual report to accompany each appropriate financial report within the required timeframe, proposed Rule 15Fk–1(c)(2)(ii)(B) would require the CCO to provide a copy of the required annual report to the board of directors, the audit committee and the senior officer of the SBS Entity at the earlier of their next scheduled meeting or within 45 days of the date of execution of the certification.[293]

Proposed Rule 15Fk–1(c)(2)(ii)(C) would require that the CCO's annual report include a written representation that the chief executive officer(s) (or equivalent officers) has/have conducted one or more meetings with the CCO in the preceding 12 months, the subject of which addresses the SBS Entity's processes to comply with the obligations of the CCO as set forth in the proposed rules and in Exchange Act Section 15F.[294] To comply with the proposed rule, the subject of the meeting(s) between the chief executive officer and the CCO referenced in the written representation must include: (1) The matters that are the subject of the CCO's annual report; (2) the SBS Entity's compliance efforts with the provisions of Section 15F and the provisions of the Exchange Act and the rules and regulations thereunder relating to its business as an SBS Entity as of the date of such a meeting; and (3) significant compliance problems under Section 15F and plans in emerging business areas relating to its business as an SBS Entity.[295] Although not required by the Dodd-Frank Act, we believe that an annual compliance meeting would help to ensure and comprehensive compliance policies.[296] Under proposed Rule 15Fk–1(c)(2)(iii), if compliance reports are separately bound from the financial statements, the compliance reports shall be accorded confidential treatment to the extent permitted by law.

Finally, proposed Rule 15Fk–1(d) would require that the compensation and removal of the CCO be approved by a majority of the board of directors of the SBS Entity. We are proposing this measure, which is not required by the Dodd-Frank Act, to promote the independence and effectiveness of the CCO. We have proposed a similar requirement for the CCOs of security-based swap data repositories [297] and of investment companies and business development companies.[298] As we explained in proposing other CCO requirements, we are concerned that an entity's commercial interests might discourage a CCO from making forthright disclosure to the board or senior officer about any compliance failures. To help address this potential conflict of interest, the Commission preliminarily believes that only the board of directors of the SBS Entity should be able to set the CCO's compensation or remove an individual from the CCO position.[299]

Request for Comments

The Commission requests comments generally on all aspects of this provision. In addition, we request comments on the following specific issues:

- Would a CCO of an SBS Entity have difficulty discharging any of these obligations? If so, why?
- Should the Commission consider additional obligations to be imposed on a CCO of an SBS Entity? If so, which ones and why?
- Should the Commission define circumstances in which a CCO may report to a senior officer rather than to the board of directors? If so, what should those circumstances be? Why?
- Do any of the CCO obligations conflict with current obligations imposed on a CCO and, if so, why?
- Would the timing of the annual report create any problems for SBS Entities?
- Should the compliance report be furnished rather than filed with the Commission? Why or why not?
- Should the Commission permit a CCO to qualify its report by certifying, under penalty of law, that a report is accurate and complete ''in all material respects''? Why or why not? Is there another approach the Commission should consider to appropriately balance the practical need for SBS Entities to attract and retain qualified CCOs with the statutory provision to require CCOs to certify their reports under penalty of law?
- Should the Commission require the chief executive officer or another senior officer to certify the report, similar to the compliance certification required under FINRA Rule 3130, instead of or in addition to the CCO? [300] Why or why not?

[290] This definition is modeled on the definition of ''material compliance matter'' in Investment Company Act Rule 38a–1(e)(2), 270.38a–1(e)(2). The Commission proposed a similar definition in its rule governing chief compliance officers of security-based swap data repositories. *See* SDR Registration Release (proposing Exchange Act Rule 13n–11(b)(6)).

[291] *See* Section 15F(k)(3)(B)(ii) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1794 (to be codified at 15 U.S.C. 78o–10(k)(3)(B)(ii)).

[292] *See* Section 15F(k)(3)(B)(i) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1794 (to be codified at 15 U.S.C. 78o–10(k)(3)(B)(i)).

[293] *Id.* This timeframe is the same as that provided by FINRA Rule 3130(c) (regarding certification of compliance processes).

[294] *See* FINRA Rule 3130.

[295] This requirement is modeled on the obligations for broker-dealers under FINRA rules. *See* Supplementary Material .04 to FINRA Rule 3130, Content of Meetings between Chief Executive Officer and Chief Compliance Officer.

[296] *See* Exchange Act Sections 15F(h)(1)(B) (authorizing the Commission to prescribe duties for diligent supervision), and 15F(h)(3)(D) (providing authority to prescribe business conduct standards). Public Law 111–203, 124 Stat. 1376, 1789 and 1790 (to be codified at 15 U.S.C. 78o–10(h)(1)(B) and 78o–10(h)(3)(D)).

[297] *See* SDR Registration Release (proposing Exchange Act Rule 13n–11(a)).

[298] *See* 17 CFR 270.38a–1(a)(4).

[299] *See* SDR Registration Release (discussing proposed Exchange Act Rule 13n–11(a)).

[300] FINRA Rule 3130 requires the CEO to certify that:

1. The Member has in place processes to:

(A) Establish, maintain and review policies and procedures reasonably designed to achieve compliance with applicable FINRA rules, MSRB rules and federal securities laws and regulations;

(B) Modify such policies and procedures as business, regulatory and legislative changes and events dictate; and

(C) Test the effectiveness of such policies and procedures on a periodic basis, the timing and extent of which is reasonably designed to ensure continuing compliance with FINRA rules, MSRB rules and federal securities laws and regulations.

2. The undersigned chief executive officer(s) (or equivalent officer(s)) has/have conducted one or more meetings with the chief compliance officer(s) in the preceding 12 months, the subject of which satisfy the obligations set forth in FINRA Rule 3130.

3. The Member's processes, with respect to paragraph 1 above, are evidenced in a report reviewed by the chief executive officer(s) (or equivalent officer(s)), chief compliance officer(s), and such other officers as the Member may deem necessary to make this certification. The final report has been submitted to the Member's board of directors and audit committee or will be submitted to the Member's board of directors and audit committee (or equivalent bodies) at the earlier of their next scheduled meetings or within 45 days of the date of execution of this certification.

Continued

• How, if at all, would the proposed CCO requirements—including those that are not expressly addressed by the Dodd-Frank Act, *e.g.,* the proposed requirements that the CCO meet with the chief executive officer and that the compensation of the CCO be set by the Board—alter the role and function that CCOs may play within SBS Entities? Do the proposed requirements promote an effective compliance function while avoiding undue constraints on a firm's discretion in organizing its business, including that compliance function? Why or why not? How, if at all, could the proposed requirements be altered to provide SBS Entities and CCOs greater flexibility in implementing an effective compliance function?

• If the CCO reports to a senior officer, should the senior officer have the ability to remove the CCO? Should the senior officer have the ability to determine the compensation of the CCO? Under what circumstances and why? If the CCO reports to the board of directors, should the compliance meeting(s) required under proposed Rule 15Fk–1(c)(2)(i)(C) be held between the CCO and the board of directors or a committee of independent directors instead of with the senior officer?

• Should the board or audit committee be required to review the annual compliance report and approve any CCO-recommended remedial steps? Should the board or audit committee be required to authorize alternative remedial steps that the board or audit committee determines are more appropriate than those in the annual compliance report? Should the Commission require the SBS Entity to report to the Commission any alternative remedial steps taken? Why or why not?

III. Request for Comments

A. Generally

The Commission requests comments on all aspects of the proposed rules. The Commission particularly requests comment on the general impact the proposals would have on the market for security-based swaps and on the behavior of participants in that market. The Commission also seeks comment on the proposals as a whole, including their interaction with the other provisions of the Dodd-Frank Act and their advantages and disadvantages when considered in total. In addition, the Commission seeks comment on the following specific issues:

• Do the proposed rules clearly define the obligations to be imposed on SBS Dealers or Major SBS Participants? Are there clarifications or instructions to the proposed requirements that would be beneficial to make? If so, what are they, and what would be the benefits of adopting them?

• Do the proposed rules (considered individually and in their entirety) provide an efficient and effective way to implement the requirements of the Dodd-Frank Act relating to the business conduct of SBS Entities? Why or why not? Are the requirements under the proposed rules appropriately tailored so that the requirements of the Dodd-Frank Act can be met consistent with an SBS Entity's maintaining an economically viable business? Why or why not?

• Do the proposed rules (considered individually and in their entirety) give full effect to the additional protections for special entities contemplated by the statute while avoiding restrictions on SBS Entities that would unduly limit their willingness or ability to provide special entities with access to security-based swaps? Why or why not? How and to what extent will the proposed rules (considered individually and in their entirety) affect the ability of special entities to engage in security-based swaps? How and to what extent will the proposed rules (considered individually and in their entirety) afford special entities the protections contemplated by the Dodd-Frank Act in connection with their security-based swap transactions?

• Would the proposed rules require disclosure of information that that commenters believe should not, or need not, be disclosed? If so, what information, and what are the problems associated with its disclosure?

• Do any proposed requirements conflict with any existing requirement, including any requirement currently imposed by an SRO, such that it would be impracticable or impossible for an SBS Entity that is a member of an SRO to meet both obligations? If so, which one(s) and why?

• Should an SBS Entity be permitted to establish compliance with the proposed business conduct standards by demonstrating compliance with other regulatory standards that impose substantially similar requirements?

• Should any proposed requirements be modified with respect to security-based swaps that are traded on a registered SEF or on a registered national securities exchange? If so, which requirements should be modified, and why?

• Should any proposed requirements be modified with respect to security-based swaps that are cleared but not SEF- or exchange-traded? If so, which requirements and why?

• Should any proposed requirements for SBS Entities be modified? If so, which requirements and why? Should different standards apply to SBS Dealers and Major SBS Participants?

• Should any additional business conduct requirements be imposed on SBS Entities? If so, which requirements and why? Should different standards apply to SBS Dealers and Major SBS Participants? Under what circumstances, and why?

• Should any additional proposed requirements be modified when the counterparty is an SBS Dealer, a Major SBS Participant, a swap dealer or a major swap participant? Another type of market intermediary?

• Are there other counterparties for which certain proposed SBS Entity requirements should be modified? If so, which requirements, in what circumstances, and why?

• Should the Commission delay the compliance date of any of the proposed requirements to allow additional time to comply with those requirements? If so, which requirements, and how much additional time?

B. Consistency With CFTC Approach

The CFTC has proposed rules related to business conduct standards for swap dealers and major swap participants as required under Section 731 of the Dodd-Frank Act.[301] Understanding that the Commission and the CFTC regulate different products, participants and markets and thus, appropriately may take different approaches to various issues, we nevertheless are guided by the objective of establishing consistent and comparable requirements. Accordingly, we request comments generally on (i) The impact of any differences between the Commission and CFTC approaches to business conduct regulation in this area, (ii) whether the Commission's proposed business conduct regulations should be modified to conform to the proposals made by the CFTC, and (iii) whether any business conduct requirements proposed by the CFTC, but not proposed by the Commission, should be adopted by the Commission.

4. The undersigned chief executive officer(s) (or equivalent officer(s)) has/have consulted with the chief compliance officer(s) and other officers as applicable (referenced in paragraph 3 above) and such other employees, outside consultants, lawyers and accountants, to the extent deemed appropriate, in order to attest to the statements made in this certification.

[301] *See* CFTC External Business Conduct Release, *supra,* note 16.

Request for Comments

The Commission requests comments generally on all aspects of the proposed rules as they relate to CFTC rules and regulations. In addition, we request comments on the following specific issues:

- Do the regulatory approaches under the Commission's proposed rulemaking pursuant to Section 764 of the Dodd-Frank Act and the CFTC's proposed rulemaking pursuant to Section 731 of the Dodd-Frank Act result in duplicative or inconsistent obligations for market participants that are subject to both regulatory regimes, or result in gaps or different levels of regulation between those regimes? If so, in what ways should such duplication, inconsistencies or gaps be addressed?
- Are the approaches proposed by the Commission and the CFTC to regulate business conduct comparable? If not, why?
- Are there approaches that would make the regulation more comparable? If so, what?
- Would be appropriate for us to adopt any particular requirements proposed by the CFTC that differ from our proposal? If so, which ones?
- Should the Commission require SBS Entities to perform periodic portfolio reconciliations in which they exchange terms and valuations of each security-based swap with their counterparty and also resolve any discrepancies within a specified period of time? [302] If so, how frequently should portfolio reconciliations be performed and within what time period should all discrepancies be resolved? Should any specific policies and procedures be proposed regarding the method of performing a portfolio reconciliation? Should the Commission require any specific policies and procedures regarding the method of valuing security-based swaps for purposes of performing a portfolio reconciliation? Please explain the current market practice among dealers for performing portfolio reconciliations.
- Should the Commission require SBS Entities to periodically perform portfolio compressions in which the SBS Entity wholly or partially terminates some or all of its security-based swaps outstanding with a counterparty and replaces those security-based swaps with a smaller number of security-based swaps whose combined notional value is less than the combined notional value of the original security-based swaps included in the exercise? [303] If not, why not? Should the Commission require SBS Entities to periodically perform portfolio compressions among multiple counterparties? If not, why not? Please explain the current market practice among dealers for performing portfolio compressions.

We request commenters to provide data, to the extent possible, supporting any such suggested approaches.

IV. Paperwork Reduction Act

Certain provisions of the proposed rules would impose new ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA''). [304] The Commission is submitting the proposed collections of information to the Office of Management and Budget (''OMB'') for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11. The titles for these collections are ''Business Conduct Standards for Security-Based Swap Dealers and Major Security-Based Swap Participants'' and ''Designation of Chief Compliance Officer of Security-Based Swap Dealers and Major Security-Based Swap Participants.'' An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has not yet assigned a control number to the proposed collections of information.

A. Summary of Collections of Information

1. Verification of Status

Proposed Rule 15Fh–3(a) would require an SBS Entity to verify that a counterparty, whose identity is known to the security-based swap dealer or a major security-based swap participant prior to the execution of the transaction, meets the eligibility standards for an ECP and whether the counterparty is a special entity. We expect that in order to verify the status of the counterparty, an SBS Entity would likely obtain written representations from the counterparty, conduct due diligence as part of its ''diligence checklist'' or as required by its internal policies and procedures, or some combination thereof, based upon prior dealings, if any, with the counterparty.

2. Disclosures by SBS Entities

Proposed Rule 15Fh–3(b) would require an SBS Entity to disclose to any counterparty (other than an SBS Entity, swap dealer, or major swap participant) information reasonably designed to allow the counterparty to assess: (1) The material risks and characteristics of a security-based swap; and (2) any material incentives or conflicts of interest that the SBS Entity may have in connection with the security-based swap. The proposed rule would also require that to the extent that these disclosures are not provided in writing prior to the execution of the transaction, the SBS Entity would be required to provide the counterparty with a written version of the disclosure no later than the time of delivery of the trade acknowledgement for the transaction. [305] Proposed Rule 15Fh–3(c) would require an SBS Entity to disclose to any counterparty (other than an SBS Entity, swap dealer, or major swap participant) the daily mark of the security-based swap. Proposed Rule 15Fh–3(d) would require an SBS Entity, before entering into a security-based swap with a counterparty other than an SBS Entity, swap dealer or major swap participant, to determine whether the security-based swap is subject to the mandatory clearing requirements of Section 3C(a) of the Exchange Act and disclose the determination to the counterparty, as well as clearing alternatives available to the counterparty. To the extent that the disclosures required by proposed Rule 15Fh–3(d) are not provided in writing prior to the execution of the transaction, the SBS Entity would be required to provide the counterparty with a written record of the disclosure no later than the delivery of the trade acknowledgement for the transaction.

3. Know Your Counterparty and Recommendations

Proposed Rule 15Fh–3(e) would require an SBS Dealer to establish, maintain and enforce policies and procedures reasonably designed to obtain and retain a record of the essential facts concerning each counterparty whose identity is known to the SBS Dealer prior to the execution of the transaction. The essential facts would be: (1) Facts required to comply with applicable laws, regulations and rules; (2) facts required to implement the SBS Dealer's credit and operational risk management policies in connection

[302] The CFTC has proposed to require periodic portfolio reconciliations. *See* Confirmation, Portfolio Reconciliation and Portfolio Compression Requirements for Swap Dealers and Major Swap Participants, 75 FR 81519 (Dec. 28, 2010).

[303] The CFTC has proposed to require periodic portfolio compressions. *Id.*

[304] 44 U.S.C. 3501 *et seq.*

[305] The Commission is separately required to propose a rule regarding reporting and recordkeeping requirements for SBS Entities. *See* Exchange Act Section 15F(f)(2), Public Law 111–203, 124 Stat. 1376, 1788 (to be codified at 15 U.S.C. 78o–10(f)(2)) (''The Commission shall adopt rules governing reporting and recordkeeping for security-based swap dealers and major security-based swap participants'').

with transactions entered into with such counterparty; (3) information regarding the authority of any person acting for such counterparty; and (4) if the counterparty is a special entity, such background information regarding the independent representative as the SBS Dealer reasonably deems appropriate.

Proposed Rule 15Fh–3(f)(1) would require an SBS Dealer to have a reasonable basis to believe: (i) Based on reasonable diligence, that the recommended security-based swap or trading strategy involving a security-based swap is suitable for at least some counterparties; and (ii) that a recommended security-based swap or trading strategy involving a security-based swap is suitable for the counterparty. To establish a reasonable basis for a recommendation, an SBS Dealer would need to have or obtain relevant information regarding the counterparty, including the counterparty's investment profile, trading objectives, and its ability to absorb potential losses associated with the recommended security-based swap or trading strategy. Under proposed Rule 15Fh–3(f)(2), an SBS Dealer would fulfill its suitability obligation in proposed Rule 15Fh–3(f)(1) with respect to a particular counterparty if: (1) The SBS Dealer reasonably determines that the counterparty (or its agent) is capable of independently evaluating the investment risks related to the security-based swap or trading strategy; (2) the counterparty (or its agent) affirmatively represents that it is exercising its independent judgment in evaluating the recommendation; and (3) the SBS Dealer discloses to the counterparty that it is acting in its capacity as a counterparty and is not undertaking to assess the suitability of the security-based swap or trading strategy. The representations to document this ''institutional suitability'' must be in writing. The requirements of proposed Rule 15Fh–3(f) would not apply if the counterparty is an SBS Entity, swap dealer or major swap participant.[306] An SBS Dealer that is recommending a security-based swap or trading strategy involving a security-based swap to a special entity would be deemed to have satisfied its obligations pursuant to proposed Rule 15Fh–3(f) with respect to the special entity if: (1) The SBS Dealer is acting as an advisor to the special entity and complies with the requirements of proposed Rule 15Fh–4(b); or (2) the SBS Dealer is deemed not to be acting as an advisor to the special entity pursuant to proposed Rule 15Fh–2(a).[307]

[306] Proposed Rule 15Fh–3(f)(1).

[307] Proposed Rule 15Fh–3(f)(3).

4. Fair and Balanced Communications

Proposed Rule 15Fh–3(g) would require that an SBS Entity communicate with its counterparties in a fair and balanced manner based on principles of fair dealing and good faith. The proposed rule would require, among other things, that any statement of potential opportunities or advantages be balanced by a statement of the corresponding risks with the same degree of specificity.

5. Supervision

Proposed Rule 15Fh–3(h) would require an SBS Entity to establish, maintain and enforce a system to supervise, and to diligently supervise, its business and its associated persons with a view to preventing violations of the applicable federal securities laws and the rules and regulations thereunder relating to its business as an SBS Entity. The proposed rule would require the SBS Entity to designate a qualified person with supervisory responsibility for each type of business for which registration as an SBS Entity would be required. The SBS Entity would be required to: Designate at least one supervisor; use reasonable efforts to determine all supervisors are qualified; establish, maintain and enforce written policies and procedures that are reasonably designed to achieve compliance with applicable securities laws, rules and regulations; and establish and maintain written policies and procedures to comply with the duties set forth in Section 15F(j) of the Exchange Act. Such written policies and procedures would be required to include, at a minimum, procedures for: Review of security-based swap transactions; review of internal and external written communications; periodic review of the business; reasonable investigation of the background of associated persons; monitoring employee personal accounts away from the firm; a description of the supervisory system, including identification of the supervisory personnel and their scope of supervisory responsibility; preventing a supervisor from supervising his or her own activities or supervising an employee who determines the supervisor's compensation or continued employment; and preventing the standard of supervision from being reduced due to conflicts of interest with the person being supervised. These supervisory requirements are similar to existing supervision requirements for registered broker-dealers.

6. SBS Dealers Acting as Advisors to Special Entities

Proposed Rule 15Fh–4(b) would require an SBS Dealer acting as an advisor to make reasonable efforts to obtain such information as it considers necessary to make a reasonable determination that a security-based swap or trading strategy involving a security-based swap is in the best interests of the special entity. The information that would be required to be collected to make this determination includes, but is not limited to: The authority of the special entity to enter into the transaction; the financial status and future funding needs of the special entity; the tax status of the special entity; the investment or financing objectives of the special entity; the experience of the special entity with respect to security-based swap transactions generally and of the type and complexity being recommended; whether the special entity has the financial capability to withstand changes in market conditions during the term of the security-based swap; and other relevant information. In order for an SBS Dealer to establish that it is not acting as an advisor under proposed Rule 15Fh–2(a): (1) The special entity must represent in writing that the special entity will not rely on advice provided by the SBS Dealer and the special entity will rely on the advice of a qualified independent representative; (2) the SBS Dealer must have a reasonable basis to believe that the special entity has a qualified independent representative; and (3) the SBS Dealer must disclose to the special entity that the SBS Dealer would not be undertaking to act in the best interest of the special entity, as otherwise required by Section 15F(h)(4) of the Exchange Act. This proposed Rule 15Fh–4(b) would not apply if the transaction is executed on a SEF or an exchange and the SBS Dealer does not know the identity of the counterparty at the time of the transaction.

7. SBS Entities Acting as Counterparties to Special Entities

Proposed Rule 15Fh–5 would require an SBS Entity to have a reasonable basis to believe that the special entity has an independent representative that is independent of the SBS Entity and that meets certain specified qualifications, including that the independent representative: Has sufficient knowledge to evaluate the transaction and related risks; is not subject to a statutory disqualification; undertakes a duty to act in the best interests of the special entity; makes appropriate and timely

disclosures to the special entity of material information concerning the security-based swap; will provide written representations to the special entity regarding fair pricing and appropriateness of the security-based swap; in the case of employee benefit plans subject to ERISA, is a fiduciary as defined in Section 3(21) of ERISA; and in the case of a State, State agency, city, county, municipality, other political subdivision of a State, or governmental plan, is subject to restrictions on certain political contributions. An SBS Entity could reasonably rely on written representations to form a reasonable basis to believe an independent representative meets certain of these qualifications. An SBS Entity would need to engage in reasonable due diligence for any qualification for which it could not reasonably rely on representations. In addition, with respect to the independence of the independent representative, the SBS Entity would need to undertake some additional inquiry, such as review of the SBS Entity's own books and records.

Proposed Rule 15Fh–5(b) would require that, before the initiation of a security-based swap, an SBS Dealer disclose in writing the capacity in which the SBS Dealer is acting. If the SBS Dealer is acting in more than one capacity with respect to the counterparty or has acted in more than one capacity with respect to the counterparty in the last twelve months, it must also disclose the material differences among such capacities. Proposed Rule 15Fh–5 would not apply if the transaction is executed on a SEF or an exchange and the SBS Entity does not know the identity of the counterparty at any time up to and including execution of the transaction.[308]

8. Political Contributions

Proposed Rule 15Fh–6 would prohibit an SBS Dealer from offering to enter into, or entering into security-based swaps with a municipal entity within two years after any contribution by the SBS Dealer or its covered associates to an official of such municipal entity, subject to certain exceptions. In order to determine compliance with the rule, the SBS Dealer would need to maintain certain records of contributions by the SBS Dealer and any of its covered associates.[309] The SBS Dealer would also need to collect information regarding contributions by its covered associates made within the six months prior to becoming covered associates.

9. Chief Compliance Officer

Proposed Rule 15Fk–1 would require an SBS Entity to designate an individual to serve as CCO. Under proposed Rule 15Fk–1, the CCO would be responsible for, among other things: Reviewing the compliance by the SBS Entity with the security-based swap requirements described in Section 15F of the Exchange Act; promptly resolving any conflicts of interest, in consultation with the board or the senior officer; administering policies and procedures required under Section 15F of the Exchange Act; establishing, maintaining and reviewing policies and procedures reasonably designed to ensure compliance with the Exchange Act and the rules and regulations thereunder relating to its business as an SBS Entity; establishing, maintaining and reviewing policies and procedures reasonably designed to remediate promptly non-compliance issues identified by the CCO; and establishing and following procedures reasonably designed for the prompt handling, management response, remediation, retesting, and resolution of non-compliance issues. The CCO would also be required under proposed Rule 15Fk–1 to submit annual compliance reports accompanying each appropriate financial report of the SBS Entity that is required to be furnished to or filed with the Commission and the board of directors and audit committee (or equivalent bodies) of the SBS Entity. These annual compliance reports are required to include a description of: (1) The compliance by the SBS Entity with the Exchange Act and rules and regulations thereunder relating to its business as an SBS Entity; (2) each policy and procedure of the SBS Entity described above; (3) the SBS Entity's enforcement of the policies and procedures relating to its business as an SBS Entity; (4) any material changes to the policies and procedures since the date of the prior report; (5) any recommendations for material changes to the policies and procedures as a result of the annual review, the rationale for the recommendations, and whether such recommendations would be incorporated; and (6) any material compliance matters. The compliance report must also include a written representation that the senior officer has conducted one or more meetings with the CCO in the preceding 12 months, and a certification that the compliance report is accurate and complete.

B. Proposed Use of Information

1. Verification of Status

Proposed Rule 15Fh–3(a) would require an SBS Entity to determine whether its counterparty is an ECP before the execution of a security-based swap other than on a registered national securities exchange or SEF. An SBS Entity would use this information to comply with Section 6(l) of the Exchange Act (15 U.S.C. 78(f)(l)), which prohibits a person from entering into a security-based swap with a counterparty that is not an ECP other than on a national securities exchange. We are not proposing to specify the means by which SBS Entities satisfy this requirement. The proposed rule also would require the SBS Entity to determine whether a counterparty is a special entity. An SBS Entity would use this information, in turn, to determine the need to comply with the requirements applicable to dealings with special entities under proposed Rules 15Fh–4(b) and 15Fh–5. In addition to assisting the CCO in determining compliance with the statute and proposed rules, this collection of information would be used by the Commission staff in its examination and oversight program.

2. Disclosures by SBS Entities

The disclosures required to be provided by SBS Entities to a counterparty (other than an SBS Entity or a swap dealer or major swap participant) would help the counterparty understand the material risks and characteristics of a particular security-based swap, as well as the material incentives or conflicts of interest that the SBS Entity may have in connection with the security-based swap. As a result, these disclosures would assist the counterparty in assessing the transaction. The disclosures would provide counterparties with a better understanding of the expected performance of the security-based swap under various market conditions. They would also give counterparties additional transparency and insight into the pricing and collateral requirements of security-based swaps. Proposed Rule 15Fh–3(d) would require SBS Entities to notify counterparties of the clearing alternatives available to them. In addition to assisting the SBS Entity with its internal supervision and the CCO to determine compliance with the statute and proposed rules, this collection of information would be used by the Commission staff in its examination and oversight program.

[308] Proposed Rule 15Fh–5(c).

[309] *See* notes 169 and 305, *supra,* regarding reporting and recordkeeping requirements generally for SBS Entities.

3. Know Your Counterparty and Recommendations

These collections of information would help an SBS Dealer to comply with applicable laws, regulations and rules. They would also assist an SBS Dealer in effectively dealing with the counterparty, including by making recommendations that are appropriate for the counterparty, and by collecting information from the counterparty necessary for the SBS Dealer's credit and risk management purposes. These collections of information would also assist an SBS Dealer in determining whether it would be reasonable to rely on various representations from a counterparty and evaluating the risks of trading with that counterparty. The information would also assist the CCO in determining that the SBS Entity had policies and procedures reasonably designed to obtain and retain essential facts concerning each known counterparty and to make suitable recommendations to its counterparties. The Commission staff would also use these collections of information in its examination and oversight program.

4. Fair and Balanced Communications

This collection of information concerning the risks of a security-based swap would assist an SBS Entity in communicating with counterparties in a fair and balanced manner. It would also assist an SBS Dealer in making suitable recommendations to counterparties, and assist the CCO in ensuring that the SBS Entity is communicating with counterparties in a fair and balanced manner based on principles of fair dealing and good faith. The receipt of information in a fair and balanced manner would assist the counterparty in making more informed investment decisions. The Commission staff would also use this collection of information in its examination and oversight program.

5. Supervision

The collection of information in connection with the establishment, maintenance and enforcement of a supervisory system would assist an SBS Entity in achieving compliance with all applicable securities laws, rules and regulations. The CCO may use these collections of information in discharging his or her duties under proposed Rule 15Fk–1 and determining whether remediation efforts are required. The collection of information would also be useful to supervisors in understanding and carrying out their supervisory responsibilities. The Commission staff would also use this collection of information in its examination and oversight program.

6. SBS Dealers Acting as Advisors to Special Entities

Certain information that would be collected under proposed Rule 15Fh–4(b) would assist an SBS Dealer that is acting as an advisor to a special entity to act in the best interests of the special entity. Other information collected under proposed Rule 15Fh–2(a) could assist an SBS Dealer seeking to establish that it is not acting as an advisor to a special entity. The collections of information would assist a CCO in determining compliance with the provisions of the Exchange Act by the SBS Dealer. The Commission staff would also use this collection of information in its examination and oversight program.

7. SBS Entities Acting as Counterparties to Special Entities

The information that would be collected under Proposed Rule 15Fh–5(a) would assist an SBS Entity in forming a reasonable basis that the special entity has an independent representative that meets the requirements of the rule. Disclosures under proposed Rule 15Fh–5(b) regarding the capacity in which an SBS Dealer is operating would reduce confusion by a special entity as to whether an SBS Dealer would be acting in the interests of the special entity or as a counterparty or principal on the other side of a transaction to the special entity with potentially adverse interests. These collections of information would also assist the CCO in determining compliance with the provisions of the Exchange Act by the SBS Entity. The Commission staff would also use this collection of information in its examination and oversight program.

8. Political Contributions

Proposed Rule 15Fh–6 is intended to deter SBS Dealers from participating, even indirectly, in pay to play practices. The information that would be collected under this proposed rule would assist the SBS Dealer and the Commission in verifying this deterrence. The proposed rule would also assist the chief compliance officer in determining compliance with the provisions of the Exchange Act by an SBS Dealer. The Commission staff would use this collection of information in its examination and oversight program.

9. Chief Compliance Officer

The information that would be collected under proposed Rule 15Fk–1 would assist the CCO in overseeing and administering compliance by the SBS Entity with the provisions of the Exchange Act and the rules and regulations thereunder relating to its business as an SBS Entity. The Commission staff would also use this collection of information in its examination and oversight program.

C. Respondents

The Commission preliminarily believes, based on data obtained from DTCC and conversations with market participants, that approximately 50 entities may fit within the definition of security-based swap dealer,[310] and as many as 10 entities may need to determine whether they come within the definition of major security-based swap participant.[311] The Commission does not expect that more than five entities will be major security-based swap participants. Accordingly, we are using this estimate for the purposes of calculating the reporting burdens. Further, because prior to the Dodd-Frank Act, market participants have not had to distinguish between swaps and security-based swaps for regulatory purposes, the Commission preliminarily believes that the majority of firms that may register as SBS Entities (approximately 35) also will be engaged in the swaps business, and will register with the CFTC as swap dealers or major swap participants. As a result, these entities would also be subject to the business conduct standards applicable to swap dealers and major swap participants. In addition, a broker-dealer may seek to register as an SBS Dealer so that it can enter into security-based swaps as a principal with customers who, among other things, may be holding securities positions and may wish to hedge those positions with security-based swaps. The Commission estimates that approximately 16 registered broker-dealers will also register as SBS Dealers.[312] Finally, the costs of registration and associated regulation may cause an entity that is not otherwise registered with the CFTC or the Commission to structure its business so as to not have to register as an SBS Entity. Consequently, the Commission estimates that fewer than eight firms not otherwise registered with the CFTC or the Commission will register as SBS Entities.

The Commission preliminarily believes, based on information currently

[310] Depending on capital and other requirements for SBS Dealers and how businesses choose to respond to such requirements, the actual number of SBS Dealers may be significantly fewer. *See also* Definitions Release.

[311] *See* Definitions Release.

[312] *Id.*

available to it, that there are and would continue to be approximately 8,500 market participants, of which approximately 1,200 are special entities.[313] Based upon the number of municipal advisors that have registered with the Commission, we estimate there will be approximately 325 third-party independent representatives for special entities.[314] The Commission also estimates that approximately 95% of special entities would use a third-party independent representative in their security-based swap transactions.[315] As a result, for the purposes of calculating reporting burdens, the Commission estimates that the remaining 5% of special entities, or 60 special entities, have employees who currently negotiate on behalf of, and advise, the special entity regarding security-based swap transactions and could likely fulfill the obligations of the independent representative.[316] Consequently, the Commission estimates a total of 385 potential independent representatives.[317] The Commission seeks comment on its estimates as to the number of participants in the security-based swap market that would be required to comply with the business conduct standards pursuant to proposed Rules 15Fh–1 through 15Fh–6 and proposed Rule 15Fk–1.

[313] The estimate is based on available market data for November 2006–September 2010 provided by DTCC. Commission staff has identified approximately 8,567 market participants and approximately 1,200 special entities during this time period, but we are using 8,500 market participants and 1,200 special entities as estimates for these purposes to allow for market participants and special entities that trade less frequently, no longer trade or trade under multiple designations. For the purposes of these estimates, we have included foreign pension plans and 501(c)(3) organizations generally within the category of special entity.

[314] As of April 15, 2011, approximately 307 entities that are registered as municipal advisors with the Commission indicated that they expected to provide advice with respect to swaps. We expect that many of these municipal advisors will also act as independent representatives for other special entities. We also expect that some number of these municipal swap advisors will limit their services to swaps and not security-based swaps. The Commission therefore estimates that approximately 325 municipal swap advisors will act as independent representatives to special entities with respect to security-based swaps, we solicit comments as to the accuracy of this information.

[315] The estimate is based on available market data for November 2006–September 2010 provided by DTCC that indicates approximately 95% of special entities used third-party investment advisers in connection with security-based swap transactions.

[316] *Id.*

[317] The estimate is based on the following calculation: 325 third-party independent representatives + 60 in-house independent representatives

D. Total Annual Reporting and Recordkeeping Burdens

Proposed Rules15Fh–1 to 15Fh–6 are intended to be very similar, to the extent practical, to the business conduct standards that would apply to swap dealers or major swap participants pursuant to the CFTC's proposed business conduct rules.[318] As a result, to the extent the SBS Entity complies with the CFTC's business conduct standards, the Commission expects there would be relatively little additional burden to comply with the requirements under the Commission's proposed business conduct standards.[319] A number of these standards are based on existing FINRA rules and, accordingly, the Commission expects that the estimated 16 SBS Entities that are also registered as broker-dealers are already complying with a number of these requirements. We expect that some SBS Dealers will be banks.[320] Banking agencies, such as the Office of the Comptroller of the Currency, have issued guidance to national banks that engage in financial derivatives transactions regarding business conduct procedures, and, accordingly, we expect that the banks that may register as SBS Entities are also already complying with these requirements.[321] In addition, to the extent that the requirements in proposed Rules 15Fh–3 and 15Fh–5 reflect industry best practices, a respondent that is already following industry best practices would already be collecting much, if not all, of this information, and would have systems in place to collect such information. We recognize that entities may need to modify existing practices and systems to comply with the specific requirements of the proposed rules. Further, while the Commission does not have information as to the number of SBS Entities that have already implemented these best practices, we understand that most of the large SBS Dealers have implemented many of the recommended best practices, and we have considered this information in developing its estimates.

[318] *See* CFTC External Business Conduct Release, *supra,* note 16.

[319] However, because the CFTC has not yet adopted final rules, we are using estimates that assume the CFTC rules are not in place and that the registrants have incurred a de novo burden to comply with the Commission rules.

[320] The estimate is based on available market data for November 2006–September 2010, the Commission estimates that approximately 240 banks executed security-based swaps during this time. The Commission anticipates that some, but not all of these banks will likely register as SBS Dealers.

[321] *See* Risk Management of Financial Derivatives, Office of Comptroller of the Currency Banking Circular No. 277 (Oct. 27, 1993).

In addition, the Commission notes that regulation of the security-based swap markets, including by means of these proposed rules, could impact market participant behavior.

1. Verification of Status

As discussed above, for the purposes of these requirements, the Commission estimates that approximately 55 SBS Entities would be required to verify whether a counterparty is an ECP or special entity, as required by proposed Rule 15Fh–3(a). This requirement is the same for the business conduct standards proposed by the CFTC.[322] The Commission also believes that many SBS Entities would not incur significant additional expense, because they already collect this information as part of their ''due diligence checklists.'' Some respondents may simply update their existing due diligence checklists. The Commission expects that to the extent an SBS Entity does not have an existing mechanism in place to determine the eligibility of the counterparty and whether it is a special entity, the SBS Entity may engage outside counsel to prepare for collecting this information. The Commission conservatively estimates that SBS Entities would need to engage outside counsel to review existing process and develop initial processes, if necessary, at a cost of $400 per hour for an average of 15 hours per respondent, resulting in a total outside initial cost burden of $6,000 for each of these SBS Entities.[323] The Commission preliminarily believes, based on information currently available to it, that there are and would continue to be a total of approximately 8,500 market participants.[324] The Commission estimates that the SBS Entities would take initially 1 hour per transaction to collect the information for an initial aggregate burden of approximately 47,000 hours or an average of approximately 855 hours per SBS Entity.[325]

[322] *See* CFTC External Business Conduct Release, 75 FR at 80658. Accordingly, the SBS Entities that would also be registered as a swap dealer or major swap participant with the CFTC would have verification procedures for engaging in swaps.

[323] The estimate is based on the Commission's experiences in similar matters such as a registrant's determination regarding whether an investor is an accredited investor for the purposes of Regulation D. The same estimate for the hourly cost for legal services was used by the Commission in the proposed consolidated audit trail rule. Consolidated Audit Trail, Exchange Act Release No. 62174, 75 FR 32556 (June 8, 2010).

[324] *See* note 313, *supra,* regarding the estimate for the number of market participants.

[325] The estimate is based on the number of unique SBS Dealer to non-SBS Dealer trading relationships identified in the market data for November 2006–

Continued

2. Disclosures by SBS Entities

The estimates in this paragraph reflect the Commission's experience with burden estimates for similar disclosure requirements and as a result of our discussions with market participants.[326] Pursuant to proposed Rule 15Fh–3(b), (c), and (d), SBS Entities would be required to provide certain disclosures to market participants. It is our understanding that most of the large SBS Dealers already provide their counterparties disclosures similar to those that would be required under proposed Rules 15Fh–3(b) and (c). Given that the material characteristics are generally included in the documentation of a security-based swap, such as the master agreement, credit support annex, trade confirmation or other documents, the Commission does not anticipate that any additional burden will be required for the disclosure of material characteristics.[327] For other required disclosures relating to material risks, incentives or conflicts of interest, the Commission anticipates that many SBS Entities would revise existing disclosures and tailor them to this context. For example, many SBS Dealers provide a statement of potential risks related to investing in certain security-based swaps in documents describing such instruments.

In some cases, such as disclosures about the daily mark for a cleared security-based swap, the proposed rules contemplate receiving the core valuation information from an external source with only limited administrative handling expected to be necessary to pass the disclosure to counterparties. For uncleared, security-based swaps, the Commission preliminarily believes that the SBS Entities may need to slightly modify the models used for calculating variation margin to calculate the daily mark required by proposed Rule 15Fh–3(c) for uncleared security-based swaps. The Commission does not currently have an expectation of the proportion of security-based swaps that will be cleared as a result of the Dodd-Frank Act and the rules promulgated thereunder.[328] Existing accounting standards and other disclosure requirements under the Exchange Act, such as FASB Accounting Standards Codification Topic 820, Fair Value Measurements and Disclosures, or Item 305 of Regulation S–K, already require the description of the methodology and assumptions with respect to models used in the derivatives context.

The Commission preliminarily believes that SBS Entities will use internal staff to revise existing disclosures to comply with proposed Rules 15Fh–3(b) and (c) and assist in preparing language to comply with proposed Rule 15Fh–3(d) regarding the clearing options available for the particular security-based swap. The Commission also anticipates that disclosures of material risks for similar types and classes of security-based swaps would be similar and subsequent transactions will require much less time to review and revise applicable disclosures.

Because the Commission is unaware of any definitive data regarding how many SBS Entities currently provide these disclosures, the Commission has conservatively estimated that all SBS Entities would require additional time to provide at least some of these disclosures. The Commission estimates that there has been an average of approximately 400,000 new security-based swap contracts traded annually between an SBS Dealer and a counterparty that is not an SBS Dealer, and these security-based swaps would likely require these disclosures.[329] In view of the factors discussed in the Cost-Benefit Analysis section and elsewhere in this release, the Commission recognizes that the time required to develop an infrastructure to provide these disclosures would vary significantly depending on, among other factors, the complexity and nature of the SBS Entity's security-based swap business, its market risk management activities, its existing disclosure practices, and other applicable regulatory requirements. Under the proposed rule, SBS Entities could use, where appropriate, standardized formats to make certain required disclosures of material information to their counterparties, and to include such disclosures in a master or other written agreement between the parties, if agreed by the parties. The Commission recognizes that some disclosures particularized to the transaction would likely be necessary to adequately meet all of an SBS Entity's disclosure obligations. The Commission also expects that because the reporting burden generally would require refining or revising existing disclosure processes, that the disclosures would be prepared internally.

As a result, the Commission estimates that SBS Entities would initially require three persons from trading and structuring, three persons from legal, two persons from operations, and four persons from compliance, for 100 hours each. This team would analyze the changes necessary to comply with the new disclosure requirements, including the redesign of current compliance systems if necessary, and the creation of functional requirements and system specifications for any systems development work that may be needed to automate the disclosure process.[330] This would amount to an initial cost burden of 66,000 hours.[331] Following the initial analysis and specifications development effort, the Commission estimates that half of these persons would be required to spend 20 hours annually to re-evaluate and modify the disclosures and system requirements as necessary, amounting to an ongoing annual burden of 6,600 hours.[332] The Commission also estimates that to create and maintain an information technology infrastructure to the specifications identified by the team above, each SBS Entity would require, on average, eight full-time persons for six months of systems development, programming and testing, amounting to a total initial

September 2010 provided by DTCC. This estimate includes each SBS Dealer affiliate with the same non-SBS Dealer entity as a separate trading relationship. As a result, this number may overestimate the actual number of trading relationships with non-SBS Dealers.

[326] *See* Disclosure of Accounting Policies for Derivative Financial Instruments and Derivative Commodity Instruments and Disclosure of Quantitative and Qualitative Information about Market Risk Inherent in Derivative Financial Instruments, Other Financial Instruments and Derivative Commodity Instruments, Securities Act Release No. 7386 (Jan. 31, 1997), 62 FR 6044 (Feb. 10, 1997).

[327] To the extent that disclosure of material characteristics is initially provided orally, the additional burden of providing a written version of the disclosure at or before delivery of the trade confirmation will be considered in connection with the overall reporting and recordkeeping burdens of the SBS Entity. *See* notes 160 and 305, *supra*.

[328] The Commission has obtained data from DTCC on new and assigned CDS trades in U.S. dollars during the month of November 2010 for ICE Trust. Cleared CDS trades were 5.24% by notional amount of all new or assigned single name trades, and 20.69% by notional amount of all new or assigned index trades.

[329] Available market data for November 2006–September 2010 provided by DTCC indicated approximately 4,000,000 transactions between SBS Entities and non-SBS Entities during that time period. Of these, approximately 40% (or 1,600,000) are new trades; the remaining are assignments and terminations, which may not require the same level of disclosure. To obtain an approximate average annual number of transactions, we divided 1,600,000 transactions by 47 (months) and multiplied by 12 and rounded to 400,000.

[330] Some SBS Entities may choose to utilize in-house counsel to review, revise and prepare these disclosures. The Commission does not currently have an estimate as to the proportion of SBS Entities that would use outside counsel, but has considered the alternative in developing its estimates.

[331] The estimate is based on the following calculation: (55 SBS Entities) × (12 persons) × (100 hours).

[332] The estimate is based on the following calculation: (55 SBS Entities) × (6 persons) × (20 hours).

burden of 440,000 hours.[333] The Commission further estimates that maintenance of the system will require two full-time persons for a total of ongoing burden of 220,000 hours annually.[334]

3. Know Your Counterparty and Recommendations

Proposed Rules 15Fh–3(e) and (f) are based on existing FINRA rules.[335] However, the ''know your counterparty'' requirement in proposed Rule 15Fh–3(e) would also require an SBS Dealer to consider its credit and operational risk management policies in determining the information to collect from its counterparty. If the SBS Dealer is a counterparty to a special entity, proposed Rule 15Fh–3(e) would also require the SBS Dealer to obtain and retain a record of the relevant background of the independent representative.[336] The Commission expects that given the institutional nature of the participants involved in security-based swaps, most SBS Dealers would obtain the representations in proposed Rule 15Fh–3(f)(2) or proposed Rule 15Fh–3(f)(3)(ii) to comply with proposed Rule 15Fh–3(f).

In addition, many SBS Dealers already collect this type of information in connection with their due diligence checklists. Banking agencies have also issued guidance to national banks regarding similar procedures.[337] However, the Commission does not currently have an estimate of how many SBS Entities are expected to be subject to this banking guidance.[338] The Commission also preliminarily believes that other SBS Dealers generally already create and maintain these records under prudent recordkeeping procedures. However, as is true in the broker-dealer context, because each SBS Dealer is likely to tailor its procedures to its particular corporate culture and existing policies and procedures, we expect that the practices of SBS Dealers in complying with the proposed rule would vary greatly. In addition, the SBS Dealer may collect the information required at various points in the relationship with its counterparty, including at the establishment of the account, periodic updates, or with the execution of each security-based swap. The Commission has considered all of the foregoing in preparing the estimate regarding reporting burdens.

The estimates in this paragraph reflect the Commission's experience with and burden estimates for similar collections of information, as well as our discussions with market participants.[339] The Commission preliminarily believes that most SBS Dealers currently have policies and procedures in place for knowing their counterparties, either through due diligence checklists or for compliance with FINRA standards. The Commission estimates that, on average, these records would require each SBS Dealer to spend approximately three to five hours initially to review existing policies and procedures and document the collection of information necessary to comply with its ''know your counterparty'' obligations for a total initial burden of 250 hours.[340] The Commission also estimates an SBS Dealer would spend an average of approximately 30 additional minutes each year per unique non-SBS Dealer counterparty to assess whether the SBS Dealer is in compliance with the requirements to make suitable recommendations, a total ongoing burden of approximately 23,500 hours annually,[341] or an average of 470 hours annually per SBS Dealer.[342] The Commission also believes that many SBS Dealers will not incur significant additional expense because they already collect this information as part of current practices.[343]

The Commission expects that much of the information relating to the background and experience of the independent representative is already included in the marketing materials of the third-party independent representatives and as a result, would only require a minimal amount of time for the independent representative to provide to the special entity and/or SBS Dealer.

4. Fair and Balanced Communications

Proposed Rule 15Fh–3(g)(3) would require that statements of potential opportunities must be balanced by an equally detailed statement of corresponding risks. In addition, we note that some risk disclosures would already be addressed in proposed Rule 15Fh–3(b) discussed above, which would require an SBS Entity to disclose the material risks of the transaction, the burden for which is discussed above. We expect this discussion of material risks of the transaction to be included in the documentation for the security-based swap. Furthermore, proposed Rule 15Fh–3(g) is based on existing FINRA rules so for the 16 registered broker-dealers that are expected to register as SBS Entities, they already would be subject to similar requirements with respect to other securities pursuant to NASD Rules 3010 and 3012. In addition, for the SBS Entity's own risk management purposes, currently for certain products, its existing marketing materials already include a general statement of risks that accompany a general description of the security-based swap. For the remaining 39 SBS Entities, the Commission assumes that SBS Entities would likely send their existing marketing materials to outside counsel for review and comment. As a result, the Commission estimates that each SBS Entity will likely incur $6,000 in legal costs, or $234,000 in the aggregate initial burden, to draft or review statements of potential opportunities and corresponding risks in the marketing materials for equity swaps, credit default swaps and total return swaps, which comprise the vast majority of security-based swaps.[344] For more bespoke transactions, the cost of outside counsel to review the marketing materials will depend on the complexity, novelty and nature of the product, but the Commission would expect a much longer review for more novel products.

[333] The estimate is based on the following calculation: (55 SBS Entities) × (4 persons) × (2,000 hours).

[334] The estimate is based on the following calculation: (55 SBS Entities) × (2 persons) × (2,000 hours).

[335] *See* note 26, *supra,* regarding FINRA Rules 2090 and 2111 (effective July 9, 2012).

[336] To the extent that an SBS Dealer is a registered broker or dealer, it should already have processes and procedures in place to comply with similar requirements with respect to other securities. *See* FINRA Rule 2090 (requiring broker-dealers to know and retain essential facts, ''concerning every customer and concerning the authority of each person acting on behalf of such customer'').

[337] *See* Risk Management of Financial Derivatives, Office of Comptroller of the Currency Banking Circular No. 277 (Oct. 27, 1993).

[338] *See* note 320, *supra,* regarding banks engaged in security-based swaps.

[339] *See* Books and Records Requirements for Brokers and Dealers under the Securities Exchange Act of 1934, Exchange Act Release No. 44992 (Oct. 26, 2001), 67 FR 58284 (Nov. 2, 2001).

[340] The Commission is conservatively using the high end of the range for the purposes of estimating these reporting burdens.

[341] The estimate is based on the following calculation: (47,000 transactions with non-SBS Dealer counterparties) × 30 minutes/60 minutes. *See* note 325 regarding the number of transactions with non-SBS Dealer counterparties.

[342] To the extent that the SBS Dealer is unfamiliar with the counterparty, the Commission would expect a greater time burden and as an SBS Dealer becomes more familiar with the particular counterparty, the Commission would expect a lesser time burden. As a result, we use 30 minutes as an average estimate.

[343] *See* Sections IV.C and D.

[344] The Commission estimates the review of the marketing materials for each of these categories would require 5 hours of outside counsel time at a cost of $400 per hour. This estimate also assumes that each SBS Entity engages in all three categories of transactions.

5. Supervision

Proposed Rule 15Fh–3(h) is based on existing FINRA rules so to the extent that an SBS Entity is a registered broker-dealer, we expect that the SBS Entity would already be complying with similar requirements with respect to other securities pursuant to NASD Rules 3010 and 3012.[345] Broker-dealers presently maintain lists of principals or branch managers responsible for supervising each of their offices pursuant to NASD 3010 and 3012 and other applicable SRO rules, and that they also have lists of associated persons who operate out of each office location. These rules currently require a broker-dealer to have supervisory systems in place that include similar obligations to achieve compliance with applicable securities laws, regulations and rules.[346] Banking agencies have also issued guidance to national banks regarding similar procedures.[347]

The estimates in this paragraph reflect the foregoing information and the Commission's experience with and burden estimates for similar collections of information. While each of the policies and procedures required by proposed Rule 15Fh–3(h) will vary in exact cost, the Commission estimates that such policies and procedures would require an average of 210 hours per respondent per policy and procedure to prepare and implement,[348] or an average of 1,890 burden hours per SBS Entity, resulting in an aggregate initial burden of 103,950 hours.[349] The Commission also expects that many SBS Entities would engage outside counsel to assist them in preparing for the collection of information required under this rule at a rate of $400 per hour [350] for an average of 450 hours per respondent for a minimum of nine policies and procedures,[351] resulting in an outside initial cost burden of $180,000 per respondent or an aggregate initial cost of $9,900,000. Once these policies and procedures are established, the Commission estimates, that on average each SBS Entity would spend approximately 540 hours (approximately 60 hours per policy and procedure [352]) each year to maintain these policies and procedures, yielding a total ongoing annual burden of approximately 29,700 hours (55 SBS Entities × 540 hours). Based on the Commission's experience in other contexts, the Commission preliminarily believes that this maintenance of policies and procedures will be conducted internally.[353]

6. SBS Dealers Acting as Advisors to Special Entities

Consistent with the requirements of proposed Rule 15Fh–2(a), parties have generally included representations in standard security-based swap documentation that both counterparties are acting as principals and that the counterparty is not relying on any communication from the SBS Dealer as investment advice. Under proposed Rule 15Fh–5, the SBS Dealer is required to have a reasonable basis to believe that the special entity has a qualified independent representative. The reporting burdens for this reasonable basis belief requirement are analyzed below in connection with the discussion of reporting burdens of ''SBS Entities Acting as Counterparties to Special Entities.'' In addition, we believe that parties are likely to provide the necessary representations and disclosures under proposed Rule 15Fh–2(a) so that the SBS Dealer would not fall within the definition of acting as an advisor, particularly for transactions in which the SBS Dealer is the counterparty to the transaction. Accordingly, we believe for these transactions that it is unlikely the SBS Dealer will be required to collect the information to determine the best interests of the special entity. Based on consultations by the Commission staff with market participants, the Commission preliminarily believes that the 50 SBS Dealers would each need approximately five hours to revise the existing representations to comply with this requirement or an aggregate initial burden of 250 hours. The Commission preliminarily believes that once each of the SBS Dealers has revised the language of the representation, such language would become part of the standard security-based swap documentation and, accordingly, there would be no further ongoing associated burden.

For transactions in which the SBS Dealer is not the counterparty and chooses to act as an advisor, the Commission estimates that an SBS Entity would require approximately 20 hours to collect the requisite information from each special entity for an aggregate initial burden of approximately 4,000 hours.[354]

7. SBS Entities Acting as Counterparties to Special Entities

When a special entity is a counterparty to a security-based swap, proposed Rule 15Fh–5 would require that an SBS Entity must have a reasonable basis for believing that the special entity has an independent representative that: (1) Has sufficient knowledge to evaluate the transaction and risks; (2) is not subject to a statutory disqualification; (3) undertakes a duty to act in the best interests of the special entity; (4) makes appropriate and timely disclosures to the special entity of material information concerning the security-based swap; (5) will provide written representations to the special entity regarding fair pricing and the appropriateness of the security-based swap; (6) in the case of employee benefit plans subject to ERISA, is a fiduciary as defined in section 3(21) of that Act (29 U.S.C. 1002(21)); and (7) in the case of a special entity defined in §§ 240.15Fh–2(e)(2) or (4) and a non-employee, third-party independent representative, is a person that is subject to rules of the Commission, the CFTC, or an SRO subject to the jurisdiction of the Commission or the CFTC, that prohibit it from engaging in specified activities if certain political contributions have been made. The Commission expects that written representations are likely to form much of the basis of the SBS Entity's belief as to the qualifications of the independent representative. The Commission also expects that in connection with its own prudent business practices the SBS Entity would confirm the status of whether the independent representative is subject to statutory disqualifications by a search on BrokerCheck or any other database available to it.[355] Furthermore, the SBS Entity is likely to have procedures in place to determine whether any of its associated persons are subject to a statutory disqualification, which it

[345] *See* Section II.C.6.

[346] *See* NASD Rule 3010.

[347] *See* Risk Management of Financial Derivatives, Office of Comptroller of the Currency Banking Circular No. 277 (Oct. 27, 1993).

[348] *See* SDR Registration Release.

[349] The estimate is based on the following calculation: (210 hours) × (9 policies and procedures) × (55 SBS Entities).

[350] *See* SDR Registration Release. The same estimate for the hourly cost for legal services was used by the Commission in the proposed consolidated audit trail rule. Consolidated Audit Trail, Exchange Act Release No. 62174 (May 26, 2010), 75 FR 32556 (June 8, 2010).

[351] *See* SDR Registration Release.

[352] *Id.*

[353] *Id.*

[354] The estimate is based on available market data for November 2006–September 2010 provided by DTCC that indicates 201 trading relationships between SBS Dealers and special entities that do not have a third-party investment adviser. For the purposes of estimating these reporting burdens, we approximate the number of trading relationships between SBS Dealers and special entities at 200. This estimate includes the following calculation: (20 hours) × (200 trading relationships).

[355] *See* Section II.D.5.c.ii and solicitation for comments thereunder.

could likely use or modify.[356] The Commission preliminarily believes that the burden to determine that the independent representative is independent of the SBS Entity would likely depend on the size of the independent representative, the size of the SBS Entity and the volume of transactions in which each is engaged. The estimates in this paragraph reflect the Commission staff's discussions with market participants. The Commission preliminarily believes that each SBS Entity initially would require written representations regarding each independent representative, but would only require updates with respect to the representations in subsequent dealings. The Commission does not currently have data regarding the number of independent representatives with which each SBS Entity interacts. As a result, for the purposes of these estimates the Commission has assumed that each SBS Entity would interact with approximately 150 third-party independent representatives and 30 in-house independent representatives, and that each SBS Entity, on average, would initially require approximately 15 hours per independent representative to collect the information necessary to comply with this requirement, or an aggregate initial burden of 148,500 hours (15 hours × 180 independent representatives × 55 SBS Entities). In addition, the Commission estimates that subsequent transactions with third-party, non-employee independent representatives would likely require an average of approximately 10 hours annually to update these representations and verifications or an aggregate initial burden of 82,500 hours (10 hours × 150 independent representatives × 55 SBS Entities). The Commission solicits comments as to the accuracy of this information.

The collection of information by the SBS Entity, would also impose some burden on the independent representatives to collect the information and provide the information to the SBS Entity and/or the special entities. The estimates in this paragraph reflect the Commission staff's discussions with market participants. The Commission expects that the main burden for the independent representatives is likely providing the representations on which the SBS Entity can rely. As a result, the Commission conservatively estimates that the reporting burden will likely be approximately 1 hour for each transaction of an annual average of 8,300 transactions [357] for the estimated 60 in-house independent representatives, equivalent to an average burden of approximately 138 hours per year per in-house independent representative.

With respect to third-party independent representatives, the Commission does not expect that any additional information would need to be collected pursuant to proposed Rule 15Fh–5(a)(6) because the independent representative would have undertaken this analysis under ERISA to confirm that it is subject to the fiduciary standards of ERISA and to determine whether it falls within one of the ''prohibited transaction exemptions'' promulgated by the Department of Labor. Similarly, under proposed Rule 15Fh–5(a)(7), the independent representative would have already determined whether it is subject to pay to play prohibitions to comply with those prohibitions. With respect to the transaction-specific requirements in proposed Rule 15Fh-5(a)(4) to (5), the Commission preliminarily believes that the reporting burden for the independent representative would likely consist of providing written representations to the SBS Entity and/or the special entity it represents. The Commission preliminarily believes that the burden on the independent representative to determine that it is independent of the SBS Entity would likely depend on the size of the independent representative, the size of the SBS Entity and the volume of transactions in which each is engaged. The estimates in this paragraph reflect the foregoing and the Commission staff's discussions with market participants. As a result, the Commission conservatively estimates that the reporting burden would likely average approximately 20 hours for each of the approximately 1,000 unique trading relationships between SBS Entities and special entities using a third-party independent representative for an aggregate initial burden of 20,000 hours or an average of approximately 62 hours for each of the estimated 325 third party independent representatives.[358]

8. Political Contributions

As noted above, the Commission estimates there will be approximately 50 SBS Dealers and has conservatively estimated that all of them will provide, or will seek to provide, security-based swap services to municipal entities. In addition, SBS Dealers' covered associates would also need to collect and provide the information required by the proposed rule to the SBS Dealer. The estimates herein take into account the burden of the covered associates and the SBS Dealers. These estimates reflect the Commission's experience with and burden estimates for similar requirements, as well as our discussions with market participants.[359] The Commission estimates that it would take, on average, approximately 185 hours per SBS Dealer and a total initial burden of 9,250 hours [360] to collect the information regarding the political contributions of the SBS Dealers and their covered associates.

Additionally, we expect some SBS Dealers may incur one-time costs to establish or enhance current systems to assist in their compliance with the proposed rule. These costs would vary widely among firms. Some SBS Dealers may not incur any system costs if they determine a system is unnecessary due to the limited number of employees they have or the limited number of municipal entity counterparties they have. Like other large firms, SBS Dealers likely already have devoted significant resources to automating compliance and reporting with existing applicable prohibitions on certain political contributions, and the proposed rule could cause them to enhance their existing systems that had originally been designed to comply with MSRB Rules G–37 and G–38 and Advisers Act Rule 206(4)–5. We believe that the cost of enhancing such a system could range from the tens of thousands of dollars for simple reporting systems, to hundreds of thousands of dollars for complex systems.[361]

9. Chief Compliance Officer

Under proposed Rule 15Fk–1, an SBS Entity's CCO would be responsible for, among other things, establishing

[356] *See* Section 15F(b)(6) of the Exchange Act, Public Law 111–203, 124 Stat. 1376, 1785 (to be codified at 15 U.S.C. 78o–10(b)(6)).

[357] The estimate is based on available market data for November 2006–September 2010 provided by DTCC that indicates 32,521 transactions during that time that involve special entities trading without an investment adviser. To obtain an approximate annual average number of transactions based on this data, we divided 32,521 transactions by 47 months and multiplied by 12 months and rounded to 8,300.

[358] The estimate is based on available market data for November 2006–September 2010 provided by DTCC that indicates approximately 1,000 unique trading relationships between SBS Entities and special entities using a third-party investment adviser during that time.

[359] *See* Political Contributions by Certain Investment Advisers, Investment Advisers Act Release No. 2910 (July 1, 2010), 75 FR 41018, 41061–41065 (July 14, 2010).

[360] The estimate is based on the following calculation: (185 hours × 50 SBS Dealers).

[361] *See* Political Contributions by Certain Investment Advisers, note 33, *supra* (adopting Advisers Act Rule 206(4)–5).).

policies and procedures reasonably designed: to ensure compliance by the SBS Entity with the Exchange Act and the rules and regulations thereunder relating to its business as an SBS Entity; to remediate promptly noncompliance issues identified by the CCO; and for prompt handling, management response, remediation, retesting, and resolution of noncompliance issues. As described above, the Commission estimates that a total of 55 respondents would be subject to this requirement. Based on the Commission's experience with and burden estimates for similar collections of information,[362] it estimates that on average the establishment and administration of the policies and procedures required under proposed Rule 15Fk–1 would require 630 hours to create and 180 hours to administer per year per respondent, for a total burden of 34,650 hours initially and 9,900 hours per year on average, on an ongoing basis. The Commission estimates that a total of $60,000 in outside legal costs will be incurred as a result of this burden per respondent, for a total initial outside cost burden of $3,300,000.[363]

A CCO would also be required under proposed Rule 15Fk–1 to prepare and submit annual compliance reports to the Commission and the SBS Entity's board of directors. Based upon the Commission's estimates for similar annual reviews by CCOs, the Commission estimates that these reports would require on average 92 hours per respondent per year.[364] Thus, the Commission estimates an ongoing annual burden of 5,060 hours.[365] Because the report will be submitted by an internal CCO, the Commission does not expect any external costs associated therewith. The Commission solicits comments as to the accuracy of this information and these estimates.

[362] *See* SDR Registration Release (citing Regulation NMS: Final Rules and Amendments to Joint Industry Plans, Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005)); Registration and Regulation of Security-Based Swap Execution Facilities, Exchange Act Release No. 63825 (Feb. 2, 2011), 76 FR 10948 (Feb. 28, 2011).

[363] This figure is the result of an estimated $400 per hour cost for outside legal services times 150 hours for 3 policies and procedures for 55 respondents. *See* SDR Registration Release.

[364] *See* Compliance Programs of Investment Companies and Investment Advisers, Investment Advisers Act Release No. 2107, 68 FR 7038 (Feb. 11, 2003); SDR Registration Release; Registration and Regulation of Security-Based Swap Execution Facilities, Exchange Act Release No. 63825 (Feb. 2, 2011), 76 FR 10948 (Feb. 28, 2011).

[365] The estimate is based on the following calculation: (92 hours) × (55 SBS Dealers).

E. Collection of Information Is Mandatory

The collections of information relating to verification of the status of the counterparty would be mandatory for all SBS Entities. The collections of information relating to disclosures by SBS Entities would be mandatory for all SBS Entities. The collections of information relating to knowing the counterparty and for suitability obligations would be mandatory for all SBS Dealers. The collection of information relating to fair and balanced communications would be mandatory for all SBS Entities. The collections of information relating to supervision would be mandatory for all SBS Entities. The collection of information relating to acting as an advisor to a special entity would be mandatory for all SBS Dealers. The collection of information relating to SBS Entities acting as counterparties to special entities would be mandatory for all SBS Entities. The collection of information relating to pay to play restrictions would be mandatory for all SBS Dealers. The collection of information relating to CCO obligations would be mandatory for all SBS Entities.

F. Responses to Collection of Information Will Be Kept Confidential

The Commission preliminarily believes the collection of information pursuant to proposed Rules 15Fh–3 to 15Fh–6 and 15Fk–1 would not be publicly available. To the extent that the Commission receives confidential information pursuant to this collection of information, such information would be kept confidential, subject to the provisions of the Freedom of Information Act (''FOIA'').

G. Request for Comment

We invite comment on these estimates. Pursuant to 44 U.S.C. 3506(c)(2)(B), we request comment in order to:

- Evaluate whether the proposed collection of information is necessary for the performance of our functions, including whether the information will have practical utility;
- Evaluate the accuracy of our estimates of the burdens of the proposed collections of information;
- Determine whether there are ways to enhance the quality, utility and clarity of the information to be collected; and
- Evaluate whether there are ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Persons wishing to submit comments on the collection of information requirements of the proposed rules should direct them to (1) the Office of Management and Budget, Attention: Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, DC 20503; and (2) Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090, with reference to File No. S7–XX–XX. Requests for materials submitted to OMB by the Commission with regard to this collection of information should be in writing, with reference to File No. S7–XX–XX, and be submitted to the Securities and Exchange Commission, Office of Investor Education and Advocacy, 100 F Street, NE, Washington, DC 20549–0213. OMB is required to make a decision concerning the collections of information between 30 and 60 days after publication, so a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

V. Cost-Benefit Analysis

The Commission is sensitive to the costs and benefits imposed by its rules. The proposed rulemaking is intended to implement the requirements under Section 15F(h) of the Exchange Act as added by Section 764(a) of the Dodd-Frank Act concerning external business conduct standards for SBS Entities. Section 15F of the Exchange Act provides the Commission with both mandatory and discretionary rulemaking authority to impose business conduct requirements on SBS Entities in their dealings with counterparties, including special entities. In addition to the reporting burdens associated with certain of the proposed rules described in Section IV.D above, the discussion below focuses on other potential costs and benefits of the decisions made by the Commission, together with the other agencies, to fulfill the mandates of the Dodd-Frank Act within its permitted discretion. As part of this analysis, we do not consider the costs and benefits of the mandates of the Dodd-Frank Act itself.[366]

As discussed in Section I.C.3, in addition to business conduct requirements expressly addressed by Title VII of the Dodd-Frank Act, we are proposing for comment certain other

[366] The Paperwork Reduction Act analysis in Section IV.D., however, describes collections of information under the proposed rules, regardless of whether the rules are proposed pursuant to mandatory or discretionary authority.

business conduct requirements for SBS Dealers that we preliminarily believe further the principles that underlie the Dodd-Frank Act. These include details of the daily mark for uncleared security-based swaps; certain disclosures related to the provision of a daily mark for uncleared security-based swaps; certain ''know your counterparty'' and suitability obligations for SBS Dealers; provisions intended to prevent SBS Dealers and independent representatives of special entities from engaging in certain ''pay to play'' activities; certain minimum requirements for the annual compliance reports to be provided by the CCO; and a requirement of board approval for decisions related to compensation or removal of the CCO.

A. Costs and Benefits of Rules Relating to Daily Mark

Section 15F(h)(3)(B)(iii) of the Exchange Act requires the Commission to adopt rules requiring the disclosure to counterparties of the daily mark. For cleared security-based swaps, upon request from the counterparty, the rule must require an SBS Entity to provide the daily mark, which under proposed Rule 15Fh–3(c) would be the daily end of day settlement price received from the appropriate clearing agency. For uncleared security-based swaps, the rules must require the SBS Entity to provide the daily mark. However, the method for computing the daily mark is not provided in the statute. Proposed Rule 15h–3(c)(2) would require that the SBS Entity meet this disclosure requirement for any uncleared security-based swap by providing the midpoint between the bid and offer, or the calculated equivalent thereof, as of the close of business unless the parties agree in writing otherwise. The SBS Entity would also be required to disclose the data sources and describe the methodology and assumptions used to prepare the daily mark. The provision of a daily mark along with the data sources, assumptions, and methodology used in its preparation, should provide a useful reference point for the counterparty.

In the absence of current valid quotes from which to calculate the mid-market price, a model would be used to estimate the daily mark. When markets are illiquid the mark provided by a model may provide a better estimate of the value of the security-based swap than a stale market price. However, the mark would only be as good as the model from which it is derived and security-based swap market participants would need to evaluate the data sources, methodology and assumptions employed to fully appreciate model-derived daily marks. Further, the model price would not necessarily reflect the price at which the security-based swap could be executed. While the market-wide disclosure of these marks could raise the quality of the model-derived daily marks, there would likely be variability in the models and data sources, methodology and assumptions, leading to different daily marks being established for similar security-based swaps. As a result, security-based swap market participants that consider the daily mark as one indicator in the reporting of their positions might present different values for similar security-based swap market positions on their respective balance sheets.

Potential limitations of a model-based daily mark notwithstanding, counterparties to SBS Entities will benefit from a good faith effort by SBS Entities to value uncleared SBS transactions. Daily marks will allow counterparties to better understand their financial relationships with SBS Entities and provide a frequently updated basis for variation margin requirements. And although daily marks would not necessarily represent a price at which at a counterparty could enter or exit the position, it would provide a meaningful reference point against which to assess, among other things, the calculation of variation margin for a security-based swap or portfolio of security-based swaps, and otherwise inform the counterparty's understanding of its financial relationship with the SBS Entity. Moreover, because SBS Entities would be required to provide the same valuation to all of their counterparties, and because counterparties could interact with multiple SBS Entities, counterparties would be assured of equal treatment and would have the ability to observe when valuations differ among SBS Entities.

The costs to SBS Entities of providing daily marks should be minimal other than the disclosure burdens previously described. Proper risk management at SBS Entities entails assessing end-of-day values. In this respect, an SBS Entity would simply be passing along a valuation similar to one that the SBS Entity currently performs, even without a rule requiring disclosure.

B. Costs and Benefits of Rules Concerning Verification of Counterparty Status, Knowing Your Counterparty, and Recommendations of Security-Based Swaps or Trading Strategies

Proposed Rule 15Fh–3(a)(2) would require an SBS Entity to verify whether a counterparty is a special entity before entering into a security-based swap with that counterparty. Although the Dodd-Frank Act does not require an SBS Entity to verify whether a counterparty is a special entity, we are mindful that Congress established a set of additional provisions addressing solely the interactions between SBS Entities and special entities in connection with security-based swaps, and we preliminarily believe that such verification would help to ensure that these counterparties do, in fact, receive the benefit of such provisions, as well as our proposed rules thereunder. The verification requirement would not apply if an SBS Entity is entering into a transaction with a special entity on a SEF or an exchange and for which the SBS Entity does not know the identity of the counterparty.

Proposed Rule 15Fh–3(e) would establish a ''know your counterparty'' requirement for SBS Dealers that would require an SBS Dealer to obtain and retain a record of essential facts regarding a counterparty that are necessary for conducting business with such a counterparty. The ''essential facts concerning a counterparty'' are those required to (1) comply with applicable laws, regulations and rules; (2) implement the SBS Dealer's credit and operational risk management policies in connection with transactions entered into with such counterparty; (3) information regarding the authority of any person acting for such counterparty; and (4) if the counterparty is a special entity, such background information regarding the independent representative as the SBS Dealer reasonably deems appropriate. To the extent that the SBS Dealer does not already collect and retain this information as a part of its normal course of business, this requirement would increase the cost to the SBS Dealer of entering into security-based swaps. The increased cost is likely to be reflected in the terms offered to the counterparty. To the extent that an SBS Dealer is unable to recover the added costs from the counterparty, the rule would provide a disincentive for recommending bespoke transactions.

Proposed Rule 15Fh–3(f) would require that the SBS Dealer have a reasonable basis to believe: (i) Based on reasonable diligence, that the recommended security-based swap or trading strategy involving a security-based swap is suitable for at least some counterparties; and (ii) that a recommended security-based swap or trading strategy is suitable for the counterparty based on relevant information the SBS Dealer has or has obtained regarding the counterparty, including the counterparty's investment

profile, trading objectives and its potential to absorb losses associated with the recommended security-based swap or trading strategy. This requirement could potentially benefit counterparties by requiring that an SBS Dealer recommend only suitable security-based swaps or trading strategies. While the proposed requirement that an SBS Dealer know essential facts regarding its counterparties to evaluate the suitability of trades for its counterparties would be a responsibility that would go beyond disclosure of material risks and so, could increase the costs to SBS Dealers in transacting with counterparties, particularly for counterparties with which an SBS Dealer has had no prior transactions, we anticipate that SBS Dealers would seek to rely on proposed Rule 15Fh–3(f)(2), which would allow an SBS Dealer to fulfill its obligations with respect to a particular counterparty if (1) The SBS Dealer reasonably determined that the counterparty, or the counterparty's agent to whom the counterparty has delegated decision making authority, is capable of exercising independent judgment, (2) the counterparty or agent affirmatively represented that it is exercising independent judgment in evaluating the recommendations, and (3) the SBS Dealer disclosed that it was acting in its capacity as a counterparty and was not undertaking to assess the suitability of the security-based swap or trading strategy for the counterparty. This provision would benefit counterparties by helping to ensure that they are in fact capable of exercising independent judgment in evaluating security-based swaps and trading strategies.

Some SBS Dealers may already have an obligation to make suitable recommendations of a security-based swap or trading strategy through other regulatory regimes to which they may be subject. For example, FINRA imposes a suitability requirement on recommendations by broker-dealers. Municipal securities dealers also have a suitability obligation when recommending municipal securities transactions to a customer. Federally regulated banks have a suitability obligation as well when acting as broker-dealers in connection with the purchase or sale of government securities. Proposed rule 15Fh–3(f) would subject SBS Dealers to similar suitability requirements. In addition, the suitability obligation would not apply to an SBS Dealer in dealings with an SBS Entity, swap dealer, or major swap participant.

One potential concern is that relatively unsophisticated counterparties would not qualify for the exception that would be provided by proposed Rule 15Fh–3(f)(2) and that the costs to SBS Dealers associated with determining suitability may be sufficiently large or difficult to assess given that SBS Dealers would choose not to engage in over-the-counter security-based swaps with certain counterparties, particularly less sophisticated counterparties. However, our analysis of the credit default swaps market over the four years prior to the passage of the Dodd-Frank Act finds that non-institutional counterparties generally have third-party representation. In particular, as previously noted, more than 95% of all trades by special entities are executed through third party investment advisers, and the remaining trades are predominantly by large, well known endowments and pension plans who would generally be characterized as sophisticated security-based swap market participants. Moreover, all counterparties may nonetheless be able to enter into security-based swaps that are traded on a registered national securities exchange, even if they are unable to find a SBS Dealer to enter a bespoke security-based swap.

C. Costs and Benefits of Rules Relating to Political Contributions by Certain SBS Entities and Independent Representatives of Special Entities

Proposed Rule 15Fh–6 would prohibit SBS Dealers from engaging in security-based swap transactions with a ''municipal entity'' if certain political contributions have been made to officials of such entities. The proposed rule is similar to rules adopted by the MSRB in Rule G–37: Political Contributions and Prohibitions on Municipal Securities Business and G–38: Solicitation of Municipal Securities Business, and by the Commission in Advisers Act Rule 206(4)–5: Political Contributions by Certain Investment Advisers.[367]

Proposed Rule 15Fh–5(a)(7) would include in the list of qualifications for a ''qualified independent representative'' that the independent representative is subject to rules of the Commission, the CFTC, or a self-regulatory organization subject to the jurisdiction of the Commission or the CFTC, that prohibit it from engaging in specified activities if certain political contributions have been made. The proposed rule would not apply if the independent representative was an employee of the special entity.

The proposed rules should yield several direct and indirect benefits. The proposed rules are intended to address pay to play relationships that interfere with the legitimate process by which ''municipal entities'' and other special entities enter into security-based swaps to mitigate risk. The proposed rules should reduce the occurrence of fraudulent conduct resulting from pay to play. Addressing pay to play practices would help protect public pension plans, investments by the public in government-sponsored savings and retirement plans and programs, and taxpayers by addressing situations in which the municipal entity, in part based on a conflict of interest, enters into a security-based swap that may be without merit or for which there exists a better alternative. Allocative efficiency would be enhanced if special entities enter into security-based swaps based on hedging needs or the characteristics of the security-based swap rather than any influence from pay to play, either from the SBS Dealer or the independent representative.

These proposed rules would encourage (1) SBS Dealers to compete for the business of municipal entities based on the merits of the transaction rather than their ability or willingness to make political contributions, and (2) independent representatives to compete based on their qualifications, service, and cost. Taxpayers may benefit from the rule because they would enjoy the benefits of appropriate risk management or investment strategies that make use of security-based swaps, and they might otherwise bear the financial burden of bailing out a municipal entity that had entered into an inappropriate security-based swap because of pay to play practices. The proposed rule may also lower transaction costs paid by ''municipal entities'' since it would not be necessary for SBS Dealers to recover expenses incurred by pay to play practices.[368]

Proposed Rule 15Fh–6 would require an SBS Dealer to incur costs to monitor contributions it and its covered associates make and to establish procedures to comply with the rule. The

[367] Political Contributions by Certain Investment Advisers, Investment Advisers Act Release No. 2910, 75 FR 41018, 41061–41065 (July 14, 2010). Many of the economic issues associated with rules relating to political contributions by SBS entities are similar to those relating to investment advisers addressed in Rule 206(4)–5.

[368] Academic research provides evidence that gross spreads on negotiated bid deals for municipal bonds were reduced following adoption of a pay to play rule prohibiting investment houses that make political contributions from selling bonds from that city/state for two years. *See* Alexander W. Butler, Larry Fauver, and Sandra Mortal, *Corruption, Political Connections, and Municipal Finance,* 22 The Review of Financial Studies 2873 (2009).

initial and ongoing compliance costs imposed by the proposed rule would vary significantly among firms, depending on a number of factors. These factors include the number of covered associates of the SBS Dealer, the degree to which compliance procedures are automated (including policies and procedures that could require pre-clearance), and the extent to which the SBS Dealer has a preexisting policy under its code of ethics or compliance program. A smaller SBS Dealer, for example, would likely have a small number of covered associates, and thus expend fewer resources to comply with the proposed rule.

An SBS Dealer subject to the proposed rule would develop compliance procedures to monitor the political contributions made by the SBS Dealer and its covered associates. We estimate that the costs imposed by the proposed rule would be higher initially, as firms establish and implement procedures and systems to comply with the rule. We expect that compliance expenses would then decline to a relatively constant amount in future years, and that annual expenses would likely be lower for smaller SBS Dealers as the systems and processes should be less complex than for larger SBS Dealers.

An SBS Dealer with municipal entity counterparties, as well as covered associates of the SBS Dealer, also may be less likely to make contributions to government officials, including candidates, at or above the *de minimis* level, potentially resulting in less funding by SBS Dealers and their covered associates for these officials' campaigns. Under the rule, SBS Dealers and covered associates would be subject to new limitations regarding which campaigns they may support and the amounts that they may contribute. In addition, these same persons would be prohibited from soliciting others to contribute or from coordinating contributions to government officials, including candidates, or payments to political parties in certain circumstances. These limitations, and any additional prohibitions imposed by firms that choose to adopt more restrictive policies or procedures, could be perceived by the individuals subject to them as a cost in the sense that they limit those individuals' ability to give direct contributions to certain candidates above the *de minimis* level.

An SBS Dealer that becomes subject to the prohibitions of the proposed rule would be prohibited from offering to enter into, or entering into, a security-based swap with a particular municipal entity counterparty, which would result in a direct loss to the SBS Dealer of revenues and profits relating to that government counterparty. However, this prohibition would likely result in a reallocation as to which SBS Dealer would generate these revenues and profits, not an overall loss to the market. The two-year time out could also limit the number of SBS Dealers able to offer to enter into or enter into security-based swap contracts with potential municipal entity counterparties.

D. Costs and Benefits Relating to the Specification of Minimum Requirements of the Annual Compliance Report and the Requirement of Board Approval of Compensation or Removal of a Chief Compliance Officer

Section 15F(k) of the Exchange Act requires an SBS Entity to designate a CCO, and imposes certain duties and responsibilities on that CCO. Proposed Rule 15Fk–1 would incorporate the provisions of Exchange Act Section 15F(k) in addition to certain provisions that are based on the current and proposed compliance obligations applicable to CCOs of other Commission-regulated entities.

The submission of the CCO's annual compliance report as required by the proposed rule would help the Commission monitor the compliance activities of SBS Entities. This report would also assist the Commission in carrying out its oversight of SBS Entities by providing the Commission with the information necessary to review compliance with rules relating to external business conduct.

Section 15Fk–1(2)(A) of the Exchange Act requires that the CCO report directly to the board or the senior officer of the SBS Entity. Proposed Rule 15Fk–1(d) would also require that the compensation and removal of the CCO would require the approval of a majority of the board of directors of the SBS Entity. The elevation of compensation and termination decisions to the board should reduce the inherent conflict of interest that arises when such decisions are made by individuals whose compliance with applicable law and regulations the CCO is responsible for monitoring. The potential separation of general supervisory responsibility of the CCO, which may reside with the senior officer of the SBS Entity, from the responsibility for compensation decisions may reduce the quality of those decisions.

In addition to the time involved with the reporting burdens, the direct costs of $3,300,000 in the aggregate associated with the submission of the annual compliance report are discussed in more detail in Section IV.D.9 above.

Request for Comments

The Commission also seeks comment on the accuracy of any of the benefits and costs it has identified and/or described above. The Commission encourages commenters to identify, discuss, analyze, and supply relevant data, information, or statistics regarding any such costs or benefits. Because the structure of the security-based swaps market and the behavior of its market participants is likely to change after the effective date of the Dodd-Frank Act and implementation of the Commission's rules promulgated thereunder, the impact of, and the costs and benefits that may result from proposed Rules 15Fh–1 through 15Fh–6 and 15Fk–1 may change over time. As commenters review the proposed rules, we urge them to consider generally the role that regulation may play in fostering or limiting the development of the market for security-based swaps.

VI. Consideration of Burden on Competition and Promotion of Efficiency, Competition and Capital Formation

Section 3(f) of the Exchange Act requires that the Commission, whenever it engages in rulemaking and is required to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action would promote efficiency, competition, and capital formation.[369] In addition, Section 23(a)(2) of the Exchange Act requires the Commission, when adopting rules under the Exchange Act, consider the effect such rules would have on competition.[370] Section 23(a)(2) of the Exchange Act also prohibits the Commission from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.

Security-based swaps are currently executed and traded in the OTC market, with five large commercial banks representing 97% of the total U.S. banking industry notional amounts outstanding of derivatives.[371] The gross notional amount of credit default swaps as of the end of 2009 was approximately $30 trillion.[372]

Section 15F(h) of the Exchange Act as added by Section 764(a) of the Dodd-Frank Act provides the Commission

[369] 15 U.S.C. 78c(f).

[370] 15 U.S.C. 78w(a)(2).

[371] *See* Office of the Comptroller of the Currency, Quarterly Report on Bank Trading and Derivatives Activities, First Quarter 2010.

[372] Data available at *http://www.isda.org/statistics/pdf/ISDA-Market-Survey-results1987-present.xls.*

with both mandatory and discretionary rulemaking authority to impose business conduct requirements on SBS Entities in their dealings with counterparties, including special entities.[373] The proposed rules to implement business conduct requirements would apply to all SBS Entities. Therefore the Commission preliminarily believes that the effect on competition among SBS Entities would be small. The Commission also preliminarily believes that the proposed business conduct standards for SBS Entities, including those for disclosure of material risks and for fair and balanced communications, would reduce information asymmetries between SBS Entities and their counterparties. The reduction of information asymmetries should promote price efficiency, promote more informed decision-making, and reduce the incidence of fraudulent or misleading representations.

Proposed Rule 15Fh–3(e) would require an SBS Dealer to use reasonable due diligence to obtain and retain a record of the essential facts concerning each counterparty whose identity is known to the SBS Dealer prior to the execution of the transaction and the authority of any person acting for such counterparty. Proposed Rule 15h–3(f) would require that the SBS Dealer have a reasonable basis to believe: (i) based on reasonable diligence, that the recommended security-based swap or trading strategy involving a security-based swap is suitable for at least some counterparties; and (ii) that a recommended security-based swap or trading strategy is suitable for the counterparty based on information the SBS Dealer has obtained through reasonable due diligence regarding the counterparty's investment profile, and the potential risks and rewards associated with the recommended security-based swap or trading strategy.

Requiring SBS Dealers to evaluate the suitability of trades for counterparties is a responsibility that goes beyond disclosure of material risks and would further increase the costs to SBS Dealers in transacting with counterparties, particularly for counterparties with which the SBS Dealer has had no prior transactions. These costs are likely to be largest when the SBS Dealer is dealing directly with small, relatively unsophisticated counterparties where a greater level of inquiry would be required. If these costs result in SBS Dealers refraining from interacting with these counterparties, and these counterparties are otherwise unable to enter into security-based swaps and lose access to risk management methods that employ security-based swaps, the suitability requirement may come at a net cost to these counterparties and would place them at a disadvantage relative to larger, more sophisticated competitors. To the extent that these counterparties do not participate in the security-based swap market as a result of these costs, liquidity could drop, increasing the hedging costs and ultimately the cost of raising capital. However, as we noted previously, current market practices reveal that relatively few counterparties enter into security-based swap agreements with an SBS Dealer without third-party representation, particularly among special entities. As a result of this third-party representation and the SBS Dealer's ability to fulfill its suitability obligations by making the determination that a counterparty's agent is capable of independently evaluating investment risk, we do not believe that market access is likely to be restricted, even for small, relatively unsophisticated counterparties. Rather, we believe that it is possible that suitability requirements would add to the integrity of, and codify, current market practices, which can in some circumstances enhance the protections for such counterparties.

The practices that are proposed in the rules would also help regulators perform their functions in an effective manner. The resulting increase in market integrity would likely affect capital formation in our capital markets positively.

Request for Comments

The Commission also seeks comment on the accuracy of any of the competitive effects it has identified and/or described above. The Commission encourages commenters to identify, discuss, analyze, and supply relevant data, information, or statistics regarding any such effects. Because the structure of the security-based swaps market and the behavior of its market participants is likely to change after the effective date of the Dodd-Frank Act and implementation of the Commission's rules promulgated thereunder, the impacts that may result from proposed Rules 15Fh–1 through 15Fh–6 and 15Fk–1 may change over time. As commenters review the proposed rules, we urge them to consider generally the role that regulation may play in fostering or limiting the development of the market for security-based swaps.

VII. Consideration of Impact on the Economy

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996, or ''SBREFA,'' [374] the Commission must advise the OMB as to whether the proposed regulation constitutes a ''major'' rule. Under SBREFA, a rule is considered ''major'' where, if adopted, it results or is likely to result in: (1) An annual effect on the economy of $100 million or more (either in the form of an increase or a decrease); (2) a major increase in costs or prices for consumers or individual industries; or (3) significant adverse effect on competition, investment or innovation. If a rule is ''major,'' its effectiveness will generally be delayed for 60 days pending Congressional review.

The Commission requests comment on the potential impact of proposed Rules 15Fh–1 through 15Fh–7 and 15Fk–1 on the economy on an annual basis, any potential increase in costs or prices for consumers or individual industries, and any potential effect on competition, investment or innovation. Commenters are requested to provide empirical data and other factual support for their view to the extent possible.

VIII. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act (''RFA'') [375] requires Federal agencies, in promulgating rules, to consider the impact of those rules on small entities. Section 603(a) [376] of the Administrative Procedure Act,[377] as amended by the RFA, generally requires the Commission to undertake a regulatory flexibility analysis of all proposed rules, or proposed rule amendments, to determine the impact of such rulemaking on ''small entities.'' [378] Section 605(b) of the RFA states that this requirement shall not apply to any proposed rule or proposed rule amendment, which if adopted, would not have a significant economic impact on a substantial number of small entities.[379]

---

[373] *See* Exchange Act Section 15F(h)(2)(C), 15 U.S.C. 78o–10(h)(2)(C).

[374] Public Law. 104–121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C., 15 U.S.C. and as a note to 5 U.S.C. 601).

[375] 5 U.S.C. 601 *et seq.*

[376] 5 U.S.C. 603(a).

[377] 5 U.S.C. 551 *et seq.*

[378] Although Section 601(b) of the RFA defines the term ''small entity,'' the statute permits agencies to formulate their own definitions. The Commission has adopted definitions for the term small entity for the purposes of Commission rulemaking in accordance with the RFA. Those definitions, as relevant to this proposed rulemaking, are set forth in Rule 0–10, 17 CFR 240.0–10. *See* Securities Exchange Act Release No. 18451 (Jan. 28, 1982), 47 FR 5215 (Feb. 4, 1982).

[379] *See* 5 U.S.C. 605(b).

For purposes of Commission rulemaking in connection with the RFA, a small entity includes: (i) When used with reference to an ''issuer'' or a ''person,'' other than an investment company, an ''issuer'' or ''person'' that, on the last day of its most recent fiscal year, had total assets of $5 million or less,[380] or (ii) a broker-dealer with total capital (net worth plus subordinated liabilities) of less than $500,000 on the date in the prior fiscal year as of which its audited financial statements were prepared pursuant to Rule 17a–5(d) under the Exchange Act,[381] or, if not required to file such statements, a broker-dealer with total capital (net worth plus subordinated liabilities) of less than $500,000 on the last day of the preceding fiscal year (or in the time that it has been in business, if shorter); and is not affiliated with any person (other than a natural person) that is not a small business or small organization.[382] With respect to investment companies in connection with the RFA, the term ''small business'' or ''small organization'' means an investment company that, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less as of the end of its most recent fiscal year.

A. Market Participants in Security-Based Swaps

Based on the Commission's existing information about the security-based swap market, the Commission preliminarily believes that the security-based swap market, while broad in scope, is largely dominated by large entities such as those that would be covered by the ''security-based swap dealer'' definition and their large institutional customers.[383] Under current law, all security-based swap market participants are effectively required to be ''eligible contract participants.'' [384] The basic thresholds under the definition of eligible contract participant are currently $10 million in total assets for natural persons, and $25 million in total assets for corporations and other legal entities.[385] Because the definition of ''small entity'' requires that issuers or persons other than broker-dealers and investment companies must have total assets of $5 million or less, by definition they cannot be eligible contract participants. Based on its knowledge of registered broker-dealers and feedback from industry participants about the security-based swap markets, the Commission preliminarily believes that registered broker-dealers that participate, or will participate after the Dodd-Frank Act becomes effective, in the security-based swap markets exceed the threshold defining when broker-dealers are ''small entities'' set out above. Finally, based on its review of data provided by the Warehouse Trust Company, a subsidiary of the Depository Trust and Clearing Corporation, to the Commission, and feedback from industry participants, the Commission preliminarily believes that investment companies that participate in the security-based swap markets exceed the threshold defining when investment companies are ''small businesses'' or ''small organizations'' set out above. Thus, the Commission preliminarily believes it is unlikely that the proposed business conduct standards rules would have a significant economic impact on a substantial number of small entities.

B. Certification

In the Commission's preliminary view, the proposed rules would not have a significant economic impact on a substantial number of small entities. For the foregoing reasons, the Commission certifies that these proposed rules would not have a significant economic impact on a substantial number of small entities for purposes of the RFA. The Commission encourages written comments regarding this certification. The Commission requests that commenters describe the nature of any impact on small entities and provide empirical data to illustrate and support the extent of the impact.

[380] *See* 17 CFR 240.0–10(a).

[381] *See* 17 CFR 240.17a–5(d).

[382] *See* 17 CFR 240.0–10(c).

[383] *See supra* notes 4 and 5.

[384] Otherwise, the security-based swap would either be a security subject to the federal securities laws, including a registration requirement under the Securities Act, or an illegal future, depending on its economic terms and the security, commodity or other asset that it references. In practice, this has meant that such transactions do not occur.

[385] Note that the definition of ''eligible contract participant'' has been amended by Congress in Section 721(a)(9) of the Dodd-Frank Act. *See* Pub. L. 111–203, 124 Stat. 1376, 1660, § 721(a)(9) (to be codified at 7 U.S.C. 1a(18)). *See also* Definitions Release at 42 (explaining that this amendment has the effect of ''(1) raising a threshold that governmental entities may use to qualify as [eligible contract participants], in certain situations, from $25 million in discretionary investments to $50 million in such investments; and (2) replacing the 'total asset' standard for individuals to qualify as [eligible contract participants] with a discretionary investment standard,'' but noting that for individuals, while the threshold remains $10 million, under the amended definition this amount would be based on discretionary investments rather than total assets).

Business Conduct Standards for Security-Based Swap Dealers and Major Security-Based Swap Participants

Statutory Authority

Pursuant to the Act and, particularly, Sections 2, 3(b), 3C, 9, 10, 11A, 15, 15F, 17(a) and (b), and 23(a) thereof (15 U.S.C. 78b, 78c(b), 78i(i), 78i(j), 78j, 78k–1, 78o, 78o–10, 78q(a) and (b), and 78w(a)), the Commission is proposing a new series of rules, Rules 15Fh–1 through 15Fh–6, and Rule 15Fk–1, to address the business conduct obligations of security-based swap dealers and major security-based swap participants.

List of Subjects in 17 CFR Part 240

Brokers, Reporting and recordkeeping requirements, Securities.

Text of the Proposed Rule

For the reasons set forth in the preamble, the Securities and Exchange Commission proposes to amend Title 17, Chapter II of the Code of Federal Regulations, as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 is revised to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78b, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78o, 78o–4, 78o–10, 78p, 78q, 78s, 78u–5, 78w, 78x, 78dd(b) and (c), 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.;* 18 U.S.C. 1350, and 12 U.S.C. 5221(e)(3), unless otherwise noted.

* * * * *

Sections 240.15Fh–1 through 240.15Fh–6 and 240.15Fk–1 are also issued under sec. 943, Pub. L. 111–203, 124 Stat. 1376.

* * * * *

2. Add §§ 240.15Fh–1 through 240.15Fh–6 to read as follows:

Sec.

§ 240.15Fh–1 Scope.

Sections 240.15Fh–1 through 240.15Fh–6, and 240.15Fk–1 are not

intended to limit, or restrict, the applicability of other provisions of the federal securities laws, including but not limited to Section 17(a) of the Securities Act of 1933 and Sections 9 and 10(b) of the Act, and rules and regulations thereunder, or other applicable laws and rules and regulations. Sections 240.15Fh–1 through 240.15Fh–6, and 240.15Fk–1 apply, as relevant, in connection with entering into security-based swaps and continue to apply, as appropriate, over the term of executed security-based swaps.

§ 240.15Fh–2 Definitions.

As used in §§ 240.15Fh–1 through 240.15Fh–6:

(a) Act as an advisor to a special entity. A security-based swap dealer *acts as an advisor to a special entity* when it recommends a security-based swap or a trading strategy that involves the use of a security-based swap to the special entity, unless:

(1) The special entity represents in writing that:

(i) The special entity will not rely on recommendations provided by the security-based swap dealer; and

(ii) The special entity will rely on advice from a qualified independent representative as defined in § 240.15Fh–5(a); and

(2) The security-based swap dealer has a reasonable basis to believe that the special entity is advised by a qualified independent representative as defined in § 240.15Fh–5(a); and

(3) The security-based swap dealer discloses to the special entity that it is not undertaking to act in the best interest of the special entity, as otherwise required by Section 15F(h)(4) of the Act.

(b) Eligible contract participant means any person as defined in Section 3(a)(66) of the Act.

(c) Independent representative of a special entity means:

(1) A representative of a special entity must be independent of the security-based swap dealer or major security-based swap participant that is the counterparty to a proposed security-based swap.

(2) A representative of a special entity is independent of a security-based swap dealer or major security-based swap participant if the representative does not have a relationship with the security-based swap dealer or major security-based swap participant, whether compensatory or otherwise, that reasonably could affect the independent judgment or decision-making of the representative.

(3) A representative of a special entity will be deemed to be independent of a security-based swap dealer or major security-based swap participant if:

(i) The representative is not and, within one year, was not an associated person of the security-based swap dealer or major security-based swap participant; and

(ii) The representative has not received more than ten percent of its gross revenues over the past year, directly or indirectly from the security-based swap dealer or major security-based swap participant.

(d) Security-based swap dealer or major security-based swap participant includes, where relevant, an associated person of the security-based swap dealer or major security-based swap participant.

(e) Special entity means:

(1) A Federal agency;

(2) A State, State agency, city, county, municipality, or other political subdivision of a State;

(3) Any employee benefit plan, as defined in section 3 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002);

(4) Any governmental plan, as defined in section 3(32) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(32)); or

(5) Any endowment, including an endowment that is an organization described in section 501(c)(3) of the Internal Revenue Code of 1986.

(f) A person is *subject to a statutory disqualification* for purposes of § 240.15Fh–5 if that person would be subject to a statutory disqualification under the provisions of Section 3(a)(39) of the Act.

§ 240.15Fh–3 Business conduct requirements.

(a) *Counterparty Status.*

(1) *Eligible contract participant.* A security-based swap dealer or a major security-based swap participant shall verify that a counterparty whose identity is known to the security-based swap dealer or a major security-based swap participant prior to the execution of the transaction meets the eligibility standards for an eligible contract participant, before entering into a security-based swap with that counterparty other than on a registered national securities exchange or registered security-based swap execution facility.

(2) *Special entity.* A security-based swap dealer or a major security-based swap participant shall verify whether a counterparty whose identity is known to the security-based swap dealer or a major security-based swap participant prior to the execution of the transaction is a special entity, before entering into a security-based swap with that counterparty.

(b) *Disclosure.* Before entering into a security-based swap, a security-based swap dealer or major security-based swap participant shall disclose to the counterparty, other than a security-based swap dealer, major security-based swap participant, swap dealer or major swap participant, information concerning the security-based swap in a manner reasonably designed to allow the counterparty to assess:

(1) *Material risks and characteristics.* The material risks and characteristics of the particular security-based swap, including, but not limited to, the material factors that influence the day-to-day changes in valuation, the factors or events that might lead to significant losses, the sensitivities of the security-based swap to those factors and conditions, and the approximate magnitude of the gains or losses the security-based swap will experience under specified circumstances.

(2) *Material incentives or conflicts of interest.* Any material incentives or conflicts of interest that the security-based swap dealer or major security-based swap participant may have in connection with the security-based swap, including any compensation or other incentives from any source other than the counterparty in connection with the security-based swap to be entered into with the counterparty.

(3) *Record.* The security-based swap dealer or major security-based swap participant shall make a written record of the non-written disclosures made pursuant to paragraph (b) of this section, and provide a written version of these disclosures to its counterparties in a timely manner, but in any case no later than the delivery of the trade acknowledgement of the particular transaction pursuant to § 240.15Fi–1.

(c) *Daily Mark.* A security-based swap dealer or major security-based swap participant shall disclose the daily mark to the counterparty, other than a security-based swap dealer, major security-based swap participant, swap dealer or major swap participant, which shall be:

(1) For a cleared security-based swap, upon the request of the counterparty, the daily end-of-day settlement price that the security-based swap dealer or major security-based swap participant receives from the appropriate clearing agency; and

(2) For an uncleared security-based swap, the midpoint between the bid and offer, or the calculated equivalent thereof, as of the close of business,

unless the parties agree in writing otherwise to a different time, on each business day during the term of the security-based swap. The daily mark may be based on market quotations for comparable security-based swaps, mathematical models or a combination thereof. The security-based swap dealer or major security-based swap participant shall also disclose its data sources and a description of the methodology and assumptions used to prepare the daily mark, and promptly disclose any material changes to such data sources, methodology and assumptions during the term of the security-based swap.

(d) *Disclosure Regarding Clearing Rights.* A security-based swap dealer or major security-based swap participant shall disclose the following information to a counterparty, other than a security-based swap dealer, major security-based swap participant, swap dealer or major swap participant:

(1) *For security-based swaps subject to clearing requirement.* Before entering into a security-based swap subject to the clearing requirement under Section 3C(a) of the Act, a security-based swap dealer or major security-based swap participant shall:

(i) Disclose to the counterparty the names of the clearing agencies that accept the security-based swap for clearing, and through which of those clearing agencies the security-based swap dealer or major security-based swap participant is authorized or permitted, directly or through a designated clearing member, to clear the security-based swap; and

(ii) Notify the counterparty that it shall have the sole right to select which of the clearing agencies described in paragraph (d)(1)(i) shall be used to clear the security-based swap.

(2) *For security-based swaps not subject to clearing requirement.* Before entering into a security-based swap not subject to the clearing requirement under Section 3C(a) of the Act, a security-based swap dealer or major security-based swap participant shall:

(i) Determine whether the security-based swap is accepted for clearing by one or more clearing agencies;

(ii) Disclose to the counterparty the names of the clearing agencies that accept the security-based swap for clearing, and whether the security-based swap dealer or major security-based swap participant is authorized or permitted, directly or through a designated clearing member, to clear the security-based swap through such clearing agencies; and

(iii) Notify the counterparty that it may elect to require clearing of the security-based swap and shall have the sole right to select the clearing agency at which the security-based swap will be cleared, provided it is a clearing agency at which the security-based swap dealer or major security-based swap participant is authorized or permitted, directly or through a designated clearing member, to clear the security-based swap.

(3) *Record.* The security-based swap dealer or major security-based swap participant shall make a written record of the non-written disclosures made pursuant to paragraph (d) of this section, and provide a written version of these disclosures to its counterparties in a timely manner, but in any case no later than the delivery of the trade acknowledgement of the particular transaction pursuant to § 240.15Fi–1.

(e) *Know Your Counterparty.* Each security-based swap dealer shall establish, maintain and enforce policies and procedures reasonably designed to obtain and retain a record of the essential facts concerning each counterparty whose identity is known to the security-based swap dealer, that are necessary for conducting business with such counterparty. For purposes of this section, the *essential facts concerning a counterparty* are:

(1) Facts required to comply with applicable laws, regulations and rules;

(2) Facts required to implement the security-based swap dealer's credit and operational risk management policies in connection with transactions entered into with such counterparty;

(3) Information regarding the authority of any person acting for such counterparty; and

(4) If the counterparty is a special entity, such background information regarding the independent representative as the security-based swap dealer reasonably deems appropriate.

(f) *Recommendations of Security-Based Swaps or Trading Strategies.*

(1) A security-based swap dealer that recommends a security-based swap or trading strategy involving a security-based swap to a counterparty, other than a security-based swap dealer, major security-based swap participant, swap dealer, or major swap participant, must have a reasonable basis to believe:

(i) Based on reasonable diligence, that the recommended security-based swap or trading strategy involving a security-based swap is suitable for at least some counterparties; and

(ii) That a recommended security-based swap or trading strategy involving a security-based swap is suitable for the counterparty. To establish a reasonable basis for a recommendation, a security-based swap dealer must have or obtain relevant information regarding the counterparty, including the counterparty's investment profile, trading objectives, and its ability to absorb potential losses associated with the recommended security-based swap or trading strategy.

(2) A security-based swap dealer may also fulfill its obligations under paragraph (g)(1) with respect to a particular counterparty if:

(i) The security-based swap dealer reasonably determines that the counterparty, or an agent to which the counterparty has delegated decision-making authority, is capable of independently evaluating investment risks with regard to the relevant security-based swap or trading strategy involving a security-based swap;

(ii) The counterparty or its agent affirmatively represents in writing that it is exercising independent judgment in evaluating the recommendations of the security-based swap dealer; and

(iii) The security-based swap dealer discloses that it is acting in its capacity as a counterparty, and is not undertaking to assess the suitability of the security-based swap or trading strategy for the counterparty.

(3) A security-based swap dealer will be deemed to have satisfied its obligations under paragraph (f)(1) of this section with respect to a special entity if:

(i) The security-based swap dealer is acting as an advisor to the special entity and complies with the requirements of § 240.15Fh–4(b); or

(ii) The security-based swap dealer is deemed not to be acting as an advisor to the special entity pursuant to § 240.15Fh–2(a).

(h) *Fair and Balanced Communications.* A security-based swap dealer or major security-based swap participant shall communicate with counterparties in a fair and balanced manner based on principles of fair dealing and good faith. In particular:

(1) Communications must provide a sound basis for evaluating the facts with regard to any particular security-based swap or trading strategy involving a security-based swap;

(2) Communications may not imply that past performance will recur or make any exaggerated or unwarranted claim, opinion or forecast; and

(3) Any statement referring to the potential opportunities or advantages presented by a security-based swap shall be balanced by an equally detailed statement of the corresponding risks.

(i) *Supervision.*

(1) *In general.* A security-based swap dealer or major security-based swap

participant shall establish, maintain and enforce a system to supervise, and shall diligently supervise its business and its associated persons, with a view to preventing violations of the provisions of applicable federal securities laws and the rules and regulations thereunder relating to its business as a security-based swap dealer or major security-based swap participant, respectively.

(2) *Minimum requirements.* The system required by paragraph (g)(1) of this section shall be reasonably designed to achieve compliance with applicable securities laws and the rules and regulations thereunder, and at a minimum, shall provide for:

(i) The designation of at least one person with authority to carry out the supervisory responsibilities of the security-based swap dealer or major security-based swap participant for each type of business in which it engages for which registration as a security-based swap dealer or major security-based swap participant is required;

(ii) The use of reasonable efforts to determine that all supervisors are qualified and meet standards of training, experience, and competence necessary to effectively supervise the security-based swap activities of the persons associated with the security-based swap dealer or major security-based swap participant;

(iii) Establishment, maintenance and enforcement of written policies and procedures addressing the supervision of the types of security-based swap business in which the security-based swap dealer or major security-based swap participant is engaged that are reasonably designed to achieve compliance with applicable securities laws and the rules and regulations thereunder, and that include, at a minimum:

(A) Procedures for the review by a supervisor of transactions for which registration as a security-based swap dealer or major security-based swap participant is required;

(B) Procedures for the review by a supervisor of incoming and outgoing written (including electronic) correspondence with counterparties or potential counterparties and internal written communications relating to the security-based swap dealer's or major security-based swap participant's business involving security-based swaps;

(C) Procedures for a periodic review, at least annually, of the security-based swap business in which the security-based swap dealer or major security-based swap participant engages that is reasonably designed to assist in detecting and preventing violations of, and achieving compliance with, applicable federal securities laws and regulations;

(D) Procedures to conduct a reasonable investigation regarding the character, business repute, qualifications, and experience of any person prior to that person's association with the security-based swap dealer or major security-based swap participant;

(E) Procedures to consider whether to permit an associated person to establish or maintain a securities or commodities account in the name of, or for the benefit of such associated person, at another security-based swap dealer, broker, dealer, investment adviser, or other financial institution; and if permitted, procedures to supervise the trading at the other security-based swap dealer, broker, dealer, investment adviser, or financial institution, including the receipt of duplicate confirmations and statements related to such accounts;

(F) A description of the supervisory system, including the titles, qualifications and locations of supervisory persons and the specific responsibilities of each person with respect to the types of business in which the security-based swap dealer or major security-based swap participant is engaged;

(G) Procedures prohibiting an associated person who performs a supervisory function from supervising his or her own activities or reporting to, or having his or her compensation or continued employment determined by, a person or persons he or she is supervising; and

(H) Procedures preventing the standards of supervision from being reduced due to any conflicts of interest of a supervisor with respect to the associated person being supervised.

(iv) Written policies and procedures reasonably designed, taking into consideration the nature of such security-based swap dealer's or major security-based swap participant's business, to comply with the duties set forth in Section 15F(j) of the Act.

(3) *Failure to supervise.* A security-based swap dealer or major security-based swap participant or an associated person of a security-based swap dealer or major security-based swap participant shall not be deemed to have failed to diligently supervise any other person, if such other person is not subject to his or her supervision, or if:

(i) The security-based swap dealer or major security-based swap participant has established and maintained written policies and procedures, and a documented system for applying those policies and procedures, that would reasonably be expected to prevent and detect, insofar as practicable, any violation of the federal securities laws and the rules and regulations thereunder relating to security-based swaps; and

(ii) The security-based swap dealer or major security-based swap participant, or associated person of the security-based swap dealer or major security-based swap participant, has reasonably discharged the duties and obligations required by the written policies and procedures and documented system and did not have a reasonable basis to believe that the written policies and procedures and documented system were not being followed.

(4) *Maintenance of written supervisory procedures.* A security-based swap dealer or major security-based swap participant shall:

(i) Promptly amend its written supervisory procedures as appropriate when material changes occur in applicable securities laws or rules or regulations thereunder, and when material changes occur in its business or supervisory system; and

(ii) Promptly communicate any material amendments to its supervisory procedures throughout the relevant parts of its organization.

§ 240.15Fh–4 Special requirements for security-based swap dealers acting as advisors to special entities.

(a) *In general.* It shall be unlawful for a security-based swap dealer or major security-based swap participant:

(1) To employ any device, scheme, or artifice to defraud any special entity or prospective customer who is a special entity;

(2) To engage in any transaction, practice, or course of business that operates as a fraud or deceit on any special entity or prospective customer who is a special entity; or

(3) To engage in any act, practice, or course of business that is fraudulent, deceptive, or manipulative.

(b) A security-based swap dealer that acts as an advisor to a special entity regarding a security-based swap shall comply with the following requirements:

(1) *Duty.* The security-based swap dealer shall have a duty to act in the best interests of the special entity.

(2) *Reasonable Efforts.* The security-based swap dealer shall make reasonable efforts to obtain such information that the security-based swap dealer considers necessary to make a reasonable determination that a security-based swap or trading strategy involving a security-based swap is in the best interests of the special entity.

This information shall include, but not be limited to:

(i) The authority of the special entity to enter into a security-based swap;

(ii) The financial status of the special entity, as well as future funding needs;

(iii) The tax status of the special entity;

(iv) The investment or financing objectives of the special entity;

(v) The experience of the special entity with respect to entering into security-based swaps, generally, and security-based swaps of the type and complexity being recommended;

(vi) Whether the special entity has the financial capability to withstand changes in market conditions during the term of the security-based swap; and

(vii) Such other information as is relevant to the particular facts and circumstances of the special entity, market conditions and the type of security-based swap or trading strategy involving a security-based swap being recommended.

(3) *Exemption.* The requirements of this § 240.15Fh–4(b) shall not apply with respect to a security-based swap if:

(i) The transaction is executed on a registered security-based swap execution facility or registered national securities exchange; and

(ii) The security-based swap dealer does not know the identity of the counterparty, at any time up to and including execution of the transaction.

§ 240.15Fh–5 Special requirements for security-based swap dealers and major security-based swap participants acting as counterparties to special entities.

(a) A security-based swap dealer or major security-based swap participant that offers to enter into or enters into a security-based swap with a special entity must have a reasonable basis to believe that special entity has a qualified independent representative. For these purposes, a qualified independent representative is an independent representative that:

(1) Has sufficient knowledge to evaluate the transaction and risks;

(2) Is not subject to a statutory disqualification;

(3) Undertakes a duty to act in the best interests of the special entity;

(4) Makes appropriate and timely disclosures to the special entity of material information concerning the security-based swap;

(5) Will provide written representations to the special entity regarding fair pricing and the appropriateness of the security-based swap; and

(6) In the case of employee benefit plans subject to the Employee Retirement Income Security Act of 1974, is a fiduciary as defined in section 3(21) of that Act (29 U.S.C. 1002(21)); and

(7) In the case of a special entity defined in §§ 240.15Fh–2(e)(2) or (4), is a person that is subject to rules of the Commission, the Commodity Futures Trading Commission or a self-regulatory organization subject to the jurisdiction of the Commission or the Commodity Futures Trading Commission prohibiting it from engaging in specified activities if certain political contributions have been made, *provided that* this paragraph (a)(7) shall not apply if the independent representative is an employee of the special entity.

(b) Before initiation of a security-based swap with a special entity, a security-based swap dealer shall disclose to the special entity in writing the capacity in which the security-based swap dealer is acting and, if the security-based swap dealer engages in business, or has engaged in business within the last twelve months, with the counterparty in more than one capacity, the security-based swap dealer shall disclose the material differences between such capacities in connection with the security-based swap and any other financial transaction or service involving the counterparty.

(c) The requirements of this § 240.15Fh–5 shall not apply with respect to a security-based swap if:

(1) The transaction is executed on a registered security-based swap execution facility or registered national securities exchange; and

(2) The security-based swap dealer or major security-based swap participant does not know the identity of the counterparty, at any time up to and including execution of the transaction.

§ 240.15Fh–6 Political contributions by certain security-based swap dealers.

(a) *Definitions.* For the purposes of this section:

(1) The term *contribution* means any gift, subscription, loan, advance, or deposit of money or anything of value made:

(i) For the purpose of influencing any election for state or local office;

(ii) For payment of debt incurred in connection with any such election; or

(iii) For transition or inaugural expenses incurred by the successful candidate for state or local office.

(2) The term *covered associate* means:

(i) Any general partner, managing member or executive officer, or other person with a similar status or function;

(ii) Any employee who solicits a municipal entity to enter into a security-based swap with the security-based swap dealer and any person who supervises, directly or indirectly, such employee; and

(iii) A political action committee controlled by the security-based swap dealer or by a person described in paragraphs (c)(2)(i) and (c)(2)(ii) of this section.

(3) The term *executive officer of a security-based swap dealer* means:

(i) The president;

(ii) Any vice president in charge of a principal business unit, division or function (such as sales, administration or finance);

(iii) Any other officer of the security-based swap dealer who performs a policy-making function; or

(iv) Any other person who performs similar policy-making functions for the security-based swap dealer.

(4) The term *municipal entity* is defined in Section 15B(e)(8) of the Act.

(5) The term *official of a municipal entity* means any person (including any election committee for such person) who was, at the time of the contribution, an incumbent, candidate or successful candidate for elective office of a municipal entity, if the office:

(i) Is directly or indirectly responsible for, or can influence the outcome of, the selection of a security-based swap dealer by a municipal entity; or

(ii) Has authority to appoint any person who is directly or indirectly responsible for, or can influence the outcome of, the selection of a security-based swap dealer by a municipal entity.

(6) The term *payment* means any gift, subscription, loan, advance, or deposit of money or anything of value.

(7) The term *regulated person* means:

(i) A person that is subject to rules of the Commission, the Commodity Futures Trading Commission or a self-regulatory organization subject to the jurisdiction of the Commission or the Commodity Futures Trading Commission prohibiting it from engaging in specified activities if certain political contributions have been made, or its officers or employees;

(ii) A general partner, managing member or executive officer of such person, or other individual with a similar status or function; or

(iii) An employee of such person who solicits a municipal entity for the security-based swap dealer and any person who supervises, directly or indirectly, such employee.

(8) The term *solicit* means a direct or indirect communication by any person with a municipal entity for the purpose of obtaining or retaining an engagement related to a security-based swap.

(b) *Prohibitions and Exceptions.*

(1) It shall be unlawful for a security-based swap dealer to offer to enter into,

or enter into, a security-based swap, or a trading strategy involving a security-based swap, with a municipal entity within two years after any contribution to an official of such municipal entity was made by the security-based swap dealer, or by any covered associate of the security-based swap dealer.

(2) The prohibition in paragraph (b)(1) does not apply:

(i) If the only contributions made by the security-based swap dealer to an official of such municipal entity were made by a covered associate:

(A) To officials for whom the covered associate was entitled to vote at the time of the contributions, *if* the contributions in the aggregate do not exceed $350 to any one official per election; or

(B) To officials for whom the covered associate was not entitled to vote at the time of the contributions, *if* the contributions in the aggregate do not exceed $150 to any one official, per election;

(ii) To a security-based swap dealer as a result of a contribution made by a natural person more than six months prior to becoming a covered associate of the security-based swap dealer, *however,* this exclusion shall not apply if the natural person, after becoming a covered associate, solicits the municipal entity on behalf of the security-based swap dealer to offer to enter into, or to enter into, security-based swap, or a trading strategy involving a security-based swap; or

(iii) With respect to a security-based swap that is initiated by a municipal entity on a registered national securities exchange or registered security-based swap execution facility and the security-based swap dealer does not know the identity of the counterparty to the transaction at any time up to and including execution of the transaction.

(3) No security-based swap dealer or any covered associate of the security-based swap dealer shall:

(i) Provide or agree to provide, directly or indirectly, payment to any person to solicit a municipal entity to offer to enter into, or to enter into, a security-based swap or any trading strategy involving a security-based swap with that security-based swap dealer unless such person is a regulated person; or

(ii) Coordinate, or solicit any person or political action committee to make, any:

(A) Contribution to an official of a municipal entity with which the security-based swap dealer is offering to enter into, or has entered into, a security-based swap security-based swap, or a trading strategy involving a security-based swap; or

(B) Payment to a political party of a state or locality with which the security-based swap dealer is offering to enter into, or has entered into, a security-based swap security-based swap, or a trading strategy involving a security-based swap.

(c) *Circumvention of Rule.* No security-based swap dealer shall, directly or indirectly, through or by any other person or means, do any act that would result in a violation of paragraph (a) or (b) of this section.

(d) *Requests for Exemption.* The Commission, upon application, may conditionally or unconditionally exempt a security-based swap dealer from the prohibition under paragraph (a)(1) of this section. In determining whether to grant an exemption, the Commission will consider, among other factors:

(1) Whether the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes of the Act;

(2) Whether the security-based swap dealer:

(i) Before the contribution resulting in the prohibition was made, adopted and implemented policies and procedures reasonably designed to prevent violations of this section;

(ii) Prior to or at the time the contribution which resulted in such prohibition was made, had no actual knowledge of the contribution; and

(iii) After learning of the contribution:

(A) Has taken all available steps to cause the contributor involved in making the contribution which resulted in such prohibition to obtain a return of the contribution; and

(B) Has taken such other remedial or preventive measures as may be appropriate under the circumstances;

(3) Whether, at the time of the contribution, the contributor was a covered associate or otherwise an employee of the security-based swap dealer, or was seeking such employment;

(4) The timing and amount of the contribution which resulted in the prohibition;

(5) The nature of the election (*e.g.,* state or local); and

(6) The contributor's apparent intent or motive in making the contribution that resulted in the prohibition, as evidenced by the facts and circumstances surrounding the contribution.

(e) *Prohibitions Inapplicable.*

(1) The prohibitions under paragraph (b) of this section shall not apply to a contribution made by a covered associate of the security-based swap dealer if:

(i) The security-based swap dealer discovered the contribution within 120 calendar days of the date of such contribution;

(ii) The contribution did not exceed $350; and

(iii) The covered associate obtained a return of the contribution within 60 calendar days of the date of discovery of the contribution by the security-based swap dealer.

(2) A security-based swap dealer may not rely on paragraph (1) of this section more than twice in any 12-month period.

(3) A security-based swap dealer may not rely on paragraph (1) of this section more than once for any covered associate, regardless of the time between contributions.

3. Add § 240.15Fk–1 to read as follows:

§ 240.15Fk–1 Designation of Chief Compliance Officer for security-based swap dealers and major security-based swap participants.

(a) *In General.* A security-based swap dealer and major security-based swap participant shall designate an individual to serve as a chief compliance officer on its registration form.

(b) *Duties.* The chief compliance officer shall:

(1) Report directly to the board of directors or to the senior officer of the security-based swap dealer or major security-based swap participant;

(2) Review the compliance of the security-based swap dealer or major security-based swap participant with respect to the security-based swap dealer and major security-based swap participant requirements described in Section 15F of the Act, and the rules and regulations thereunder, where the review shall include establishing, maintaining, and reviewing written policies and procedures reasonably designed to achieve compliance with Section 15F of the Act and the rules and regulations thereunder, by the security-based swap dealer or major security-based swap participant;

(3) In consultation with the board of directors or the senior officer of the security-based swap dealer or major security-based swap participant, promptly resolve any conflicts of interest that may arise;

(4) Be responsible for administering each policy and procedure that is required to be established pursuant to Section 15F of the Act and the rules and regulations thereunder;

(5) Establish, maintain and review policies and procedures reasonably

designed to ensure compliance with the Act and the rules and regulations thereunder relating to its business as a security-based swap dealer or major security-based swap participant;

(6) Establish, maintain and review policies and procedures reasonably designed to remediate promptly non-compliance issues identified by the chief compliance officer through any:

(i) Compliance office review;

(ii) Look-back;

(iii) Internal or external audit finding;

(iv) Self-reporting to the Commission and other appropriate authorities; or

(v) Complaint that can be validated; and

(7) Establish and follow procedures reasonably designed for the prompt handling, management response, remediation, retesting, and resolution of non-compliance issues.

(c) *Annual Reports.*

(1) In general. The chief compliance officer shall annually prepare and sign a report that contains a description of:

(i) The compliance of the security-based swap dealer or major security-based swap participant with respect to the Act and the rules and regulations thereunder relating to its business as a security-based swap dealer or major security-based swap participant; and

(ii) Each policy and procedure of the security-based swap dealer or major security-based swap participant described in paragraph (b) of this section, (including the code of ethics and conflict of interest policies).

(2) *Requirements.*

(i) Each compliance report shall also contain, at a minimum, a description of:

(A) The security-based swap dealer or major security-based swap participant's enforcement of its policies and procedures relating to its business as a security-based swap dealer or major security-based participant;

(B) Any material changes to the policies and procedures since the date of the preceding compliance report;

(C) Any recommendation for material changes to the policies and procedures as a result of the annual review, the rationale for such recommendation, and whether such policies and procedures were or will be modified by the security-based swap dealer or major security-based swap participant to incorporate such recommendation; and

(D) Any material compliance matters identified since the date of the preceding compliance report.

(ii) A compliance report under paragraph (c)(1) of this section also shall:

(A) Accompany each appropriate financial report of the security-based swap dealer or major security-based swap participant that is required to be furnished to or filed with the Commission pursuant to Section 15F of the Act and rules and regulations thereunder;

(B) Be submitted to the board of directors and audit committee (or equivalent bodies) and the senior officer of the security-based swap dealer or major security-based swap participant at the earlier of their next scheduled meeting or within 45 days of the date of execution of the required certification;

(C) Include a written representation that the chief executive officer(s) (or equivalent officer(s)) has/have conducted one or more meetings with the chief compliance officer(s) in the preceding 12 months, the subject of which addresses the obligations in this section, including:

(1) The matters that are the subject of the compliance report;

(2) The SBS Entity's compliance efforts as of the date of such a meeting; and

(3) Significant compliance problems and plans in emerging business areas relating to its business as a security-based swap dealer or major security-based swap participant; and

(D) Include a certification that, under penalty of law, the compliance report is accurate and complete.

(iii) Confidentiality. If compliance reports are separately bound from the financial statements, the compliance reports shall be accorded confidential treatment to the extent permitted by law.

(d) *Compensation and Removal.* The compensation and removal of the chief compliance officer shall require the approval of a majority of the board of directors of the security-based swap dealer or major security-based swap participant.

(e) *Definitions.* For purposes of this rule, references to:

(1) The board or board of directors shall include a body performing a function similar to the board of directors.

(2) The senior officer shall include the chief executive officer or other equivalent officer.

(3) Complaint that can be validated shall include any written complaint by a counterparty involving the security-based swap dealer or major security-based swap participant or person associated with a security-based swap dealer or major security-based swap participant that can be supported upon reasonable investigation.

(4) A material compliance matter means any compliance matter about which the board of directors of the security-based swap dealer or major security-based swap participant would reasonably need to know to oversee the compliance of the security-based swap dealer or major security-based swap participant, and that involves, without limitation:

(i) A violation of the federal securities laws relating to its business as a security-based swap dealer or major security-based swap participant, by the firm or its officers, directors, employees or agents;

(ii) A violation of the policies and procedures relating to its business as a security-based swap dealer or major security-based swap participant by the firm or its officers, directors, employees or agents; or

(iii) A weakness in the design or implementation of the policies and procedures relating to its business as a security-based swap dealer or major security-based swap participant.

By the Commission.

Dated: June 29, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–16758 Filed 7–15–11; 8:45 am]

BILLING CODE 8011–01–P

FEDERAL REGISTER

Vol. 76 Monday,
No. 137 July 18, 2011

Part IV

Department of Housing and Urban Development

Consolidated Delegation of Authority to the General Counsel and Consolidated Redelegation of Authority to the Office of General Counsel; Notices

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5543–D–01]

Consolidated Delegation of Authority to the General Counsel

AGENCY: Office of the Secretary, HUD.

ACTION: Notice of Delegation of Authority.

SUMMARY: On December 1, 2009, HUD published in the **Federal Register** a consolidated notice of delegation of authority from the Secretary to the General Counsel. Today's **Federal Register** notice updates the December 1, 2009, consolidated delegation of authority and supersedes all previous delegations of authority from the Secretary to the General Counsel.

DATES: *Effective Date:* July 9, 2011.

FOR FURTHER INFORMATION CONTACT: John P. Opitz, Associate General Counsel for Finance and Administrative Law, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street, SW., Room 8150, Washington, DC 20410–0500, telephone number 202–708–1999. (This is not a toll-free number.) Individuals with speech or hearing impairments may access this number through TTY by calling 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On December 1, 2009, at 74 FR 62801, HUD published a consolidated notice of delegation of authority from the Secretary to the General Counsel. Today's **Federal Register** notice updates the December 1, 2009, consolidated delegation of authority and supersedes all previous delegations of authority from the Secretary to the General Counsel. Published elsewhere in today's **Federal Register** is a redelegation of authority from the General Counsel to subordinate employees within the Office of General Counsel.

Section A of this notice contains general delegations from the Secretary to the General Counsel.

Section B of this notice contains a delegation from the Secretary to the General Counsel regarding enforcement authority. In this section, the Secretary delegates authority to the General Counsel to issue suspensions, debarments, and limited denials of participation, under 2 CFR Part 2424 (adopting the Office of Management and Budget (OMB) guidance in subparts A through I of 2 CFR Part 180, as supplemented by 2 CFR part 2424). In a separate notice published in today's **Federal Register**, the General Counsel redelegates this authority to the Principal Deputy General Counsel, the Deputy General Counsel for Enforcement and Fair Housing, the Director of the Departmental Enforcement Center, the Deputy Director of the Departmental Enforcement Center, and the Directors of the satellite Departmental Enforcement Centers.

Section C of this notice contains a delegation from the Secretary to the General Counsel when acting as the Designated Agency Ethics Official. The Secretary previously named the General Counsel as HUD's Designated Agency Ethics Official (DAEO) and authorized the DAEO to waive any provisions in 5 CFR Part 7501 (Supplemental Standards of Conduct for Employees of the Department of Housing and Urban Development). *See* 5 CFR 7501.102, 7501.103. The Secretary has also named the Deputy General Counsel for Operations as the Alternate Designated Agency Ethics Official to act in the absence of the DAEO. *See* 5 CFR 7501.102. In this notice, the Secretary delegates the authority to the DAEO to authorize the Alternate DAEO to perform the waiver function of the DAEO in 5 CFR Part 7501 concurrently with the DAEO.

In addition to the authority published in today's consolidated delegation of authority, the Secretary has delegated other authorities to the General Counsel by regulation. These delegations include:

1. Naming the General Counsel as HUD's Designated Agency Ethics Official; 5 CFR 7501.102.

2. Authorizing the General Counsel, and in some instances, the appropriate Associate General Counsel or Regional Counsel, to respond to subpoenas and/or other demands from the courts or other authorities; 24 CFR Part 15.

3. Designating the General Counsel as the source selection authority for the procurement of outside legal services through either the lowest price technically acceptable or a tradeoff process; 48 CFR 2415.303(a)(3).

4. Designating the General Counsel as a responsible official to ensure the implementation of the policies of the National Environmental Policy Act (NEPA) and other environmental requirements of the Department, including the performance of the responsibilities of a Program Environmental Clearance Officer pursuant to 24 CFR 50.10(a), 50.16.

5. Authorizing the General Counsel, as set forth in 24 CFR Parts 103 and 180, to exercise authority pertaining to civil rights statutes, including the Fair Housing Act, 42 U.S.C. 3601 *et seq.;* Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. 200d *et seq.;* Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 791 *et seq.;* the Age Discrimination Act of 1975, as amended, 42 U.S.C. 6101 *et seq.;* and Section 109 of the Housing and Community Development Act of 1974, as amended, 42 U.S.C. 5301 *et seq.*

6. Authorizing the General Counsel to initiate a civil money penalty action pursuant to Sections 102 and 103 of the Department of Housing and Urban Development Reform Act of 1989 (42 U.S.C. 3537a(c), 3545); 24 CFR Part 4 in accordance with the provisions of 24 CFR Part 30.

7. Authorizing the General Counsel to appoint and fix the compensation of a foreclosure commissioner or commissioners and alternate commissioners, in accordance with the Multifamily Mortgage Foreclosure Act of 1981 (12 U.S.C. 3701 *et seq.*); 24 CFR 27.10.

HUD's program Assistant Secretaries have also delegated authority to the General Counsel. The Assistant Secretary for Housing-Federal Housing Commissioner has delegated authority to the General Counsel to issue a notice of violation under the terms of a regulatory agreement; to issue a notice of default under the terms of housing assistance payments contracts (HAPs), Rental Assistance Payment Contracts, Project Rental Assistance Contracts, or Use Agreements; to impose civil money penalties; and to take all actions permitted under 24 CFR 30.36, 30.45, and 30.68.

Section 30.36 of HUD's regulations (24 CFR 30.36) authorizes the Assistant Secretary for Housing-Federal Housing Commissioner, or designee, to initiate civil money penalty action against any principal, officer, or employee of a mortgagee or lender, or other participant or any provider of assistance to a borrower in connection with any such mortgage or loan, including: sellers, borrowers, closing agents, title companies, real estate agents, mortgage brokers, appraisers, loan correspondents, dealers, consultants, contractors, subcontractors, and inspectors. Section 30.45 of HUD's regulations (24 CFR 30.45) authorizes the Assistant Secretary for Housing-Federal Housing Commissioner, or designee, to initiate civil money penalty action against any mortgagor of a multifamily property with a mortgage insured, co-insured, or held by the Secretary, pursuant to Title II of the National Housing Act or to Section 202 of the Housing Act of 1959.

Section 30.68 of HUD's regulations (24 CFR 30.68) authorizes the Assistant Secretary for Housing-Federal Housing Commissioner, or designee, to initiate

civil money penalty action against any owner, general partner of a partnership, or agent employed to manage the property that has an identity of interest with the owner or general partner receiving project-based assistance under Section 8 of the United States Housing Act of 1937 for a knowing and material breach of housing assistance payment (HAP) contracts.

Section A. Authority

The Secretary of Housing and Urban Development hereby delegates the following authorities to the General Counsel:

1. To interpret the authority of the Secretary and to determine whether the issuance of any rule, regulation, statement of policy, or standard promulgated by HUD is consistent with that authority.

2. To direct all litigation affecting HUD and to sign, acknowledge, and verify on behalf of and in the name of the Secretary all declarations, bills, petitions, pleas, complaints, answers, and other pleadings in any court proceeding brought in the name of or against the Secretary or in which the Secretary is a named party.

3. To direct the referral of cases and other matters to the Attorney General for appropriate legal action and to transmit information and material pertaining to the violation of law or HUD rules and regulations. Excepted from this authority, however, are those referrals and transmittals that the Inspector General is authorized to make by law or by delegation of authority.

4. To accept, on behalf of the Secretary, service of all summons, subpoenas, and other judicial, administrative, or legislative processes directed to the Secretary or to an employee of HUD in an official capacity, and to execute affidavits asserting HUD's deliberative process privilege.

5. Where not inconsistent with regulations pertaining to proceedings before administrative law judges, to approve the issuance of subpoenas or interrogatories pertaining to investigations for which responsibility is vested in the Secretary.

6. To consider, ascertain, adjust, determine, compromise, allow, deny, or otherwise dispose of claims under the Federal Tort Claims Act, 28 U.S.C. 1346(b), 2671 *et seq.* and the Military Personnel and Civilian Employees' Claims Act of 1974, 31 U.S.C. 3721 *et seq.*

7. To act upon the appeals and issue final determinations on appeals of denial of access or record correction under the Privacy Act of 1974, except appeals regarding records maintained by the Office of Inspector General (Pub. L. 93–579), 5 U.S.C. 552(c).

8. To make written requests, for purposes of civil or criminal law enforcement activities, to other agencies for the transfer of records or copies of records maintained by such agencies under subsection (b)(7) of the Privacy Act of 1974, as amended (5 U.S.C. 552a(b)(7)).

9. To act upon appeals under the Freedom of Information Act, 5 U.S.C. 552, except appeals from decisions of the Office of Inspector General.

10. To appoint a foreclosure commissioner or commissioners, or a substitute foreclosure commissioner, to replace a previously designated foreclosure commissioner under:

(a) Section 805 of the Single Family Mortgage Foreclosure Act of 1994, 12 U.S.C. 3754; the power to fix compensation for the foreclosure commissioner under Section 812 of the Single Family Mortgage Foreclosure Act of 1994, 12 U.S.C. 3761; and to promulgate regulations necessary to carry out the provisions of the Single Family Mortgage Foreclosure Act of 1994; and

(b) Section 365 of the Multifamily Mortgage Foreclosure Act of 1981, 12 U.S.C. 3701, *et seq.;* the power to fix compensation for the foreclosure commissioner under Section 369(c) of the Multifamily Mortgage Foreclosure Act of 1981, 12 U.S.C. 3701, *et seq.;* and to promulgate regulations necessary to carry out the provisions of the Multifamily Mortgage Foreclosure Act of 1981.

11. To make determinations and certifications required under Section 1114 of the Right to Financial Privacy Act, 12 U.S.C. 3401, *et seq.*

12. To designate authorized officials to exercise the powers or perform the duties of the General Counsel, through an order of succession (subject to the provisions of the Federal Vacancies Reform Act of 1998, 5 U.S.C. 3345–3349d), during any period when, by reason of absence, disability, or vacancy in office, the General Counsel for HUD is not available.

13. Where not inconsistent with other regulations pertaining to proceedings before administrative law judges, to serve as an Attesting Officer and to cause the seal of HUD to be affixed to such documents as may require its application and to certify that a copy of any book, paper, microfilm, or other document is a true copy of that in the files of HUD.

14. To act as the designated official under Section 5(a) of Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights, issued March 15, 1987, (53 FR 8859, March 18, 1988) consistent with Executive Order 13406, Protecting the Property Rights of the American People, issued June 23, 2006 (71 FR 36973, June 28, 2006).

15. To make determinations of federalism implications, preemption, or the need for consultations with state and local officials as required by Executive Order 13131, Federalism, issued August 4, 1999 (64 FR 43255, August 10, 1999).

Section B. Enforcement Authority

The Secretary hereby delegates the following authority to the General Counsel:

1. To issue suspensions, debarments, and limited denials of participation, under 2 CFR part 180.

Section C. Authority Delegated to the Designated Agency Ethics Official

The Secretary hereby delegates the following authority to the General Counsel when acting as HUD's Designated Agency Ethics Official:

1. To authorize the Alternate Designated Agency Ethics Official to perform the waiver function of the Designated Agency Ethics Official, as provided by 5 CFR Part 7501, concurrently with the Designated Agency Ethics Official.

Section D. Authority To Redelegate

The General Counsel is authorized to redelegate to employees of HUD any of the authority delegated under Sections A, B, and C above.

Section E. Authority Superseded

This delegation supersedes all previous delegations of authority from the Secretary to the General Counsel.

Authority: Section 7(d) Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: July 9, 2011.

Shaun Donovan,

Secretary.

[FR Doc. 2011–18016 Filed 7–15–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5543–D–02]

Consolidated Redelegation of Authority to the Office of General Counsel

AGENCY: Office of General Counsel, HUD.

ACTION: Notice of Redelegation of Authority.

SUMMARY: This redelegation of authority consolidates and updates past redelegations of authority from the General Counsel to subordinate employees.

DATES: *Effective Date:* July 9, 2011.

FOR FURTHER INFORMATION CONTACT: John P. Opitz, Associate General Counsel for Finance and Administrative Law, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street, SW., Room 8150, Washington, DC 20410–0500, telephone number 202–708–1999. (This is not a toll-free number.) Individuals with speech or hearing impairments may access this number through TTY by calling 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Elsewhere in today's **Federal Register** is a notice of a consolidated delegation of authority from the Secretary to the General Counsel. In that notice, the General Counsel is authorized to redelegate to employees of HUD authority delegated by the Secretary in that notice to the General Counsel. Through this notice, the General Counsel is redelegating certain authority to other employees of the Office of General Counsel.

Section A of this notice contains concurrent redelegations from the General Counsel to the Principal Deputy General Counsel, the Deputy General Counsel for Operations, the Deputy General Counsel for Housing Programs and the Deputy General Counsel for Enforcement and Fair Housing.

Section B of this notice contains redelegations from the General Counsel to specific positions within the Office of General Counsel.

Section C of this notice contains redelegations to the Departmental Enforcement Center within the Office of General Counsel.

Section D contains redelegations from the General Counsel, in his or her capacity as the Designated Agency Ethics Official, to the Deputy General Counsel for Operations when acting as the Alternate Designated Agency Ethics Official. The Secretary previously named the General Counsel as HUD's Designated Agency Ethics Official (DAEO) and authorized the DAEO to waive any provisions in 5 CFR part 7501 (Supplemental Standards of Conduct for Employees of the Department of Housing and Urban Development). See 5 CFR 7501.102 and 5 CFR 7501.103. The Secretary has also named the Deputy General Counsel for Operations as the Alternate Designated Agency Ethics Official to act in the absence of the DAEO. See 5 CFR 7501.102. Pursuant to the provisions of 5 CFR 2638.204, a DAEO may redelegate to one or more ethics officials all duties of the DAEO under 5 CFR 2638.203, except those functions in 5 CFR 2634.605(c)(2) and 5 CFR 2638.203(b)(3). In this notice, the DAEO delegates to the Alternate DAEO the authority to perform all the functions of the DAEO under 5 CFR 2638.203 concurrently with the DAEO, except those functions described in 5 CFR 2634.605(c)(2) and 5 CFR 2638.203(b)(3). In the consolidated delegation of authority from the Secretary to the General Counsel, the Secretary delegated the authority to the DAEO to redelegate authority to the Alternate DAEO to perform the waiver function of the DAEO in 5 CFR part 7501 concurrently with the DAEO. In this notice, the DAEO redelegates the authority to the Alternate DAEO to perform the waiver function of the DAEO in 5 CFR part 7501 concurrently with the DAEO.

Section E of this notice redelegates Regional Counsel settlement authority, which is detailed in the Litigation Handbook and its appendices, i.e., HUD Handbook 1530.1 REV–5. First, for Federal Party Litigation, i.e., when HUD is a party, the Regional Counsel may now recommend to the U.S. Department of Justice (DOJ) whether to approve Routine Settlements of all cases that they are handling except where the settlement involves more than $1 million. *See* Litigation Handbook, ¶ 2–3(g)(1)(a). This notice increases that amount to $2 million. Second, for Non-Federal Party Litigation, i.e., when HUD has an interest but is not a party, the Litigation Handbook now authorizes the Regional Counsel to approve Routine Settlements not exceeding $500,000 without the concurrence of the Program Associate General Counsel. *See* Litigation Handbook, ¶¶ 2–3(g)(2), 3–3(b)(5). This notice increases that amount to $1 million. This notice does not alter any other requirement or guideline in the Litigation Handbook.

These redelegations revoke and supersede all previous delegations of authority from the General Counsel to subordinate employees, but specifically do not revoke the divisions of responsibility set forth in the Office of General Counsel Litigation Handbook and its appendices, except where specifically stated in Section E.

Section A. Authority Delegated to the Principal Deputy General Counsel and Deputy General Counsels

The General Counsel retains and redelegates the following authority concurrently to the Principal Deputy General Counsel, the Deputy General Counsel for Operations, the Deputy General Counsel for Housing Programs and the Deputy General Counsel for Enforcement and Fair Housing.

1. To interpret the authority of the Secretary and to determine whether the issuance of any rule, regulation, statement of policy, or standard promulgated by HUD is consistent with that authority.

2. To direct all litigation affecting HUD and to sign, acknowledge and verify on behalf of and in the name of the Secretary all declarations, bills, petitions, pleas, complaints, answers, and other pleadings in any court proceeding brought in the name of or against the Secretary or in which he/she is a named party.

3. To direct the referral of cases and other matters to the Attorney General for appropriate legal action and to transmit information and material pertaining to the violation of law or HUD rules and regulations. There are excepted from this authority, however, those referrals and transmittals that the Inspector General is authorized to make by law or by delegation of authority.

4. To accept, on behalf of the Secretary, service of all summons, subpoenas, and other judicial, administrative, or legislative processes directed to the Secretary or to an employee of HUD in an official capacity and to execute affidavits asserting HUD's deliberative process privilege.

5. Where not inconsistent with other regulations pertaining to proceedings before administrative law judges, to approve the issuance of subpoenas or interrogatories pertaining to investigations for which responsibility is vested in the Secretary.

6. To consider, ascertain, adjust, determine, compromise, allow, deny or otherwise dispose of claims under the Federal Tort Claims Act, 28 U.S.C. 1346(b), 2671 *et seq.* and the Military Personnel and Civilian Employees' Claims Act of 1974, 31 U.S.C. 3721 *et seq.*

7. To act upon the appeals and issue final determinations on appeals of denial of access or record correction under the Privacy Act of 1974, except appeals regarding records maintained by the Office of Inspector General (Pub. L. 93–579), 5 U.S.C. 552(c).

8. To make written requests, for purposes of civil or criminal law enforcement activities, to other agencies for the transfer of records or copies of records maintained by such agencies under subsection (b)(7) of the Privacy Act of 1974, as amended (5 U.S.C. 552a(b)(7)) (''Privacy Act'').

9. To act upon appeals under the Freedom of Information Act, 5 U.S.C. 552, except appeals from decisions of the Office of Inspector General.

10. To appoint a foreclosure commissioner or commissioners, or a substitute foreclosure commissioner to replace a previously designated foreclosure commissioner under:

(a) Section 805 of the Single Family Mortgage Foreclosure Act of 1994, 12 U.S.C. 3754; the power to fix compensation for the foreclosure commissioner under Section 812 of the Single Family Mortgage Foreclosure Act of 1994; 12 U.S.C. 3761, and to promulgate regulations necessary to carry out the provisions of the Single Family Mortgage Foreclosure Act of 1994; and

(b) Section 365 of the Multifamily Mortgage Foreclosure Act of 1981, 12 U.S.C. 3701, *et seq.;* the power to fix compensation for the foreclosure commissioner under Section 369(c) of the Multifamily Mortgage Foreclosure Act of 1981; 12 U.S.C. 3701, *et seq.,* and to promulgate regulations necessary to carry out the provisions of the Multifamily Mortgage Foreclosure Act of 1981.

11. To make determinations and certifications required under Section 1114 of the Right to Financial Privacy Act, 12 U.S.C. 3401, *et seq.*

12. To designate authorized officials to exercise the powers or perform the duties of the General Counsel, through an order of succession (subject to the provisions of the Federal Vacancies Reform Act of 1998, 5 U.S.C. 3345–3349d), during any period when by reason of absence, disability, or vacancy in office, the General Counsel for HUD is not available.

13. To serve as an Attesting Officer and to cause the seal of HUD to be affixed to such documents as may require its application and to certify that a copy of any book, paper, microfilm, or other document is a true copy of that in the files of HUD.

14. To act as the designated official under Section 5(a) of Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights, issued March 15, 1987 (53 FR 8859, March 18, 1988) consistent with Executive Order 13406, Protecting the Property Rights of the American People, issued June 23, 2006 (71 FR 36973, June 28, 2006).

15. To make determinations of federalism implications, preemptions, or the need for consultation with state and local officials as required by Executive Order 13131, Federalism, issued August 4, 1999 (64 FR 43255, August 10, 1999).

Section B. Authority Redelegated to Specific Positions Within the Office of General Counsel

The General Counsel hereby retains and redelegates the following authority to the Principal Deputy General Counsel, the Deputy General Counsel and to specific positions identified below within the Office of General Counsel. This authority may not be further redelegated unless expressly stated in the redelegation.

1. To the Associate General Counsel for Litigation and to Regional Counsel, the authority to accept, on behalf of the Secretary, service of all summons, subpoenas, and other judicial, administrative, or legislative processes directed to the Secretary or to an employee of HUD Headquarters in an official capacity. The Associate General Counsel for Litigation may redelegate this authority within the Office of Litigation and the Regional Counsel may redelegate this authority to Associate Regional Counsel for Housing Finance and Programs within their operating jurisdictions.

2. To the Associate General Counsel for Finance and Administrative Law, or designee, the authority to implement the policies of the National Environmental Policy Act (NEPA) and other environmental requirements of HUD, including the performance of the responsibilities of the Program Environmental Clearance Officer for the Office of General Counsel; 24 CFR 50.10(a), 50.16. The Associate General Counsel retains and redelegates this authority to the Assistant General Counsel, Administrative Law Division, and to the Senior Environmental Attorney.

3. To the Associate General Counsel for Fair Housing and to Regional Counsel, the authority to process cases arising under the Fair Housing Act, as set forth in 24 CFR parts 103 and 180 (with the exception of 24 CFR 180.675). The Associate General Counsel for Fair Housing retains this authority and further redelegates it to the Assistant General Counsel for Fair Housing Enforcement and the Assistant General Counsel for Fair Housing Compliance.

4. To the Associate General Counsel for Fair Housing and to Regional Counsel, the authority to process cases arising under Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, Section 109 of the Housing and Community Development Act of 1974, and the Age Discrimination Act of 1975, as set forth in 24 CFR part 180 (with the exception of 24 CFR 180.675). The Associate General Counsel for Fair Housing retains this authority and further redelegates it to the Assistant General Counsel for Fair Housing Compliance and the Assistant General Counsel for Fair Housing Enforcement.

5. To the Associate General Counsel for Fair Housing, the authority under 24 CFR 180.675(b), (c), (d) and (e) concerning petitions for review. The Associate General Counsel for Fair Housing retains and redelegates this authority to the Assistant General Counsel for Fair Housing Enforcement and the Assistant General Counsel for Fair Housing Compliance.

6. To the Associate General Counsel for Program Enforcement, the Associate General Counsel for Finance and Administrative Law, the Associate General Counsel for Ethics and Personnel Law, the Associate General Counsel for Litigation, the Associate General Counsel for Fair Housing and each Regional Counsel, the authority to make written requests, for purposes of civil or criminal law enforcement activities, to other agencies for the transfer of records or copies of records maintained by such agencies under subsection (b)(7) of the Privacy Act of 1974, as amended (5 U.S.C. 552a(b)(7)) (''Privacy Act''), except appeals involving records maintained by the Office of Inspector General.

7. To the Associate General Counsel for Ethics and Personnel Law and the Regional Counsel the authority to make determinations and certifications required under section 1114 of the Right to Financial Privacy Act, 12 U.S.C. 3401, *et seq.*

8. To the Associate General Counsel for the Office of Assisted Housing and Community Development, the authority to make legal determinations on behalf of the Department of Housing and Urban Development on matters involving the financing of obligations guaranteed under section 108 of the Housing and Community Development Act of 1974, as amended, 42 U.S.C. 5308.

9. To the Senior Counsel for Appeals, the Associate General Counsel for Ethics and Personnel Law, the Associate General Counsel for Finance and Administrative Law, and the Regional Counsel, the authority to act upon appeals emanating from Headquarters or Regional Offices under the Freedom of Information Act (''FOIA''), 5 U.S.C. 552, except appeals from decisions of the Office of Inspector General. To the Regional Counsel, the authority to act upon appeals emanating from Field Offices under the Freedom of Information Act (''FOIA''), 5 U.S.C. 552, except appeals from decisions of the Office of Inspector General.

10. To the Associate General Counsel for Ethics and Personnel Law and the Assistant General Counsel, Ethics Law Division, the authority to serve as Deputy Agency Ethics Officials in Headquarters responsible for undertaking Standards of Conduct program duties as directed by the General Counsel. The Associate General Counsel for Ethics and Personnel Law and the Assistant General Counsel, Ethics Law Division, may redelegate these duties to the Deputy Assistant General Counsel, Ethics Law Division. To the Regional Counsel, the authority to serve as Deputy Agency Ethics Officials responsible for undertaking Standards of Conduct program duties for the Regional and Field Offices as directed by the General Counsel. The Regional Counsel may redelegate their duties to Deputy Regional Counsel.

11. To Regional Counsel, the authority to appoint a foreclosure commissioner or commissioners, or a substitute foreclosure commissioner to replace a previously designated foreclosure commissioner under Section 805 of the Single Family Mortgage Foreclosure Act of 1994, 12 U.S.C. 3754; the power to fix compensation for the foreclosure commissioner under Section 812 of the Single Family Mortgage Foreclosure Act of 1994, 12 U.S.C. 3761. This authority may be redelegated to the Deputy Regional Counsel with the approval of the General Counsel.

12. To Regional Counsel, the authority to appoint a foreclosure commissioner or commissioners, or a substitute foreclosure commissioner to replace a previously designated foreclosure commissioner, under Section 365 of the Multifamily Mortgage Foreclosure Act of 1981 and the power to fix compensation for the foreclosure commissioner under Section 369C of the Multifamily Mortgage Foreclosure Act of 1981 (12 U.S.C. 3701, *et seq.*). This authority may be redelegated to the Deputy Regional Counsel.

13. To Regional Counsel for Region I (Boston, MA), through the Federal Tort Claims Center, the power and authority to consider, ascertain, adjust, determine, compromise, allow, deny or otherwise dispose of claims under the Federal Tort Claims Act and the Military Personnel and Civilian Employees' Claims Act of 1964. This authority may be redelegated by the Deputy Regional Counsel for Region I (Boston, MA).

14. To Regional Counsel, the authority to concur on the issuance and settlement of limited denials of participation (LDPs) issued by HUD program officials pursuant to 2 CFR part 2424.

15. To the positions listed below, the authority to serve as Attesting Officers and to cause the seal of HUD to be affixed to such documents as may require its application and to certify that a copy of any book, paper, microfilm, or other document is a true copy of that in the files of HUD:

(a) Each Associate General Counsel;
(b) Each Assistant General Counsel;
(c) Each Regional Counsel;
(d) Each Deputy Regional Counsel; and
(e) Each Associate Regional Counsel for Housing Finance and Programs.

This authority may be redelegated.

Section C. Authority Redelegated to the Departmental Enforcement Center

The General Counsel retains and redelegates the following authority to the Principal Deputy General Counsel, the Deputy General Counsel for Enforcement and Fair Housing, Director of the Departmental Enforcement Center, the Deputy Director of the Departmental Enforcement Center, and the Directors of the satellite Departmental Enforcement Centers. This authority may not be further redelegated unless expressly stated in the redelegation.

1. The authority to take all actions permitted under 24 CFR 30.36, not to include the authority to waive any regulations issued under the authority of the Assistant Secretary for Housing-Federal Housing Commissioner.

2. The authority to take all actions permitted under 24 CFR 30.45, not to include the authority to waive any regulations issued under the authority of the Assistant Secretary for Housing-Federal Housing Commissioner.

3. The authority to take all actions permitted under 24 CFR 30.68, not to include the authority to waive any regulations issued under the authority of the Assistant Secretary for Housing-Federal Housing Commissioner or the Assistant Secretary for Public and Indian Housing.

4. The authority to issue notice of default under the terms of a section 8 housing assistance payments contract, Rental Assistance Payment contract, Project Rental Assistance Contract or Use Agreement, issued under the authority of the Assistant Secretary for Housing-Federal Housing Commissioner.

5. The authority to issue notice of violation under the terms of a regulatory agreement entered under contract issued under the authority of the Assistant Secretary for Housing-Federal Housing Commissioner.

6. The authority to initiate a civil money penalty action against:

(a) Employees who improperly disclose information pursuant to section 103 of the Department of Housing and Urban Development Reform Act of 1989 (42 U.S.C. 3537a(c)) and 24 CFR part 4, subpart B in accordance with the provisions of 24 CFR part 30.

(b) Applicants for assistance, as defined in 24 CFR part 4, subpart A, who knowingly and materially violate the provisions of subsections (b) or (c) of Section 102 of the Department of Housing and Urban Development Reform Act of 1989 (42 U.S.C. 3545) in accordance with the provisions of 24 CFR part 30.

7. The authority to issue suspensions, debarments, and limited denials of participation, under 2 CFR part 2424.

Section D. Authority Redelegated to the Alternate Designated Agency Ethics Official

The General Counsel, acting as the Designated Agency Ethics Official (DAEO), hereby retains and redelegates the following authorities to the Deputy General Counsel for Operations when acting as the Alternate Designated Agency Ethics Official. This authority may not be further redelegated.

1. To perform all the functions of the DAEO under 5 CFR 2638.203 concurrently with the DAEO, except those functions described in 5 CFR 2634.605(c)(2) and 5 CFR 2638.203(b)(3).

2. To perform the waiver function of the DAEO in 5 CFR part 7501 concurrently with the DAEO.

Section E. Settlement Authority Redelegated to the Regional Counsel

The General Counsel hereby retains and redelegates the following authority to the Regional Counsel. This authority may not be further redelegated.

1. To recommend whether DOJ should approve Routine Settlements of all Federal Party Litigation that they are handling except where the settlement involves more than $2 million.

2. Except where the settlement involves more than $1 million, to approve Routine Settlement of Non-Federal Party Litigation without the concurrence of the Program Associate General Counsel.

The settlement authority granted in this section does not supersede the requirements or guidelines in the Litigation Handbook, except in respect to the dollar amount increases.

Section F. Authority Superseded

This delegation supersedes all previous delegations of authority from the General Counsel to subordinate positions within the Office of General

Counsel, but specifically do not revoke the divisions of responsibility set forth in the Office of General Counsel Litigation Handbook and its appendices, except where specifically stated in Section E.

Authority: Section 7(d) Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: July 9, 2011.

Helen R. Kanovsky,

General Counsel.

[FR Doc. 2011–18017 Filed 7–15–11; 8:45 am]

BILLING CODE 4210–67–P

Reader Aids

Federal Register

Vol. 76, No. 137

Monday, July 18, 2011

CUSTOMER SERVICE AND INFORMATION

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **www.ofr.gov.**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

Reminders. Effective January 1, 2009, the Reminders, including Rules Going Into Effect and Comments Due Next Week, no longer appear in the Reader Aids section of the Federal Register. This information can be found online at **http://www.regulations.gov.**

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, JULY

38547–38960 1
38961–39244 5
39245–39762 6
39763–40214 7
40215–40590 8
40591–40776 11
40777–41040 12
41041–41374 13
41375–41588 14
41589–41992 15
41993–42468 18

CFR PARTS AFFECTED DURING JULY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

2 CFR

Proposed Rules:
Ch. XIV 40645

3 CFR

Proclamations:
8691 40215

Executive Orders:
13578 40591
13579 41587
13580 41989

5 CFR

831 41993
841 41993
842 41993
2634 38547
2635 38547

Proposed Rules:
Ch. XXI 39315

6 CFR

5 ..... 39245, 42003, 42004, 42005

Proposed Rules:
5 39315

7 CFR

946 41589
989 42006
1210 42009
1260 42012
3430 ..... 38548, 40593

Proposed Rules:
800 42067
930 42072

10 CFR

50 40777
430 39245
835 38550

Proposed Rules:
20 42074
30 40282
150 40282
Ch. II 40646
430 40285
Ch. III 40646
Ch. X 40646

12 CFR

Ch. I 39246
48 41375
202 41590
204 42015
217 42015
222 41602
230 42015
Ch. III 39246
329 41392
330 41392
349 40779
380 41626

Proposed Rules:
Ch. I 39315
Ch. V 39315
Ch. XV 39315
Ch. XVIII 38577, 39315

14 CFR

25 ..... 38550, 39763, 41041, 41045
33 ..... 40594, 42020
39 ..... 39248, 39251, 39254, 39256, 40217, 40219, 40222, 40596, 41395, 41647, 41651, 41653, 41657, 41659, 41662, 41665, 41667, 41669, 41673, 42024, 42029, 42031, 42033
71 ..... 39259, 40597, 40598, 40797, 41397
91 39259
97 ..... 40598, 40600
121 40798

Proposed Rules:
25 41142
33 39795
39 ..... 39033, 39035, 40286, 40288, 40291, 41144, 41430, 41432
71 ..... 38580, 38581, 38582, 38584, 38585, 39038, 40293, 40295, 41145, 41147, 41725
139 40648
234 41726
241 41726

15 CFR

4 39769
730 40602
738 41046
740 41046
748 ..... 40602, 40804
754 40602
806 39260

Proposed Rules:
713 41366
714 41372
716 41366
730 41958
732 41958
734 41958
738 41958
740 41958
742 41958
743 41958
744 41958
746 41958
748 41958
756 41958
762 41958
770 41958
772 41958
774 41958

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO's Federal Digital System (FDsys) at *http://www.gpo.gov/fdsys*. Some laws may not yet be available.

H.R. 2279/P.L. 112–21

Airport and Airway Extension Act of 2011, Part III (June 29, 2011; 125 Stat. 233)

S. 349/P.L. 112–22

To designate the facility of the United States Postal Service located at 4865 Tallmadge Road in Rootstown, Ohio, as the ''Marine Sgt. Jeremy E. Murray Post Office''. (June 29, 2011; 125 Stat. 236)

S. 655/P.L. 112–23

To designate the facility of the United States Postal Service located at 95 Dogwood Street in Cary, Mississippi, as the ''Spencer Byrd Powers, Jr. Post Office''. (June 29, 2011; 125 Stat. 237)

Last List June 28, 2011

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.