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WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, September 14, 2010
9 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No. FAA–2006–25877; Amendment No. 91–317]

RIN 2120–AJ44

Inclusion of Reference to Manual Requirements

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; technical amendment.

SUMMARY: The Federal Aviation Administration (FAA) is making a minor technical change to a final rule published in the **Federal Register** on October 16, 2009. That final rule established new requirements for the certification of products and articles. In that final rule, the FAA inadvertently did not change an affected regulatory reference in one section. The FAA is issuing this technical amendment to correct that oversight.

DATES: *Effective Date:* Effective on April 16, 2011.

FOR FURTHER INFORMATION CONTACT: Kim Barnette, Aircraft Maintenance Division, AFS–300, Federal Aviation Administration, 950 L'Enfant Plaza North, SW., Washington, DC 20024; telephone: (202) 385–6403; facsimile: (202) 385–6474; e-mail: *Kim.A.Barnette@faa.gov.*

SUPPLEMENTARY INFORMATION: The FAA published a final rule entitled "Production and Airworthiness Approvals, Parts Marking, and Miscellaneous Amendments" in the **Federal Register** on October 16, 2009 (74 FR 53368). That final rule established new requirements for the certification of products and articles. That final rule also redesignated § 21.305 as § 21.8 but did not revise a cross reference in § 91.107(a)(3)(iii)(B)(3)(iv) to reflect the redesignation. This technical amendment will correct § 91.107(a)(3)(iii)(B)(3)(iv) to reference newly redesignated § 21.8.

List of Subjects in 14 CFR Part 91

Afghanistan, Agriculture, Air traffic control, Aircraft, Airmen, Airports, Aviation safety, Canada, Cuba, Ethiopia, Freight, Mexico, Noise control, Political candidates, Reporting and recordkeeping requirements, Yugoslavia.

■ Accordingly, Title 14 of the Code of Federal Regulations (CFR) part 91 is amended as follows:

The Amendment

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(g), 1155, 40103, 40113, 40120, 44101, 44111, 44701, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, articles 12 and 29 of the Convention on International Civil Aviation (61 Stat.1180).

■ 2. Amend § 91.107 by revising paragraph (a)(3)(iii)(B)(3)(iv) to read as follows:

§ 91.107 Use of safety belts, shoulder harnesses, and child restraint systems.

(a) * * *

(3) * * *

(iii) * * *

(B) * * *

(3) * * *

(*iv*) That the seat or child restraint device furnished by the operator, or one of the persons described in paragraph (a)(3)(iii)(A) of this section, was approved by the FAA in accordance with § 21.8 or Technical Standard Order C–100b, or a later version.

* * * * *

Issued in Washington, DC on August 9, 2010.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

[FR Doc. 2010–19912 Filed 8–11–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 242

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 100

[Docket No. FWS–R7–SM–2010–0048; 70101–1261–0000L6]

Subsistence Management Regulations for Public Lands in Alaska, Subpart D; Seasonal Adjustments

AGENCY: Forest Service, USDA; Fish and Wildlife Service, Interior.

ACTION: Seasonal adjustments.

SUMMARY: This provides notice of the Federal Subsistence Board's (Board) in-season management actions for the 2009–10 regulations for taking wildlife. These actions provide exceptions to the regulations currently in effect for Subsistence Management of Public Lands in Alaska. Those regulations established seasons, harvest limits, and methods and means for taking of wildlife for subsistence uses during the 2008–09 and 2009–10 regulatory years.

DATES: The various seasonal adjustments were effective on the dates of the applicable public notices that were advertised by mail, e-mail, radio, newspaper, and the Federal Subsistence Management Program (Program) Web page.

FOR FURTHER INFORMATION CONTACT: Chair, Federal Subsistence Board, c/o U.S. Fish and Wildlife Service, Attention: Peter J. Probasco, Office of Subsistence Management; (907) 786–3888 or *subsistence@fws.gov.* For questions specific to National Forest System lands, contact Steve Kessler, Subsistence Program Leader, USDA, Forest Service, Alaska Region, (907) 743–9461 or *skessler@fs.fed.us.*

SUPPLEMENTARY INFORMATION:

Background

Under Title VIII of the Alaska National Interest Lands Conservation Act (ANILCA) (16 U.S.C. 3111–3126), the Secretary of the Interior and the Secretary of Agriculture (Secretaries) jointly implement the Federal Subsistence Management Program. This

Program grants a preference for subsistence uses of fish and wildlife resources on Federal public lands and waters in Alaska. The Secretaries first published regulations to carry out this Program in the **Federal Register** on May 29, 1992 (57 FR 22940). These regulations have subsequently been amended several times. Because this Program is a joint effort between Interior and Agriculture, these regulations are located in two titles of the Code of Federal Regulations (CFR): Title 36, "Parks, Forests, and Public Property," and Title 50, "Wildlife and Fisheries," at 36 CFR 242.1–28 and 50 CFR 100.1–28, respectively. The regulations contain subparts as follows: Subpart A, General Provisions; subpart B, Program Structure; subpart C, Board Determinations; and subpart D, Subsistence Taking of Fish and Wildlife.

Federal Subsistence Board

Consistent with subpart B of these regulations, the Secretaries established a Federal Subsistence Board to administer the Program. The Board comprises:

- Chair appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture;
- Alaska Regional Director, U.S. Fish and Wildlife Service;
- Alaska Regional Director, U.S. National Park Service;
- Alaska State Director, U.S. Bureau of Land Management;
- Alaska Regional Director, U.S. Bureau of Indian Affairs; and
- Alaska Regional Forester, U.S. Forest Service.

Through the Board, these agencies participate in the development of regulations for subparts A, B, and C, which set forth the basic program, and they continue to work together on regularly revising the subpart D regulations, which, among other things, set forth specific harvest seasons and limits.

Federal Subsistence Regional Advisory Councils

In administration of the Program, Alaska is divided into 10 subsistence resource regions, each of which is represented by a Regional Advisory Council. The Regional Advisory Councils provide a forum for rural residents with personal knowledge of local conditions and resources to have a meaningful role in the subsistence management of fish and wildlife on Federal public lands in Alaska. The Regional Advisory Council members represent diverse geographical, cultural, and user interests within each region.

Current Management Actions

These actions provide exceptions to the Subsistence Management Regulations for Public Lands in Alaska, announced in a final rule published in the **Federal Register** June 24, 2008 (73 FR 35726), and currently in effect. These actions are authorized and in accordance with 50 CFR 100.19(d)–(e) and 36 CFR 242.19(d)–(e), which allow the Board to restrict subsistence uses of fish or wildlife on public lands if necessary to ensure the continued viability of a fish or wildlife population. According to these regulations, temporary changes directed by the Board are effective following notice in the affected areas. Such notice via mail, e-mail, radio, newspaper, and the Federal subsistence management program webpage is then followed by notice in the **Federal Register**.

Moose—Units 1B, 1C South of Point Hobart, and 3

Adjusts the harvest limit of moose by adding "or antlers with 2 brow tines on both sides". This action was necessary to provide the same opportunity to federally qualified users as hunters enjoy under State regulations.

Goat—Unit 5A, That Area Between the Hubbard Glacier and the West Nunatak Glacier on the North and East Sides of Nunatak Fjord

Closes the subsistence hunting season to promote recovery of the goat population. This action was necessary for conservation concerns.

Marten (Trapping)—Unit 3, Kuiu Island

Closes the subsistence trapping season to promote recovery of the marten population. This action was necessary for conservation concerns.

Moose—Unit 5A, Except Nunatak Beach

Delegates authority to the U.S. Forest Service, Yakutat District Ranger to establish a quota for moose and to close the season when the quota has been filled. This action facilitates management flexibility and responsiveness and was necessary for conservation concerns.

Caribou—Unimak Island Only

Closes the fall and winter subsistence hunting seasons to promote recovery of the caribou population. This action was necessary for conservation concerns.

Lynx (Trapping—Units 7 and 15)

Adjusts the season dates from January 1–31 to January 1–February 15. Local observations indicate the lynx populations are increasing. This action provides additional opportunity to subsistence users.

Unit 18, Unit Regulations

Prohibits the possession or use of lead shot size T or smaller. This action was necessary for conservation and public safety concerns.

Deer—Unit 4, Northeast Chichagof Controlled Use Area

Closes the harvest of female deer during the period November 14–January 31, 2009 to maintain existing populations and preserve reproductive potential. This action was necessary for conservations concerns.

Musk Ox—Unit 22D, Remainder

Removes the closure on the January 15–March 15, 2010, season. A harvest quota is in place. This action provides additional opportunity for subsistence users.

Moose—Unit 18, Remainder

Adjusts the season dates to January 22–February 28, 2010, and adjusts the harvest limit from one antlered bull to one moose. This action provides additional opportunity for subsistence users from a healthy moose population.

Moose—Unit 24B, Kanuti National Wildlife Refuge and Bureau of Land Management (BLM) Lands

Establishes a 5-day season, March 27–31, 2010, with a harvest limit of one bull and a harvest quota of five bull moose, and expands the hunt area to include all Refuge and BLM lands in the unit. The refuge manager is authorized to close the season if a cow is taken. This action provides additional opportunity for subsistence users and should spread the harvest over a larger area, thereby minimizing harvest impacts.

Conformance With Statutory and Regulatory Authorities

Administrative Procedure Act

The Board finds that additional public notice and comment requirements under the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) for these seasonal adjustments are impracticable, unnecessary, and contrary to the public interest. Lack of appropriate and immediate action would generally fail to serve the overall public interest and conflict with Section 815(3) of ANILCA. Therefore, the Board finds good cause pursuant to 5 U.S.C. 553(b)(3)(B) to waive additional public notice and comment procedures prior to implementation of this action and under 5 U.S.C. 553(d)(3), to make these adjustments effective as indicated in the **DATES** section.

National Environmental Policy Act

A Final Environmental Impact Statement (FEIS) was published on February 28, 1992, and a Record of Decision on Subsistence Management for Federal Public Lands in Alaska (ROD) was signed April 6, 1992. The final rule for Subsistence Management Regulations for Public Lands in Alaska, subparts A, B, and C (57 FR 22940, published May 29, 1992), implemented the Federal Subsistence Management Program and included a framework for an annual cycle for subsistence hunting and fishing regulations. A final rule that redefined the jurisdiction of the Federal Subsistence Management Program to include waters subject to the subsistence priority was published on January 8, 1999 (64 FR 1276).

Section 810 of ANILCA

An ANILCA Section 810 analysis was completed as part of the FEIS process on the Federal Subsistence Management Program. The intent of all Federal subsistence regulations is to accord subsistence uses of fish and wildlife on public lands a priority over the taking of fish and wildlife on such lands for other purposes, unless restriction is necessary to conserve healthy fish and wildlife populations. The final section 810 analysis determination appeared in the April 6, 1992, ROD and concluded that the Program, under Alternative IV with an annual process for setting subsistence regulations, may have some local impacts on subsistence uses, but will not likely restrict subsistence uses significantly.

During the subsequent environmental assessment process for extending fisheries jurisdiction, an evaluation of the effects of this rule was conducted in accordance with section 810. That evaluation also supported the Secretaries' determination that the rule will not reach the "may significantly restrict" threshold that would require notice and hearings under ANILCA section 810(a).

Paperwork Reduction Act

An agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. This rule does not contain any new collections of information that require OMB approval. OMB has reviewed and approved the following collections of information associated with the subsistence regulations at 36 CFR part 242 and 50 CFR part 100: Subsistence hunting and fishing applications, permits, and reports, Federal Subsistence Regional Advisory Council Membership Application/Nomination and Interview Forms (OMB Control No. 1018–0075, expires January 31, 2013).

Regulatory Planning and Review (Executive Order (E.O.) 12866)

The Office of Management and Budget (OMB) has determined that this rule is not significant and has not reviewed this rule under E.O. 12866. OMB bases its determination upon the following four criteria:

(a) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government.

(b) Whether the rule will create inconsistencies with other agencies' actions.

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(d) Whether the rule raises novel legal or policy issues.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which include small businesses, organizations, or governmental jurisdictions. In general, the resources to be harvested under this rule are already being harvested and consumed by the local harvester and do not result in an additional dollar benefit to the economy. However, we estimate that 2 million pounds of meat are harvested by subsistence users annually and, if given an estimated dollar value of $3.00 per pound, this amount would equate to about $6 million in food value Statewide. Based upon the amounts and values cited above, the Departments certify that this rulemaking will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

Under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*), this rule is not a major rule. It does not have an effect on the economy of $100 million or more, will not cause a major increase in costs or prices for consumers, and does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

E.O. 12630

Title VIII of ANILCA requires the Secretaries to administer a subsistence priority on public lands. The scope of this Program is limited by definition to certain public lands. Likewise, these regulations have no potential takings of private property implications as defined by E.O. 12630.

Unfunded Mandates Reform Act

The Secretaries have determined and certify under the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.,* that this rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities. The implementation of this rule is by Federal agencies and there is no cost imposed on any State or local entities or tribal governments.

E.O. 12988

The Secretaries have determined that these regulations meet the applicable standards provided in Sections 3(a) and 3(b)(2) of E.O. 12988, regarding civil justice reform.

E.O. 13132

In accordance with E.O. 13132, this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment. Title VIII of ANILCA precludes the State from exercising subsistence management authority over fish and wildlife resources on Federal lands unless it meets certain requirements.

E.O. 13175

ANILCA does not specifically provide rights to tribes for the subsistence taking of wildlife, fish, and shellfish. However, the Secretaries have elected to provide tribes an opportunity to consult on this rule. The Board provided a variety of opportunities for consultation through: Proposing changes to the existing rule; commenting on proposed changes to the existing rule; engaging in dialogue at the Regional Advisory Council meetings; engaging in dialogue at the Board's meetings; and providing input in person, or by mail, e-mail, or phone, at any time during the rulemaking process.

E.O. 13211

This Executive Order requires agencies to prepare Statements of Energy Effects when undertaking certain actions. However, this rule is not a significant regulatory action under E.O. 13211, affecting energy supply, distribution, or use, and no Statement of Energy Effects is required.

Drafting Information

Theo Matuskowitz drafted these regulations under the guidance of Peter J. Probasco of the Office of Subsistence Management, Alaska Regional Office, U.S. Fish and Wildlife Service, Anchorage, Alaska. Additional assistance was provided by

- Daniel Sharp, Alaska State Office, Bureau of Land Management;
- Sandy Rabinowitch and Nancy Swanton, Alaska Regional Office, National Park Service;
- Dr. Glenn Chen and Patricia Petrivelli, Alaska Regional Office, Bureau of Indian Affairs;
- Jerry Berg, Alaska Regional Office, U.S. Fish and Wildlife Service; and
- Steve Kessler, Alaska Regional Office, U.S. Forest Service.

Authority: 16 U.S.C. 3, 472, 551, 668dd, 3101–3126; 18 U.S.C. 3551–3586; 43 U.S.C. 1733.

Dated: June 29, 2010.

Polly Wheeler,

Acting Chair, Federal Subsistence Board.

Dated: June 30, 2010.

Steve Kessler,

Subsistence Program Leader, USDA–Forest Service.

[FR Doc. 2010–19909 Filed 8–11–10; 8:45 am]

BILLING CODE 3410–11–P, 4310–55–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2008–0871; FRL–9187–9]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Transportation Conformity Regulations; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: On June 18, 2010 (75 FR 34644), EPA published a direct final rule to approve revisions to the Maryland State Implementation Plan (SIP). The revisions amended Maryland's transportation conformity regulations and general conformity regulations. EPA's approval did not include Maryland's regulation regarding conflict resolution associated with conformity determinations (COMAR 26.11.26.06). EPA has determined that it cannot proceed with approval of these SIP revisions until and unless it also approves Maryland's regulation regarding conflict resolution associated with conformity determinations. Therefore, EPA is withdrawing its direct final rule approving Maryland's conformity regulations. This withdrawal action is being taken under section 110 of the Clean Air Act.

DATES: The direct final rule published at 75 FR 34644 on June 18, 2010, is withdrawn as of August 12, 2010.

ADDRESSES: EPA has established docket number EPA–R03–OAR–2008–0871 for this action. The index to the docket is available electronically at *http://www.regulations.gov* and in hard copy at Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

FOR FURTHER INFORMATION CONTACT: Martin Kotsch, (215) 814–3335, or by e-mail at *kotsch.martin@epa.gov.*

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 2, 2010.

W.C. Early,

Acting Regional Administrator, Region III.

■ Accordingly, the amendment to the table in 40 CFR 52.1070(c), published June 18, 2010 (75 FR 34646), is withdrawn as of August 12, 2010.

[FR Doc. 2010–19812 Filed 8–11–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2005–NM–0009; FRL–9187–8]

Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Revisions to Emissions Inventory Reporting Requirements, and General Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is taking direct final action to approve revisions to the New Mexico State Implementation Plan (SIP). These revisions concern two separate actions. First, we are approving revisions to regulations on Emission Inventories (EIs) submitted by stationary sources of air pollutants. EIs are critical for the efforts of state, local, and federal agencies to attain and maintain the National Ambient Air Quality Standards (NAAQS) that EPA has established for criteria pollutants such as ozone, particulate matter, and carbon monoxide. The revisions add new definitions; modify existing definitions; and require stationary sources of air pollutants located in New Mexico outside of Bernalillo County to report emissions location information, $PM_{2.5}$ emissions, and ammonia emissions to New Mexico Environment Department (NMED). The revisions also allow NMED to require speciation of hazardous air pollutants for emissions reporting. Second, we are approving revisions to the New Mexico Administrative Code (NMAC), 20.2.1 NMAC—General Provisions. We are adding a new definition for Significant Figures into the New Mexico SIP. The EPA is approving these two actions pursuant to section 110 of the Federal Clean Air Act (CAA, Act).

DATES: This direct final rule will be effective October 12, 2010 without further notice unless EPA receives adverse comments by September 13, 2010. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket No EPA–R06–OAR–2005–NM–0009, by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.*
- Follow the online instructions for submitting comments.
- EPA Region 6 "Contact Us" Web site: *http://epa.gov/region6/r6coment.htm.* Please click on "6PD (Multimedia)" and select "Air" before submitting comments.
- *E-mail:* Mr. Guy Donaldson at *donaldson.guy@epa.gov.* Please also send a copy by e-mail to the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.
- *Fax:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), at fax number 214–665–7263.
- *Mail:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.
- *Hand or Courier Delivery:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Such deliveries are accepted only between the hours of 8 a.m. and 4 p.m. weekdays, and not on legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket No. EPA–R06–OAR–2005–NM–0009. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *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 *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an "anonymous access" system, which means 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 *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 *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 *www.regulations.gov* or in hard copy at the Air Planning Section (6PD–L), 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 FOIA 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 submittal is also available for public inspection during official business hours, by appointment, at the NMED, Air Quality Bureau, 1301 Siler Road, Building B, Santa Fe, New Mexico 87507.

FOR FURTHER INFORMATION CONTACT: Mr. Emad Shahin for Emission Inventory inquiries, Air Planning Section (6PD–L), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone 214–665–6717; fax number 214–665–7263; e-mail address *shahin.emad@epa.gov,* and Mr. Alan Shar for General Provisions inquiries, Air Planning Section (6PD–L), telephone 214–665–6691; fax number 214–665–7263; e-mail address *shar.alan@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document "we", "us", or "our" refer to EPA.

Outline

I. What actions are we taking?

A. Emission Inventories

We are approving revisions to the New Mexico SIP submitted by the State to meet the EI requirements of the CAA. The revisions were submitted to EPA Region 6 on April 11, 2002, December 3, 2003, and April 25, 2005.

The revisions to part 20.2.73 NMAC (Notice of Intent and Emissions Inventory Requirements) allow NMED to meet EPA's Air Emissions Reporting Requirements (40 CFR Part 51, Subpart A). In addition, the revisions will allow the NMED to collect more specific data regarding Hazardous Air Pollutants. We are approving these SIP revisions pursuant to section 110 of the CAA. The reporting of emissions and emissions-related data will help NMED to attain and maintain the NAAQS. See Chapter A of the TSD for more information.

B. General Provisions

We received a SIP submittal package, with a letter dated April 8, 2010 from the Governor of New Mexico on behalf of the NMED, concerning NMAC, Title 20 Environment Protection, Chapter 2 Air Quality, Part 1 General Provisions (20.2.1 NMAC—General Provisions). This submittal revises the New Mexico SIP by adding a new section 20.2.1.116 Significant Figures to the existing state rule 20.2.1 NMAC—General Provisions. Adopting 20.2.1.116 Significant Figures should facilitate calculating air emissions and determining compliance with an emission standard. We are approving this SIP revision pursuant to section 110 of the Act.

C. EPA's Action

EPA is publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no relevant adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if relevant adverse comments are received. This rule will be effective on October 12, 2010 without further notice unless we receive relevant adverse comments by September 13, 2010. If we receive relevant adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will then address all public comments in a subsequent final rule based on the proposed rule. However, we will not institute a second comment period on this action. Any parties interested in commenting must do so now. Please note that if we receive adverse comments on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment. Further, in accordance with a Consent Decree, we will finalize our action on the Emissions Inventory portion of this SIP revision no later than January 2, 2011[1].

II. What is a SIP?

Section 110 of the CAA requires states to develop air pollution regulations and control strategies to ensure that air quality meets the NAAQS established by EPA. NAAQS are established under section 109 of the CAA, and currently address six criteria pollutants: carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide.

The SIP is a set of air pollution regulations, control strategies, other means or techniques, and technical analyses developed by the state, to ensure that the state meets the NAAQS.

[1] Notice of Proposed Settlement Agreement and Consent Decree, 75 FR 11886, March 12, 2010, and *http://www.regulations.gov,* docket No. EPA–HQ–OGC–2010–0221.

The SIP is required by section 110 and other provisions of the CAA. These SIPs can be extensive, containing state regulations or other enforceable documents and supporting information such as emissions inventories, monitoring networks, and modeling demonstrations. Each state must submit these regulations and control strategies to EPA for approval and incorporation into the federally-enforceable SIP. Each federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin.

III. What is the background of these actions?

A. Emission Inventory

Emissions inventories are surveys of actual and/or allowable emissions of air pollutants in an area. Emissions inventories are critical for the efforts of state, local, and federal agencies to attain and maintain the NAAQS that EPA has established for criteria pollutants such as ozone, particulate matter, and carbon monoxide. States use emissions inventories submitted by stationary sources in developing the inventories required by the Clean Air Act. In 2005, New Mexico revised its SIP for air quality to amend the State regulations on emissions inventories submitted by stationary sources of air pollutants. The principal statutory authority for emissions inventory reporting requirements is found in section 110(a)(2)(F) of the Act, which provides that SIPs must require periodic reports on the nature and amounts of emissions and emissions-related data as may be prescribed by the EPA Administrator.

On April 11, 2002 New Mexico submitted to EPA a SIP revision that included an amendment to the NMAC regulation 20.2.73, Notice of Intent and Emission Inventory Requirements, Section 7, Definitions, which revised the definition of "Potential Emission Rate". On December 1, 2003 submitted another revision to the SIP that added three new definitions to Section 7, and revised Section 20.2.73.300, Emission Inventory Requirements, to require smelters to submit an annual report of sulfur input in tons per year, and added emission tracking requirements for sulfur dioxide emission inventories. In July 2004 NMED proposed to revise the State's regulations on emissions inventories. On April 25, 2005 New Mexico submitted SIP revisions that required sources to report emissions location information, PM 2.5 and ammonia emissions, and allowed NMED to require reporting of speciated hazardous air pollutants.

B. General Provisions

The purpose of the General Revisions (20.2.1 NMAC) is to establish general requirements which apply to all parts of Chapter 2 (20.2.1 through 20.2.99 NMAC). We received a request to review and approve a revision to the General Provisions (20.2.1 NMAC) with a letter dated April 8, 2010. This submittal revises the New Mexico SIP by adding a new section, 20.2.1.116—Significant Figures, to the existing state rule 20.2.1 NMAC—General Provisions. The previous version of the 20.2.1 NMAC—General Provisions was approved by EPA on September 26, 1997 (62 FR 50518) at 52.1620(c)(66) effective November 25, 1997. We are approving this revision to the 20.2.1 NMAC—General Provisions as a direct final action.

IV. What is EPA's evaluation of these revisions?

A. Emission Inventories

New Mexico submitted revisions to 20.2.73 NMAC for inclusion into the SIP that amend requirements on emissions inventories submitted by stationary sources of air pollutants located in New Mexico outside of Bernalillo County. The emissions inventory requirements for stationary sources of air pollutants were revised to (1) include reporting on emissions location information, $PM_{2.5}$ emissions, and ammonia emissions; and (2) allow NMED to require speciation of hazardous air pollutants for emissions reporting. In 2002, EPA issued the consolidated emissions reporting rule (CERR), (June 10, 2002 **Federal Register**, 67 FR 39602). The rule consolidated the various emissions reporting requirements that already exist into one place in the CFR, established new reporting requirements related to particulate matter less than or equal to 2.5 microns ($PM_{2.5}$) and regional haze, and established new requirements for the statewide reporting of area source and mobile source emissions. On December 17, 2008, EPA issued the Air Emissions Reporting Rule (73 FR 76539) which revised the emissions reporting requirements. The requirements can be found at 40 CFR 51 Subpart A. We have evaluated the State's submittal and have determined that the revisions meet the applicable requirements of the CAA and EPA's regulations. For more information on our evaluation, please see our Technical Support Document found in the electronic docket at *http://www.regulations.gov.*

Approval of these revisions will make New Mexico's emission inventory requirements consistent with EPA's Air Emissions Reporting Requirements and will make EPA's approved SIP consistent with the State's rules.

B. General Provisions

The revision to 20.2.1 NMAC—General Provisions, adds a new section 116, which sets forth the procedure to properly round significant digits in an air emission calculation, and its reporting to the NMED. These significant figures procedures will clarify any confusion with regards to emission calculations and reporting of the values. Section 116 adopts the same significant figures procedures described in EPA's June 6, 1990 Memorandum, from William G. Laxton, Technical Support Division Director to John S. Seitz, Stationary Source Compliance Division Director, entitled "Performance Test Calculation Guidelines." A copy of this guidance document is available in the EPA docket No. EPA–R06–OAR–2005–NM–0009 for public inspection and review. These significant figures procedures will assist the sources in properly reporting air emissions, and assist the NMED's personnel in determining sources' compliance with applicable emissions limitations. This section should facilitate enforcement of the rules, and enhance the New Mexico SIP.

V. Final Action

Today we are approving revisions to two portions of the New Mexico SIP. First, we are approving revisions to regulations on EIs submitted by stationary sources of air pollutants, in three SIP revisions submitted on April 11, 2002, December 1, 2003, and April 25, 2005. The revisions add new definitions, modify existing definitions, and require stationary sources of air pollutants located in New Mexico outside of Bernalillo County to report emissions location to NMED. The revisions also allow NMED to require speciation of hazardous air pollutants for purposes of reporting. Second, we are approving revisions to the 20.2.1 NMAC—General Provisions. We are also adding a new definition for Significant Figures into the New Mexico SIP, a revision that was submitted on April 8, 2010. EPA is approving these two actions pursuant to section 110 of the Act.

VI. 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. 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 action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not 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 Clean Air Act;
- 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);
- 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; and
- Is not a "major rule" as defined by 5 U.S.C. 804(2) under the Congressional Review Act, 5 U.S.C. 801 *et seq.,* added by the Small Business Regulatory Enforcement Fairness Act of 1996. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule."

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 12, 2010. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (See section 307(b)(2) of the Act.)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: August 3, 2010.

Al Armendariz,

Regional Administrator, Region 6.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart GG—New Mexico

■ 2. The table in § 52.1620(c) entitled "EPA Approved New Mexico Regulations" is amended by:
■ a. Revising the entry for Part 1 under New Mexico Administrative Code (NMAC) Title 20—Environment Protection, Chapter 2—Air Quality.
■ b. Revising the entry for Part 73 under New Mexico Administrative Code (NMAC) Title 20—Environment Protection, Chapter 2—Air Quality.

The revisions read as follows:

§ 52.1620 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED NEW MEXICO REGULATIONS

State citation	Title/subject	State approval/submittal date	EPA approval date	Comments
New Mexico Administrative Code (NMAC) Title 20—Environment Protection Chapter 2—Air Quality				
Part 1	General Provisions	4/8/2010	8/12/2010 [Insert *FR* page number where document begins].	
* *	* *	*	* *	*
Part 73	Notice of Intent and Emissions Inventory Requirements.	4/25/2005	8/12/2010 [Insert *FR* page number where document begins].	
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[FR Doc. 2010–19819 Filed 8–11–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2010–0035; FRL–9187–5]

Approval and Promulgation of Air Quality Implementation Plans; MN

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving Minnesota's request to amend its State Implementation Plan (SIP) for sulfur dioxide (SO_2). The Minnesota Pollution Control Agency (MPCA) submitted the SIP revision request to EPA on November 23, 2009, and supplemented it on March 3, 2010. EPA's approval revises SIP requirements applicable to Saint Mary's Hospital, located in Rochester, Minnesota, by adding a 2500 kilowatt (KW) reciprocating internal combustion engine (RICE) electric generator and reducing the allowable diesel fuel sulfur content for two existing RICE electric generators. The revision also includes administrative changes in the identification of emissions units. These revisions are included in a joint Title I/Title V document for Saint Mary's Hospital, which replaces the document currently approved into the SIP for the facility. These revisions will result in reducing the SO_2 impact in the Rochester area, and strengthen the existing SO_2 SIP.

DATES: This direct final rule will be effective October 12, 2010, unless EPA receives adverse comments by September 13, 2010. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2010–0035, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *E-mail: bortzer.jay@epa.gov.*
3. *Fax:* (312) 629–2054.
4. *Mail:* Jay Bortzer, Chief, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Jay Bortzer, Chief, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2010–0035. 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 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 *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Charles Hatten, Environmental Engineer, at (312) 886–6031 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Charles Hatten, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6031, *hatten.charles@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This supplementary information section is arranged as follows:

I. General Information

A. Does this action apply to me?

This action applies only to the Saint Mary's Hospital, located at 1216 Second St., Rochester, Minnesota (Olmsted County).

B. Has public notice been provided?

Minnesota published a public notice of the revisions to the SIP on August 22, 2009. The comment period began on August 23, 2009, and ended on September 23, 2009. In the public notice, Minnesota stated it would hold a public hearing if one were requested during the comment period. This follows the alternative public participation process EPA approved on June 5, 2006 (71 FR 32274). For limited types of SIP revisions that the public has shown little interest in, a public hearing is not automatically required. Because no one requested a public hearing, Minnesota did not hold a public hearing.

Background

Saint Mary's Hospital is a tertiary care hospital which includes several buildings located on a 49 acre campus. The Saint Mary's Hospital is owned and operated by the Mayo Foundation. The facility is a culpable source located in the Rochester area's nonattainment plan for the SO_2 National Ambient Air Quality Standard (NAAQS). However, the area currently meets the NAAQS for SO_2, and was officially redesignated as attainment on May 8, 2001. (66 FR 14087)

The primary emission units at the facility are three identical fossil fuel-

fired boilers (Nos. 1, 2, and 3), which exhaust through a common stack; one cogeneration turbine; and two emergency RICE generators. Each boiler burns natural gas as fuel with distillate oil as a backup fuel. The cogeneration turbine burns only natural gas. One of the RICE generators burns only distillate oil; the other can burn distillate oil or operate in a dual-fuel mode (95% natural gas and 5% distillate oil/very low sulfur diesel).

Saint Mary's Hospital is planning to make a physical change to the facility by adding a new RICE electric generator. The facility will also be required to reduce the allowable diesel fuel sulfur content for two existing emergency RICE electric generators. The State provided a modeling analysis of the effect of the changes at the facility on local SO_2. Below, in Section III, a more detailed discussion of the modeling analysis and its results can be found.

II. What revision did the State request be incorporated into the SIP?

The State has requested that EPA approve, as a revision to the Minnesota SIP, a new joint Title I/Title V document that incorporates: (1) Administrative changes in the identification of emission units, (2) the installation a 2500 KW RICE electric generator, and (3) a reduction in the allowable diesel fuel sulfur content for two existing RICE electric generators.

A. What prior SIP actions are pertinent to this action?

The facility has been subject to a federally enforceable permit incorporated into Minnesota's SIP as a joint Title I/Title V document, containing requirements for ensuring the attainment of the NAAQS for SO_2. As a result, the facility is subject to fuel usage limitations to restrict the total facility SO_2 emissions.

B. What are Title I conditions and Joint Title I/Title V documents?

SIP control measures were contained in permits issued to culpable sources in Minnesota until 1990 when EPA determined that limits in state-issued permits are not federally enforceable because the permits expire. Minnesota then issued permanent Administrative Orders to culpable sources in nonattainment areas from 1991 to February of 1996.

Minnesota's consolidated permitting regulations, approved into the SIP on May 2, 1995 (60 FR 21447), includes the term "Title I condition" which was written, in part, to satisfy EPA requirements that SIP control measures remain permanent. A "Title I condition" is defined as "any condition based on source-specific determination of ambient impacts imposed for the purposes of achieving or maintaining attainment with the national ambient air quality standard and which was part of the state implementation plan approved by EPA or submitted to the EPA pending approval under section 110 of the act * * *." The rule also states that "Title I conditions and the permittee's obligation to comply with them, shall not expire, regardless of the expiration of the other conditions of the permit." Further, "any Title I condition shall remain in effect without regard to permit expiration or reissuance, and shall be restated in the reissued permit."

Minnesota has initiated using joint Title I/Title V documents as the enforceable document for imposing emission limitations and compliance requirements in SIPs. The SIP requirements in joint Title I/Title V documents submitted by MPCA are cited as "Title I conditions," therefore ensuring that SIP requirements remain permanent and enforceable. EPA reviewed the State's procedure for using joint Title I/Title V documents to implement site-specific SIP requirements and found it to be acceptable under both Titles I and V of the Clean Air Act (July 3, 1997, letter from David Kee, EPA, to Michael J. Sandusky, MPCA). Further, a June 15, 2006, letter from EPA to MPCA clarifies procedures to transfer requirements from Administrative Orders to joint Title I/Title V documents.

III. What is EPA's analysis of the State submission?

This SIP revision replaces the joint Title I/Title V document currently approved into the SIP for Saint Mary's Hospital with a new joint Title I/Title V document, Air Permit No. 10900008–003. The new joint document includes administrative changes in the identification of emission units, adds a 2500 KW RICE electric generator, and reduces the allowable diesel fuel sulfur content for two existing RICE electric generators.

Administrative Changes

The new joint document reflects administrative changes in how the emission units are described. Boilers 1, 2, and 3 were listed in the joint document previously issued to Saint Mary's Hospital and identified as EU038, EU039, and EU040. In the new joint document, Air Permit No. 10900008–003, these boilers are now identified as EU001, EU002, and EU003. Correspondingly, the two existing emergency RICE generators, which were previously identified as EU0041 and EU0042, are now identified as EU005 and EU006.

New Electric Generator

The amendment to the SIP allows the installation of a new RICE electric generator. The new RICE generator, identified as EU012, is a 2500 kilowatt non-emergency compression ignition diesel engine subject to 40 CFR part 60, subpart IIII, for 2007 model year engines with displacement less than 10 liters per cylinder. In § 60.4207 of 40 CFR part 60, subpart IIII, the new electric generator is subject to a requirement to burn only diesel fuel with a sulfur content of less than 500 parts per million (ppm) by weight. This represents a limit of 0.05% sulfur by weight. Further, as of October 1, 2010, this diesel fuel oil limit will decrease to 15 ppm by weight (0.0015% sulfur by weight). This new diesel fuel oil limit is imposed by 40 CFR 80.510 upon owners or operators of new engines subject to 40 CFR part 60, subpart IIII, and is listed as a SIP condition to ensure that it will not exceed this Federal standard.

In addition to the above said requirements, the SO_2 emissions for new RICE generator will be limited to 1.52 tons per year based upon an operational restriction of 2045 hours per year.

Reduced SO_2 Limits

The existing boilers, cogeneration turbine, and generators are subject to fuel sulfur limits in order to comply with the NAAQS requirements for SO_2. As noted above, the cogeneration turbine burns only natural gas, and therefore is not subject to any Title I SIP conditions for SO_2. The SO_2 SIP emission limits for the boilers are unchanged. The boilers must burn only natural gas and low-sulfur distillate fuel, less than 0.5% sulfur by weight.

The existing generators have been subject to a requirement to burn distillate oil with sulfur content less than 0.41% by weight. In order to add the new generator and ensure that the emissions from the facility remain at or below current SIP levels, Saint Mary's Hospital agreed to align the fuel sulfur requirements of the existing generators with the new generator. Thus, the existing generators will be subject to the same requirements as the new generator; namely, a requirement to burn only diesel fuel with a sulfur content of less than 500 ppm by weight. This new limit of 0.05% sulfur by weight is considerably lower than the old limit of 0.41% sulfur by weight, resulting in a decrease in the amount of SO_2 emissions from the existing generators

by a factor of 8.2 (0.41/0.05). Further, the diesel fuel oil limit for the existing generators will decrease to 15 ppm by weight (0.0015% sulfur by weight) as of October 1, 2010, which is the same as the limit imposed on the new generator by 40 CFR 80.510.

Modeling

The SIP revision does not include any increases in SO_2 emission limits but, because some of the changes being made to the facility may affect the release and dispersion of SO_2 emissions, Saint Mary's Hospital performed an air quality analysis to address the facility's impact on the SO_2 NAAQS. The facility was modeled both with and without the new generator. The modeling was done with the AERMOD air dispersion model using meteorological data from 1986 to 1990, and included flagpole receptors in downtown Rochester. The high-first-high results for each standard averaging time (1 hour, 3 hour, 24 hour, and annual) were compared for the two scenarios at each receptor. With the addition of the 500 ppm by weight fuel oil sulfur content for the two existing generators, the results showed equivalent or decreased ambient impacts from the facility at each receptor, even after the installation of the new generator.

TABLE—HIGH-SECOND-HIGH AMBIENT SO_2 CONCENTRATION FROM FACILITY

Averaging time	Modeled concentration (μg/m³)						Background	Total	Standard
	1986	1987	1988	1989	1990	Max			
Facility Prior to Modification									
1-hour	328	318	337	317	336	337	26	363	1300
3-hour	244	253	249	269	250	269	13	282	1300
24-hour	124	134	110	127	132	134	5	139	365
Annual	21	21	20	21	20	21	3	24	60
Facility After Modification									
1-hour	301	300	320	303	319	320	26	346	1300
3-hour	237	245	242	262	238	262	13	275	1300
24-hour	109	117	94	121	125	125	5	130	365
Annual	15	15	14	14	13	15	3	18	60

The modeling shows that the high-second-high impacts from the facility will decrease due to the changes from this SIP revision: the installation of the new generator and the decreased fuel oil sulfur limits on the two existing generators. This assures that ambient air quality will be protected.

IV. What action is EPA taking?

EPA is approving the revision to Minnesota's SIP to replace the joint Title I/Title V document currently approved into the SIP for Saint Mary's Hospital with a new joint Title I/Title V document, Air Permit No. 10900008–003. The new joint document includes administrative changes in the identification of emission units, adds a 2,500 KW RICE electric generator, and reduces the allowable diesel fuel sulfur content for two existing RICE electric generators. In approving this joint Title I/Title V document, EPA is incorporating into the SIP only those requirements in the joint document labeled as "Title I Condition: SIP for SO_2 NAAQS."

Since this SIP revision will decrease SO_2 impacts in the Rochester area, Saint Mary's revision will strengthen the existing SO_2 SIP.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective October 12, 2010 without further notice unless we receive relevant adverse written comments by September 13, 2010. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. If we do not receive any comments, this action will be effective October 12, 2010.

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 Clean Air Act and applicable Federal regulations. 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 action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not 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 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.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 12, 2010. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: August 2, 2010.

Bharat Mathur,

Acting Regional Administrator, Region 5.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart Y—Minnesota

■ 2. In § 52.1220 the table in paragraph (d) is amended by revising the entry for "Saint Mary's Hospital" to read as follows:

§ 52.1220 Identification of plan.

* * * * *

(d) * * *

EPA-APPROVED MINNESOTA SOURCE-SPECIFIC PERMITS

Name of source	Permit No.	State effective date	EPA approval date	Comments
* *	*	*	* *	* *
St. Mary's Hospital	10900008–003	03/01/10	08/12/10, [Insert page number where the document begins].	Only conditions cited as "Title I condition: SIP for SO_2 NAAQS."
* *	*	*	* *	* *

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[FR Doc. 2010–19822 Filed 8–11–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1987–0002; FRL–9188–8]

National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List: Deletion of the Rogers Road Municipal Landfill Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 6 is publishing a direct final notice of deletion of the Rogers Road Municipal Landfill Superfund Site (Site), located near Jacksonville, Pulaski County, Arkansas from the National Priorities List (NPL). The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Arkansas, through the Arkansas Department of Environmental Quality (ADEQ), because EPA has determined that all appropriate response actions under CERCLA, other than operation, maintenance, and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: This direct final rule will be effective October 12, 2010 unless EPA receives adverse comments by September 13, 2010. If adverse comments are received, EPA will publish a timely withdrawal of the direct final notice of deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–1987–0002 by one of the following methods:

http://www.regulations.gov (Follow the on-line instructions for submitting comments)

E-mail: walters.donn@epa.gov.

Fax: 214–665–6660

Mail: Donn Walters, Community Involvement, U.S. EPA Region 6 (6SF–TS), 1445 Ross Avenue, Dallas, TX 75202–2733, (214) 665–6483 or 1–800–533–3508.

Hand Delivery: Donn Walters, Community Involvement, U.S. EPA Region 6 (6SF–TS), 1445 Ross Avenue, Dallas, TX 75202–2733. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SFUND–1987–0002 EPA 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 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 at *http://www.regulations.gov* or in hard copy at:

U.S. EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, (214) 665–7362 by appointment only Monday through Friday 9 a.m. to 12 p.m. and 1 p.m. to 4 p.m.; Jacksonville City Hall, 1 Municipal Drive, Jacksonville, AR 72076, (501) 982–3181, Monday through Friday, 8 a.m. to 5 p.m.;

Arkansas Department of Environmental Quality (ADEQ), 5301 Northshore Drive, North Little Rock, Arkansas 72118, (501) 682–0744, Monday through Friday 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Shawn Ghose M.S., P.E., Remedial Project Manager (RPM), U.S. EPA Region 6 (6SF–RA), 1445 Ross Avenue, Dallas, TX 75202–2733, (214) 665–6782 or 1–800–533–3508 or *ghose.shawn@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

EPA Region 6 office is publishing this direct final notice of deletion of the Rogers Road Municipal Landfill Superfund Site (Site) from the National Priorities List (NPL). The NPL constitutes Appendix B of 40 CFR part 300, which is the Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in Section 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for Fund-financed remedial actions if conditions warrant such action.

Because EPA considers this action to be noncontroversial and routine, this action will be effective October 12, 2010 unless EPA receives adverse comments by September 13, 2010. Along with this direct final Notice of Deletion, EPA is co-publishing a Notice of Intent to Delete in the "Proposed Rules" section of the **Federal Register**. If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely withdrawal of this direct final Notice of Deletion before the effective date of the deletion, and the deletion will not take effect. The EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments already received. There will be no additional opportunity to comment.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Rogers Road Landfill Superfund Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. All appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Pursuant to CERCLA section 121(c) and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews even if a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Deletion Procedures

The following procedures apply to deletion of the Site:

(1) The EPA consulted with the State of Arkansas prior to developing this direct final Notice of Deletion and the Notice of Intent to Delete co-published today in the "Proposed Rules" section of the **Federal Register**.

(2) EPA has provided the State 30 working days for review of this notice and the parallel Notice of Intent to Delete prior to their publication today, and the State, through the ADEQ, has concurred on the deletion of the Site from the NPL.

(3) Concurrently with the publication of this direct final Notice of Deletion, a

notice of the availability of the parallel Notice of Intent to Delete is being published in a major local newspaper, Jacksonville Times. The newspaper notice announces the 30-day public comment period concerning the notice of intent to delete the Site from the NPL.

(4) The EPA placed copies of documents supporting the proposed deletion in the deletion docket and made these items available for public inspection and copying at the Site information repositories identified above.

(5) If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely notice of withdrawal of this direct final Notice of Deletion before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments already received.

Deletion of a site from the NPL does not itself create, alter or revoke any individual's rights or obligations. Deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Site Deletion

The following information provides EPA's rationale for deleting this Site from the NPL:

A. Site Background and History

The Rogers Road Municipal Landfill Superfund Site (Site; EPA ID ARD981055809) encompasses about 10 acres in Pulaski County, outside the city limits of Jacksonville, Arkansas, approximately 12 miles northeast of Little Rock, Arkansas. An estimated 10,000 people live within three miles of the Site and are supplied by municipal drinking water. Less than one-half mile west of the Rogers Road Municipal Landfill Superfund Site is the Jacksonville Municipal Landfill Superfund Site. Because of the proximity of the two sites and the similarities in their features and characteristics, the Superfund site-related activities were carried out concurrently. Within a one-half mile radius of the Site, the population was estimated between 153 and 204. Sometime prior to 1974, the residents of Rogers Road were supplied with municipal water by the City of Jacksonville.

The City of Jacksonville purchased the land comprising the Rogers Road Landfill in September 1953 and operated a municipal landfill on the property. Open burning and trenching were the primary methods of waste disposal used at the Site. The dates of operation of the Rogers Road Landfill remain a matter of dispute and varying testimony and representations in a number of judicial and administrative venues. However, it is undisputed that after October 1974, operation of the Rogers Road facility had ceased. The landfill was formally closed in July 1973, when the predecessor agency to the ADEQ, the Arkansas Department of Pollution Control and Ecology, refused to grant a landfill permit, because of the high water table and poor drainage in the area.

Specific waste types and quantities were not recorded by the Site owner/operators; however, in addition to municipal waste, several drums of industrial waste from a local herbicide manufacturer, Vertac Chemical Corporation (Vertac), were believed to have been disposed of in the landfill. On-site soil and about 30 decaying drums were found to be contaminated with dioxin (2,3,7,8-tetrachlorodibenzo (P) dioxin expressed as 2,3,7,8-TCDD equivalents), the herbicides 2,4-D and 2,4,5-T, and the pesticide dieldrin.

In early 1986, the City of Jacksonville fenced the Site to prevent public access. The Rogers Road Municipal Landfill was identified to EPA on May 10, 1983, through a citizen's complaint. At that time, EPA was conducting a site inspection of the Jacksonville Landfill. After a field investigation, the Rogers Road Municipal Landfill was proposed for inclusion on the National Priorities List (NPL) of uncontrolled hazardous waste sites on January 22, 1987 (52 FR 2492). The site was added to the NPL on July 22, 1987 (52 FR 27620).

B. Remedial Investigation and Feasibility Studies

A Remedial Investigation (RI) was conducted between November 1988 and March 1990, and a risk assessment was performed based on the analytical findings of the RI. The results of the RI and risk assessment and prior investigations are summarized in the RI Report (Peer and Resource Applications, Inc., 1990a). The Feasibility Study (FS) was also released at this time (Peer and Resource Applications, 1990b). Onsite soil and decaying drums were found to be contaminated with dioxin (2,3,7,8-tetrachlorodibenzo-p-dioxin [TCDD] equivalents), the herbicides 2,4-D and 2,4,5-T, and the pesticide dieldrin (EPA, 1996).

The investigations undertaken at the Rogers Road landfill revealed that contaminants in the soil comprised the principal threat posed by the site. The contamination in the soil was limited to the drum disposal area. A remedy was chosen based on the following criteria:

- Remedy the contaminated soil using thermal treatment and soil cover to ensure it no longer presents a threat to human health or the environment.
- Eliminate the health risks due to ponded water onsite by filling in the existing site trenches with clean fill.
- Establish a method of long term monitoring to ensure that the soil cover is properly maintained and the groundwater quality is adequately monitored.

The remedial actions undertaken to meet these criteria are described in the Section on Remedial Action.

C. Selected Remedy

The Remedial Investigation (RI) for the Site, which described the nature and extent of contamination, was released to the public in July 1990. The Feasibility Study (FS) was also released at this time. A 60-day public comment period began on July 9, 1990, and ended on September 7, 1990. In addition, a public meeting was held on July 18, 1990, to present the results of the RI/FS and to accept public comment.

EPA reviewed the results of the July 1990 RI/FS conducted by the EPA contractor, Peer Consultants, and all public comments received. On September 27, 1990, a Record of Decision (ROD) for the Site was issued. The selected remedy included:

- Excavation of contaminated soil and debris containing greater than 10 parts per billion (ppb) equivalent 2,3,7,8-TCDD and backfilling the excavated area;
- Transportation of the excavated material to the Vertac Chemical Corporation Superfund Site in Jacksonville, Arkansas;
- Incineration of the excavated contaminated material and disposal of residuals at Vertac;
- Steam-cleaning and disposal of large items of refuse removed from contaminated areas at the Rogers Road Site;
- Covering soil, debris and water meeting the criteria stated below with twelve inches of soil:

(1) 2,3,7,8-TCDD concentrations > 1.0 and ≤ 10 ppb,

(2) Cumulative Hazard Index > .7 for 2,4,5-T; 2,4,5 TP; and dieldrin; or

(3) Dieldrin > 37 ppb;

- Backfilling the site trench;

• Institutional controls such as fence maintenance and land-use restrictions limiting ground water use on and immediately downgradient of the site; and

• Ground water monitoring for at least 5 years.

On June 20, 1994, a Consent Decree (CD) between EPA and the City of Jacksonville regarding the Site was entered in Federal District Court. This CD and the CD for the nearby Jacksonville Landfill Site were the first in the country between a municipality and EPA that utilized this type of mixed work settlement. Under the agreement, EPA performed the work that involved handling the hazardous substances, including picking-up the hot spots of contamination, transporting the material to Vertac, incineration, and decontamination.

The city performed the non-hazardous work, including fencing, backfilling, grading, re-vegetating, inspection and maintenance, installation of additional ground water wells, ground water sampling and analysis and land-use controls.

D. Response Actions

On August 22, 1995, Ecology and Environment (E&E), the EPA Technical Assistance Team (TAT) and the Emergency Response Cleanup Service (ERCS) contractor, Riedel-Peterson, mobilized to begin remedial operations at the Site. After preliminary road work was completed, excavation of contaminated soil was initiated.

During the action, Riedel-Peterson recontainerized contaminated material that was in decaying drums and excavated soil. This material, along with investigation-derived waste such as contaminated personal protective equipment, was transported to the Vertac Site for treatment at the incinerator. Confirmation soil samples were collected after this initial excavation to verify the degree of contaminant removal and to determine the areas of moderate contamination (2,3,7,8-TCDD concentrations > 1.0 and ≤ 10 ppb and dieldrin > 37 ppb) which would later be covered with clean soil.

A total of 200 cubic yards of contaminated soil and 76 drums of hazardous materials (including 19 drums of investigation-derived wastes) were transported to Vertac and incinerated. This is a higher volume than the 130 cubic yards estimated in the ROD. Despite this increase in volume, remedial activities went smoothly. Incineration at Vertac began on October 20, 1994, and ended on December 4, 1994. The January 20, 1995, Technical Assistance Report for the Rogers Road Municipal Landfill written by E&E, details the Remedial Action (RA) activities performed by EPA and its contractors.

The total cost for the RA was $129,070.00 for the excavation, preliminary sampling, and transportation of the waste and $1.07 million for the confirmatory sampling and incineration at Vertac.

During the fall of 1994, the City of Jacksonville continued regrading activities and installed the three additional ground water monitoring wells between the Jacksonville Landfill and the Rogers Road Landfill as required by the ROD and CD. The city demobilized in late October when heavy rains in the area made passage through the Site difficult. City activities recommenced in July 1995 when the Site was sufficiently dry for vehicles to pass. The city regrading activities were completed in September 1995. A list of all Site activities undertaken by the city is included in the weekly activity reports in the Site file.

Demonstration of Quality Assurance/ Quality Control (QA/QC) for Cleanup Activities

Because of the simplicity of this action, one work plan was submitted which encompassed the Remedial Design (RD) and RA activities at the Site, consistent with the ROD and the CD. The Quality Assurance Project Plan for the RA detailed the strict sampling and analytical program. All procedures and protocol for confirmatory sample analysis included in this document were in accordance with EPA procedures. The selection of the locations for confirmatory sampling and a graphical presentation of the concentrations of contaminants at these locations are documented in the January 20, 1995, Technical Assistance Report (the Remedial Action Completion Report) for the Rogers Road Municipal Landfill.

A total of 93 soil samples were taken during the RA to confirm attainment of clean-up standards. Samples were collected from points on a 14 x 14 foot grid pattern extending outside of the boundary of contamination as established during the Remedial Investigation. Eighty-six of these samples were analyzed for dioxin and related compounds and 13 were analyzed for dieldrin, in accordance with the Quality Assurance Sampling Plan (QASP) prepared for the Remedial Action by the TAT.

EPA provided direct oversight of the excavation and confirmatory soil sampling activities. The Jacksonville Community Relations Office maintained administrative support for the project five days a week.

The QA/QC program utilized throughout the remedial action was sufficiently rigorous and was adequately complied with to enable EPA to determine that all analytical results are accurate to the degree needed to assure satisfactory execution of the remedial action consistent with the ROD and the RD/RA work plan.

Construction was completed in early 1995. A site inspection occurred on September 20, 1995, which showed that the remedial objectives had been achieved. The EPA also checked the Site on September 1, 1998. At that time, the constructed remedy was still performing as designed and was controlling the risks to human health and the environment as specified in the ROD. The soil cover was in excellent shape with no evidence of subsidence, erosion, animal burrows, or standing water. The grass cover was well-established and provided thorough coverage of the soil cover. The site fences had been maintained and there was no evidence of trespassers.

E. Clean-Up Standards

The remedial action (RA) cleanup activities at the Site are consistent with the objectives of the NCP and will provide protection to human health and the environment. Specifically, confirmatory sampling conducted at the conclusion of the cleanup verified that the site achieved the ROD cleanup standards: All contaminated soil and debris containing greater than 10 part per billion (ppb) equivalent 2,3,7,8-TCDD were excavated and all soil and debris with 2,3,7,8-TCDD concentrations > 1.0 and ≤ 10 ppb, or with a Cumulative Hazard Index > .7 for 2,4,5-T; 2,4,5 TP and dieldrin were either excavated or covered with one foot of clean soil. In addition, no soil was left on-site with a dieldrin concentration above 37 ppb. Ground water samples taken in November 1994, June 1995, December 1995, October 1996, and November 1997, did not show dioxin contamination, nor did they show any site-related, statistically significant concentrations of organic contaminants or inorganic (metals) contaminants above acceptable health-based levels. The sampling results documented in the Technical Assistance Report showed that the drum disposal area excavation exceeded the 1 ppb dioxin cleanup level and was remediated to 0.01 ppb or 10 ppt level of dioxin.

The confirmatory sampling at the Site and backfilling of the Site with clean soil provide assurances that the Site will

no longer pose a threat to human health or the environment as long as the institutional controls are enforced and the soil cover is maintained. The source of contaminants identified in the ROD, the disintegrating drums and adjacent contaminated soil, has been addressed through excavation and covering with a clean soil cover. The cleanup also eliminated the impacts to the ground water from the chemicals of concern at the Site (*i.e.,* the possible source of contamination had been removed).

At this time, the Site has been cleaned up to eliminate the exposure pathway by the remedy required by the ROD. Health concerns are adequately addressed by institutional controls. Institutional controls were required by the Site remedy and were imposed in 2008 in the form of an Environmental Protection Easement and Declaration of Restrictive Covenants recorded in Pulaski County, Arkansas. The property interest was conveyed by the Site owner to the City of Jacksonville with a third party beneficiary enforcement interest granted to the EPA. This instrument prevents disturbance of remedial components in the fenced, capped area of the Site, and it prohibits all residential, agricultural, food service, and ground water uses of that area as well. In addition, development of that area in any form not expressly prohibited, can only be undertaken with the prior notice to, and review and approval of, the EPA. Any ground water use within the 20.2 acre tract that includes the fenced area (1.38 acres) and adjoining areas is prohibited without prior notice and approval of the EPA, and no development of any kind can take place in that tract without 90 days prior notice to the EPA. These restrictions provide a significant margin of protection and a buffer for any potential exposure pathways. In addition, the institutional controls provide broad access rights to the Site for EPA for carrying out remedial maintenance, surveillance, inspection, investigation, and response, among other things.

The discontinuance of the ground water monitoring past 1997 have been justified in an Explanation of Significant Differences (ESD) signed in August 2009. Public notice of the ESD was published in Jacksonville Times in September 2009.

F. Operations and Maintenance

The Site is designed to require very little maintenance. Site operations and maintenance (O&M) activities that have been performed by the city of Jacksonville since the 1995 site completion include routine site inspections to ensure that positive drainage (as defined in the CD Statement of Work) is occurring and that the perimeter fence is intact. These activities have maintained the protectiveness of the remedy

The city of Jacksonville, as agreed upon in the CD and accompanying Statement of Work and as detailed in the Remedial Action (RA) Work Plan, has assumed all responsibility for O&M at the Site. Plans for O&M are in place and are sufficient to maintain the protectiveness of the remedy. The city is fulfilling its obligation to perform the O&M and it is expected that the city of Jacksonville will be able to provide future maintenance with a minimal amount of work.

In June 1999 Arkansas Department of Environmental Quality (ADEQ) provided a State concurrence for Deletion. However, Deletion was put on hold pending resolution of land use restrictions on the property. The implementation of Institutional Control (IC) was delayed by significant legal questions surrounding title to the property of the Site. Eventually, legal agreement was reached after extended negotiations between EPA, the city of Jacksonville, and the Site owners as to the form of restrictive covenants to be recorded in the deed records for Pulaski County, Arkansas. Restrictive covenants were then executed by the heir to the property and recorded in the deed records for the site on February 29, 2008.

G. Five-Year Review

The EPA must conduct a statutory five-year review of the remedy no less than every five years after the initiation of the remedial action pursuant to CERCLA Section 121(c). Based on the five-year reviews, EPA will determine whether human health and the environment continue to be adequately protected by the implemented remedy. Five-year reviews for this Site were completed in September 2000 and September 2005. The 2005 FYR identified a gap of 20 feet in the fence surround the capped area. The fence was repaired in May 2010. In each of these reviews EPA determined that the remedy is protective of human health and the environment and is functioning as intended.

The next five-year review will occur no later than September 2010.

H. Community Involvement

Because of the high community interest in the nearby Vertac Corporation Superfund Site, a Community Relations Office, staffed by an EPA contractor, was established in 1990. The purpose of this office is to disseminate information to citizens and the press and to give citizens a focal point for their questions.

An active campaign to notify local residents and receive input prior to the Site excavation and transportation was conducted. Landowners adjacent to the Site were visited and transportation was coordinated with local authorities and representatives of the Little Rock Air Force Base which is located near the transportation route.

A community open house meeting was held on August 22, 1994, to discuss the remedial action and receive citizen input.

A Site close-out open house and ribbon-cutting ceremony were held on September 25, 1995.

Public participation activities required in CERCLA Section 113(k), 42 U.S.C. 9613(k), and CERCLA Section 117, 42 U.S.C. 9617, have been satisfied, and documents which EPA generated and/or relied on are available to the public in these information repositories.

I. Determination That the Site Meets the Criteria for Deletion in the NCP

The NCP specifies that EPA may delete a site from the NPL if "all appropriate responsible parties or other persons have implemented all appropriate response actions required" or "all appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate". 40 CFR 300.425(e)(1). EPA, with concurrence of the State of Arkansas, through the Department of Environmental Quality by a letter dated July 3, 2008, believes these criteria for deletion have been satisfied. Therefore, EPA is proposing the deletion of the site from the NPL.

V. Deletion Action

The EPA, with concurrence of the State of Arkansas through the Arkansas Department of Environmental Quality, has determined that all appropriate responses under CERCLA, other than operation, maintenance, monitoring and five-year reviews, have been completed. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication. This action will be effective October 12, 2010 unless EPA receives adverse comments by September 13, 2010. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion and it will

not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

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.

Dated: August 4, 2010.

Lawrence E. Starfield,

Acting Regional Administrator, EPA Region 6.

■ For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

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.

Appendix B to Part 300—[Amended]

■ 2. Table 1 of Appendix B to Part 300 is amended by removing "Rogers Road Municipal Landfill", "Jacksonville, Arkansas".

[FR Doc. 2010–19924 Filed 8–11–10; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 541 and 552

[GSAR Amendment 2010–04; GSAR Case 2008–G511 (Change 47) Docket 2009–0008; Sequence 1]

RIN 3090–AI85

General Services Administration Acquisition Regulation; Rewrite of GSAR Part 541, Acquisition of Utility Services

AGENCIES: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is amending the General Services Administration Acquisition Regulation (GSAR) to improve the acquisition of utility services. Two clauses specific to utility services are being added to this part, they are the availability of funds clause which replaces the FAR clause and the disputes clause which supplements the FAR clause.

DATES: *Effective Date:* September 13, 2010.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Lori Sakalos, Procurement Analyst, at (202) 208–0498. For information pertaining to status or publication schedules, contact the Regulatory Secretariat (MVCB), Room 4041, 1800 F Street, NW., Washington, DC 20405, (202) 501–4755. Please cite Amendment 2010–04, GSAR case 2008–G511 (Change 47).

SUPPLEMENTARY INFORMATION:

A. Background

This rule is part of the GSAM Rewrite Project to revise the regulation in order to maintain consistency with the Federal Acquisition Regulation (FAR), update regulations, and implement streamlined and innovative acquisition procedures. The GSA Acquisition Manual (GSAM) incorporates the GSAR as well as internal agency acquisition policy.

On February 15, 2006, GSA published in the **Federal Register** at 71 FR 7910, an Advanced Notice of Proposed Rulemaking (ANPR) with a request for comments on the entire GSAM. As a result, no public comments were received on GSAR part 541. In addition, applicable statutes, GSA Acquisition Letters, Public Buildings Service (PBS) Procurement Instructional Bulletins, and GSA delegations of authority were considered in developing the initial draft. Prior to publication of a proposed rule, there was internal review and comment.

The proposed rule aligned GSAR part 541 to the structure of FAR part 41. This rule added GSA-unique clauses in GSAR Subpart 541.5—Solicitation Provisions and Contract Clauses.

Two GSA–unique clauses are prescribed under GSAR subpart 541.5. These clauses are outlined in GSAR section 541.501, Solicitation provisions and contract clauses, and shall be inserted by contracting officers in all utility contracts and solicitations. The first clause, GSAR 552.241–70, Availability of Funds for the Next Fiscal Year or Quarter is added as regulatory text for inclusion in all GSA utility solicitations and contracts instead of FAR 52.239–19. The second clause, GSAR 552.241.71/552.233–71, Disputes (Utility Contracts), was relocated from GSAM part 533 and added to this subpart to specifically align with utility acquisitions.

Discussion of Comments

A proposed rule for GSAR part 541 was published in the **Federal Register** on May 19, 2009, at 74 FR 23374. The public comment period for GSAR part 541 closed on July 20, 2009. A total of 2 comments were received by the close of the comment period.

Comment: One commenter stated that the proposed rule adds a new clause GSAR "552.241–xx, Availability of Funds for the Next Fiscal Year or Quarter" and FAR 52.232–19 is not currently used in Utility contracts (which generally last for many years) since the clause is to be used in one-year IDIQ or requirements contracts which cross fiscal years. The respondent would like to use GSAR 552.232–73, which doesn't require fill-ins instead of the new clause added to GSAR part 541.

Response: GSA does not concur with the commenter. The new clause is specific to utility acquisitions and is not intended to be limited to a one-year acquisition. Furthermore, the clause at GSAR 552.232–73 that the commenter would prefer to use was deleted from the GSAR on recommendation of GSA's Office of General Counsel. The new clause has fill-ins for the contracting officer which can coincide with the acquisitions period of performance.

Since this is a utilities contract, the explicit language in 31 U.S.C. 1308 allows GSA to obligate and record amounts quarterly (in accordance with our apportionment). This satisfies the recordation statute.

Additionally, in order to limit GSA's legal liability to the contractor and satisfy the Anti-Deficiency Act (ADA), GSA has to have an ADA clause that sets limits on the amount of our liability (either by amount of money or by set period of time) and the clause must provide that the limit can only be increased by affirmative action of the Government.

Comment: The second commenter stated that the proposed rule moves the existing GSAR clause 552.233–71 (Disputes-Utilities Contracts) from GSAR part 533 to GSAR part 541.

However, preceding GSAR change #24, which is the rewrite of GSAR part 533, deleted the clause in entirety since the use of FAR clauses is preferred. The subject clause was deleted from the Public Building Service (PBS) contract writing system clause module. In the meantime, there is no authority to use the clause in the GSAR and no prescription to use it.

Response: GSA does not concur with the commenter. There are no FAR clauses which adequately address disputes for utility contracts. However,

GSAR 552.241–71 (currently GSAR 552.233–71) will be relocated to this part. All clauses relevant to utilities contracts will now be located in GSAR part 541. The rewrite of GSAR part 541 will provide an authority and prescription for use. After publication of this rule, PBS can add the clause back in their contract writing system.

This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

B. Regulatory Flexibility Act

The General Services Administration certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the revisions are not considered substantive. The revisions only update and reorganize existing coverage.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the GSAR do not impose recordkeeping or information collection requirements, or otherwise collect information from offerors, contractors, or members of the public that require approval of the Office of Management and Budget under 44 U.S.C. chapter 35, *et seq.*

List of Subjects in 48 CFR Parts 541 and 552

Government procurement.

Dated: August 4, 2010.

Joseph A. Neurauter,

Senior Procurement Executive, Office of Acquisition Policy, General Services Administration.

■ Therefore, GSA amends 48 CFR chapter V as set forth below:

■ 1. Add part 541 to read as follows:

PART 541—ACQUISITION OF UTILITY SERVICES

Subpart 541.5—Solicitation Provisions and Contract Clauses

Sec.

541.501 Solicitation provision and contract clauses.

Authority: 40 U.S.C. 121(c).

Subpart 541.5—Solicitation Provisions and Contract Clauses

541.501 Solicitation provisions and contract clauses.

In addition to the solicitation terms, provisions and contract clauses at FAR 41.501(c), the contracting officer shall include the following clauses—

(a) *552.241–70, Availability of Funds for the Next Fiscal Year or Quarter.* As prescribed in 541.501, insert the clause 552.241–70, Availability of Funds for the Next Fiscal Year or Quarter, instead of FAR 52.232–19, in all utility acquisitions; and

(b) *552.241–71, Disputes (Utility Contracts).* As prescribed in 541.501, insert clause 552.241–71, Disputes (Utility Contracts), in solicitations and contracts for utility services subject to the jurisdiction and regulation of a utility rate commission.

■ 2. The authority citation for 48 CFR part 552 continues to read as follows:

Authority: 40 U.S.C. 121(c).

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. Add sections 552.241–70 and 552.241–71 to read as follows:

552.241–70, Availability of Funds for the Next Fiscal Year or Quarter.

As prescribed in 541.501, insert the clause 552.241–70, Availability of Funds for the Next Fiscal Year or Quarter, instead of FAR 52.232–19, in all utility acquisitions.

Availability of Funds for the Next Fiscal Year or Quarter (AUG 2010)

Funds are not presently available for performance under this contract beyond _____. The Government's obligation for performance of this contract beyond that date is contingent upon the availability of appropriated funds from which payment for contract purposes can be made. No legal liability on the part of the Government for any payment may arise for performance under this contract beyond _____, until funds are made available to the Contracting Officer for performance and until the Contractor receives notice of availability, to be confirmed in writing by the Contracting Officer.

(End of clause)

552.241–71 Disputes (Utility Contracts).

As prescribed in 541.501, insert clause 552.241–71, Disputes (Utility Contracts), in solicitations and contracts for utility services subject to the jurisdiction and regulation of a utility rate commission.

Disputes (Utility Contracts) (AUG 2010)

The requirements of the Disputes clause at FAR 52.233–1 are supplemented to provide that matters involving the interpretation of tariffed retail rates, tariff rate schedules, and tariffed terms provided under this contract are subject to the jurisdiction and regulation of the utility rate commission having jurisdiction.

(End of clause)

[FR Doc. 2010–19724 Filed 8–11–10; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

48 CFR Chapter 14

RIN 1093–AA11

Acquisition Regulation Rewrite

AGENCY: Office of the Secretary, Interior.

ACTION: Final rule.

SUMMARY: The Department of the Interior (DOI) has adopted as final an interim rule amending the Department of the Interior Acquisition Regulation (DIAR). This action revises the DIAR, 48 CFR chapter 14, but does not impose any new requirements on DOI contractors. The revisions to the DIAR published in the interim rule became effective May 17, 2010.

DATES: This rule is effective on August 12, 2010.

FOR FURTHER INFORMATION CONTACT: Tiffany A. Schermerhorn, Senior Procurement Analyst, Office of Acquisition and Property Management, Office of the Secretary, telephone (202) 513–0747, fax (202) 219–4244, or e-mail *tiffany_schermerhorn@ios.doi.gov.*

SUPPLEMENTARY INFORMATION:

DOI published an interim final rule in the **Federal Register** at 75 FR 19828 on April 15, 2010, to revise the Department of the Interior Acquisition Regulation (DIAR) in order to update references to other Federal and Departmental directives, remove obsolete material and references, and clarify and streamline internal policies and procedures.

The comment period closed June 14, 2010. No public comments were received. DOI has concluded that the interim rule should be adopted as a final rule with no changes.

List of Subjects in 48 CFR Chapter 14

Government procurement.

■ Accordingly, the interim rule published in the **Federal Register** at 75 FR 19828 on April 15, 2010, is adopted as final without change.

Dated: August 3, 2010.

Pamela K. Haze,

Deputy Assistant Secretary, Budget, Finance, Performance and Acquisition.

[FR Doc. 2010–19891 Filed 8–11–10; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 0907301205–0289–02]

RIN 0648–AY14

Fisheries of the Northeastern United States; Atlantic Herring Fishery; Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS announces final specifications for the 2010–2012 fishing years for the Atlantic herring (herring) fishery. The intent of this final rule is to conserve and manage the herring resource and provide for a sustainable fishery. This final rule also makes minor corrections to existing regulations.

DATES: Effective August 12, 2010.

ADDRESSES: Copies of supporting documents used by the New England Fishery Management Council (Council), including the Environmental Assessment (EA) and Regulatory Impact Review (RIR)/Initial Regulatory Flexibility Analysis (IRFA), are available from: Paul J. Howard, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950, telephone (978) 465–0492. The EA/RIR/IRFA is also accessible via the Internet at *http://www.nero.nmfs.gov*. Copies of the Small Entity Compliance Guide are available via the Internet at *http://www.nero.nmfs.gov* and from the Regional Administrator, Northeast Region, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01915–2298.

FOR FURTHER INFORMATION CONTACT: Carrie Nordeen, Fishery Policy Analyst, (978) 281–9272, fax (978) 281–9135.

SUPPLEMENTARY INFORMATION:

Background

Proposed 2010–2012 specifications were published on April 20, 2010 (75 FR 20550), with public comment accepted through May 20, 2010. These final specifications are unchanged from those that were proposed. A complete discussion of the development of the specifications appears in the preamble to the proposed rule and is not repeated here.

The 2010–2012 herring specifications are based on the provisions currently in the Herring Fishery Management Plan (FMP), and also provide the necessary elements for a transition to the new annual catch limit (ACL) and accountability measure (AM) requirements of the Magnuson-Stevens Fishery Conservation and Management Act (MSA). The ACL and AM process was developed by the Council in Amendment 4 to the Herring FMP, which was submitted to NMFS by the Council on April 23, 2010. Amendment 4 will be implemented for the 2011 fishing year, if approved by NMFS.

2010–2012 Final Specifications

The following specifications are established by this action: Allowable biological catch (ABC), optimum yield (OY), domestic annual harvest (DAH), domestic annual processing (DAP), total foreign processing (JVPt), joint venture processing (JVP), internal water processing (IWP), U.S. at-sea processing (USAP), border transfer (BT), total allowable level of foreign fishing (TALFF), and the total allowable catch (TAC) from each management area.

TABLE 1.—SPECIFICATIONS AND AREA TACS FOR THE 2010–2012 ATLANTIC HERRING FISHERY

Atlantic Herring Specifications (mt) for 2010–2012	
MSY Fishing Level	2010–145,000 2011–134,000 2012–127,000
Allowable Biological Catch	106,000
Optimum Yield	91,200
Domestic Annual Harvest	91,200
Border Transfer	4,000
Domestic Annual Processing	87,200
Joint Venture Processing Total	0
Joint Venture Processing	0
Internal Waters Processing	0
U.S. At-Sea Processing	0
Total Allowable Foreign Fishing	0
Reserve	0
Area 1A Total Allowable Catch (TAC)	26,546*
Area 1B TAC	4,362
Area 2 TAC	22,146
Area 3 TAC	38,146
Fixed Gear Set-Aside	295
Research Set-Aside	0

*If New Brunswick weir fishery landings through October 15 are less than 9,000 mt, then 3,000 mt will be added to the Area 1A TAC in November.

Comments and Responses

There were seven comments received from Congresswoman Chellie Pingree; the Herring Alliance; four industry entities (Northern Pelagic Group, LLC; Cape Seafoods Inc.; Lunds Fisheries Inc.; the Small Pelagic Group); and one individual.

Comment 1: Congresswoman Pingree noted the negative impacts on Maine communities, but supported the proposed specifications because they are consistent with the best available scientific advice, and are better than alternative proposals that would have reduced the quota even more.

Response: There are no changes from the proposed specifications.

Comment 2: The Herring Alliance noted their view that caution is warranted in management because of the ecosystem role of herring as a forage species, past declines in the New England herring stock, and concern that in other regions, stocks with spawning subcomponents have had some of those subcomponents extirpated. The group ultimately commented in support of the proposed action, but noted that though the proposed specifications are consistent with the scientific and statistical committee's (SSC) advice, the SSC also suggested that the Council should consider a conservative catch limit of 90,000 mt, given the substantial uncertainty in the stock assessment. The commenters said this emphasized their opinion that the final specifications should be set no higher than those that were proposed. In addition, they pointed out that the proposed management area TACs pose a relatively high risk for the inshore stock component.

Response: This action established the specifications at the level that was proposed. The SSC's final advice to the Council was that, in the face of several sources of uncertainty, it would be

inappropriate to allow catches to increase above recent catch until a new benchmark assessment can be completed. The sources of uncertainty cited were the retrospective pattern in the assessment (that overestimates stock biomass) and the uncertain mixing ratios of stock subcomponents. Despite this uncertainty in the recent stock assessment, the analysis does suggest that recent catch levels have maintained a relatively abundant stock size and low fishing mortality. The SSC noted that there could be a range of values that represent recent catch: 90,000 mt (2008); 106,000 mt (2006–08 average); or 108,000 mt (2004–08 average). While the commenter is correct in stating that the SSC suggested that the Council should consider a conservative catch limit (e.g., 90,000 mt), the SSC also noted that the choice of the time period used to derive ABC depended upon the Council's tolerance for risk. NMFS concludes that these final specifications, which set the ABC at 106,000 mt for all three years, are consistent with the SSC's technical advice.

In the specifications documents submitted by the Council, it noted the need to consider its concerns about the risk of depleting spawning components of the stock and the need to consider the role of herring in the ecosystem as a forage species. The specifications documents include a risk assessment that was prepared to evaluate the impacts of the various TAC allocation alternatives on the individual spawning components of the herring stock complex. While the Atlantic herring stock is assessed as one stock, it is comprised of an inshore Gulf of Maine stock component, and an offshore Nantucket Shoals/Georges Bank stock component. These two stock components are segregated during spawning season, but mix at other times of the year; thus each component is vulnerable to fishing mortality independent of the other component. The best scientific information available indicates that the inshore stock component comprises approximately 18 percent of the total stock. The inshore stock component is present in Areas 1A, 1B and 2 at various times of the year; it does not range into Area 3. Most herring is harvested in the inshore herring management areas; thus, while the inshore stock component is a relatively small portion of the stock, it is also the subject to more fishing effort than the offshore component because of its proximity to shore. As a result, the need to minimize the risk of overfishing the inshore stock component is a major factor in determining the area TAC allocations.

The Council's plan development team (PDT) conducted a risk assessment to examine the removal rates from the inshore and offshore stock components of the various TAC alternatives considered by the Council, in order to evaluate the risk of overfishing to the inshore stock of various TAC allocation alternatives. The analysis generates a relative exploitation rate, which is then compared to the target exploitation rate for the entire stock complex. Risk is defined in the analysis as it relates to the potential for fishing a stock component at a level that may be higher than the target exploitation rate. The PDT determined, given the current fishing mortality at maximum sustainable yield (F_{msy})for the herring stock (F=0.27, or an exploitation rate of 0.24), that an exploitation rate on the inshore stock component that ranged from 0.24 to 0.28 could be viewed as risk neutral, assuming that productivity of this subcomponent is higher than most other herring stocks in the NW Atlantic.

This action is estimated to result in an exploitation rate on the inshore stock component of 0.42 in 2010, 0.45 in 2011, and 0.50 in 2012. While these rates present a higher risk to the inshore stock component than some of the other TAC allocation alternatives, the lower risk alternatives reduced the inshore area TAC allocations to levels that would have had greater negative impacts on the herring fishery than this action. This action, while not risk neutral for the inshore stock component, is predicted to result in exploitation rates on the inshore stock component similar to those that occurred from 2000–2007, when exploitation fluctuated around 0.47. Maintaining this exploitation rate is consistent with the SSC advice to maintain catch at recent levels.

Comment 3: All four industry groups opposed the Council's recommended specifications for 2010–2012. They gave a number of reasons for their views, which are similar in many ways. Therefore, these comments are summarized together, without attributing each point to a group.

The industry groups argued that the specifications are unnecessarily restrictive given the conclusion of the 2009 Transboundary Resource Assessment Committee stock assessment that the fishery is not overfished or subject to overfishing. They also contended that the TRAC stock assessment is flawed, and that the SSC should have rejected it and instead recommended that the 2009 specifications be maintained until a new benchmark stock assessment can be conducted. They cited concern about the high level of precaution the SSC used in recommending a buffer between the maximum sustainable yield (MSY) fishing level and the ABC. They argue that the SSC's initial recommendation to reduce the MSY fishing level by 40 percent to account for scientific uncertainty was a matter of guesswork, and therefore entirely arbitrary.

They contended that the ABC recommendation, and the resultant TACs, represent multiple layers of precaution, and represent an overly conservative reaction to the uncertainty in the stock assessment. They noted that there are three layers of scientific uncertainty that affect TAC levels: (1) the severe retrospective pattern in the updated stock assessment; (2) the SSC recommendation for a 40% reduction in ABC to account for scientific uncertainty; and (3) the additional 41% reductions in the Gulf of Maine that they contend result from the PDT's risk assessment. They requested a peer review to determine if what they characterize as cumulative, multiple reductions in catch levels, are necessary and scientifically valid.

They questioned the scientific validity of the PDT's risk assessment, which resulted in the area TAC allocations. They requested that the PDT's risk assessment analysis be peer-reviewed. In addition, they noted that the additional layer of precaution used in establishing area TACs, which is based on what they characterize as a two-stock component theory, is contrary to the TRAC's historical approach to assessing the Atlantic herring resource as a single stock component.

They noted that the proposed reduction in the Area 1A TAC will be particularly damaging to herring vessels and coastal communities in Maine and Massachusetts, and to the New England lobster fishery which depends on herring for bait. They contended that neither the proposed rule nor the economic analysis in the EA adequately consider the economic consequences of the proposed Area 1A TAC. They noted that, in their view, the recent closure of the last sardine factory in the U.S. was a direct result of the proposed TAC reduction.

They argued that the proposed reduction in the Area 2 TAC threatens the success of the Atlantic mackerel fishery during the winter months due to the catch of herring in the mackerel fishery; they contended that the proposed rule did not examine the economic impacts of the TAC on the Atlantic mackerel fishery.

They objected to the fact that this action sets the specifications for three years, though it is not entirely clear what they are suggesting should occur to address this concern. They noted that NMFS should collect additional data to assess the resource as it prepares for the next benchmark stock assessment in 2012.

They noted that the statement in the proposed rule that suggests that the fishery may land the same amount of herring as it has in recent years is outrageous, though they do not fully explain their reasoning. NMFS assumes that they do not agree that the TAC reductions in the Gulf of Maine could be compensated for by fishing in Area 3.

Response: For the most part, these comments reflect differing opinions about the stock assessment for herring and the validity of the SSC's advice. The commenters offered no alternative scientific analyses to support their opinions, nor did they cite any specific legal requirements that would be violated if the proposed specifications were implemented. As more specifically discussed below, NMFS has determined that the precautionary approach reflected in the specifications is consistent with the best scientific information available, and other applicable Magnuson-Stevens Act requirements.

While the TRAC concluded that recent catches have maintained a relatively abundant stock size and low fishing mortality, and that the stock is not overfished or subject to overfishing, it also noted concerns about the stock assessment results, primarily a retrospective pattern that results in an overestimation of stock biomass. While the SSC reviewed the TRAC results and initially recommended a 40 percent buffer between the MSY fishing level and ABC, that initial advice was not arbitrary, as characterized by the commenter. The initially proposed 40 percent buffer corresponded to the average retrospective inconsistency in the estimate of exploitable biomass presented in the TRAC assessment; the SSC believed that the magnitude of this inconsistency was sufficient to account for all sources of uncertainty in the assessment. In addition, that initial advice was revisited at the request of the Council, and these specifications are being set consistent with the SSC's revised advice that ABC should not exceed recent catch. The Council responded to the advice by recommending an ABC of 106,000 mt, which corresponds to average total US and Canadian catch from 2006–2008. The SSC also noted that exploitable biomass is projected to decline during 2010–2012 due to the recruitment of poorer than average year-classes. The ABC of 106,000 mt provides a 27 percent buffer from the F_{msy} based catch level of 145,000 mt in 2010, in order to ensure that Fmsy is not exceeded for the stock complex, given the uncertainties in the assessment.

To consider the risk of depleting individual spawning components, the PDT conducted a risk assessment (see Response #2) to evaluate the risk of overfishing the inshore stock component. Such analyses are frequently conducted by Council PDTs, and are not formally peer-reviewed. PDTs are comprised of technical experts identified by the Council specifically to offer technical advice that will assist in making sound fishery management decisions. NMFS disagrees with the contention that such advice must be formally peer-reviewed before it is considered in management. The risk assessment prepared by the PDT provides a useful tool for considering the risk of overfishing the stock components by estimating exploitation rates.

NMFS disagrees that the PDT's risk assessment, which estimates mortality rates on both the inshore and offshore stock components under the proposed management area TAC options, is contrary to the TRAC's approach to assessing the Atlantic herring resources as a single stock complex. The commenters offer no scientific analyses that refute the risk assessment method of estimating the exploitation risk to each individual stock component in establishing management area TACs. Though the herring stock is assessed as a single unit, there is ample evidence that there are inshore and offshore stock components that can be affected by fishing mortality independent of each other. The most compelling evidence supporting the existence of separate inshore and offshore components was the collapse of the offshore component in the early 1970s after years of heavy exploitation by foreign fishing fleets. During the decade that the offshore stock component was in a depressed state, the smaller inshore stock component supported the coastal fishery.

As noted in the Response to Comment 12, the concern that is addressed in this action is the fact that in recent years, most of the harvest has come from the inshore stock component, which is vulnerable to overfishing because of its proximity to shore and because it has substantially less biomass than the offshore component. These management areas are of particular economic importance to the industry, and the collapse of the inshore stock component would eliminate the opportunity to participate in the nearshore fishery for herring. This action is intended to prevent such a situation from occurring.

The analysis of the economic impacts of the TAC allocations shows clearly that the reductions in the Area 1A TAC are likely to adversely impact fishery participants from ports in Maine and New Hampshire, and to a lesser extent ports in Massachusetts and Rhode Island. These impacts were carefully considered in selecting TAC allocations intended to balance the biological concerns against the economic concerns. NMFS notes that preventing overfishing of the inshore stock component is critical for the long-term health of the inshore fishery.

The discussion of economic impacts in the proposed rule summarizes the impacts on the regulated participants in the herring fishery; the Regulatory Flexibility Act only requires a discussion of impacts on regulated entities in the IRFA. While not addressed in the proposed rule, the Council's analysis of economic impacts does address the possible negative impacts that may be felt by participants in the lobster and mackerel fisheries. The analysis notes that herring is an important bait for the lobster fishery. The reductions in the TAC in Area 1A are likely to result in increased bait prices, especially considering the expected demand for bait related to recent high levels of lobster landings. The analysis also discusses the impacts of this action on the mackerel fishery, and notes that the reduction in the Area 2 TAC may require mackerel vessels to take steps to avoid catching herring, which could potentially increase their operating costs. The analysis acknowledges the possibility that mackerel fishing may cease because mackerel fishermen will not want to risk catching herring in excess of allowed levels. NMFS cannot comment on the cause of the recent sardine plant closure.

The commenters expressed concern that this action establishes specifications for three years. NMFS notes that the fishery management plan specifies that the Council will conduct an annual review of the status of the fishery, and may adjust the specifications at any time through the specifications process, if the review indicates an adjustment is warranted.

NMFS recognizes that, while this action does not reduce the total potential harvest of herring below the 2008 harvest level, it does reduce specific area allocations to levels lower than recent harvest. While the impact of

these reductions may be mitigated if the industry can increase harvest above recent levels in Area 3, NMFS recognizes the fact that fishing in this offshore area increases operating costs. Therefore, it may not be possible for the herring industry to mitigate the negative economic impacts of the inshore TAC reductions.

Comment 4: One individual commented that all herring quotas should be cut in half.

Response: The proposed ABC and area TACs were reduced from the 2009 levels, for reasons noted in Responses 2 and 3.

Classification

The Assistant Administrator for Fisheries has determined that the need to implement these measures in an expedited manner in order to help achieve conservation objectives for Atlantic herring constitutes good cause, under authority contained in 5 U.S.C. 553(d)(3), to waive the 30-day delay in effectiveness. If there is a delay in implementing the TACs in this action, the herring fleet will continue to fish in federal waters under the TACs that are currently in effect. The 2009 allocations are higher than the measures specified in this action for 2010 and also higher than those that have been implemented for the 2010 fishing year by the states under the Atlantic States Marine Fisheries Commission (ASMFC) FMP. The allocations in this action were developed to reflect an updated estimate of the annual catch that can be harvested in light of the scientific uncertainty about the results of the TRAC's stock assessment. Herring is a highly mobile, pelagic species, and herring populations have shown variable aggregation patterns in recent years. Analysis of this year's fishing activity indicates that the herring fleet has been successfully targeting aggregations in an area of Georges Bank (in management Area 3) where herring do not typically migrate until October. Due to the seasonal and annual variability in its distribution, the herring fleet is quick to target herring aggregations as they become available in each management area; the fleet is capable of landing over 2,000 mt in a single week. If the effective date for this action is delayed, increased fishing activity in response to fish availability could lead to an unanticipated pulse of landings. Given that the specifications reduce the total available TAC by 37 percent from the 2009 level, and reduce individual management area TACs by as much as 56 percent from the 2009 levels, it is necessary to waive the 30-day delay in effective date and implement the provisions in this rule immediately to ensure that the 2010 individual area TACs are not exceeded before the implementation of this action.

This action is authorized by 50 CFR part 648 and has been determined to be not significant for the purposes of Executive Order 12866.

A Final Regulatory Flexibility Analysis (FRFA) was prepared, which consists of and incorporates the IRFA, a summary of the significant issues raised by the public comments in response to the IRFA, NMFS responses to those comments, the analyses contained in the Council document and the accompanying EA, and the discussion and summary of the analyses contained in the preamble to this action. A copy of the analyses is available from the Council (see **ADDRESSES**).

Statement of Objective and Need

This final rule announces final 2010–2012 specifications for the herring fishery. A complete description of the reasons why this action is being considered, and the objectives of and legal basis for this action, are contained in the preamble to the proposed rule and are not repeated here.

A Summary of the Significant Issues Raised by the Public Comments in Response to the IRFA, a Summary of the Assessment of the Agency of Such Issues, and a Statement of Any Changes Made in the Proposed Rule as a Result of Such Comments

NMFS received seven comments on the proposed specifications. Three of the comments were specific to the IRFA. Comment 3 outlines concerns by three industry groups that the analysis in the proposed rule understated the economic impacts of the specified area TACs on the herring, mackerel, and lobster fisheries. NMFS' assessment of the issues raised by these comments is contained in the response to these comments and is not repeated here. The comments did not result in any changes to the area TACs, which were reduced to meet biological objectives specified in the FMP.

Description and Estimate of Number of Small Entities to Which the Rule Will Apply

Based on 2009 permit data, the number of fishing vessels eligible to fish in each permit category in the herring fishery are as follows: 41 for Category A (limited access, All Areas), 4 for Category B (limited access, Areas 2 and 3), 54 for Category C (limited access, incidental), and 2,272 for Category D (open access). There are no large entities participating in this fishery, as defined in section 601 of the RFA. Therefore, there are no disproportionate economic impacts on small entities.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

This action does not contain any new collection-of-information, reporting, recordkeeping, or other compliance requirements. It does not duplicate, overlap, or conflict with any other Federal rules.

Description of the Steps the Agency Has Taken to Minimize the Significant Economic Impact on Small Entities Consistent with the Stated Objective of the Applicable Statutes, including a Statement of the Factual, Policy, and Legal Reasons for Selecting the Alternative Adopted in the Final Rule and Why Each of the Other Significant Alternatives to the Rule Considered by the Agency which Affect the Impact on Small Entities was Rejected

This action will not reduce the stock-wide TAC below the level of landings in 2008 (83,580 mt), the last year for which data was complete at the time the impacts analyses were conducted. On a stock-wide level, no loss of revenue is projected because the herring fishery would have an opportunity to harvest the same amount of herring as in recent years. The impacts of the reductions to the area TAC allocations may vary, however.

This action reduces the Area 1A TAC by 41 percent, from 45,000 mt to 26,546 mt. In 2008, landings from Area 1A were 40,390 mt. The reduction from 2008 landings levels of 13,844 mt would result in a loss of revenue of $3.6 million, at the average 2008 price of $260/mt. This may be offset by the provision that would allocate an additional 3,000 mt of herring to Area 1A in November, if the catch in the New Brunswick weir fishery is lower than estimated. The value of this additional allocation is $780,000, which could reduce the revenue loss to $2.8 million.

The TACs in Areas 2 and 3 established by this action are higher than historical landings from those areas (2008 landings from Area 2 were 22,495 mt; from Area 3, 13,144 mt). It is possible that the impacts associated with the Area 1A TAC reduction will be offset by increases in the harvest from other management areas. However, conditions associated with harvesting herring from Areas 2 and 3 may not be ideal. If the Area 1A TAC is attained during the summer, fish may only be available in Areas 1B and 3, since Area 2 is primarily a winter fishing ground.

Area 3 is a large, offshore area, and it is never certain that fish will aggregate in such a way that they are available to fishing operations. Smaller vessels may not be able to fish safely offshore. For larger vessels that can safely fish in Area 3, increasing the amount of offshore fishing will increase operating costs. Sea time is likely to increase and the length of each trip will increase, resulting in higher trips costs, particularly for fuel. The degree to which fishing costs will change is difficult to predict, so an overall estimate of increased costs can not be made. However, observer data shows that each additional day at sea for a midwater trawl vessel increases the trip cost by an average of $2,800.

Alternatives to this action included options for setting the ABC, OY, and management area TACs. The first of 2 non-preferred alternatives for ABC and OY was based on the SSC's initial advice to the Council that ABC equal 90,000 mt for the 2010–2012 fishing years (Alternative 2). Because the herring resource is not overfished, and the MSA-mandated ACL provisions do not need to be established until 2011, the Herring Committee developed a second non-preferred alternative for ABC that would set ABC at the FMSY-based catch level (145,000 mt) for 2010 and at 90,000 mt for 2011 and 2012 (Alternative 1). In all alternatives, OY is a reduction of ABC by 14,800 mt to account for potential catch in the New Brunswick weir fishery. For the 2 non-preferred ABC alternatives, the resulting OY was 130,200 mt in 2010 and 75,200 mt in 2011 and 2012 under Alternative 1, and 75,200 mt in all 3 years under Alternative 2.

As described in the response to Comment #2, the SSC revised its advice, and the Council recommended an ABC of 106,000 mt for the 2010–2012 fishing years; the corresponding OY for all years is 91,200 mt. Unless there is scientific information to the contrary, the Council is required to set the ABC consistent with the SSC's recommendation. Alternative 1 was not selected because the ABC recommended for 2010 exceeds the SSC's recommendation. Under Alternative 2, the ABC recommended is 16,000 mt less than the selected ABC. This alternative was not selected because the selected ABC has higher potential to economically impact fishery participants than the preferred alternative.

There were 8 management area TAC allocation schemes presented in the EA that, when applied to the ABC and OY values under Alternatives 1 and 2, resulted in 32 sets of potential management area TAC allocations. The 8 management area TAC allocations schemes included the following: 1) allocation based on distribution of herring catch in the four management areas from 1999–2008; 2) allocation based on distribution of TACs in the 2001 fishing year with an Area 2 reserve; 3) allocation based on distribution of TACs in the 2001 fishing year without an Area 2 reserve; 4) allocation based on distribution of TACs in the 2009 fishing year; 5) allocation that maximizes catch in Area 1A, and allows 1A landings in July, August, and September; 6) allocation that maximizes catch in Area 1A, and allows 1A landings in May, June and July; 7) allocation that maximizes catch in Area 2; 8) allocation that reduces the quota in a relatively balanced manner across areas.

The specification of management area TACs has the greatest potential to economically impact fishery participants, especially the specification of the TAC in Area 1A, therefore this section focuses on the Area 1A TAC alternatives. Of the 32 management area TAC allocations considered, only two alternatives specified Area 1A TACs that are higher than status quo (i.e., 45,000 mt). Alternative 1/Option 1 had an Area 1A TAC that was 31,000 mt higher than status quo and Alternative 1/Option 2A had an Area 1A TAC that was 400 mt higher than status quo. At a $260 per mt (average price in 2008), these alternatives would have resulted in fleet-wide revenue increases of approximately $8 million (Alternative 1/Option 1) or $104,000 (Alternative 1/Option 2). These alternatives were not selected because they would not have reduced the relative exploitation rate on the inshore stock component. The other alternatives have Area 1A TACs that are lower than status quo (10–90 percent less). As discussed in the response to Comment 12, the selected alternative reduces the relative exploitation rate on the inshore stock component compared to the status quo, while maintaining harvest opportunities in inshore areas. Similar to alternatives with Area 1A TACs higher than status quo, alternatives that feature smaller reductions to the Area 1A TAC (10–20 percent less), which would have less economic impact on the industry than the selected alternative, were not chosen because they did not sufficiently reduce the relative exploitation rate on the inshore stock component. Alternatives with substantially lower Area 1A TACs (80–90 percent less) were not selected because they had too great a potential to negatively impact the herring industry through loss of revenue and fishing opportunities. The economic impacts of reducing the Area 1A TAC and displacing effort into other management areas are discussed earlier in the preamble.

Similarly, for all other management areas (Area 1B, Area 2 and Area 3), the selected alternative was determined to best balance the exploitation rate on the inshore stock component against providing adequate harvest opportunities. The TAC alternatives for Area 1B ranged from 2,538 mt to 8,854 mt; all 32 alternatives were below the status quo (10,000 mt). The TAC alternatives for Area 2 ranged from 3,817 mt to 67,700 mt; 6 of the 32 alternatives were above the status quo (30,000 mt). Finally the TAC alternatives for Area 3 ranged from 15,100 mt to 85,949 mt; 3 of the 32 alternatives were above the status quo (60,000 mt). The alternatives considered for Areas 1B, Area 2 and Area 3 where the TACs were lower than the status were not selected because they had too great a potential to negatively impact the herring industry through loss of revenue and fishing opportunities. The alternatives considered for these management areas where the TACs were higher than the status quo were not selected because they would not have reduced the relative exploitation rate on the inshore stock component.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule, or group of related rules, for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule and shall designate such publications as "small entity compliance guides." The agency shall explain the actions a small entity is required to make to comply with a rule or group of rules. As part of this rulemaking process, a small entity compliance guide will be sent to all holders of permits issued for the herring fishery. In addition, copies of this final rule and guide (i.e., permit holder letter) are available from the Regional Administrator (see **ADDRESSES**) and may be found at the following web site: *http://www.nero.noaa.gov*.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: August 6, 2010.

Eric C. Schwaab,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

■ For the reasons set out in the preamble, 50 CFR part 648 is amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.14, paragraphs (r)(1)(vi)(A) and (r)(1)(viii)(B) are revised to read as follows:

§ 648.14 Prohibitions.

(r) * * *

(1) * * *

(vi) * * *

(A) For the purposes of observer deployment, fail to notify NMFS at least 72 hr prior to departing on a trip aboard a vessel with an All Areas Limited Access Herring Permit and/or an Areas 2 and 3 Limited Access Herring Permit fishing with either midwater trawl or purse seine gear on a declared herring trip.

* * * * *

(viii) * * *

(B) Fail to notify the NMFS Office of Law Enforcement of the time and date of landing via VMS, if a vessel with an All Areas Limited Access Herring Permit and/or an Areas 2 and 3 Limited Access Herring Permit fishing with either midwater trawl or purse seine gear, at least 6 hr prior to landing herring at the end of a declared herring trip.

* * * * *

■ 3. In § 648.201, paragraph (h) is added to read as follows:

§ 648.201 Closures and TAC controls.

* * * * *

(h) If NMFS determines that the New Brunswick weir fishery landed less than 9,000 mt through October 15, NMFS will allocate an additional 3,000 mt to the Area 1A TAC in November. NMFS will notify the Council of this adjustment and publish the adjustment in the **Federal Register**.

[FR Doc. 2010–19870 Filed 8–11–10; 8:45 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 75, No. 155
Thursday, August 12, 2010

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 THE TREASURY

Internal Revenue Service

26 CFR Part 300

[REG–139343–08]

RIN 1545–BI71

User Fees Relating to Enrollment and Preparer Tax Identification Numbers; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking and notice of a public hearing.

SUMMARY: This document contains a correction to a notice of proposed rulemaking and notice of a public hearing (REG–139343–08) that was published in the **Federal Register** on Friday, July 23, 2010 (75 FR 43110). The proposed regulations contain proposed amendments to regulations relating to the imposition of certain user fees on certain tax practitioners. The proposed regulations establish a new user fee for individuals who apply for or renew a preparer tax identification number.

FOR FURTHER INFORMATION CONTACT: Emily M. Lesniak, (202) 622–4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking and notice of a public hearing that is the subject of this document is under section 6109 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking and notice of a public hearing (REG–139343–08) contains an error that is misleading and is in need of clarification.

Correction to Publication

Accordingly, the notice of proposed rulemaking and notice of a public hearing which was the subject of FR Doc. 2010–18198 is corrected as follows:

On page 43110, column 1, in the heading, line 5, the language "RIN 1545–B171" is corrected to read "RIN 1545–BI71".

LaNita VanDyke,

Branch Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2010–19881 Filed 8–11–10; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 49

[EPA–R09–OAR–2007–0296, FRL–9188–9]

Approval and Promulgation of Gila River Indian Community's Tribal Implementation Plan

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve the Gila River Indian Community's (GRIC or the Tribe) Tribal Implementation Plan (TIP) under the Clean Air Act (CAA) to regulate air pollution within the exterior boundaries of the Tribe's reservation. The proposed TIP is one of four CAA regulatory programs that comprise the Tribe's Air Quality Management Plan (AQMP). EPA approved the Tribe for treatment in the same manner as a State (Treatment as State or TAS) for purposes of administering the AQMP and other CAA authorities on October 21, 2009. In this action we propose to act only on those portions of the AQMP that constitute a TIP containing severable elements of an implementation plan under CAA section 110(a). The proposed TIP includes general and emergency authorities, ambient air quality standards, permitting requirements for minor sources of air pollution, enforcement authorities, procedures for administrative appeals and judicial review in Tribal court, requirements for area sources of fugitive dust and fugitive particulate matter, general prohibitory rules, and source category-specific emission limitations. The purpose of the proposed TIP is to implement, maintain, and enforce the National Ambient Air Quality Standards (NAAQS) in the GRIC reservation. The intended effect of today's proposed action is to make the GRIC TIP federally enforceable.

DATES: Comments must be received on or before September 13, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2007–0296, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: tax.wienke@epa.gov*
- *Fax:* 415–947–3579
- *Mail:* Wienke Tax, Air Planning Office, Environmental Protection Agency, Region 9 Office, 75 Hawthorne Street, San Francisco, CA 94105–3901.
- *Hand Delivery:* Wienke Tax, Air Planning Office, Environmental Protection Agency, Region 9 Office, 75 Hawthorne Street, San Francisco, CA 94105–3901. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8 to 4:55 excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R09–OAR–2007–0296. 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 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. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI 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 form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Planning Office, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, California, 94105–3901. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Wienke Tax, Air Planning Office, Environmental Protection Agency, Region 9 Office, 75 Hawthorne Street, San Francisco, CA 94105–3901, (415) 947–4192 or *tax.wienke@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, the terms "we", "us", and "our" refer to EPA.

Table of Contents

I. Background

EPA is proposing to approve a TIP submitted by the GRIC for approval under section 110 of the CAA. The proposed TIP contains general and emergency authorities; procedures for the preparation, adoption, and submission of the GRIC's TIP and broader air quality management plan (AQMP) [1]; provisions adopting the National Ambient Air Quality Standards (NAAQS) for sulfur dioxide, particulate matter, nitrogen dioxide, ozone, lead and carbon monoxide, as Tribal standards [2]; permit requirements for new and existing minor sources of air pollutants; procedures for civil and criminal enforcement; requirements and procedures for administrative appeals and judicial review in Tribal court; requirements for area sources of fugitive dust and fugitive particulate matter; general prohibitory rules for existing and new sources; and source category-specific emission limits and standards for existing and new sources. The Tribe also submitted an inventory of emission sources on the reservation and information about its air quality monitoring program to support the TIP.

The Gila River Indian Community is an Indian tribe federally recognized by the U.S. Secretary of the Interior (*see* 67 FR 46328, July 12, 2002). The GRIC Department of Environmental Quality (DEQ) was established by executive order in August 1995 by then-Governor Mary Thomas. Beginning in 1998, the GRIC DEQ, with assistance from EPA, began developing a draft AQMP with the goal of submitting it to EPA for approval under the CAA. On December 6, 2006, the GRIC also submitted a request that we find the Tribe eligible for TAS pursuant to section 301(d) of the CAA and Title 40, part 49 of the Code of Federal Regulations (CFR), for the purpose of implementing the AQMP. Specifically, the GRIC DEQ requested a TAS eligibility determination for purposes of implementing four CAA programs that together comprise the AQMP: (1) A Tribal Implementation Plan (TIP) that includes source-specific rules and a minor source permit program under CAA section 110; (2) the Federal New Source Performance Standards (NSPS) under CAA section 111; (3) the Federal National Emissions Standard for Hazardous Air Pollutants (NESHAP) under CAA section 112; and (4) an operating permit program under title V of the Act. In addition, the Tribe requested TAS for receiving notifications as an "affected State" under title V of the CAA and submitting recommendations to EPA on air quality designations under CAA section 107(d). On October 21, 2009, EPA determined that the Tribe is eligible for TAS for these purposes.[3]

The GRIC formally submitted the AQMP to EPA Region 9 on February 21, 2007, and submitted supplemental materials on July 11, 2007, June 22, 2009, and July 17, 2010. Having found that the GRIC is eligible for TAS to implement these regulatory programs, EPA is now proposing to approve the Tribe's TIP. We intend to act on the Tribe's title V operating permit program and request for delegation of the NSPS and NESHAPs in separate notice and comment processes, as appropriate.

Approval and implementation of the GRIC TIP will be an important step in ensuring that basic air quality protection is in place to protect public health and welfare in the GRIC reservation, consistent with the CAA's overarching goals of protecting air resources throughout the nation, including air resources in Indian Country.

[1] The TIP is one of four regulatory programs that comprise the AQMP. The other three AQMP programs implement the New Source Performance Standards (NSPS) under CAA 111; the National Emission Standards for Hazardous Air Pollutants (NESHAP) under CAA 112; and title V operating permit requirements. Although the procedural requirements in the GRIC's AQMP apply to the adoption, submission, and revision of all AQMP programs, in this action we are proposing to approve these procedures as part of and only for the purposes of the TIP.

[2] To date, GRIC has adopted only those Federal NAAQS that were effective as of October 2006. This does not alter the applicability, within the GRIC reservation, of any CAA requirement based on a new or revised NAAQS that the Tribe has not yet adopted under Tribal law. Nonetheless, to avoid confusion, we encourage the GRIC to adopt all new or revised Federal NAAQS as Tribal standards and to submit them to EPA as revisions to the TIP.

[3] EPA has also previously approved the Tribe's applications for TAS eligibility for tribal water pollution control grants under Section 106 of the Clean Water Act (CWA) (March 1990), air pollution control grants under Section 105 of the CAA (March 1999), and non point source management grants under Section 319 of the CWA (February 2004).

II. CAA Requirements and the Role of Indian Tribes

A. What authorities may Indian Tribes obtain under the CAA?

The CAA is implemented in two basic ways.[4] In the first approach, EPA is primarily responsible both for setting national standards or interpreting the requirements of the Act and for implementing the Federal requirements that are established. In general, this approach is reserved for programs requiring a high degree of uniformity in their implementation—*e.g.,* regulation of substances that deplete stratospheric ozone under Title VI of the Act. *See* 59 FR 43956 at 43957.

The principal method of CAA implementation, however, is through a cooperative partnership between the states and EPA. While this partnership can take several shapes, generally EPA issues national standards or Federal requirements and the states assume primary responsibility for implementing these requirements. Prior to assuming implementation responsibility, states must submit their programs to EPA and must demonstrate that their programs meet minimum Federal CAA requirements. Among these requirements is the mandate that states demonstrate that they have adequate legal authority and resources to implement the programs. If a State program is approved or if the authority to implement a Federal program is delegated to a State, EPA maintains an ongoing oversight role to ensure that the program is adequately enforced and implemented and to provide technical and policy assistance. *See* 59 FR 43956 at 43957.

As part of the 1990 Amendments to the CAA, Congress enacted Section 301(d) authorizing EPA to "treat Indian tribes as States" under the Act so that Tribes may develop and implement CAA programs in the same manner as States within Tribal reservations or in other areas subject to Tribal jurisdiction. Section 301(d)(2) of the Act authorizes EPA to promulgate regulations specifying those provisions of the CAA "for which it is appropriate to treat Indian tribes as States." 42 U.S.C. 7601(d)(2).

On February 12, 1998, EPA issued a final rule specifying those provisions of the CAA for which it is appropriate to treat eligible Indian tribes in the same manner as states, known as the Tribal Authority Rule (TAR). 63 FR 7254, codified at 40 CFR part 49. As a general matter, EPA determined in the TAR that it is not appropriate to treat tribes in the same manner as states for purposes of specific program submittal and implementation deadlines. This is because, among other reasons (discussed at 59 FR at 43964–65), although the CAA contains many provisions mandating the submittal of State plans, programs, or other requirements by certain dates, the Act does not similarly require tribes to develop and seek approval of CAA programs. Thus, tribes are generally not subject to CAA provisions that specify a deadline by which something must be accomplished, *e.g.,* provisions mandating the submission of State implementation plans under section 110(a) and Part D of the Act. 40 CFR 49.4. As a result, tribes are also not subject to the section 179 sanctions and certain other Federal oversight mechanisms in the Act that are triggered when states fail to meet these deadlines or when EPA disapproves a program submittal. 40 CFR 49.4(c), (d).

A tribe that meets the eligibility criteria for TAS may, however, choose to implement a CAA program. A tribe may also submit reasonably severable portions of a CAA program, if it can demonstrate that its proposed air program is not integrally related to program elements not included in the plan submittal and is consistent with applicable statutory and regulatory requirements. 40 CFR 49.7(c); see also CAA 110(o). This modular approach is intended to give tribes the flexibility to address their most pressing air quality issues and acknowledges that tribes often have limited resources with which to address their environmental concerns. Consistent with the exceptions listed in 40 CFR 49.4, once submitted, a tribe's proposed air program will be evaluated in accordance with applicable statutory and regulatory criteria in a manner similar to the way EPA would review a similar State submittal. 40 CFR 49.9(h). EPA expects tribes to fully implement and enforce their approved programs and, as with states, EPA retains its authority to impose sanctions for failure to implement an approved air program. *See* 59 FR 43956 at 43965 (Aug. 25, 1994) (explaining EPA's rationale for treating Tribes in the same fashion as States for purposes of mandatory sanctions for nonimplementation of an approved part D program (CAA 179(a)(4)) and with respect to EPA's discretionary authority to impose sanctions (CAA 110(m)); 40 CFR 49.4.

B. What criteria must an Indian Tribe meet to be treated in the same manner as a State under the CAA?

Under section 301(d) of the CAA and the TAR, EPA may treat a tribe in the same manner as a State for purposes of administering certain CAA programs or grants if the tribe demonstrates that: (1) It is a federally-recognized tribe; (2) it has a governing body carrying out substantial governmental duties and powers; (3) the functions to be exercised by the tribe pertain to the management and protection of air resources within the exterior boundaries of the reservation (or other areas under the tribe's jurisdiction); and (4) it can reasonably be expected to be capable of carrying out the functions for which it seeks approval, consistent with the CAA and applicable regulations.

To receive EPA approval of a CAA program, a tribe must, as a threshold matter, obtain a determination from EPA that it meets these eligibility requirements. 40 CFR 49.6. As discussed in section III below, we previously determined that the GRIC meets these eligibility requirements for purposes of implementing the TIP and other CAA authorities.

C. What is a CAA Implementation Plan?

Under the CAA, EPA has established NAAQS, or minimum air quality standards, for six pollutants found in ambient air: carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO_2), ozone (O_3), particulate matter (PM), and sulfur dioxide (SO_2). The NAAQS are based on comprehensive studies of available ambient air monitoring data, health effects data, and studies of effects on materials. The primary standards are designed to protect the public from health risks, including children, people with asthma, and the elderly. The secondary standards are designed to prevent unacceptable effects on the public welfare, *e.g.,* damage to crops and vegetation, buildings and property, and ecosystems.

An implementation plan is a set of programs and regulations developed by the appropriate regulatory agency to protect public health and welfare through the attainment and maintenance of the NAAQS. The regulatory agency is generally free to choose whatever mix of requirements it determines best suits its specific circumstances so long as the implementation plan meets applicable requirements and ensures attainment and maintenance of the NAAQS. These plans can be developed by states, eligible Indian tribes, or the EPA, depending on which entity has

[4] For a brief description of some of the many programs contained in the CAA, see "Addendum A to Preamble—General Description of Clean Air Act Programs," 59 FR 43956 at 43976 (August 25, 1994) (Indian Tribes: Air Quality Planning and Management, proposed rule).

jurisdiction in a particular area. Implementation plans developed by states are called State Implementation Plans or SIPs. Similarly, plans developed by eligible Indian tribes are called Tribal Implementation Plans or TIPs. Occasionally, EPA will develop an implementation plan for a specific area. This is referred to as a Federal Implementation Plan or FIP. Following final approval and publication in the **Federal Register**, the provisions of a SIP, TIP or FIP become federally enforceable.

The contents of a typical implementation plan may fall into three broad categories: (1) Agency-adopted control measures which consist of prohibitory rules or source-specific requirements (*e.g.,* orders, consent decrees or permits); (2) agency-submitted "non-regulatory" components (*e.g.,* attainment plans, rate of progress plans, emission inventories, transportation control measures, statutes demonstrating legal authority, monitoring programs); and (3) additional requirements promulgated by the EPA (in the absence of a commensurate agency provision) to satisfy a mandatory Clean Air Act section 110 or part D requirement. The implementation plan is a living document which can be revised by the State or eligible Indian Tribe as necessary to address air pollution problems. Changes to the plan, such as new and/or revised regulations, that EPA approves following notice and comment rulemaking become part of the federally-enforceable implementation plan.

A geographic area that meets or does better than a primary standard is called an attainment area. An area for which there is insufficient information to determine whether the area meets the NAAQS is called an unclassifiable area. An area that does not meet a standard, or that contributes pollution to a nearby area that does not meet a standard, is called a nonattainment area. An area may be designated attainment or unclassifiable/attainment for some pollutants and nonattainment for others.

The CAA requires that the NAAQS be met nationwide and requires states to adopt SIPs that provide for the implementation, maintenance, and enforcement of the NAAQS. CAA 110(a). For attainment and unclassifiable areas, the CAA requires states to submit the basic program elements specified in section 110(a)(2) necessary to implement the NAAQS—*e.g.,* enforceable emission limitations and other control measures (CAA 110(a)(2)(A)), a program to provide for the enforcement of these measures (CAA 110(a)(2)(C)), and necessary assurances that the State will have adequate personnel, funding, and authority under State law to carry out the plan (CAA 110(a)(2)(E)(i)). For nonattainment areas, in addition to these basic program elements, the CAA requires states to adopt SIPs containing specific program elements in part D, Title I of the Act, in accordance with specified deadlines based on the severity of the air pollution problem.

D. What is a Tribal Implementation Plan?

Section 301(d) of the CAA and the TAR authorize eligible Indian tribes to implement various CAA programs, including TIPs under section 110 of the Act. TIPs (1) are optional; (2) may be modular; (3) have flexible submission schedules; and (4) allow for joint tribal and EPA management.[5]

1. Optional

The CAA requires each State to adopt a SIP. Unlike states, Indian tribes are not required to adopt a CAA implementation plan. In the TAR, we recognized that not all Indian tribes will have the need or the desire to implement an air pollution control program, and we specifically determined that it was not appropriate to treat tribes in the same manner as states for purposes of plan submittal and implementation deadlines. *See* 40 CFR 49.4(a) (exempting Tribes from the plan submittal deadlines for nonattainment areas set out in sections 172(a)(2), 182, 187, 189, and 191 of the Act); *see also* 59 FR 43956, 43964–67 (Aug. 25, 1994) (proposed TAR preamble) and 63 FR 7254, 7264–66 (Feb. 12, 1998) (final TAR preamble).

2. Modular

The TAR allows eligible Indian tribes to submit partial elements of a CAA program, so that they can target their most important air quality issues without the corresponding burden of developing entire CAA programs. Under this modular approach, TIP elements that the eligible Indian tribe submits must be "reasonably severable" from program elements that the tribe chooses not to submit. "Reasonably severable" elements are those that are not integrally related to program elements not included in the TIP. *See* 40 CFR 49.7(c); *see also* 59 FR 43956, 43961–69 (Aug. 25, 1994) (proposed TAR preamble) and 63 FR 7254 (Feb. 12, 1998) (final TAR preamble). So, for example, a tribe may choose to submit a TIP that addresses only specific types of sources and/or specific air pollutants.

3. Have Flexible Submission Schedules

Neither the CAA nor the TAR requires Indian tribes to develop TIPs. Therefore, unlike states, Indian tribes are not required to meet the plan submittal or implementation deadlines specified in the CAA. Indian tribes may establish their own schedules and priorities for developing TIP elements (*e.g.,* regulations to limit emissions of a specific air pollutant) and submitting them to the EPA. Indian tribes will not face sanctions for failing to submit or for submitting incomplete or deficient TIPs. *See* 40 CFR 49.4; 59 FR 43956, 43964–65 (Aug. 25, 1994) (proposed TAR preamble) and 63 FR 7254 at 7265 (Feb. 12, 1998) (final TAR preamble).

4. Allow for Joint Tribal and EPA Management

Consistent with the CAA and the TAR, a tribe may revise a TIP and take on new programs based on changes in tribal need or capacity. In any case, EPA retains its general authority to directly implement CAA requirements in Indian Country as necessary or appropriate to protect tribal air resources. *See* CAA 301(a), 301(d)(4); 40 CFR 49.11; 59 FR 43956, 43958–61 (Aug. 25, 1994) (proposed TAR preamble explaining EPA's CAA authorities in Indian Country); 63 FR 7254, 7262–64 (Feb. 12, 1998) (final TAR preamble). Thus, where a tribe chooses not to adopt a CAA program or adopts only a partial program, EPA may exercise its discretionary authority to issue such regulations as are necessary or appropriate to protect tribal air resources. This type of joint management allows tribes to focus on their specific air quality needs while ensuring adequate protection of tribal air resources.

The CAA also authorizes EPA to enforce the regulations in an approved TIP. CAA 113. We work cooperatively with the Indian Tribe in exercising this enforcement authority.

III. Evaluation of the GRIC's Implementation Authorities

A. How did the GRIC demonstrate eligibility to be treated in the same manner as a State under the CAA?

By letter dated November 17, 2006 and submitted to EPA on December 6, 2006, the GRIC requested an EPA determination that the Tribe is eligible for TAS for the purposes of implementing four CAA programs: (1) A

[5] For guidance on development of TIPs, see "Developing a Tribal Implementation Plan," Office of Air Quality Planning and Standards, U.S. EPA, October 2002 (EPA 452/R–02–010), *http://www.epa.gov/air/tribal/tip2002/index.html.*

TIP that includes source-specific rules and a minor source permit program under CAA section 110; (2) the Federal NSPSs under CAA section 111; (3) the Federal NESHAPs under CAA section 112; and (3) an operating permit program under title V of the Act. In addition, the Tribe requested TAS for receiving notifications as an "affected State" under title V of the CAA and for submitting recommendations to EPA on air quality designations under CAA section 107(d). The GRIC submitted supplemental materials for its TAS eligibility request on October 6, 2008 and March 18, 2009. EPA notified appropriate governmental entities and the public of the Tribe's application and addressed all comments received as part of that process.

On October 21, 2009, based on the information submitted by the Tribe, and after consideration of all comments received in response to notice of the Tribe's request, EPA determined that the GRIC met the eligibility requirements of CAA section 301(d) and 40 CFR 49.6 for these purposes under the CAA. *See* Memorandum, "Gila River Indian Community: Eligibility Determination under 40 CFR part 49 for Clean Air Act Sections 107, 110, 111, 112, 114, and Title V," signed by Laura Yoshii, Acting Regional Administrator, EPA Region 9, October 21, 2009 (TAS Decision Document). Specifically, EPA determined that the GRIC had demonstrated: (1) That it is an Indian tribe recognized by the Secretary of the Interior (see 67 FR 46328 (July 12, 2002)); (2) that it has a governing body carrying out substantial governmental duties and functions; (3) that the functions to be exercised by the Tribe pertain to the management and protection of air resources within the exterior boundaries of the Tribe's reservation;[6] and (4) that the Tribe is reasonably expected to be capable of carrying out the functions to be exercised in a manner consistent with the terms and purposes of the CAA and all applicable regulations.

EPA notified the Tribe of this TAS eligibility determination by letter the same day. See letter dated October 21, 2009, from Laura Yoshii, Acting Regional Administrator, EPA Region 9, to the Honorable William Rhodes, Governor, Gila River Indian Community.

[6] The TAS Decision Document describes the geographic area within which the Tribe is approved for TAS.

B. How would the GRIC administer and enforce the TIP?

The proposed TIP would be implemented primarily by the GRIC DEQ Air Quality Program staff and the Tribe's attorneys. Established in 1995, the GRIC DEQ has grown from an initial staff of six to a staff of 26 in 2009. The Air Quality Program staff has degrees ranging from Associate's to Master's degrees. They have received extensive training in TIP development, permit writing and regulatory enforcement.[7] Since 1995, the staff has also demonstrated considerable capabilities in the programmatic, administrative, and legal functions of implementing an air quality program. On January 9, 2003, the GRIC became the first Tribal Government that EPA recognized as capable of issuing permits with enforceable limitations on a source's potential to emit, following case-by-case EPA review.[8]

As discussed above in section III.A, EPA evaluated the Tribe's implementation and enforcement capabilities as part of our determination that the GRIC is eligible for TAS to implement this TIP and other CAA programs. Specifically, as part of that determination, EPA found that the GRIC is reasonably expected to be capable of implementing and enforcing the TIP and other AQMP programs in a manner consistent with the terms and purposes of the CAA and all applicable regulations. *See* TAS Decision Document. Also as part of that determination, EPA entered into a Memorandum of Agreement with the GRIC to facilitate intergovernmental cooperation in addressing criminal violations of the AQMP. *See* Memorandum of Agreement Between the Gila River Indian Community and the U.S. Environmental Protection Agency Regarding Criminal Enforcement of the Tribal Implementation Plan Pursuant to the Clean Air Act and 40 CFR part 49, dated October 21, 2009 (Criminal Enforcement MOA).

The GRIC DEQ staff is responsible for inspecting facilities within the exterior boundary of the reservation and responding to any complaints received. The GRIC air quality staff, and if needed, the GRIC tribal police, will assume enforcement activities for the purposes of compliance with air regulations. Other GRIC agencies will also provide compliance and enforcement assistance, as appropriate, in accordance with applicable Tribal and Federal law. *See* GRIC AQMP, Part 1, Section 2.2.

Part III of the AQMP contains enforcement ordinances that establish requirements and procedures for civil and criminal enforcement. These ordinances authorize the GRIC DEQ to issue administrative compliance orders, assess civil penalties, and take other enforcement actions against persons who violate requirements of the TIP or other requirements of the AQMP within the exterior boundaries of the reservation. These enforcement provisions are discussed further in Section IV.C.3 of this notice.

[7] *See* letter dated November 17, 2006, from William R. Rhodes, Governor, Gila River Indian Community, to Wayne Nastri, Regional Administrator, U.S. EPA Region 9 (transmitting TAS application), at page 10.

[8] *See* letter dated January 9, 2003, from Jack Broadbent, Director, Air Division, U.S. EPA Region 9, to Dr. Patricia Mariella, Director, Gila River Indian Community DEQ.

IV. Evaluation of the GRIC's Tribal Implementation Plan

A. What air quality goals does the GRIC TIP address?

The Gila River Indian Reservation is located in south-central Arizona, adjacent to the Phoenix Metropolitan Area, in Pinal and Maricopa Counties. The entire reservation is designated attainment or unclassifiable/attainment for the following NAAQS pollutants: Lead (Pb), carbon monoxide (CO), nitrogen dioxide (NO_2), sulfur dioxide (SO_2), particulate matter of 2.5 microns or less ($PM_{2.5}$), and ground-level ozone. 40 CFR 81.303. EPA had initially included the Maricopa County portion of the GRIC reservation in the Maricopa County CO nonattainment area, but in 2005 we corrected the nonattainment boundary to exclude the GRIC reservation and redesignated the reservation to "nonclassifiable/attainment" for the CO NAAQS. *See* 69 FR 60328 (October 8, 2004)(proposed rule) and 70 FR 11553 (March 9, 2005)(final rule), as corrected by 70 FR 52926 (September 6, 2005). Similarly, EPA had initially included the Maricopa County portion of the GRIC reservation in the Phoenix metropolitan 1-hour ozone nonattainment area, but in 2005 we corrected the nonattainment boundary to exclude the GRIC reservation and redesignated the reservation to "unclassifiable/attainment" for the 1-hour ozone NAAQS. *See* 70 FR 13425 (March 21, 2005)(proposed rule) and 70 FR 68339 (November 10, 2005)(final rule).[9]

[9] As explained in the final rule, the effect of this action was to attach the Maricopa County portion of the GRIC reservation to the pre-existing "unclassifiable/attainment" area for the 1-hour ozone NAAQS that consists of all of those portions of the State of Arizona (including the rest of the

More recently, on October 14, 2009, we notified the Governor of Arizona and affected Arizona tribes, including the GRIC, that EPA was reviewing the initial recommendation to designate Pinal County as attainment/unclassifiable for the 2006 annual $PM_{2.5}$ standard, given recent data indicating violations of the standard in the Pinal County area. On December 30, 2009, we notified the same entities that EPA was also initiating a redesignation of Pinal County to nonattainment for the 1997 annual $PM_{2.5}$ standard and for the 1987 24-hour standard for particulate matter of 10 microns or less (PM_{10}).[10] We have asked the Tribes in Pinal County, including the GRIC, to provide recommendations concerning their Indian country lands.

The only criteria pollutant for which a portion of the reservation is currently designated nonattainment is PM_{10}. The northern portion of the GRIC reservation lies within the Maricopa County (Phoenix Planning Area) serious PM_{10} nonattainment area. Approximately 92,000 acres of the GRIC reservation, along its northern boundary, were included in the Maricopa County area when it was originally designated as nonattainment (*see* 52 FR 29383, August 7, 1987) and reclassified from moderate to serious for the PM_{10} NAAQS. 61 FR 21372 (May 10, 1996)(reclassification to serious nonattainment effective June 10, 1996). The remainder of the GRIC reservation is located in the portion of Pinal County that is currently designated as unclassifiable/attainment for $PM_{10.}$ 40 CFR 81.303.

While State and local regulatory agencies in the Maricopa County PM_{10} nonattainment area have developed SIPs to comply with the nonattainment area requirements of subpart 4 of Part D, title I of the CAA, these SIP requirements do not apply within the exterior boundaries of the GRIC reservation. Rather, the CAA, as amended in 1990, broadly authorizes EPA to protect Tribal air resources by directly implementing the Act's requirements in Indian Country. CAA § 301(d)(4); 40 CFR 49.11; 59 FR 43956, 43958–61 (Aug. 25, 1994) (proposed TAR preamble explaining EPA's CAA authorities in Indian Country); 63 FR 7254, 7262–64 (Feb. 12, 1998) (final TAR). As discussed above, section 301(d) of the CAA also authorizes EPA to approve Indian Tribes to implement their own CAA programs in Indian Country, provided they meet specified requirements.

The GRIC's TIP rules establish a basic air pollution control program for the protection of air resources within the GRIC reservation. The regulations in the TIP are enforceable and function independently of the PM_{10} nonattainment area requirements of subpart 4 of Part D, Title I of the Act and, therefore, are not integrally related to these plan requirements. As such, the GRIC's plan submittal is reasonably severable from the PM_{10} nonattainment area plan elements not included in the submittal, consistent with 40 CFR 49.7(c). We therefore turn to our evaluation of the GRIC DEQ's plan submittal in accordance with the applicable statutory and regulatory requirements.

B. What procedural requirements did the GRIC satisfy?

Section 110(a) of the CAA requires that implementation plans be adopted by the State after reasonable notice and public hearing. EPA has promulgated specific procedural requirements for SIP revisions in 40 CFR part 51, subpart F. These requirements include publication of notices, by prominent advertisement in the relevant geographic area, of a public hearing on the proposed revisions, a public comment period of at least 30 days, and an opportunity for a public hearing.

The GRIC DEQ developed the AQMP from 1998 to 2006 in consultation with EPA Region 9. Following an extensive public comment process, on December 13, 2006, the GRIC Tribal Council adopted the AQMP under Tribal Law.[11] The GRIC formally submitted the AQMP, which includes the TIP, to EPA Region 9 on February 21, 2007. On July 11, 2007, the GRIC submitted public process documentation for the AQMP, including documentation of a duly noticed public hearing held by the GRIC DEQ on July 20, 2006, in Chandler, Arizona. We find that the GRIC's process for adopting and submitting the TIP satisfied the procedural requirements for adoption and submission of implementation plans under CAA section 110(a) and EPA's implementing regulations.

C. What authorities and requirements does the GRIC TIP contain?

The AQMP is comprised of four regulatory programs: (1) A Tribal implementation plan (TIP) for the implementation, maintenance, and enforcement of the NAAQS under CAA 110; (2) regulations adopting the Federal New Source Performance Standards (NSPS) under CAA 111 as Tribal standards; (3) regulations adopting the Federal National Emission Standard for Hazardous Air Pollutants (NESHAP) under CAA 112 as Tribal standards; and (4) a Tribal operating permits program under title V of the Act.

In this action, we propose to act only on the TIP. We intend to issue separate **Federal Register** notices proposing action on the Tribe's requests for delegation of authority to implement and enforce the Federal NSPSs and to implement and enforce the Federal NESHAPs, consistent with applicable CAA and regulatory requirements. The GRIC DEQ is currently revising its title V permit regulations and has requested that EPA not act at this time on the title V provisions it submitted with the AQMP. *See* Letter dated June 22, 2009, from Margaret Cook, Executive Director, GRIC DEQ, to Laura Yoshii, Acting Regional Administrator, EPA Region 9, "Re: Technical Corrections to the GRIC Air Quality Management Plan."

We discuss below each element of the TIP and our evaluation of it in light of applicable CAA requirements.[12]

1. General Provisions

Part I of the AQMP, "General Provisions," contains definitions, general authorities of the Director, procedures for the preparation, adoption, and submittal of plan elements and revisions, and provisions adopting Federal NAAQS as Tribal standards.[13]

Specifically, Section 1.0 of Part I contains definitions that generally apply to all AQMP programs, including the TIP.

Section 2.0 establishes the Director's general authorities, which include the responsibilities for: (1) Consulting with and making recommendations to the GRIC Governor and Community Council on matters concerning implementation of the AQMP; (2) encouraging industrial, commercial, residential and general development of the Community in a manner that protects and preserves

Reservation that lies in Pinal County) that are not designated as a "nonattainment" area or as an "attainment" area subject to a maintenance plan. 70 FR 68339 at 68344.

[10] EPA's air quality designations for the 2006 24-hour Fine Particle ($PM_{2.5}$) standard were published in the **Federal Register** on November 13, 2009. 74 FR 58688.

[11] *See* Gila River Indian Community Ordinance GR–06–06 (December 13, 2006). Although the Ordinance indicates that the Tribal Council adopted the AQMP on December 6, 2006, we generally refer to the adoption date as December 13, 2006, consistent with the date of the GRIC Governor's signature.

[12] Throughout this discussion, the term "Director" means the Director of the GRIC DEQ. For ease of reference, we refer to each section of the TIP as a section of the AQMP, consistent with the structure of the Tribe's submittal.

[13] *See* footnote 2.

air quality; and (3) notifying Community members and other members of the public on a regular basis of incidences and areas in which the Tribe's adopted NAAQS were exceeded during the preceding calendar year, including the health risks associated with such exceedances. GRIC AQMP Part I, Section 2.1. These provisions satisfy the requirement in CAA section 110(a)(2)(J) to meet applicable requirements of CAA section 121 (relating to consultation) and section 127 (relating to public notification), and also satisfy the requirement in CAA section 110(a)(2)(M) to provide for consultation and participation by local political subdivisions affected by the plan.

In addition, if the Director determines that air pollution in any area constitutes or may constitute an emergency risk [14] to the health of those in the area or if the ambient air quality standards adopted by the GRIC are likely to be exceeded, the Director must notify the GRIC Governor. The Governor may then restrain or enjoin any person from engaging in emissions-generating activity that presents an imminent and substantial endangerment to the public health or welfare or to the environment. The Governor may also, to the extent of the Governor's authority, declare that an emergency exists and prohibit, restrict, or condition any of the following: motor vehicle traffic; retail, commercial, manufacturing, governmental, industrial or similar activity; operation of incinerators and other facilities that emit the air pollutant of concern; the burning or other consumption of fuels; the burning of any materials; any and all other activity which contributes or may contribute to the emergency. Orders of the Governor issued under this provision are enforceable by the GRIC DEQ and the GRIC tribal police. GRIC AQMP Part I, Section 2.2. These provisions meet the requirement in CAA section 110(a)(2)(G) to provide for authority comparable to the emergency powers in section 303 of the Act.

Section 3.0 establishes procedural requirements for preparation, adoption, submission to EPA, and revision of the AQMP. These requirements include publication of notices, by prominent advertisement in the *Gila River Indian News* and by other appropriate means, a public comment period of at least 30 days, and a public hearing following reasonable notice of such hearing.[15] Section 3.0 also contains technical support requirements and procedures for parallel processing. These provisions satisfy the applicable procedural requirements of CAA section 110(a)(2) and 40 CFR part 51, subpart F.

Finally, Section 4.0 of Part I contains the GRIC DEQ's provisions adopting Federal primary and secondary standards and measuring methods for SO_2, PM_{10}, $PM_{2.5}$, CO, ozone (8-hour), NO_2, and Pb as Tribal air quality standards. These standards and measuring methods are consistent with the Federal NAAQS that were effective in October 2006, shortly before the GRIC adopted the AQMP. *See* 40 CFR 50.4–50.8, 50.10–50.12 (2006). We are proposing to approve these air quality standards and measurement methods into the TIP.

We note that several revisions to the Federal NAAQS have become effective since October 2006,[16] and that all Federal NAAQS apply within the GRIC reservation whether or not the Tribe adopts these standards into the TIP under Tribal law. See footnote 2, above. The GRIC's TIP provides for progress toward the implementation, enforcement, and maintenance of the Federal NAAQS by regulating emissions of NAAQS pollutants within the reservation and establishing enforceable procedures to determine whether construction or modification of minor sources will interfere with attainment or maintenance of the NAAQS, as effective in October 2006. Accordingly, we are proposing to approve the TIP, including those Federal NAAQS that the Tribe has adopted under Tribal law, as a program containing severable elements of a plan under CAA section 110(a) that provides for the implementation, enforcement, and maintenance of the NAAQS. We note, however, that EPA retains its discretionary authority under CAA sections 301(a) and 301(d)(4) to directly implement CAA programs in the GRIC reservation and to promulgate such Federal implementation plan provisions as are necessary or appropriate to protect air quality in the GRIC reservation.

2. Permit Requirements

Part II of the AQMP contains permit requirements for new and existing sources of air pollution. Specifically, it contains a title V operating permit program for "title V sources," and a preconstruction review and operating permit program to regulate "non-title V sources" (or "minor sources").

a. Title V Permit Requirements

By letter dated June 22, 2009, the GRIC DEQ requested that EPA not act on the title V operating permit regulations submitted as part of the AQMP on February 22, 2007. EPA understands that the GRIC DEQ intends to submit a revised title V operating permit program at a later date, after adopting revisions to address requirements of the CAA and implementing regulations.[17] As such, we are not taking action today on those elements of Part II of the AQMP that pertain to title V permit program requirements.[18] At this time, EPA remains the title V permitting authority for all title V sources within the exterior boundaries of the GRIC reservation.

b. Non-Title V Permit Requirements

Section 110(a)(2)(C) of the Act requires that each implementation plan include a program to regulate the construction and modification of stationary sources, including a permit program as required by parts C and D of title I of the Act, as necessary to assure that the NAAQS are achieved. Parts C and D, which pertain to prevention of significant deterioration (PSD) and nonattainment, respectively, address the major NSR programs for major stationary sources, and the permitting program for "nonmajor" (or "minor") stationary sources is addressed by section 110(a)(2)(C) of the Act. We commonly refer to the latter program as the "minor NSR" program. A minor stationary source is a source whose "potential to emit" is lower than the major source applicability threshold for a particular pollutant as defined in the applicable major NSR program.

The requirements that minor source programs must meet to be approved are outlined in 40 CFR 51.160 through 51.164. These regulations require states to develop "legally enforceable

[14] The Director's determination must be based on scientific data in coordination with the GRIC Office of Emergency Management (OEM) and consistent with OEM protocol. *See* AQMP Part I, Section 2.2.A.

[15] Consistent with 40 CFR 51.102(c), however, the AQMP does not require a public hearing for any change to an increment of progress to an approved individual compliance schedule unless the change is likely to cause the source to be unable to comply with the final compliance date in the schedule. AQMP Part I, Section 3.2.D(3).

[16] *See* 71 FR 61224, October 17, 2006 (revised standards for particulate matter, effective December 18, 2006); 73 FR 67051, November 12, 2008 (revised standards for lead, effective January 12, 2009); 75 FR 2938, January 19, 2010 (proposed rule to revise 8-hour ozone standards); 75 FR 6474, February 9, 2010 (revised standards for NO_2, effective April 12, 2010); 75 FR 35520, June 22, 2010 (revised standards for SO_2, effective August 23, 2010).

[17] EPA has, however, determined that the Tribe is eligible for TAS to implement a title V permit program (as noted above in Section III.A). Accordingly, the Tribe's submittal at a later date of a revised title V permit program need not be accompanied by another TAS eligibility request.

[18] These include all regulatory definitions associated with title V requirements in Section 1.0; title V program applicability provisions in Section 2.0; the title V permitting regulations in Section 3.0; and requirements for title V permit revisions in Section 5.0.

procedures" to enable the State "to determine whether the construction or modification of a [source] will result in—(1) a violation of applicable portions of the control strategy; or (2) interference with attainment or maintenance of a national standard * * *." 40 CFR 51.160(a). The program must identify the types and sizes of sources subject to review, and the State's plan must discuss the basis for determining which facilities will be subject to review. 40 CFR 51.160(e).

Every State implementation plan currently contains a minor NSR program. Minor sources located on the GRIC reservation, however, have not to date been subject to preconstruction review under the CAA. EPA has proposed a Federal NSR permit program that would apply to, among others, minor sources in Indian Country where there is no EPA-approved permit program under the CAA, but this rulemaking has not yet been finalized. 71 FR 48696 (August 21, 2006) (proposed rule to implement NSR in Indian Country).

Although the Act does not require tribes to develop and seek EPA approval of NSR permit programs, where a tribe decides to do so, EPA evaluates the program in accordance with applicable statutory and regulatory criteria in a manner similar to the way EPA would review a similar State submittal. 40 CFR 49.9(h); 59 FR 43956 at 43965 (Aug. 25, 1994) (proposed TAR preamble); 63 FR 7254 (Feb. 12, 1998) (final TAR preamble). For the reasons discussed below, we propose to approve the GRIC's minor NSR program in accordance with the TAR and the criteria for approval of minor NSR programs at 40 CFR 51.160 through 51.164. It is important to note, however, that we are proposing to approve this as a base program suitable to the GRIC's reservation. Other Tribal NSR programs may differ significantly and should each be evaluated on a case-by-case basis in light of air quality needs in the relevant area.

The GRIC DEQ's minor NSR permit program, entitled "Non-Title V Permit Requirements," applies to stationary sources that are neither "major" under the Act [19] nor subject to the requirements of CAA title V.[20] AQMP Part II, Section 2.1. For all major sources, major modifications, and sources otherwise subject to title V on the reservation, EPA will continue to implement applicable CAA permitting requirements, including the requirements of parts C and D of title I of the Act, as appropriate.

Specifically, the GRIC's minor NSR permit program applies to any person who proposes to construct, operate, or modify any source that emits or has the potential to emit "regulated air pollutants," unless the source or modification is either (1) a major source or major modification and/or subject to title V of the Act, or (2) exempt from review as "de minimis" under the AQMP. *See* Part II Sections 2.1.B, 2.1.C, 5.1.A. "Regulated air pollutant" is defined as any criteria pollutant, any air contaminant subject to an NSPS under CAA 111, any hazardous air pollutant (HAP) listed under CAA 112(b) or "ultrahazardous" air pollutant listed under CAA 112(r)(3), or any class I or II substance listed in CAA section 602.

A stationary source that is not a "major stationary source" under the CAA and that does not operate in conjunction with another facility or source that is subject to permit requirements may be exempt under Section 2.1.C from permit requirements as a "de minimis facility," if the source's "actual emissions" [21] of air pollutants are equal to or less than all of the following levels:

TABLE 1—"DE MINIMIS" THRESHOLDS IN THE GRIC'S MINOR NSR PERMIT PROGRAM [22]

Any single regulated air pollutant except a hazardous air pollutant	1 ton per year (tpy).
Any single hazardous air pollutant (HAP), or Any combination of HAPs	1000 lbs per year (single HAP), or 1 tpy (combination of HAPs).
Any single ultrahazardous air pollutant, or any combination of ultrahazardous air pollutants	300 lbs per year.

In addition, Section 2.1.C(2) identifies several types of minor sources that are categorically treated as "de minimis facilities" and, therefore, exempt from permit requirements. These categorical "de minimis facilities" include agricultural equipment used in normal farm operations, except for equipment that is subject to requirements of title V or 40 CFR parts 60 or 61; air-conditioning equipment and general combustion equipment with aggregated input capacity of less than 2 MMBtu/hour or, if oil-fired, maximum rated input capacity or aggregated input capacity of less than 500,000 Btu/hour; stationary storage tanks used for storing organic liquids with true vapor pressure of 1.5 psia or less, or that have a capacity of 250 gallons or less; and portable internal combustion engines that, individually, have a rating less than 500 horsepower output or operate less than 200 hours per calendar year.

The GRIC DEQ's supporting documentation demonstrates that these *de minimis* facilities are appropriately exempt from permit requirements based on their insignificant environmental impacts, in accordance with the criteria set forth in *Alabama Power Co.* v. *Costle,* 636 F.2d 323 (D.C. Cir. 1979). *See* Letter dated June 22, 2009, from Margaret Cook, Executive Director, GRIC DEQ, to Laura Yoshii, Acting Regional Administrator, EPA Region 9, "Re: Technical Corrections to the GRIC Air Quality Management Plan," enclosure entitled "Minor New Source Review Demonstration."

The GRIC DEQ's minor NSR permit program requires each applicant for a "non-title V" permit to submit, among other things, a certified application containing information about the facility, the industrial process, the nature and amount of emissions, and any information needed to determine applicable technology-based emission limitations. In some cases, the GRIC DEQ may also require the source to

[19] Section 302(j) of the CAA generally defines "major stationary source" as any stationary source that has the potential to emit at least 100 tons per year (tpy) of any air pollutant, unless the statute specifies a different threshold. Part D of title I of the Act establishes lower major source thresholds based on severity of air pollution in nonattainment areas. For hazardous air pollutants (HAP), CAA section 112 defines "major source" as a source that emits or has the potential to emit considering controls, in the aggregate, 10 tpy or more of any HAP or 25 tpy or more of any combination of HAP.

[20] Title V requirements apply to, among other sources, any major source, any source subject to an NSPS under CAA 111, and any source subject to a NESHAP under CAA 112. 40 CFR 71.3(a), (b).

[21] For any emissions unit at a minor source that has not begun normal operations, "actual emissions shall be based on applicable control equipment requirements and projected conditions of operation." AQMP Part II, Section 1.0.D (definitions).

[22] AQMP Part II, Section 2.1.C(1).

model its impact on ambient air quality in accordance with 40 CFR part 51, Appendix W.

Importantly, any new minor source that has a "potential to emit" (PTE) at or above specified levels, or a modification at an existing minor source that increases a source's PTE by specified levels, will be subject to a technology-based emission limitation that reflects the Best Reasonable and Demonstrated Technology (BRDT), as determined by the GRIC DEQ on a case-by-case basis. BRDT is defined as "an emission limitation or design equipment, work practice or operational standard" that is "based on the maximum degree of reduction of each criteria pollutant or hazardous air pollutant determined on a case-by-case basis" or by rule, "taking into account energy, environmental, and economic impact, feasibility of achieving the emission limitation for a particular source, and the existing air quality in the area to be impacted by the source." Part II Section 1.0. The PTE levels (or, for modifications, PTE increases) at which BRDT applies are identified in Table 2.

TABLE 2—PTE THRESHOLDS AT WHICH BRDT APPLIES IN THE GRIC'S MINOR NSR PERMIT PROGRAM [23]

For a new source, any single criteria pollutant	75 tpy.
For a new source, any single HAP	3 tpy.
For a new source, any combination of HAPs	5 tpy.
For a new source, any single or any combination of ultrahazardous air pollutants	300 lbs per year.
For a modification, an increase of any single criteria pollutant (that does not make the source a major source)	25 tpy.
For a modification, any single new HAP or increase in a HAP already emitted by the source	3 tpy.
For a modification, an increase in any combination of HAPs already emitted by the source	5 tpy.

Each non-title V permit is issued for a five-year term and must include, among other things: (1) Enforceable emissions limitations or source- or unit-specific requirements that assure maintenance of the Tribe's adopted ambient air quality standards, protection of public health, compliance with all applicable control standards, such as BRDT, NSPSs, NESHAPs, and other requirements of the CAA [24]; (2) monitoring, testing, reporting, and recordkeeping requirements adequate to evaluate the source's compliance; (3) a requirement that any revision of an emission limitation, monitoring, testing, reporting, or recordkeeping requirement be made in accordance with the permit revision procedures for non-title V sources at Part II, Section 5.0 of the AQMP; (4) a requirement to allow the GRIC DEQ or EPA representatives to enter and inspect the premises at reasonable times; (5) a requirement to submit an annual compliance certification, and (6) a requirement to submit an annual emissions report. Part II, Section 4.4.A. A non-title V permit authorizes both construction and operation of the minor source or modification.

The permit program establishes administrative procedures for the GRIC DEQ action on permit applications, including public notice and a comment period of at least 30 days on all proposed new permits, permit renewals, and significant permit revisions.[25] AQMP Part II, section 4.6.A. The program also provides for public hearings on such permit applications upon written request. The issuance or denial of a non-title V permit may be appealed administratively to the GRIC DEQ and, thereafter, judicially to the GRIC Tribal Court. *See* discussion below at section IV.C.4, "Administrative Appeals and Judicial Review." Finally, the permit program contains stack height procedures consistent with the requirements of 40 CFR 51.164; continuous source emissions monitoring requirements generally consistent with the provisions of 40 CFR part 51, appendix P; requirements for the treatment of confidential information; and permit fee provisions. AQMP Part II, sections 6.0, 9.0, 10.0, and 11.0. Our Technical Support Document (TSD) contains more information about these provisions and suggestions for improvement that do not affect our proposed action.

We propose to approve these procedures as legally enforceable procedures that establish a base program suitable to the GRIC's reservation and that satisfy the minimum requirements of CAA section 110(a)(2)(C) and 40 CFR 51.160 through 51.164.

3. Enforcement

Part III of the AQMP contains requirements and procedures for civil and criminal enforcement against persons who violate AQMP provisions.

Section 1.0 of Part III authorizes the Director to take several kinds of civil enforcement actions against persons who violate AQMP requirements. First, if the Director has reasonable cause to believe that a person has violated or is violating a provision of the AQMP or any requirement of a permit issued under Part II, the Director may issue an administrative compliance order (ACO) requiring compliance as expeditiously as practicable but no later than 1 year after the date the ACO was issued. An ACO becomes final and enforceable in the Community Court, unless within 30 days after receipt of the ACO, the alleged violator requests a hearing before an administrative law judge (ALJ) in accordance with the provisions of Part IV of the AQMP. If a hearing is requested, the ACO does not become final until the ALJ has issued a recommended decision and the Director has issued a final decision on the appeal.

Second, the Director may assess an administrative civil penalty of up to $5,000 per day per violation, and/or the GRIC Community Court may issue a civil judicial penalty of up to $10,000 per day per violation, to any person found to be in violation of an ordinance, an ACO, or any provision of a permit issued under Part II. Each day of a failure to perform any act or duty for which a civil penalty may be assessed constitutes a separate offense. The Director is required to consider specified factors in assessing civil penalties, such as the size of the business, the economic impact of the penalty on the business, and the violator's good faith efforts to comply.

[23] Part II, Sections 4.2.A(2), 4.2.A(3)(c), 4.2.B.

[24] Generally, a source that is subject to an NSPS under section 111 or a NESHAP under section 112 of the CAA will be subject to title V permitting requirements and, therefore, not subject to GRIC's non-title V permit program. EPA has, however, exempted certain NESHAP area sources by rule from title V permitting requirements. In those limited cases where a NESHAP area source is exempt from title V, such source may be required to obtain a GRIC non-title V permit that identifies the applicable NESHAP, among other requirements.

[25] A significant permit revision is, among other things, any change to a non-title V permit that will result in an increase in the source's potential to emit a regulated pollutant of more than either 25 tons per year or certain "significant" levels in Section 1.0 of Part II, whichever is less. AQMP Part II, Section 5.5.a(3).

Third, at the request of the GRIC Director, the GRIC General Counsel may file an action for a temporary restraining order, a preliminary injunction, a permanent injunction, or any other relief provided for by law if the Director has reasonable cause to believe that: (1) A person has violated or is violating any provision of an ordinance, an order requiring compliance with an ordinance, or any provision of a permit; (2) a person has violated or is violating an effective compliance order; or (3) a person is creating an imminent and substantial endangerment to public health or the environment.

Finally, the Director may deny a request for a permit if the applicant is incapable of meeting the requirements of an ordinance, and the Director may revoke a permit issued by DEQ based on a finding of noncompliance with material conditions in the permit or when continued operation would violate an ordinance or create a consistent pattern of imminent and substantial endangerment to public health or the environment. Any such denial or revocation of a permit by the Director may be appealed to an ALJ and thereafter to the Community Court, in accordance with the appeal provisions in Part IV of the AQMP. These provisions provide for enforcement of the measures contained in the TIP, as required by CAA section 110(a)(2)(C), and provide necessary assurances that the Tribe will have adequate authority under Tribal law to carry out the TIP, as required by CAA section 110(a)(2)(E)(i).

Section 2.0 of Part III establishes procedures for criminal enforcement and referral of certain criminal matters to EPA. Specifically, Section 2.1 requires the GRIC's General Counsel to consult with the appropriate Federal agencies and, as appropriate, refer for Federal prosecution any person who has willfully or knowingly violated an AQMP provision or a permit issued under Part II. The procedures for the GRIC DEQ's referral of potential criminal violations to the appropriate Federal agencies, for possible criminal prosecution under Section 113(c) of the CAA, are outlined in the Criminal Enforcement MOA discussed above in Section III.B of this notice.

Section 3.0 of Part III contains citizen suit provisions. By letter dated July 17, 2010, the GRIC DEQ requested that EPA not act on these provisions as part of the TIP. The GRIC clarified that these provisions, which remain effective under Tribal law, are not intended to alter the Tribe's liability to civil suit based on established principles of Tribal sovereign immunity and the provisions of the CAA, nor are they intended to limit any existing Federal jurisdiction under the CAA. *See* letter dated July 17, 2010 from Margaret Cook, Executive Director, GRIC DEQ, to Deborah Jordan, Air Division Director, EPA Region 9, "Re: Gila River Indian Community Tribal Implementation Plan." Nothing in our proposed action alters the effect of the citizen suit provisions of CAA section 304 as they may apply to the Tribe consistent with established principles of Tribal sovereign immunity.

4. Administrative Appeals and Judicial Review

Part IV of the AQMP contains requirements and procedures for administrative appeals, final administrative decisions, and judicial review of final administrative decisions.

Section 1.0 states that the provisions of Part IV apply to "all appealable agency actions," which are: (1) The issuance or denial of an air quality permit; (2) a significant revision to an air quality permit; (3) failure of the GRIC DEQ to act on an air quality permit in a timely manner or as required by the provisions of Part II; (4) revocation of an air quality permit; (5) the issuance of a compliance order; or (6) the imposition, by order, of an administrative civil penalty. Section 2.0 contains relevant definitions.

Section 3.0 establishes procedures for administrative appeals. Specifically, any party whose legal rights, duties, or privileges were determined by an "appealable agency action" may file a notice of appeal with the DEQ within 30 days after receiving notice of the action from the DEQ. Any other party who will be adversely affected by the issuance or denial of a permit and who exercised any right to comment on the action may also file such a notice of appeal, provided that the grounds for appeal are limited to issues raised in that party's comment. Within 5 business days of DEQ's receipt of a notice of appeal containing the required information, the Director must provide specific information regarding the notice to the GRIC Governor's office, after which the Governor must assign an ALJ to the matter and schedule a hearing, in accordance with specified timeframes. Section 3.0 also authorizes the ALJ to schedule a pre-hearing conference in accordance with specified criteria, and establishes procedures and evidentiary requirements for the hearing.

Section 4.0 of Part IV establishes requirements and procedures for the Director's final administrative decision following the hearing and the ALJ's issuance of a recommended decision. The Director may accept, reject or modify the ALJ's recommended decision, but prior to rejecting or modifying the recommendation, the Director must consult with and obtain the written consent of the GRIC Governor or his/her designee. The Director's decision becomes final unless, within 35 days, a party appeals the final decision judicially.

Section 5.0 establishes requirements and procedures for judicial review of final administrative decisions, jurisdiction over which is vested in the GRIC Community Court. Except in cases where trial de novo is appropriate or justice demands the admission of new or additional evidence, judicial review is limited to the administrative record before the court. Section 5.0 specifies the GRIC Community Court's authorities and the limits on those authorities. For example, the court may stay the Director's final decision in whole or in part for substantial good cause, pending final disposition of the case, and may ultimately modify, affirm, or reverse the decision. The court may not, however, reverse a finding of fact by the Director unless it is "clearly erroneous" and may not reverse the Director's final administrative decision unless it has "no substantial evidentiary basis in the record or is erroneous as a matter of law." Part IV, Section 5.7. Decisions of the GRIC Community Court may be further appealed to the GRIC Court of Appeals.

These provisions establish adequate procedures for review of the Director's decisions under the TIP. Our finding applies only to this TIP under section 110 of the Act and does not apply to other CAA programs submitted by the Tribe, each of which we will evaluate separately in accordance with applicable CAA and regulatory requirements.

5. Area Source Emission Limits

Part V of the AQMP contains two rules that regulate air pollution from specific types of area sources. The purpose of these rules is to reduce emissions of particulate matter from open burning and fugitive dust-generating activities.

Section 1.0 (Open Burning) limits the types of materials that can be openly burned within the GRIC reservation and requires permits for open burning of specified materials. Three types of fires are allowed only if the GRIC DEQ issues an open burn permit: (1) Residential fires to dispose of yard waste, except for materials that generate toxic fumes; (2) commercial fires to dispose of vegetative waste resulting from land clearing, commercial development or other large scale permitted fires; and (3)

agricultural fires for weed control or abatement, clearing fields or the disposal of other naturally grown products, except for materials that generate toxic fumes. The rule requires: (1) that any person seeking an open burn permit submit to the DEQ an application with specific information, (2) identifies types of conditions that the DEQ may include in a permit, and (3) contains specific criteria for the DEQ's grant or denial of an open burn permit.

The rule categorically prohibits open burning of certain materials, such as garbage resulting from the processing, storage, service or consumption of food; asphalt shingles; tar paper; plastic and rubber products; petroleum products; transformer oils; hazardous material containers; tires; construction and demolition debris; and asbestos containing materials. Certain other types of open fires are exempted from the rule—*e.g.,* fires used only for the domestic cooking of food, fires used for cultural, religious or ceremonial purposes, and fires used only for providing warmth.

Section 2.0 (General Requirements for Fugitive Dust-Producing Activities) regulates fugitive dust and fugitive particulate matter emissions from earthmoving, land clearing, and demolition activities, construction sites, unpaved parking lots at industrial plants, and other activities that generate dust. The rule prohibits all owners/operators of sources of fugitive dust or fugitive particulate matter emissions, as well as owners/operators of certain unpaved parking lots and haul/access roads, from allowing visible emissions to exceed 20 percent opacity at any time.

Under this rule, two types of permit applications must be accompanied by a dust control plan. First, any person required to obtain an earthmoving permit under the rule must submit a dust control plan and obtain the GRIC DEQ's approval before commencing any dust generating operation. An earthmoving permit is required for any source owner/operator seeking to conduct certain earthmoving operations, except for normal farming practices. Second, any person who is required to obtain a title V permit, a non-title V permit, or a general permit under Part II of the AQMP must submit a dust control plan and obtain the GRIC DEQ's approval before commencing dust generating operations. A proposed dust control plan must contain specific information, including an illustration of the entire project site boundaries and acres to be disturbed, the expected duration of the project, and control measures or combinations thereof to be applied to all actual and potential fugitive dust-generating operations.

In addition to the requirements for dust control plans, the rule establishes specific control measures and work practices for specified dust-generating operations, which apply to the specified activities independent of any approved dust control plans. The rule also contains detailed test methods and recordkeeping requirements to ensure that compliance with the required control measures, work practice standards, and any approved dust control plans can be verified. Certain specified activities and individuals are exempted from the rule—*i.e.,* owners and occupants of single family residences, owners or managers of residential buildings with four or less units, normal farming practices, and public roads owned or maintained by any Federal, tribal, or local government.

We have determined that Part V of the AQMP contains specific, well-defined requirements that meet EPA's enforceability requirements under CAA section 110(a)(2)(A). As described above, the rules contain test methods and recordkeeping requirements adequate to determine compliance; clearly identify the activities that are subject and those that are exempt from rule requirements; and do not allow for variations from the rules other than those specified in limited exemptions. EPA is proposing to approve these rules as elements of a base TIP suitable to the GRIC's reservation and regulatory capacities. Our TSD contains more information about each of these rules and suggestions for rule improvement that do not affect our proposed action.

6. Generally Applicable Individual Source Requirements for Existing and New Sources

Part VI of the AQMP contains three rules that regulate visible emissions, volatile organic compound (VOC) emissions, and degreasing and solvent metal cleaning operations. The purpose of these rules is to reduce visible emissions and emissions of particulate matter and gaseous organic compounds.

Section 1.0 (Visible Emissions) generally prohibits the discharge of any air contaminant into the ambient air from any single source of emissions, other than uncombined water, in excess of 20 percent opacity. Compliance is determined by observations of visible emissions conducted in accordance with EPA Test Method 9 (40 CFR part 60, appendix A), except that for purposes of measuring visible emissions from intermittent sources, at least twelve (12) rather than twenty-four (24) consecutive readings are required at 15-second intervals for the averaging time. Part VI, Section 1.0, subsection 4.0. The rule provides limited exceptions for certain activities or equipment, such as the charging or back-charging of an electric arc furnace for which construction commenced prior to February 2, 1963, and for equipment or processes used to train individuals in opacity observations.

Section 2.0 (VOC Usage, Storage and Handling) generally limits the discharge of VOC emissions from operations involving the usage, storage, transfer or disposal of VOC-containing materials. For example, the rule prohibits the discharge of more than 15 pounds of VOCs a day from any device in an operation involving heat, and prohibits the discharge of more than 40 pounds of VOCs a day from any device in an operation involving the use of non-complying solvents.[26] If these VOC limits are exceeded, the rule requires application of specific control methods that achieve at least 85 percent overall control efficiency or compliance with certain operating standards. Owners or operators who choose to use an emissions control system (ECS) to reduce VOC emissions must provide to the GRIC DEQ for approval an Operation and Maintenance Plan (O&M Plan), together with the initial application for an operating permit.

The rule establishes detailed control techniques and operational standards for the handling, storage and disposal of VOC-containing materials, monitoring and inspection requirements, recordkeeping and reporting requirements, and specific test methods. Certain specified facilities and activities are exempt from the rule—*e.g.,* organic solvent manufacturing facilities and the overland transport of organic solvents and VOC-containing materials; the spraying or other employment of insecticides, pesticides, or herbicides; and metal processing operations such as foundries, smelters, melting or roasting of metal, ore, or dross. Part VI, Section 2.0, subsection 1.2.

Section 3.0 (Degreasing and Solvent Metal Cleaning) establishes equipment specifications and operating standards for degreasing and solvent metal cleaning operations. The rule applies to all new and existing solvent cleaning operations that use VOCs, including cold cleaning, open-top vapor degreasing, and conveyorized degreasing operations.

[26] The rule defines "non-complying solvent" as a solvent that exceeds the applicable percentage composition limit for any of four specific chemical groupings. Section 2.0, subsection 2.0 (definitions).

Specifically, Section 3.0 establishes generally applicable solvent handling requirements, operating and signage requirements, and equipment specifications for solvent cleaning operations. The rule also contains equipment specifications and operating standards specific to owners and operators of cold cleaning degreasers, open-top vapor degreasers, and conveyorized degreasers. Any owner or operator of a solvent cleaning business in operation on or after November 1, 2004 must submit an O&M Plan for an ECS to the GRIC DEQ. An owner/operator of an open-top vapor degreaser or conveyorized degreaser may, in lieu of meeting certain equipment specifications, meet the requirements of the rule through the use of an ECS.

The rule establishes specific monitoring, reporting, and recordkeeping requirements and test methods for determining compliance. Additionally, upon startup of a new solvent cleaner, replacement of an existing solvent cleaner with a different model, change of a control device used on a solvent cleaner, or upon request by the GRIC DEQ, the owner of any solvent cleaner must perform tests and submit a compliance certification to the GRIC DEQ. Certain specified activities are exempt from the rule—*e.g.,* solvent cleaning operations specifically regulated by another rule in Part VI; laundering and housekeeping supplies and activities; and cleaning solutions containing 20 percent or less VOC by either weight or volume.

We have determined that Part VI of the AQMP contains specific, well-defined requirements that meet EPA's enforceability requirements under CAA section 110(a)(2)(A). As described above, the rules contain test methods and monitoring, recordkeeping, and reporting requirements adequate to determine compliance; clearly identify the activities that are subject and those that are exempt from rule requirements; and do not allow for variations from the rules other than those specified in limited exemptions. EPA is proposing to approve these rules as elements of a base TIP suitable to the GRIC's reservation and regulatory capacities. Our TSD contains more information about each of these rules and suggestions for rule improvement that do not affect our proposed action.

7. Source/Category-Specific Emission Limits for Existing and New Sources

Part VII of the AQMP contains three rules that regulate secondary aluminum production facilities, aerospace manufacturing and rework operations, and nonmetallic mineral mining and processing operations. The purpose of these rules is to reduce visible emissions and emissions of VOCs and particulate matter from these operations.

Section 1.0 (Secondary Aluminum Production) applies to all new, existing and modified secondary aluminium production facilities. The requirements of Section 1.0 are in addition to the requirements of the Federal NESHAP for Secondary Aluminum Production at 40 CFR part 63, subpart RRR, which are incorporated by reference into the rule.[27]

Specifically, Section 1.0 prohibits any person from causing, allowing or permitting the discharge into the atmosphere of any air contaminant, other than uncombined water, in excess of 20 percent opacity from any emission source at a secondary aluminium production facility. The rule also requires that the owner/operator of any source subject to the rule propose a VOC baseline emission rate (in tpy) as part of its initial permit application to the GRIC DEQ, and to demonstrate annually by February 15 that total VOC emissions in the preceding calendar year were reduced by at least three percent of the VOC baseline emission rate. This demonstration is required for five consecutive years after issuance of the source's initial permit, for a total VOC reduction of at least 15 percent from the VOC baseline emission rate.

Additionally, the rule requires any owner/operator using an ECS to reduce emissions to submit an O&M plan for approval to the GRIC DEQ. It also requires any person engaged in incinerating, adsorbing, or otherwise processing organic materials to properly install, maintain, calibrate, and operate monitoring devices to determine whether air pollution control equipment is functioning properly. Finally, the rule establishes recordkeeping requirements and test methods for determining compliance.

Section 2.0 (Aerospace Manufacturing and Rework Operations) applies to any aerospace manufacturing or rework facility whose plantwide PTE exceeds 10 pounds of VOCs per day. The rule establishes VOC content limits for primers, topcoats, chemical milling maskants, and specialty coatings. In lieu of meeting the applicable coating limits in the rule, an owner/operator of a subject facility may comply with the rule by installing and operating an approved ECS, provided the owner/operator can demonstrate to the GRIC DEQ that the control system will achieve a combined VOC emission capture and control efficiency of at least 81% by weight. The rule establishes techniques for the application of primers and topcoats, as well as operational standards for hand-wipe cleaning, solvent cleaning, and housekeeping. The rule also establishes detailed recordkeeping and reporting requirements and identifies specific methods for determining compliance. Certain specified activities are exempt from the rule—*e.g.,* research and development operations, chemical milling (except for application of chemical milling maskants), electronic parts and assemblies (except for cleaning and topcoating of completed assemblies), and wastewater treatment operations.

Section 3.0 (Nonmetallic Mineral Mining and Processing) regulates VOC emissions from cutback asphalt operations and particulate matter (PM–10) emissions from sand and gravel facilities. Specifically, the rule applies to any commercial and/or industrial nonmetallic mineral mining or rock product plant, concrete batch plant, hot mix asphalt plant, or vermiculite and/or perlite processing plant.

First, the rule establishes several general prohibitions, including a prohibition on the sale, offer for sale, use, or application of the following materials at facilities covered by the rule: (1) Rapid cure cutback asphalt, (2) any cutback asphalt material, road oils, or tar that contains more than 0.5 percent by volume VOCs that evaporate at 500 degrees Fahrenheit or less, or (3) any emulsified asphalt or emulsified tar containing more than 3.0 percent by volume VOCs that evaporate at 500 degrees Fahrenheit or less.

Second, the rule establishes specific limitations on visible emissions and emissions of PM–10 from nonmetallic mineral processing plants, concrete batch plants, hot mix asphalt plants, and vermiculate and perlite processing facilities. Any person subject to the rule must install and operate a wet dust suppression system or other control method approved by the GRIC DEQ to minimize fugitive dust emissions from any material handling system, conveyance system transfer point, screening operation or crusher without a capture and collection system, and nonmetallic mineral loading/unloading operation, unless the materials have sufficient moisture content to prevent

[27] Section 1.0 incorporates by reference 40 CFR part 63, subpart RRR, as effective July 1, 2006. Part VII, Section 1.0, subsection 1.0. Subpart RRR contains emission limits for dioxins, furans and other hazardous air pollutants that may be formed during the smelting of aluminum scrap. Subpart RRR also contains testing, monitoring, recordkeeping, reporting, and labelling requirements to ensure compliance with the limits and standards.

visible emissions in excess of the limits in the rule.

Third, any owner/operator using an ECS to reduce emissions must submit an O&M Plan for approval to the GRIC DEQ, together with the initial application for an operating permit. The O&M Plan must contain specific conditions and procedures to ensure proper operation of the ECS, and the owner/operator must fully comply with each submitted O&M Plan, unless notified otherwise in writing by the GRIC DEQ.

Finally, the rule establishes detailed monitoring, reporting and recordkeeping requirements, as well as specific methods for determining compliance with the PM–10 emission limitations and opacity limitations in the rule.

We have determined that Part VII of the AQMP contains specific, well-defined requirements that meet EPA's enforceability requirements under CAA section 110(a)(2)(A). As described above, the rules contain test methods and monitoring, recordkeeping, and reporting requirements adequate to determine compliance; clearly identify the activities that are subject and those that are exempt from rule requirements; and do not allow for variations from the rules other than those specified in the limited exemptions. EPA is proposing to approve these rules as elements of a base TIP suitable to the GRIC's reservation and regulatory capacities. Our TSD contains more information about each of these rules and suggestions for rule improvement that do not affect our proposed action.

D. What other information has the GRIC submitted to support the TIP?

1. Emissions Inventory

An emissions inventory is a quantitative list of the amounts and types of pollutants that are entering the air from the pollution sources in a given jurisdiction. The inventory may be comprehensive, looking at all pollutants, or focused on only selected pollutants of concern. The fundamental elements in an emissions inventory are the characteristics and locations of the air emissions sources, and the amounts and types of pollutants emitted. Periodic inventories are used to track changes in emissions over time, estimate the effectiveness of emission reduction strategies, and track the progress of air quality.[28]

The GRIC DEQ has chosen an annual emission inventory as its approach to identifying the pollutants emitted and the pollution sources in its jurisdiction. The most recent emissions inventory that the GRIC DEQ submitted to EPA uses a baseline year of 2007 and provides estimates of the VOC, nitrogen oxides (NO_X), carbon monoxide (CO), sulfur oxides (SO_X) and PM_{10} emissions from point sources, area sources, and mobile sources within the GRIC reservation. *See* Letter dated June 22, 2009, from Margaret Cook, Executive Director, GRIC DEQ, to Laura Yoshii, Acting Regional Administrator, EPA Region 9, "Re: Technical Corrections to the GRIC Air Quality Management Plan," enclosure entitled "2007 Emissions Inventory Update for the Gila River Indian Community." We find that the method used by the GRIC DEQ to produce the emissions inventory is acceptable, and that the inventory is comprehensive, accurate, and current. Table 3 provides a summary of the GRIC emissions inventory.

TABLE 3—SUMMARY OF EMISSIONS (BY POLLUTANT) FROM AIR POLLUTANT EMISSION SOURCES ON THE GRIC RESERVATION, 2007

[Tons/year] [a]

Pollutant→Source	PM–10	CO	NO_X	VOC	SO_X
Point	1048	161	175	142	31
Mobile	386	10,588	2055	929	37
Area	759	63	52	56	0
Total	2193	10,812	2282	1127	68

[a] From Table 4–1, *2007 Emissions Inventory Update for the Gila River Indian Community.* Totals may not be precise due to rounding.

The emissions inventory is not part of the TIP but supports the GRIC's ongoing evaluations of air pollution within the reservation and efforts to further develop its regulatory programs to address the Tribe's air quality needs.

2. Air Quality Monitoring Network

An air quality monitoring network consists of one or more sites where instruments are located to measure the concentrations of pollutants in the air at regular intervals. Meteorological stations often are part of an air quality monitoring network. Data collected by the monitoring network can be used to identify changes in air quality and to determine whether the area meets the NAAQS for the criteria pollutants.

An air quality monitoring network should be designed to meet at least one of the following basic monitoring objectives:

- To determine highest concentrations expected to occur in the area covered by the network;
- To determine representative concentrations in areas of high population density;
- To determine the impact on ambient pollution levels of significant sources or source categories; and
- To determine general background pollution concentration levels.

EPA's ambient air monitoring regulations in 40 CFR part 58 establish minimum quality assurance requirements and monitor network design criteria. Effective December 18, 2006, these regulations require that monitoring organizations submit to EPA, beginning July 1, 2007, an annual monitoring plan that explains how the siting and operation of each monitor in the network meets the quality assurance requirements of 40 CFR part 58, among other things. 40 CFR 58.10. Although Indian Tribes are generally not required to monitor ambient air, Tribes may choose to do so and, in some cases, may be required by EPA to institute quality assurance programs that comply with 40 CFR part 58 appendix A and to insure that the monitoring data they collect is representative of their respective airsheds. 71 FR 61236 at 61242 (October 17, 2006) (final rule: revisions to ambient air monitoring regulations).

The GRIC submitted its first annual monitoring network plan pursuant to the requirements of 40 CFR 58.10 on

[28] *See* "Developing a Tribal Implementation Plan," Office of Air Quality Planning and Standards, US EPA, October 2002 (EPA 452/R–02–010), *http://www.epa.gov/air/tribal/tip2002/index.html,* at Chapter 3.

December 19, 2007.[29] *See* Gila River Indian Community Department of Environmental Quality, Air Quality Program, 2006 Tribal Ambient Air Monitoring Network Review (2006 Annual Network Plan). The 2006 Annual Network Plan describes the Tribe's ozone and PM_{10} monitoring networks and how each monitor in these networks meets the Tribe's monitoring objectives consistent with the quality assurance requirements of 40 CFR part 58. EPA reviewed and approved the GRIC's 2006 Annual Network Plan on May 9, 2008. *See* letter dated May 9, 2008, from Sean Hogan, Air Quality Analysis Office, US EPA Region 9, to Leroy Williams, Air Quality Program, GRIC DEQ.

The GRIC's ozone monitoring network is comprised of two State and Local Air Monitoring Station (SLAMS) monitors in the reservation. *See* 2006 Annual Network Plan at 7. One of these monitors is located at the GRIC DEQ building in Sacaton, Arizona, about 40 miles southeast of Phoenix. The other SLAMS monitor in the ozone monitoring network is at St. Johns-Gila Crossing North Middle School. Both monitors are regional/rural scale monitors designed to monitor population exposure and are long-term trends sites that operate on a seasonal schedule, from April through October. The areas surrounding both monitors are a mixture of residential areas and businesses. *Id.* at 7–9.

The GRIC's PM_{10} monitoring network consists of one SLAMS monitoring site located at the Casa Blanca-Va Ki Elementary School. *See* 2006 Annual Network Plan at 9. This monitor is designed to measure neighborhood and regional-scale air pollutant concentrations and operates on a one-in-three-day sampling schedule. The area surrounding the monitor is a mixture of residential areas, businesses, and agricultural operations. The GRIC also operates several PM_{10} Special Purpose Monitor (SPM) stations throughout the reservation and anticipates adding three continuous PM_{10} SLAMS monitors to its PM_{10} monitoring network, at the Casa Blanca, St. Johns, and Sacaton sites. *Id.* at 4, 9–11.

The air quality data collected by the GRIC DEQ are used for a variety of purposes including: determining compliance with the NAAQS, determining the location of maximum pollutant concentrations, determining the effectiveness of air pollution control programs, evaluating the effects of air pollution on public health, supporting dispersion models, developing cost-effective pollution control strategies, and determining air quality trends. *See* 2006 Annual Network Plan at 1. The GRIC regularly submits its data to EPA's Air Quality System (AQS) database.

The GRIC Air Program also monitored for $PM_{2.5}$ in two locations in the reservation between 2002 and 2004. On September 21, 2004, EPA Region 9 concurred with the GRIC DEQ's request to discontinue operation of the $PM_{2.5}$ monitors based on the low concentrations of recorded $PM_{2.5}$ data and a determination that $PM_{2.5}$ monitoring in the reservation is not required by EPA regulations. *See* letter dated September 21, 2004, from Robert S. Pallarino, EPA Region 9, to Leroy Williams, GRIC DEQ.

The air quality monitoring network is not part of the TIP but supports the GRIC's ongoing evaluations of air pollution within the reservation and efforts to further develop its regulatory programs to address the Tribe's air quality needs.

V. Proposed Action

Under CAA sections 110(o), 110(k)(3) and 301(d), EPA is proposing to fully approve the TIP submitted by the GRIC DEQ on February 21, 2007, as supplemented on July 11, 2007, June 22, 2009, and July 17, 2010. The TIP includes general and emergency authorities, ambient air quality standards, permitting requirements for minor source of air pollution, enforcement authorities, procedures for administrative appeals and judicial review in Tribal court, requirements for area sources of fugitive dust and fugitive particulate matter, general prohibitory rules, and source category-specific emission limitations and standards. These provisions establish a base TIP that is suitable for the GRIC's reservation and regulatory capacities and that meets all applicable minimum requirements of the CAA and EPA regulations.

We are proposing to act only on those portions of the GRIC AQMP that constitute a TIP containing severable elements of an implementation plan under section 110(a) of the CAA, as discussed in this notice. We are not proposing today to act on those elements of the GRIC AQMP that address requirements of CAA title V or any other program under the Act. We intend to take separate action on other CAA programs submitted by the GRIC DEQ, as appropriate.

VI. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735 (October 4, 1993)), this proposed action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)). This proposed action merely proposes to approve laws of an eligible Indian tribe as meeting Federal requirements and imposes no additional requirements beyond those imposed by Tribal law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*). Because this rule proposes to approve pre-existing requirements under Tribal law and does not impose any additional enforceable duty beyond that required by Tribal law, it 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).

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." EPA has concluded that this proposed rule will have tribal implications in that it will have substantial direct effects on the GRIC. However, it will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law. EPA is proposing to approve the GRIC's TIP at the request of the Tribe. Tribal law will not be preempted as the GRIC incorporated the TIP into Tribal Law on December 13, 2006. The Tribe has applied for, and fully supports, the proposed approval of the TIP. If it is finally approved, the TIP will become federally enforceable.

EPA worked and consulted with officials of the GRIC DEQ early in the process of developing this proposed regulation to permit them to have meaningful and timely input into its development. In order to administer an approved TIP, tribes must be determined eligible (40 CFR part 49) for TAS for the purpose of administering a TIP. During the TAS eligibility process, the Tribe and EPA worked together to

[29] On September 12, 2006, the GRIC submitted a Quality Assurance Project Plan (QAPP) for its ambient air monitoring program. EPA approved the QAPP for collection of environmental data on April 13, 2007. See letter dated April 13, 2007, from Eugenia McNaughton and Sean Hogan, US EPA Region 9, to Leroy Williams, GRIC DEQ.

ensure that the appropriate information was submitted to EPA. The GRIC and EPA also worked together throughout the process of development and Tribal adoption of the TIP. The Tribe and EPA also entered into a criminal enforcement MOA.

This action also does not have Federalism implications because it does not have substantial direct effects 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, as specified in Executive Order 13132 (64 FR 43255 (August 10, 1999)). This action merely proposes to approve a Tribal rule implementing a TIP covering areas within the exterior boundaries of the GRIC reservation, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule 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, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994). This proposed rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885 (April 23, 1997)), because it is not economically significant.

The requirements of section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 272) do not apply to this proposed rule. In reviewing TIP submissions, the EPA's role is to approve an eligible tribe's submission, provided that it meets the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the Tribe to use voluntary consensus standards (VCS), the EPA has no authority to disapprove a TIP submission for failure to use VCS. It would thus be inconsistent with applicable law for the EPA, when it reviews a TIP submission, to use VCS in place of a TIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the NTTAA do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

List of Subjects in 40 CFR Part 49

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: July 29, 2010.

Jeff Scott,

Acting Regional Administrator, EPA Region IX.

[FR Doc. 2010–19926 Filed 8–11–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2005–NM–0009; FRL–9187–7]

Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Revisions to Emissions Inventory Reporting Requirements, and General Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve revisions to the New Mexico State Implementation Plan (SIP). These revisions concern two separate actions. First, we are proposing to approve revisions to regulations on Emissions Inventories (EIs) submitted by stationary sources of air pollutants. EIs are critical for the efforts of State, local, and federal agencies to attain and maintain the National Ambient Air Quality Standards that EPA has established for criteria pollutants such as ozone, particulate matter, and carbon monoxide. The revisions add new definitions, modify existing definitions, and require stationary sources of air pollutants located in New Mexico outside of Bernalillo County to report emissions location information, $PM_{2.5}$ emissions, and ammonia emissions to New Mexico Environment Department (NMED). The revisions also allow NMED to require speciation of hazardous air pollutants for emissions reporting. Second, we are proposing to approve revisions to the General Provisions of the NMAC (20.2.1 NMAC—General Provisions). We are proposing to add a new definition for Significant Figures into the New Mexico SIP. EPA is proposing to approve these two actions pursuant to section 110 of the Federal Clean Air Act.

DATES: Written comments must be received on or before *September 13, 2010.*

ADDRESSES: Comments may be mailed to Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the Addresses section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Mr. Emad Shahin for Emission Inventory inquiries, Air Planning Section (6PD–L), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone 214–665–6717; fax number 214–665–7263; e-mail address *shahin.emad@epa.gov,* and Mr. Alan Shar for General Provisions inquiries, Air Planning Section (6PD–L), telephone 214–665–6691; fax number 214–665–7263; e-mail address *shar.alan@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule, which is located in the rules section of this **Federal Register**.

Dated: August 3, 2010.

Al Armendariz,

Regional Administrator, Region 6.

[FR Doc. 2010–19820 Filed 8–11–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2010–0035; FRL–9187–6]

Approval and Promulgation of Air Quality Implementation Plans; MN

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve Minnesota's request to amend its State Implementation Plan (SIP) for sulfur dioxide (SO_2). The Minnesota Pollution Control Agency submitted the SIP revision request to EPA on November 23, 2009, and supplemented it on March 3, 2010. The approval of this request would revise SIP requirements applicable to Saint Mary's Hospital, located in Rochester, Minnesota by adding a 2500 kilowatt (KW) reciprocating internal combustion engine (RICE) electric generator and reducing the allowable diesel fuel sulfur content for two existing RICE electric generators. The revision also includes administrative changes in the identification of emissions units. These revisions are included in a joint Title I/Title V document for Saint Mary's Hospital, which would replace the document currently approved into the SIP for the facility. These revisions will result in reducing the SO_2 impact in the Rochester area, and strengthening the existing SO_2 SIP.

DATES: Comments must be received on or before September 13, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2010–0035, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *E-mail: bortzer.jay@epa.gov.*
3. *Fax:* (312) 629–2054.
4. *Mail:* Jay Bortzer, Chief, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Jay Bortzer, Chief, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Charles Hatten, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6031, *hatten.charles@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because EPA views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: August 2, 2010.

Bharat Mathur,

Acting Regional Administrator, Region 5.

[FR Doc. 2010–19825 Filed 8–11–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1987–0002; FRL–9188–7]

National Oil and Hazardous Substance Pollution Contingency Plan National Priorities List: Intent To Delete the Rogers Road Municipal Landfill Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 6 is issuing a Notice of Intent to Delete the Rogers Road Municipal Landfill Superfund Site located near Jacksonville, Pulaski County, Arkansas from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Arkansas, through the Arkansas Department of Environmental Quality (ADEQ), have determined that all appropriate response actions under CERCLA, other than operation and maintenance and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments Site must be received by *September 13, 2010.*

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–1987–0002, by one of the following methods:

http://www.regulations.gov (Follow the on-line instructions for submitting comments)

E-mail: walters.donn@epa.gov.

Fax: 214–665–6660.

Mail: Donn Walters, Community Involvement, U.S. EPA Region 6 (6SF–TS), 1445 Ross Avenue, Dallas, TX 75202–2733, (214) 665–6483 or 1–800–533–3508.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SFUND–1987–0002. EPA 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 thorough *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* website is an "anonymous access" system, which means 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 automatically be 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 at *http://www.regulations.gov* or in hard copy at: U.S. EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, (214) 665–7362, by appointment only Monday through Friday 9 a.m. to 12 p.m. and 1 p.m. to 4 p.m.; or Jacksonville City Hall, 1 Municipal Drive, Jacksonville, AR 72076, (501) 982–3181, Monday through Friday, 8 a.m. to 5 p.m. ; Arkansas Department of Environmental Quality (ADEQ), 5301 Northshore Drive, North Little Rock, Arkansas 72118, (501) 682–0744, Monday through Friday 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Shawn Ghose M.S., P.E., Remedial Project Manager (RPM), U.S. EPA Region 6 (6SF–RA), 1445 Ross Avenue, Dallas, TX 75202–2733, *ghose.shawn@epa.gov* 665–6782 or 800–533–3508.

SUPPLEMENTARY INFORMATION: In the "Rules and Regulations" Section of today's **Federal Register**, we are publishing a direct final Notice of Deletion of the Rogers Road Municipal Landfill Superfund because we view this as a noncontroversial revision and anticipate no adverse comment. We have explained our reasons for this deletion in the preamble to the direct final Notice of Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this deletion action, we will not take further action on this Notice of Intent to Delete. If we receive adverse comment(s), we will withdraw the direct final Notice of Deletion, and it will not take effect. We will, as appropriate, address all public comments in a subsequent final Notice of Deletion based on this Notice of Intent to Delete. We will not institute a second comment period on this Notice of Intent to Delete. Any parties interested in commenting must do so at this time.

For additional information see the Direct Final Notice of Deletion located in the "Rules" section of this **Federal Register**.

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: August 4, 2010.

Lawrence E. Starfield,

Acting Regional Administrator, EPA Region 6.

[FR Doc. 2010–19925 Filed 8–11–10; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2010–0059; 92220–1113–0000–C6]

RIN 1018–AW26

Endangered and Threatened Wildlife and Plants; Removing the Tennessee Purple Coneflower From the Federal List of Endangered and Threatened Plants

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; availability of draft post-delisting monitoring plan.

SUMMARY: Under the authority of the Endangered Species Act of 1973, as amended (Act), we, the U.S. Fish and Wildlife Service (Service), propose to remove the plant *Echinacea tennesseensis* (Tennessee purple coneflower) from the Federal List of Endangered and Threatened Plants due to recovery. This action is based on a thorough review of the best available scientific and commercial data, which indicate that this species' status has improved to the point that *E. tennesseensis* is not likely to become endangered within the foreseeable future throughout all or a significant portion of its range. Our review of the status of this species shows that all of the threats to the species have been eliminated or significantly reduced, adequate regulatory mechanisms exist, and populations are stable. We also announce the availability of the draft post-delisting monitoring plan. This proposed rule completes the 5-year status review for the species, initiated on September 21, 2007.

DATES: To ensure that we are able to consider your comments on this proposed rule, they must be received or postmarked on or before October 12, 2010. We must receive requests for public hearings, in writing, at the address shown in the **FOR FURTHER INFORMATION CONTACT** section, by September 27, 2010.

ADDRESSES: You may submit comments by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Search for docket number FWS–R4–ES–2010–0059 and then follow the instructions for submitting comments.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–R4–ES–2010–0059; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will not accept comments by e-mail or fax. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Mary Jennings, Field Supervisor, U.S. Fish and Wildlife Service, Cookeville Field Office, 446 Neal Street, Cookeville, TN 38501; telephone (931) 528–6481. Individuals who are hearing-impaired or speech-impaired may call the Federal Information Relay Service at (800) 877–8339 for TTY assistance 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION:

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and effective as possible. Therefore, we request comments or information from other concerned government agencies, the scientific community, industry, or other interested parties concerning this proposed rule. The comments that will be most useful and likely to influence our decisions are those that are supported by data or peer-reviewed studies and those that include citations to, and analyses of, applicable laws and regulations. Please make your comments as specific as possible and explain the

basis for them. In addition, please include sufficient information with your comments to allow us to authenticate any scientific or commercial data you reference or provide. In particular, we seek comments concerning the following:

(1) Biological data concerning *Echinacea tennesseensis.*

(2) Relevant data concerning any threats (or lack thereof) to *Echinacea tennesseensis,* including but not limited to:

(a) Whether or not climate change is a threat to the species;

(b) What regional climate change models are available, and whether they are reliable and credible to use as step-down models for assessing the effect of climate change on the species and its habitat; and

(c) The extent of Federal and State protection and management that would be provided to *Echinacea tennesseensis* as a delisted species.

(3) Additional information concerning the range, distribution, population size, and trends of *Echinacea tennesseensis,* including the locations of any additional populations of this species.

(4) Current or planned activities within the geographic range of *Echinacea tennesseensis* colonies that may impact or benefit the species.

(5) The draft post-delisting monitoring plan.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*) directs that a determination as to whether any species is an endangered or threatened species must be made "solely on the basis of the best scientific and commercial data available."

Prior to issuing a final rule on this proposed action, we will take into consideration all comments and any additional information we receive. Such information may lead to a final rule that differs from this proposal. All comments and recommendations, including names and addresses, will become part of the administrative record.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We will not consider comments sent by e-mail or fax or to an address not listed in the **ADDRESSES** section. If you submit a comment via *http://www.regulations.gov*, your entire comment—including any personal identifying information—will be posted on the Web site. Please note that comments posted to this Web site are not immediately viewable. When you submit a comment, the system receives it immediately. However, the comment will not be publicly viewable until we post it, which might not occur until several days after submission.

If you mail or hand-deliver a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. To ensure that the electronic docket for this rulemaking is complete and all comments we receive are publicly available, we will post all hardcopy submissions on *http://www.regulations.gov*.

In addition, comments and materials we receive, as well as supporting documentation used in preparing this proposed rule will be available for public inspection in two ways:

(1) You can view them on *http://www.regulations.gov*. In the Enter Keyword or ID box, enter FWS–R4–ES–2010–0059, which is the docket number for this rulemaking.

(2) You can make an appointment, during normal business hours, to view the comments and materials in person at the U.S. Fish and Wildlife Services' Cookeville Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Public Availability of Comments

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

Section 4(b)(5)(E) of the Act provides for one or more public hearings on this proposal, if requested. We must receive requests for public hearings, in writing, at the address shown in the **FOR FURTHER INFORMATION CONTACT** section by the date shown in the **DATES** section of this document. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** at least 15 days before the first hearing.

Previous Federal Actions

Section 12 of the Act directed the Secretary of the Smithsonian Institution to prepare a report on those plants considered to be endangered, threatened, or extinct. On July 1, 1975, the Service published a notice in the **Federal Register** (40 FR 27873) accepting the Smithsonian report as a petition to list taxa named therein under section 4(c)(2) [now 4(b)(3)] of the Act and announcing our intention to review the status of those plants. *Echinacea tennesseensis* was included in that report (40 FR 27880). Tennessee purple coneflower is the common name for *E. tennesseensis;* however, we will primarily use the scientific name of this species throughout this proposed rule to clarify taxonomic issues or the legal status of the plant.

On June 16, 1976, we published a proposed rule in the **Federal Register** (41 FR 24524) to designate approximately 1,700 vascular plant species, including *Echinacea tennesseensis,* as endangered under section 4 of the Act. On June 6, 1979, we published a final rule in the **Federal Register** (44 FR 32604) designating *E. tennesseensis* as endangered. The final rule identified the following threats to *E. tennesseensis:* loss of habitat due to residential and recreational development; collection of the species for commercial or recreational purposes; grazing; no State law protecting rare plants in Tennessee; and succession of cedar glade communities in which *E. tennesseensis* occurred. On February 14, 1983, we published the Tennessee Coneflower Recovery Plan (Service 1983, 41 pp.), a revision of which we published on November 14, 1989 (Service 1989, 30 pp.). On September 21, 2007, we initiated a 5-year status review of this species (72 FR 54057). This rule, once finalized, will complete the status review.

For additional details on previous Federal actions, see discussion under the Recovery Plan and Recovery Plan Implementation sections below.

Species Information

A member of the sunflower family (Asteraceae), *Echinacea tennesseensis* is a perennial herb with a long and fusiform (*i.e.,* thickened toward the middle and tapered towards either end), blackened root. In late summer, the species bears showy purple flower heads on one-to-many hairy branches. Linear to lance-shaped leaves up to 20 centimeters (cm; 8 inches (in.)) long and 1.5 cm (0.6 in.) wide arise from the base of *E. tennesseensis* and are beset with coarse hairs, especially along the

margins. The ray flowers (*i.e.,* petals surrounding the darker purple flowers of the central disc) are pink to purple and spread horizontally or arch slightly forward from the disc to a length of 2–4 cm (0.8–1.8 in.).

The following description of this species' life history is summarized from Hemmerly (1986, pp. 193–195): seeds are shed from plants during fall and winter and begin germinating in early March of the following year, producing numerous seedlings by late March. Most of the seedling growth occurs during the first 6 or 7 weeks of the first year, during which plants will grow to a height of up to 2–3 cm (0.8–1.2 in). Plants remain in a rosette stage and root length increases rapidly during these weeks. Flowering stems and seeds are produced on some plants by the end of the second season. Individuals of *Echinacea tennesseensis* can live up to at least 6 years, but the maximum lifespan is probably much longer (Baskauf 1993, p. 37).

Echinacea tennesseensis was first collected in 1878 in Rutherford County, Tennessee, by Dr. A. Gattinger and later described by Beadle (1898, p. 359) as *Brauneria tennesseensis* on the basis of specimens collected by H. Eggert in 1897 from "a dry, gravelly hill" near the town of LaVergne. Fernald (1900, pp. 86–87) did not accept Beadle's identification of *B. tennesseensis* as a distinct species, instead he merged it with the more widespread *E. angustifolia.* This treatment was upheld by many taxonomists until McGregor (1968, pp. 139–141) classified the taxon as *E. tennesseensis* (Beadle) Small, based on examination of materials from collections discussed above and from collections by R. McVaugh in 1936. As McGregor (1968, p. 141) was unable to locate any plants while conducting searches during the months of June through August, 1959–1961, he concluded that the species was very rare or possibly extinct in his monograph of the genus *Echinacea.* The species went unnoticed until its rediscovery in a cedar glade in Davidson County, Tennessee as reported by Baskin *et al.* (1968, p. 70), and subsequently in Wilson County, Tennessee by Quarterman and Hemmerly (1971, pp. 304–305), who also noted that the area believed to be the type locality (Rutherford County) for the species was destroyed by the construction of a trailer park.

More recently, Binns *et al.* (2002, pp. 610–632) revised the taxonomy of the genus *Echinacea* and in doing so reduced *E. tennesseensis* to one of five varieties of *E. pallida.* Their taxonomic treatment considers *E. pallida var. tennesseensis* (Beadle) Small to be a synonym of their *E. tennesseensis* (Beadle) Binns, B. R. Baum, & Arnason, comb. nov. (Binns *et al.* 2002, p. 629). However, this has not been unanimously accepted among plant taxonomists (Estes 2008, pers. com.; Weakley 2008, pp. 139–140). Kim *et al.* (2004) examined the genetic diversity of *Echinacea* species and their results conflicted with the division of the genus by Binns *et al.* (2002, pp. 617–632) into two subgenera, *Echinacea* and *Pallida,* one of which—*Echinacea*—included only E. purpurea. Mechanda *et al.* (2004, p. 481) concluded that their analysis of genetic diversity within *Echinacea* only supported recognition of one of the five varieties of *E. pallida* that Binns *et al.* (2002, pp. 626–629) described, namely *E. pallida var. tennesseensis.* While Mechanda *et al.* (2004, p. 481) would also reduce *E. tennesseensis* from specific to varietal status, the conflicting results between these two investigations point to a lack of consensus regarding the appropriate taxonomic rank of taxa within the genus *Echinacea.* Because clear acceptance of the taxonomic revision by Binns *et al.* (2002, pp. 610–632) is lacking, and Flora of North America (*http://www.efloras.org/florataxon.aspx?flora_id=1&taxon_id=250066491,* accessed December 3, 2009) and a flora under development by Weakley (2008, pp. 139–140) both retain specific status for *E. tennesseensis,* we will continue to recognize *E. tennesseensis* as a species during this rulemaking process until a change in the best available scientific data indicates we should do otherwise.

Echinacea tennesseensis is restricted to limestone barrens and cedar glades of the Central Basin, Interior Low Plateau Physiographic Province, in Davidson, Rutherford, and Wilson Counties in Tennessee (Tennessee Department of Environment and Conservation (TDEC) 2006, p. 2). These middle Tennessee habitats typically occur on thin plates of Lebanon limestone that are more or less horizontally bedded, though interrupted by vertical fissures in which sinkholes may be readily formed (Quarterman 1986, p. 124). Somers *et al.* (1986, pp. 180–189) described seven plant community types from their study of 10 cedar glades in middle Tennessee. They divided those communities into xeric (dry) communities, which occurred in locations with no soil or soil depth less than 5 cm (2 in.), and subxeric (moderately dry) communities that occurred on soils deeper than 5 cm (2 in.) (Somers *et al.* 1986, p. 186). Quarterman (1986, p. 124) noted that soil depths greater than 20 cm (8 in.) in the vicinity of cedar glades tend to support plant communities dominated by eastern red cedar (*Juniperus virginiana*) and other woody species. Somers *et al.* (1986, p. 191) found *E. tennesseensis* in four of the community types they classified, but could not determine the fidelity of the species to a particular community type because it only occurred on three of the glades they studied and was infrequently encountered in plots within those sites. The communities where *E. tennesseensis* occurred spanned two xeric and two subxeric types. The xeric community types, named for the dominant species that either alone or combined constituted greater than 50 percent cover, were the (1) *Nostoc commune* (blue-green algae)–*Sporobolus vaginiflorus* (poverty dropseed) and (2) *Dalea gattingeri* (purpletassels) communities. The subxeric types were the (1) *S. vaginiflorus* and (2) *Pleurochaete squarrosa* (square pleurochaete moss) communities. Mean soil depths across these communities ranged from 4.1 to 7.7 cm (1.6 to 3.0 in.) (Somers *et al.* 1986, pp. 186–188).

Echinacea tennesseensis was only known from three locations, one each in Davidson, Rutherford, and Wilson Counties, when the species was listed as endangered in 1979 (44 FR 32604; June 6, 1979). In 1989, when the species' recovery plan was completed, there were five extant populations ranging in size from approximately 3,700 to 89,000 plants and consisting of one to three colonies each (Clebsch 1988, p. 14; Service 1989, p. 2). The recovery plan defined a population as a group of colonies in which the probability of gene exchange through cross pollination is high, and a colony was defined as all *E. tennesseensis* plants found at a single site that are separated from other plants within the population by unsuitable habitat (Service 1989, p. 1). While analysis of genetic variability within *E. tennesseensis* did not reveal high levels of differentiation among these populations (Baskauf *et al.* 1994, p. 186), recovery efforts have been implemented and tracked with respect to these geographically defined populations. The geographic distribution of these populations and their colonies was updated in a TDEC (1996, Appendix I) status survey to include all known colonies at that time, including those from a sixth population introduced into glades at the Stones River National Battlefield in Rutherford County. For the purposes of this proposed rule, we have followed these population delineations and have assigned most colonies that have been

discovered since the status survey was completed to the geographically closest population.

The six *Echinacea tennesseensis* populations occur within an approximately 400 square kilometer (km^2; 154 square miles (mi^2)) area and include between 2 and 11 colonies each. Surveys conducted by TDEC and the Service in 2005 confirmed the presence of *E. tennesseensis* at 36 colonies, and the number of flowering stems in each was counted (TDEC 2006, pp. 4–5). Fifteen of these are natural colonies; the remaining 21 have been established through introductions for the purpose of recovering *E. tennesseensis* (TDEC 1991, pp. 3–7; TDEC 1996, Appendix I; Lincicome 2008, pers. com.). Three of the 21 introduced colonies constitute the sixth population that was established at a Designated State Natural Area (DSNA) in the Stones River National Battlefield (TDEC 1996, Appendix I).

We do not consider 2 of the 21 introduced colonies as contributing to recovery and do not include them in our analysis of the current status of *E. tennesseensis.* One of these two excluded colonies is located in Marshall County, well outside of the known range of the species. The other excluded colony is located in Rutherford County, and is believed to contain hybrids with *E. simulata* (see the Recovery Plan Implementation section below for additional information). Excluding these 2 colonies brings the number of introduced colonies considered for recovery to 19 and the total number of colonies to 34. However, an additional introduced colony that was not monitored during 2005, but for which TDEC maintains an element occurrence record, brings the number of introduced colonies we consider here to 20 and the total number of colonies considered for this proposed rulemaking to 35.

In reviewing the 2006 TDEC report summarizing results of the 2005 surveys, we discovered computational errors in the reported estimates of flowering adults and total individuals based on the number of flowering stems counted (TDEC 2006, pp. 4–5, Table 2). We reanalyzed those data to provide revised estimates after consulting with TDEC, but cite their 2006 report throughout this proposed rule because it is the source of data for flowering stem counts that were used to estimate colony sizes. To generate revised estimates of the number of flowering adults and total individuals, we used the number of flowering stems reported in Table 2 of TDEC (2006, pp. 4–5). Based on analyses by TDEC (2006, pp. 3–4) to estimate ratios of flowering stems to numbers of individual flowering adults and juveniles (discussed in further detail under number 5 in the Recovery Plan Implementation section below), we then (1) divided the number of flowering stems by 1.75 to estimate the number of flowering adults, and (2) multiplied the estimated number of adults by 14 to estimate the number of juvenile plants. The estimated total number of individuals is the sum of the number of flowering adults and number of juvenile plants. The revised estimates of existing *E. tennesseensis* populations and colonies, shown in Table 1 below, include information on whether each colony was natural or introduced. Summarizing the data in Table 1, natural colonies, or those not known to have been established through introductions, included 83,895 flowering stems in 2005 (TDEC 2006, p. 6), which translated to an estimated 47,941 individual flowering plants and 719,101 total individuals, including juveniles (*i.e.,* non-flowering plants with leaves greater than 2 cm (0.78 in) length) and seedlings (*i.e.,* plants with leaves less than 2 cm (0.78 in)). Introduced colonies, excluding the two colonies we do not consider as contributing to recovery (as mentioned above), accounted for 23,454 flowering stems, and an estimated 13,402 individual flowering plants and 201,178 total individuals (TDEC 2006, p. 6). Natural colonies constituted approximately 78 percent of the total individuals, and introduced colonies constituted approximately 22 percent. In this proposed rule, we use the colony numbers assigned by TDEC (1996, Appendix I) and have assigned additional colony numbers sequentially to those colonies that have been discovered since that report was issued. In some instances, there are gaps evident in the sequence of colony numbers discussed, representing colonies that have been documented in the past but that were either extirpated or of unknown status at the time of this proposed rule.

Recovery Plan

Section 4(f) of the Act directs us to develop and implement recovery plans for the conservation and survival of endangered and threatened species unless we determine that such a plan will not promote the conservation of the species. The Act directs that, to the maximum extent practicable, we incorporate into each plan:

(1) Site-specific management actions as may be necessary to achieve the plan's goals for conservation and survival of the species;

(2) Objective, measurable criteria which, when met, would result in a determination in accordance with the provisions of section 4 of the Act, that the species be removed from the Federal List of Endangered and Threatened Wildlife and Plants (List); and

(3) Estimates of the time required and cost to carry out the plan's goal and to achieve intermediate steps toward that goal.

However, revisions to the List (adding, removing, or reclassifying a species) must reflect determinations made in accordance with sections 4(a)(1) and 4(b) of the Act. Section 4(a)(1) requires that the Secretary determine whether a species is endangered or threatened (or not) because of one or more of five threat factors. Therefore, recovery criteria must indicate when a species is no longer endangered or threatened by any of the five factors. In other words, objective, measurable criteria, or recovery criteria, contained in recovery plans must indicate when an analysis of the five threat factors under 4(a)(1) would result in a determination that a species is no longer endangered or threatened. Section 4(b) requires the determination made under section 4(a)(1) as to whether a species is endangered or threatened because of one or more of the five factors be based on the best available science.

Thus, while recovery plans are intended to provide guidance to the Service, States, and other partners on methods of eliminating or ameliorating threats to listed species and on criteria that may be used to determine when recovery is achieved, recovery plans are not regulatory documents and cannot substitute for the determinations and promulgation of regulations required under section 4(a)(1). Determinations to remove a species from the list made under section 4(a)(1) must be based on the best scientific and commercial data available at the time of the determination, regardless of whether these data differ from the recovery plan.

In the course of implementing conservation actions for a species, new information is often gained that requires recovery efforts to be modified accordingly. There are many paths to accomplishing recovery of a species, and recovery may be achieved without all criteria being fully met. For example, one or more criteria may have been exceeded while other criteria may not have been accomplished, yet the Service may judge that, overall, the threats have been minimized sufficiently, and the species is robust enough, to reclassify the species from endangered to threatened or perhaps delist the species.

In other cases, recovery opportunities may have been recognized that were not known at the time the recovery plan was finalized. These opportunities may be used instead of methods identified in the recovery plan.

Likewise, information on the species may be learned that was not known at the time the recovery plan was finalized. The new information may change the extent that criteria need to be met for recognizing recovery of the species. Overall, recovery of species is a dynamic process requiring adaptive management—planning, implementing, and evaluating the degree of recovery of a species that may, or may not, fully follow the guidance provided in a recovery plan.

Thus, while the recovery plan provides important guidance on the direction and strategy for recovery, and indicates when a rulemaking process may be initiated, the determination to remove a species from the List is ultimately based on an analysis of whether a species is no longer endangered or threatened. The following discussion provides a brief review of recovery planning for *Echinacea tennesseensis,* as well as an analysis of the recovery criteria and goals as they relate to evaluating the status of the species.

The Service first approved the Tennessee Coneflower Recovery Plan on February 14, 1983 (Service 1983, 41 pp.) and revised it on November 14, 1989 (Service 1989, 30 pp.). The recovery plan includes the following delisting criterion: *Echinacea tennesseensis* will be considered recovered when there are at least five secure wild populations, each with three self-sustaining colonies of at least a minimal size. A colony will be considered self-sustaining when there are two juvenile plants for every flowering one. Minimal size for each colony is 15 percent cover of flowers over 669 square meters (m^2; 800 square yards (yd^2); 7,200 square feet (ft^2)) of suitable habitat. Downlisting (reclassification from endangered to threatened) will be considered when each of the five secure wild populations has two colonies (Service 1989, p. iii, p. 12).

Establishing multiple populations during the recovery of endangered species serves two important functions:

(1) Providing redundancy on the landscape to minimize the probability that localized stochastic disturbances will threaten the entire species, and

(2) Preserving the genetic structure found within a species by maintaining the natural distribution of genetic variation among its populations.

In the case of *E. tennesseensis,* the need for multiple distinct populations to maintain genetic structure is diminished, as Baskauf *et al.* (1994, p. 186) determined that the majority of genetic variability within this species is maintained within each population rather than distributed among them. These data were not available at the time the recovery plan was completed. With respect to redundancy, the current number of *E. tennesseensis* colonies exceeds the total number required by the recovery plan for delisting this species, and we believe the current distribution of secured colonies among geographically distinct populations, which are separated by distances of 1.8 to 9 miles (2.9–14.5 km), is adequate for minimizing the likelihood that isolated stochastic disturbances would threaten the continued survival of this species.

Nonetheless, the criterion set forth in the Recovery Plan for delisting *Echinacea tennesseensis* has been met, as described below. Additionally, the level of protection currently afforded to the species and its habitat, as well as the current status of threats, are outlined below in the Summary of Factors Affecting the Species section.

There currently are six geographically defined *Echinacea tennesseensis* populations, including the five described in the recovery plan (Service 1989, pp. 3–7) and one introduced population at the Stones River National Battlefield (TDEC 1996, Appendix I). There currently are 19 colonies of *E. tennesseensis* that occur entirely or mostly on protected lands, with 5 of the populations containing three or more colonies each. The Allvan population is the lone exception, as only one of its two colonies is secure at this time. The 19 secured colonies accounted for an estimated 761,055 individual plants in 2005, or approximately 83 percent of the total species' distribution; colonies that we do not consider secure accounted for 159,224 individual plants, or approximately 17 percent of the total species' distribution.

While data on numbers of juvenile plants have not been collected from all colonies, monitoring data that have been collected for this demographic attribute have typically exceeded the value used in defining self-sustaining in the recovery plan–i.e., that there be two juvenile plants for every flowering adult in a colony. The average of this ratio in natural colonies for a given year of monitoring has ranged from 2.5 to 15.6, based on data collected at two to six sites per year in 1998, 2000, 2001, and 2004 (TDEC 2005, p. 21). Ratios of juvenile to flowering adult plants in introduced colonies were first estimated during 2006, when the average was found to be 1.08 juveniles per adult from a single year of data collected at six introduced colonies (TDEC 2007, p. 5). Drew and Clebsch (1995, p. 67) witnessed considerable variability in mortality rates among stage classes of *Echinacea tennesseensis* measured over the periods 1987–1988 and 1988–1989, which they attributed to interannual variability in rainfall. They determined that seedlings—plants with a cumulative leaf length less than 30 cm (11.8 in)—had a high probability (*i.e.,* approximately 50 percent) of dying during drought conditions that they observed in their first year of study (Drew and Clebsch 1995, p. 66). This underscores the importance of continuing to monitor numbers of flowering adult and juvenile plants in a representative sample of both natural and introduced colonies during the post-delisting monitoring period.

The recovery plan further requires that each self-sustaining colony consist of 15 percent cover of flowers over 669 m^2 (800 yd^2, 7,200 ft^2) of suitable habitat, which has not been met in all cases. However, we have determined that these percent cover and habitat area requirements do not reflect the best available scientific information. Drew and Clebsch (1995, pp. 61–67) conducted monitoring during 1987 through 1989 that established baseline conditions for five of the colonies included in the recovery plan (Service 1989, pp. 3–7); in doing so, they found that percent flower cover of *Echinacea tennesseensis* at these sites ranged from 2 to 12 percent, never exceeding the 15 percent threshold stipulated in the recovery plan. Total percent cover of all vegetation in the habitats where these colonies occur ranged from 42 to 59 percent, meaning that *E. tennesseensis* would have to have constituted 25 to 40 percent of the total vegetative cover to have occupied 15 percent flower cover in these sites. In contrast, *E. tennesseensis* only constituted between 5 and 22 percent of total vegetative cover in plots studied by Drew and Clebsch (1995, p. 63). In addition to the fact that the recovery plan articulated a requirement that was not met by the reference colonies known to exist when the plan was published, a disadvantage of using cover estimates for monitoring a rare species such as *E. tennesseensis* is that this value can change during the course of a growing season. Density estimates, on the other hand, remain fairly stable once seedlings become established following germination (Elzinga *et al.* 1998, p. 178). We believe that either total counts of plants in

various life-history classes within a colony of *E. tennesseensis* (TDEC 2005, pp. 3–4, 16–20), or sampling within a known area to generate density estimates that can be extrapolated to an entire colony, provide superior metrics over cover estimates for monitoring trends in populations.

The recovery plan requirement that each colony occupy 669 m^2 (800 yd^2, 7,200 ft^2) of suitable habitat does not reflect the range of variability observed in several natural colonies that have been discovered since the recovery plan was completed. Many of these colonies are constrained by the small patches of cedar glade habitat where they occur and provide evidence of a wider range of natural variability in habitat patch size and colony size in this species that was not recognized at the time the recovery plan was published. We believe a better measure of the sustainability of both natural and introduced colonies is whether they have persisted over time and remained stable or increased in number. There currently are 31 out of the total 35 colonies that meet this definition, 19 of which are the colonies described above as secure.

Recovery Plan Implementation

The current recovery plan identifies six primary actions necessary for recovering *Echinacea tennesseensis:*

(1) Continue systematic searches for new colonies;

(2) Secure each colony;

(3) Provide a seed source representative of each natural colony;

(4) Establish new colonies;

(5) Monitor colonies and conduct management activities, if necessary, to maintain the recovered state in each colony; and

(6) Conduct public education projects.

Each of these recovery actions has been accomplished. The Service entered into a cooperative agreement with TDEC in 1986, as authorized by section 6 of the Act, for the conservation of endangered and threatened plant species, providing a mechanism for TDEC to acquire Federal funds that have supported much of the work described here. The State of Tennessee and other partners have provided matching funds in order to receive funding from the Service under this agreement.

Recovery Action (1): Continue Systematic Searches for New Colonies

Eight colonies of *Echinacea tennesseensis* were known to exist when the recovery plan was completed (Service 1989, pp. 3–7). TDEC and its contractors conducted searches of cedar glades, identified through the use of aerial photography and topographic maps, during the late 1980s through 1990 and found five previously unknown colonies of *E. tennesseensis* (TDEC 1991, p.1). Two of these colonies were considered additions to the Vine population (TDEC 1991, p. 2), or population 3 as described in the recovery plan (Service 1989, pp. 4–5). One colony was considered an addition to the Mt. View population (TDEC 1991, p. 2), or population 1 of the recovery plan (Service 1989, p. 3). A fourth colony was considered an addition to the Couchville population (TDEC 1991, p. 3), or population 5 of the recovery plan (Service 1989, p. 7). The fifth colony was smaller, not in a natural habitat setting, and not assigned to any of the recovery plan populations in the TDEC report (1991, p. 2). Other colonies have been discovered during the course of surveys conducted in the cedar glades of middle Tennessee, and the number of extant natural colonies now totals 15. A summary of the currently known populations and their colonies is provided below in Table 1, and in the discussion concerning recovery action number (5). Because systematic searches for new colonies have been conducted since the completion of the recovery plan and led to the discovery of previously unknown colonies, we consider this recovery action to be completed.

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Table 1. Summary of Tennessee purple coneflower populations and colonies. Includes data on origin, whether colonies are secure or self-sustaining, flowering stem counts from 2005 surveys, and estimates generated from flowering stem count data. * = Colonies selected for post-delisting monitoring.

Population	Population Name	Colony Number	EO Number[#]	Ownership	Origin	Secure Y/N	Self-Sustaining Y/N	Flowering Stems	Estimated Adults	Estimated Individuals
1	Mount View	1.1*	001	TDEC–DNA[a]	Natural	Y	Y	5,430	3,103	46,543
		1.2	022	COE[b]	Introduced	Y	Y	252	144	2,304
		1.4	031	COE	Introduced	Y	Y	596	341	5,109
							TOTALS	**6,278**	**3,588**	**53,956**
2	Vesta	2.1	011	Private	Natural	Y	Y	2,820	1,611	24,171
		2.1*	006	TDEC–DNA	Natural	Y	Y	4,970	2,840	42,600
		2.2	002	TDEC–DNA	Natural	Y	Y	4,274	2,442	36,634
		2.3	038	TDF[c] (DSNA[d])	Introduced	Y	Y	139	79	1,191
		2.4	039	TDF (DSNA)	Introduced	N	N	1	1	9
		2.6*	040	TDEC–SP	Introduced	N	Y	252	144	2,160
		2.7	048	TDF (DSNA)	Introduced	N	N	6	3	51
		2.8	050	TDEC–DNA	Natural	Y	Y	2,143	1,225	18,369
		2.9+	053	Private	Introduced	N	Y	n/a	n/a	n/a
							TOTALS	**14,605**	**8,345**	**125,185**
3	Vine	3.1*	005	TDEC–DNA	Natural	Y	Y	7,555	4,317	64,757
		3.2*	016	TDEC–DNA	Natural	Y	Y	12,457	7,118	106,774
		3.2	015	Private	Natural	N	Y	432	247	3,703
		3.2	012	Private	Natural	N	Y	610	349	5,229
		3.2*	017	TDEC–DNA	Natural	Y	Y	12,457	7,118	106,774
		3.3	014	Private	Natural	N	N	11	6	94
		3.4*	021	Private (DSNA)	Natural	Y	Y	12,979	7,417	111,249
		3.5	013	Private	Natural	N	Y	2,529	1,445	21,677
		3.6	018	Private	Natural	N	Y	157	90	1,346

Population	Population Name	Colony Number	EO Number[#]	Ownership	Origin	Secure Y/N	Self-Sustaining Y/N	Flowering Stems	Estimated Adults	Estimated Individuals
		3.7	007	Private	Introduced	N	Y	1,705	974	14,614
		3.8*	030	TDF	Introduced	N	Y	1,863	1,065	15,969
		3.9	036	TDF	Introduced	Y	Y	2,744	1,568	23,520
		3.10	033	Private	Natural	N	Y	5,374	3,071	46,063
		3.11	041	Private	Natural	N	Y	1,935	1,106	16,586
							TOTALS	**62,808**	**35,891**	**538,355**
4	Allvan	4.2*	027	COE (DSNA)	Introduced	Y	Y	6,183	3,533	52,997
		4.3*	047	COE	Introduced	N	Y	385	220	3,300
							TOTALS	**6,568**	**3,753**	**56,297**
5	Couchville	5.1*	010	TDEC–DNA	Natural	Y	Y	7,353	4,202	63,026
		5.2	020	Private	Natural	N	Y	392	224	3,360
		5.3	024	TDEC–SP	Introduced	N	Y	1,607	918	13,774
		5.4	035	TDEC–SP	Introduced	Y	Y	863	493	7,397
		5.4	026	TDEC–SP	Introduced	Y	Y	987	564	8,460
		5.5*	025	TDEC–SP	Introduced	N	Y	1,300	743	11,143
		5.6	032	TDEC–SP	Introduced	Y	Y	846	483	7,251
		5.7	008	TDEC–SP	Natural	N	N	17	10	146
		5.8	049	COE (DSNA)	Introduced	Y	Y	101	58	866
							TOTALS	**13,466**	**7,695**	**115,423**
6	Stones River National Battlefield	6.1*	009	NPS[@] (DSNA)	Introduced	Y	Y	2,535	1,449	21,729
		6.2	028	NPS (DSNA)	Introduced	Y	Y	237	135	2,031
		6.3	029	NPS (DSNA)	Introduced	Y	Y	852	487	7,303
							TOTALS	**3,624**	**2,071**	**31,063**

Population	Population Name	Colony Number	EO Number#	Ownership	Origin	Secure Y/N	Self-Sustaining Y/N	Flowering Stems	Estimated Adults	Estimated Individuals
							GRAND TOTALS	107,349	61,343	920,279

[a]Tennessee Department of Environment and Conservation – Division of Natural Areas Designated State Natural Areas (DSNA), [b]U.S. Army Corps of Engineers, [c]Tennessee Division of Forestry, [d]DSNA that are not owned by TDEC–DNA, [e]National Park Service.

[+] Colony 2.9 was not monitored during 2005, because it was not reported to TDEC–DNA until 2006, at which time there were thousands of plants (Lincicome 2006, pers. com).

EO Number = Element Occurrence Number assigned and tracked by Tennessee Natural Heritage Program

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Recovery Action (2): Secure Each Colony

We have assessed the security of each *Echinacea tennesseensis* colony based on observations about threats and defensibility ranks reported in the 1996 status survey of this species (TDEC 1996, Appendix I) and information in our files concerning protection actions, such as construction of fences. We consider a total of 19 colonies, including 14 of the 16 colonies within DSNAs, to be secure. Colonies 2.4 and 2.7, which lie within portions of the extensive Cedars of Lebanon State Forest DSNA that have been threatened by past outdoor recreational vehicle (ORV) use or that are generally degraded cedar glade habitat are not secure. The State of Tennessee's Natural Area Preservation Act of 1971 (T.C.A. 11–1701) protects DSNAs from vandalism and forbids removal of endangered and threatened species from these areas. TDEC monitors these sites and protects them as needed through construction of fences or placement of limestone boulders to prevent illegal ORV access. We do not consider secure the nine colonies that exist only on private land and are not under some form of management agreement. The introduced population at the Stones River National Battlefield, designated a DSNA in 2003, consists of three secured colonies requiring no protective management, as the National Park Service (NPS) controls access to the site.

The recovery plan states that *Echinacea tennesseensis* will be considered recovered when there are "at least five secure wild populations, each with three self-sustaining colonies of at least a minimal size." There are now 19 secure, self-sustaining colonies of *E. tennesseensis* distributed among six populations (Table 1), fulfilling the recovery plan intentions of establishing a sufficient number and distribution of secure populations and colonies to remove the risk of extinction for this species within the foreseeable future. Therefore, we consider this recovery action completed.

Recovery Action (3): Provide a Seed Source Representative of Each Natural Colony

The Missouri Botanical Garden (MOBOT), an affiliate institution of the Centers for Plant Conservation (CPC), collected accessions of seeds from each of the six populations currently in existence during 1994 (Albrecht 2008a, pers. com.). This collection is maintained according to CPC guidelines (Albrecht 2008b, pers. com.). Five of the accessions taken by MOBOT were provided to the National Center for Genetic Resource Preservation (NCGRP) in Fort Collins, Colorado, for long-term cold storage. The NCGRP protocol is to test seed viability every 5 years for accession, and MOBOT also tests seed viability on a periodic basis and collects new material for accessions every 10 to 15 years (Albrecht 2008b, pers. com.).

While these accessions do not contain seed from every unique colony, they represent each of the populations of *Echinacea tennesseensis.* These accessions provide satisfactory material should establishment of colonies from reintroductions or additional introductions become necessary in the future, as Baskauf *et al.* (1994, pp.184–186) concluded that there is a low level of genetic differentiation among populations of *E. tennesseensis* and the origin of seeds probably is not a critical concern for establishing new populations. Therefore, we consider this recovery action completed.

Recovery Action (4): Establish New Colonies

TDEC (2006, pp. 3–6) reported flowering stem counts for 21 introduced colonies, but we have eliminated 2 of these from our analysis of the current status of *Echinacea tennesseensis.* One of these excluded colonies was introduced into a privately owned glade well outside of the known range of the species in Marshall County, consists of only a few vegetative stems, and is of doubtful viability. The other excluded, introduced colony is located in Rutherford County, approximately 7 miles from the nearest *E. tennesseensis* population, and is believed to contain hybrids with *E. simulata.* The number of flowering stems reported from the monitored colonies during 2005 ranged from 1 to 6,183.

All but 1 of the 19 introduced colonies known from 2005 have greater than 100 flowering stems, and the estimated total number of plants in these colonies ranged from 866 to 52,997 (TDEC 2006, pp. 4–5). An additional introduced colony (2.9) that was not surveyed during 2005, but contained thousands of plants in 2006 (Lincicome 2006, pers. com.), brings the number of extant introduced colonies to 20. These 20 colonies were established at various times since 1970 through the introductions of seed or transplanted individuals (TDEC 1991, pp. 3–7; TDEC 1996, Appendix I; Lincicome 2008, pers. com.), often from an undocumented or mixed origin with respect to the source populations (Hemmerly 1976, p. 81; Hemmerly 1990, pp. 1–8; TDEC 1991, pp. 4–8; Clebsch 1993, pp. 8–9). Numerous nurseries have grown *E. tennesseensis* for the purpose of providing seeds and plants for establishing new colonies (TDEC 1991, pp. 3–8). Baskauf *et al.* (1994, pp. 184–186) determined that less than 10 percent of the genetic variability of *E. tennesseensis* is distributed among populations and concluded from this low level of differentiation that the origin of seed used in establishing new populations probably is not a critical consideration. We summarize the distribution of these introduced colonies among *E. tennesseensis* populations in the discussion concerning recovery action number (5) below. Because 20 new colonies have been established, we consider this recovery action completed.

Recovery Action (5): Monitor Colonies and Conduct Management Activities, if Necessary, To Maintain the Recovered State in Each Colony

Drew and Clebsch (1995, pp. 62–67) conducted the first monitoring of *Echinacea tennesseensis* during the summers of 1987 through 1989. They produced estimates of density, total numbers of *E. tennesseensis,* the area occupied in the primary colony of each of the five populations included in the recovery plan (Service 1989, pp. 3–7), and information on the demographic structure of these populations. TDEC monitored each of these same *E. tennesseensis* colonies one or more times in the years 1998, 2000, and 2001, and again in 2004 with some modifications to the protocol used in the previous 3 years (TDEC 2005, pp. 3–5). TDEC used monitoring data collected during 2004 (TDEC 2005, pp. 16–21) to establish that (1) the total number of adult plants in a colony could be estimated by dividing the number of flowering stems by 1.75, and (2) the number of juveniles and seedlings combined could be estimated by multiplying the estimated number of adults by 14. These relationships were established using only data from natural populations, so they might not accurately represent ratios among life-history classes in introduced populations. TDEC (2007, pp. 2–7) reported summary data for monitoring plots in four introduced colonies that were sampled during 2006, but the data have not been analyzed to establish relationships for estimating numbers of adults, juveniles, and seedlings from flowering stem counts. The average ratio of juveniles to flowering adults estimated from the 2004 monitoring was the highest ever recorded; however, this ratio provided the best data available for estimating overall colony sizes in

combination with flowering stem counts that were conducted in 2005 at all but one colony (TDEC 2006, pp. 2–5).

Because it is not possible to conduct intensive monitoring of multiple stage classes of *Echinacea tennesseensis* at all colonies in a single year, TDEC and the Service conducted flowering stem censuses of all known *E. tennesseensis* colonies in 2005 in order to derive population estimates using the approach described above. While the total stem estimates provided by TDEC (2006, pp. 4–5) and Drew and Clebsch (1995, pp. 62–67) cannot be statistically compared, they provide a basis for examining long-term persistence and apparent stability in the sizes of the colonies included in the recovery plan from observations made 16 years apart.

The Mount View population (number 1 in the recovery plan) consisted of a single known colony when the recovery plan was completed (Service 1989, p. 3). This population now includes two more colonies, one introduced, in addition to the original colony 1.1, which is located in Mount View DSNA. These three colonies are located within an approximately 2.5 km^2 (1 mi^2) area in Davidson County. In 1987, Drew and Clebsch (1995, p. 62) estimated the size of the population at colony 1.1 to be 12,000 plants occupying an area of 830 m^2 (8,934 ft^2). Based on number of flowering stems reported by TDEC (2006, p. 4) for this colony in 2005, there were an estimated 46,543 plants. Colony 1.2 was discovered on private land in 1990 (TDEC 1996, Appendix I, p. III), and Clebsch (1993, p. 18) estimated there were 9,057 plants occupying an area of 682 m^2 (7,341 ft^2) in 1993. The colony on private land was bulldozed in 1999. Colony 1.2 now consists of plants introduced onto adjacent U.S. Army Corps of Engineers (COE) lands to provide long-term protection (TDEC 2003, p. 2). TDEC (2006, p. 4) estimated there were 2,304 plants at colony 1.2 in 2005. TDEC (2006, p. 5) reported 5,109 plants at colony 1.4. This colony was established on COE lands, near a public use area at J. Percy Priest Reservoir, using plants grown at Tennessee Tech University and was estimated to have consisted of 70–80 plants in 1996 (TDEC 1996, Appendix I, p. V). Each of the colonies in the Mount View population is considered secure, and the available data indicate they are self-sustaining based on the fact that they have remained stable or increased over time. While colony 1.2 was reduced in size when the private lands where it occurred were developed, the colony has increased in size since it was relocated onto COE lands and a fence was constructed. The total number of plants estimated in the Mount View population in 2005 was 53,956.

The Vesta population (number 2 in the recovery plan) consisted of two known colonies when the recovery plan was completed (Service 1989, pp. 3–4). This population now consists of eight colonies primarily located within an area of approximately 3 km^2 (1.5 mi^2) in Wilson County. Five of these colonies (2.3, 2.4, 2.6, 2.7, and 2.9) were introduced. Colony 2.1 occurs primarily in the Vesta Cedar Glade DSNA, with approximately 15 percent lying outside the DSNA on private lands. Drew and Clebsch (1995, p. 62) estimated that this colony consisted of 20,900 plants occupying an area of 1,420 m^2 (15,285 ft^2) in 1987. TDEC (2006, p. 4) estimated a total of 66,771 plants at this colony in 2005. Colonies 2.2 and 2.8 are located entirely within the Vesta Cedar Glade DSNA in glade openings that are separated by forested habitat; colony 2.2 was reported in the recovery plan to have consisted of approximately 5,000 plants occupying an area of approximately 140 m^2 (1,500 ft^2), in addition to several small clumps that Hemmerly (1976, pp. 81) established from seed. TDEC (1996, Appendix I, p. VII) estimated this colony occupied an area of 374 m^2 (4,026 ft^2) in 1996, and estimated a total of 36,634 plants at this colony in 2005 (TDEC 2006, p. 4). Colony 2.8 is located in a glade opening, approximately one-tenth of a mile southwest of colony 2.2, and TDEC (2006, p. 5) estimated a total of 18,369 plants at this colony in 2005. Colonies 2.3, 2.4, and 2.7 are located in the Cedars of Lebanon State Forest DSNA. Colony 2.3 was planted in 1983 with seeds produced in a Tennessee Valley Authority greenhouse from Vesta population stock; in 1996, TDEC (1996, Appendix I, p. VIII) observed 50 to 100 plants occupying an area of approximately 15 m^2 (161 ft^2). TDEC (2006, p. 5) estimated a total of 1,191 plants here in 2005. Colony 2.4 consisted of only 9 plants in 2005, most of which were seedlings (TDEC 2006, p. 5). Colony 2.7 is a small occurrence believed to have been introduced, but for which no reliable data prior to 2005 exist, at which time the colony consisted of an estimated 51 plants (TDEC 2006, p. 5). Colony 2.6 was planted at the entrance to Cedars of Lebanon State Park prior to 1982 and was observed in 1996 to include approximately 100 plants (TDEC 1996, Appendix I, p. XI); in 2005 there were an estimated 2,160 plants (TDEC 2006, p. 5). Colony 2.9 was introduced into a powerline right-of-way on private land adjacent to Cedars of Lebanon State Forest in 1994 and was brought to TDEC's attention in 2006, at which time there were thousands of plants (Lincicome 2006, pers. com.). Of the four secure colonies (2.1, 2.2, 2.3, and 2.8) in this population, we have data to demonstrate that three have remained stable or increased over time. We do not have historic data for colony 2.8, but the large number of individuals estimated at this colony in 2005 suggests that it should be self-sustaining. The total number of plants from the Vesta population in secured and self-sustaining colonies was estimated to be 122,965 plants in 2005. Colonies that we do not consider secure accounted for an estimated 2,220 total plants in 2005.

The Vine population (number 3 in the recovery plan) consisted of three known colonies at the time the recovery plan was completed (Service 1989, pp. 4–6). This population now consists of 11 colonies located within an area of approximately 17 km^2 (7 mi^2) in Wilson and Rutherford Counties. Three of these colonies (3.7, 3.8, and 3.9) were introduced. Approximately two-thirds of the land on which colony 3.1 is located lies within Vine Cedar Glade DSNA, with the remaining one-third on private land. Drew and Clebsch (1995, p. 62) estimated that colony 3.1 consisted of 20,200 plants occupying an area of 800 m^2 (8611 ft^2) in 1987. TDEC (1996, Appendix I, p. XI–XII) reported the plants occupied about 760 m^2 in 1996, and estimated there were 64,757 plants in 2005 (TDEC 2006, p. 4). Most of colony 3.2 is located in a site acquired by TDEC using a Recovery Land Acquisition Grant and matching State funds for addition to the State's natural areas system and was estimated in the recovery plan to contain as many as 50,000 plants (Service 1989, p. 5). Data are summarized here for four element occurrences that TDEC tracks and which make up this colony. TDEC (1996, Appendix I, p. XIII) estimated a total of 94,537 plants at this colony in 1996, occupying an area of 5,889 m^2 (63,389 ft^2); in 2005 there were an estimated 222,480 plants (TDEC 2006, p. 4). The portions of the colony that lie entirely or mostly within the protected lands contained an estimated 213,548 of these plants. Colony 3.3 is located in a privately owned site that was highly disturbed and consisted of 90 plants in 1996 (TDEC 1996, Appendix I, p. XIV). This colony contained an estimated 94 individuals in 2004, and remains a small colony of questionable viability today (TDEC 2006, p. 4) because it occurs in highly disturbed habitat. Colony 3.4 is located in the Gattinger

Glade and Barrens DSNA, which is owned by the developers of the Nashville Super Speedway who donated a conservation easement to the State of Tennessee. Clebsch (1993, p. 18) estimated there were 71,576 plants at colony 3.4 in 1993. TDEC estimated this colony occupied an area of 2,723 m^2 (23,310 ft^2) in 1996 and estimated a total of 111,249 plants at this colony in 2005 (TDEC 2006, p. 4). While damage from off-road vehicle (ORV) use has been historically observed at this colony in the past (TDEC 1996, Appendix I, p. XV), it has not been noted since the site became a DSNA, and we consider it secure. Colonies 3.3 through 3.7 occur on private land. Clebsch (1993, p. 18) estimated a total of 15,769 plants at colony 3.5 in 1993, occupying an estimated area of 669 m^2 (7,201 ft^2). TDEC (1996, Appendix I, p. XVI) observed that the density of plants had decreased at this colony in 1996, while the plants occupied a larger area—an estimated 1,483 m^2 (15,963 ft^2). TDEC (2006, p. 4) estimated a total of 21,677 plants at this colony in 2005. TDEC (1996, Appendix I, p. XVII) observed about 50 plants in a 1 m^2 (11 ft^2) area at colony 3.6 in 1996, but by 2005 the colony contained an estimated 1,346 plants. Colony 3.7 was established from seeds planted in 1978 and 1979 on private property owned by a native plant enthusiast. While many plants were killed during drought conditions in 1980, TDEC (1996, Appendix I, p. XVIII) reported that there were approximately 250 plants at this colony in 1985 and between 300 and 500 plants in 1996. TDEC (2006, p. 4) estimated a total of 14,614 plants at this colony in 2005. Colonies 3.8 and 3.9 were established from seeds planted into two sites at Cedars of Lebanon State Forest in 1990 and 1991. In 1996, TDEC (1996, Appendix I, p. XIX) counted 452 plants by surveying eight glades/barrens within the larger complex where colony 3.8 is located. TDEC (2006, p. 5) estimated a total of 15,969 plants at colony 3.8 in 2005. TDEC (1996, Appendix I, p. XX) observed approximately 200 to 300 plants occupying an estimated area of 51 m^2 (549 ft^2) at colony 3.9 in 1996; in 2005, they estimated 23,520 total plants at this colony (TDEC 2006, p. 5). We have no data prior to 2005 for colonies 3.10 and 3.11, both of which are located on private land. In 2005, TDEC (2006, p. 5) estimated a total of 46,063 plants at colony 3.10, which is located near the Nashville Super Speedway; colony 3.11 contained an estimated 16,586 plants. These data provide evidence that the four secure colonies (*i.e.,* 3.1, 3.2, 3.4, and 3.9) in this population have remained stable or increased over time. The total number of plants from the Vine population in secured and self-sustaining colonies was estimated to be 413,074 total plants in 2005. Colonies that we do not consider secure accounted for an estimated 125,281 total plants in 2005.

The Allvan population (number 4 in the recovery plan) consisted of one known colony (4.1) at the time the recovery plan was completed; two other colonies had been extirpated from this population (Service 1989, p. 6). This population now consists of two introduced colonies on public lands, as colony 4.1 has been lost to disturbance. Drew and Clebsch (1995, pp. 62–64) estimated a total of 3,700 plants at colony 4.1 in 1987, occupying an estimated area of 470 m^2 (5,059 ft^2), and noted the vegetation at this site differed from the other colonies probably as a result of human disturbance. TDEC (1996, Appendix I, p. XXI) noted the poor condition of *Echinacea tennesseensis* plants during a site visit to colony 4.1 in 1996, and observed no plants at this colony in 2005 (TDEC 2006, p. 4). Colonies 4.2 and 4.3 were established from seeds and cultivated juveniles planted on COE lands at J. Percy Priest Reservoir in the years 1989 through 1991 (TDEC 1991, pp. 5–6), and earthen berms have been constructed at both sites to deter ORV traffic and reduce visibility of these colonies. In 1996, colony 4.2 contained many robust adult plants, but few seedlings and non-flowering adults, in an area of 32 m^2 (344 ft^2) (TDEC 1996, Appendix I, p. XXII). In 2005, TDEC estimated a total of 52,997 plants at this site. This secure colony is located in the Elsie Quarterman Cedar Glade DSNA, on COE lands at J. Percy Priest Reservoir, and appears to be self-sustaining based on the increases observed over time. Colony 4.3 is located near the COE Hurricane Public Access Area. In 1996, this colony consisted of many robust adult plants and abundant juveniles in an area of about 68 m^2 (732 ft^2) (TDEC 1996, Appendix I, p. XXIII). In 2005, TDEC (2006, p. 5) estimated a total of 3,300 plants at this colony. We believe this colony is self-sustaining; however, it is vulnerable to impacts from illegal ORV access as noted above. The total number of plants in the one secured and self-sustaining colony in the Allvan population contained an estimated 52,997 plants in 2005. The colony that we do not consider secure accounted for an estimated 3,300 total plants in 2005.

The Couchville population (number 5 in the recovery plan) consisted of a single known colony spanning approximately eight privately owned tracts when the recovery plan was completed (Service 1989, p. 7). This population now consists of three natural and five introduced colonies, all located within an approximately 2.8 km^2 (1.1 mi^2) area of Davidson and Rutherford Counties on lands owned by the State of Tennessee (except for colony 5.2, which is on private land). Drew and Clebsch (1995, p. 62) estimated a total of 89,300 plants at colony 5.1 in 1987, occupying an estimated area of 13,860 m^2 (149,189 ft^2). TDEC (2006, p. 4) estimated a total of 63,026 plants at this site in 2005. Colony 5.2 is divided between two privately owned properties. The plants in this colony are found in habitats of varying quality, having been subjected to past disturbance in some places, and in 1993, vegetative plants were observed occupying an area of approximately 1,823 m^2 (19,623 ft^2) (TDEC 1996, Appendix I, p. XXV). TDEC (2006, p. 4) estimated a total of 3,360 plants at this colony in 2005. Colonies 5.3 through 5.6 were established from seed and juveniles planted at Long Hunter State Park during 1989 through 1991. TDEC (1996, Appendix I, p. XXVI) observed 428 plants at colony 5.3 in 1996, and noted that they were spread out over a wide area; in 2005, TDEC (2006, p. 4) estimated a total of 13,774 plants at this colony. TDEC (1996, Appendix I, p. XXVII) observed that a thriving population containing thousands of individuals had become established at colony 5.4 by 1996, and that the plants north of the road dividing this colony occupied an area of 2,153 m^2 (23,175 ft^2); in 2005, TDEC (2006, p. 5) estimated a total of 7,397 and 8,460 plants were on the north and south sides of the road, respectively. Colony 5.5 consisted of less than 200 total plants occupying an estimated area of 53 m^2 (570 ft^2) in 1996 (TDEC 1996, Appendix I, pp. XXVIII–XXIX); in 2005, there were an estimated 11,143 plants (TDEC 2006, p. 4). Colony 5.6 consisted of approximately 2,000 plants occupying an area of 51 m^2 (549 ft^2) in 1996 (TDEC 1996, Appendix I, pp. XXIX–XXX); in 2005, there were an estimated 7,251 plants (TDEC 2006, p. 5). Colony 5.7, for which no historic monitoring data are available, is the only naturally occurring colony at Long Hunter State Park. TDEC (2006, p. 4) estimated that a total of 146 plants were found here in 2005. Colony 5.8 was established in 2000 at the Fate Sanders Barrens DSNA, located on COE lands at J. Percy Priest Reservoir. This colony is located approximately 3.5 km (2.8 mi) southeast of colony 5.3 in the Couchville population. TDEC planted

199 plants into two areas at this site in 2000 (Lincicome 2008, pers. com.) and estimated a total of 866 plants at this colony in 2005 (TDEC 2006, p. 5). The data above demonstrate that the secure colonies (5.1, 5.4, 5.6, and 5.8) in the Couchville population are self-sustaining based on stable or increasing numbers over time. In addition, although the number of plants in colony 5.1 decreased between 1987 and 2005, we conclude that colony 5.1 is secured and self-sustaining for the foreseeable future due to the large number of individuals at this site persisting over a 20-year period. The total number of plants from the Couchville population in secured and self-sustaining colonies was estimated to be 87,000 total plants in 2005. Colonies that we do not consider secure accounted for an estimated 28,423 total plants in 2005.

The Stones River National Battlefield population (i.e., population 6, not included in the recovery plan) consists of three colonies established through introductions into an area that is now a DSNA. Colony 6.1 was established from seeds introduced by Hemmerly in 1970 (1976, pp. 10, 81), as part of investigations into seedling survival under field conditions. This colony consists of two groupings of plants, one of which consisted of 3,880 plants and the other 28 plants in 1995; the colony occupied an area of 39 m^2 (420 ft^2) in 1996 (TDEC 1996, Appendix I, p. XXXI). TDEC (2006, p. 4) estimated a total of 21,729 plants at this colony in 2005. Colonies 6.2 and 6.3 are thought to have been established by a neighbor of the battlefield in the mid-1990s (Hogan 2008, pers. com.) and consisted of 134 and 401 plants, respectively, in 1995 (TDEC 1996, Appendix I, p. XXXII). In 2005, TDEC (2006, p. 4) estimated that there were 2,031 plants at colony 6.2 and 7,303 plants at colony 6.3. The total number of plants estimated in the Stones River National Battlefield population in 2005 was 31,063 total plants, all in secured and self-sustaining colonies.

Numerous partners are involved in managing *Echinacea tennesseensis* populations on their lands. TDEC compared management options at the Vesta Cedar Glade DSNA, including mowing, discing, burning, and application of selective herbicides for removal of grasses (Clebsch 1993, pp. 2–8). TDEC and TNC have used grazing of goats, mechanical removal, and herbicide applications to control woody species encroachment on the margins of cedar glade openings at Mount View Glade DSNA (TDEC 2003, pp. 4–9). TDEC applies prescribed fire or mechanical removal, as needed and within constraints imposed by locations within the urban interface, to control woody species, including the invasive exotic privet (*Ligustrum sp.*), at many DSNAs where *E. tennesseensis* occurs; these include Mount View Glade, Vesta Cedar Glade, Vine Cedar Glade, Cedars of Lebanon State Forest Natural Area, Gattinger's Cedar Glade and Barrens, Elsie Quarterman Cedar Glade, Fate Sanders Barrens, and Couchville Cedar Glade and Barrens. TDEC works with the Tennessee Division of Forestry (TDF) to ensure that colonies in the Cedars of Lebanon State Forest, which includes three DSNAs, receive necessary management and collaborates with TDF to implement all prescribed burns that are conducted on DSNAs. TDEC also has cooperated with COE on construction of fences or earthen berms around sites at J. Percy Priest Reservoir that have been threatened by urban encroachment and illegal ORV use. The NPS monitors the introduced population at the Stones River National Battlefield and controls woody plant encroachment and vegetation succession in the glade openings where the colonies occur, as necessary.

Because TDEC and other entities have monitored *Echinacea tennesseensis* populations many times since the time of listing and have managed colonies on protected lands to minimize threats from vegetation succession and ORV use, and will continue to do so in the foreseeable future, we consider this recovery action completed.

Recovery Action (6): Conduct Public Education Projects

Echinacea tennesseensis was featured in newspaper (Paine 2002, p. 6B) and magazine (Simpson and Somers 1990, pp. 14–16; Campbell 1992, p. 32; Daerr 1999, p. 50) articles to educate the general public about the species, the cedar glade ecosystem it occupies, and the conservation efforts directed towards them. The Service published "An Educator's Guide to the Threatened and Endangered Species and Ecosystems of Tennessee," which includes instructional materials about the cedar glades of middle Tennessee and two federally listed plant species found in the glades, *E. tennesseensis* and *Astragalus bibullatus* (Pyne's ground-plum) (Service no date, pp. 50–53). TDEC personnel periodically lead guided wildflower walks in the cedar glades DSNAs and educate the public about *E. tennesseensis* and other Federal and State listed plant species during those walks. In 2000, TDEC published 10,000 copies of an educational poster featuring Tennessee's rare plants, including *E. tennesseensis.* Because numerous public education projects have been conducted, we consider this recovery action completed.

Summary of Factors Affecting the Species

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for listing, reclassifying, or removing species from the Federal Lists of Endangered and Threatened Wildlife and Plants. "Species" is defined by the Act as including any species or subspecies of fish or wildlife or plants, and any distinct vertebrate population segment of fish or wildlife that interbreeds when mature (16 U.S.C. 1532(16)). Once the "species" is determined we then evaluate whether that species may be endangered or threatened because of one or more of the five factors described in section 4(a)(1) of the Act. For species that are already listed as endangered or threatened, the analysis of threats must include an evaluation of both the threats currently facing the species, and the threats that are reasonably likely to affect the species in the foreseeable future following the delisting or downlisting and the removal or reduction of the Act's protections.

We must consider these same five factors in reclassifying or delisting a species. We may delist a species according to 50 CFR 424.11(d) if the best available scientific and commercial data indicate that the species is neither endangered nor threatened for the following reasons: (1) The species is extinct; (2) the species has recovered and is no longer endangered or threatened (as is the case for *Echinacea tennesseensis*); and/or (3) the original scientific data used at the time the species were classified were in error.

A species is "endangered" if it is in danger of extinction throughout all or a "significant portion of its range" and is "threatened" if it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range. The word "range" is used here to refer to the range in which the species currently exists, and the word "significant" refers to the value of that portion of the range being considered to the conservation of the species.

The Act does not define the term "foreseeable future." However, in a January 16, 2009, memorandum addressed to the Acting Director of the Service from the Office of the Solicitor, Department of the Interior, concluded, " * * * as used in the [Act], Congress intended the term 'foreseeable future' to describe the extent to which the Secretary can reasonably rely on

predictions about the future in making determinations about the future conservation status of the species" (U.S. Department of the Interior 2009). "Foreseeable future" is determined by the Service on a case-by-case basis, taking into consideration a variety of species-specific factors such as lifespan, genetics, mating systems, demography, threat projection timeframes, and environmental variability.

In considering the foreseeable future as it relates to the status of *Echinacea tennesseensis,* we defined the "foreseeable future" to be the extent to which, given the amount and substance of available data, events, or effects can and should be anticipated, or the threats reasonably extrapolated. We considered the historical data to identify any relevant existing threats acting on the species, ongoing conservation efforts, data on species abundance and persistence at individual sites since the time of listing, identifiable informational gaps and uncertainties regarding residual and emerging threats to the species, as well as population status and trends, its life history, and then looked to see if reliable predictions about the status of the species in response to those factors could be drawn. We considered the historical data to identify any relevant existing trends that might allow for reliable prediction of the future (in the form of extrapolating the trends). We also considered whether we could reliably predict any future events (not yet acting on the species and, therefore, not yet manifested in a trend) that might affect the status of the species, recognizing that our ability to make reliable predictions into the future is limited by the variable quantity and quality of available data.

Following a rangewide threats analysis we evaluate whether *Echinacea tennesseensis* is threatened or endangered in any significant portion(s) of its range.

Factor A. Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

The final rule to list *Echinacea tennesseensis* as endangered (44 FR 32604; June 6, 1979) identified the following habitat threats: habitat loss due to residential and recreational development and succession of cedar glade communities in which the species occurred.

Losses of cedar glade habitat and colonies of *Echinacea tennesseensis* to residential development have posed a significant threat to *E. tennesseensis.* At the time of listing, one population of *E. tennesseensis* had been reduced in size due to housing construction and another was destroyed during the construction of a trailer park. The three extant occurrences at that time were all located on private lands, one of which was imminently threatened by surrounding residential development. This Davidson County occurrence has since been protected as a DSNA. Approximately two-thirds of the Wilson County occurrence that was on public lands is now a DSNA, and one-third remains on private lands. The Rutherford County occurrence was located in a gravel parking lot of a commercial property and has been destroyed. Since the time of listing, protection of natural colonies on publicly owned conservation lands and establishment of additional colonies through introductions have effectively diminished the threat residential development once posed to the survival of *E. tennesseensis.*

The final listing rule for *Echinacea tennesseensis* described recreational development as a threat facing the Davidson County (*i.e.,* Mount View) population, but did not address the specific nature of the recreational development. The Mount View, Allvan, and Couchville populations occur in close proximity to J. Percy Priest Reservoir, construction of which was completed in 1967. It is possible that development of recreational facilities following completion of the reservoir presented a threat to *E. tennesseensis* or cedar glade habitats. However, four of the secure and self-sustaining colonies (*i.e.,* colonies 1.2, 1.4, 4.2, and 5.8) are located within the now-protected lands buffering the reservoir, three of which were designated as Environmentally Sensitive Areas in the J. Percy Priest 2007 Master Plan Update (Corps 2007, pp. 3–1 to 4–3). Therefore, recreational development no longer poses a threat to the survival of *E. tennesseensis.*

There are now 27 colonies, distributed among the six populations of *Echinacea tennesseensis,* which occur entirely or primarily on conservation lands in either State or Federal ownership. The lone exception to public ownership of these conservation lands is the Gattinger Glade DSNA, which is managed by TDEC but privately owned and protected under a conservation easement. We consider 19 of these colonies to be secure and self-sustaining. Sixteen colonies, all but two of which are secure, are located entirely or primarily within DSNAs that were designated at various times between 1974 and 2009. TDEC manages most of these DSNAs, in some cases cooperatively with TDF, for the purpose of conserving *E. tennesseensis* and the cedar glades and barrens ecosystem on which it depends. All but one of these DSNAs lie within or adjacent to State or Federal conservation lands that provide complementary conservation benefits by maintaining functioning ecosystems within which these colonies occur and harboring additional protected colonies of *E. tennesseensis.*

Providing a large, protected cedar glade and forest ecosystem connected to the Vesta Cedar Glade, Vine Cedar Glade, and Cedars of Lebanon State Forest DSNAs, the non-DSNA lands in the Cedars of Lebanon State Forest also contain three colonies. An additional colony is located at the Cedars of Lebanon State Park, which is adjacent to the Cedars of Lebanon State Forest. Long Hunter State Park contains six colonies and provides a functioning ecosystem buffer to the Couchville Cedar Glade and Barrens DSNA. COE lands at J. Percy Priest Reservoir provide habitat for three colonies in addition to the colonies in the Elsie Quarterman Cedar Glade and Fate Sanders Barrens DSNAs that lie within these lands. The Gattinger Cedar Glade is the only DSNA on private land that contains a colony of *Echinacea tennesseensis.* While this property is not buffered by other public lands, it lies within a large tract of land owned by the Nashville Super Speedway, which has been a partner in the conservation of *E. tennesseensis.* The three colonies at Stones River National Battlefield are included among the 16 within DSNAs, and lie within a protected buffer provided by NPS lands.

Given the statutory nature of the DSNA designation and TDEC's demonstrated commitment to protecting lands maintaining the quality of habitats in the DSNAs, we find that the colonies located in DSNAs or in acquired lands that will be added to Tennessee's natural area system will receive adequate long-term protection and necessary management to control vegetation succession and disturbance from human activities. Although colonies 2.4 and 2.7 contain an estimated 9 and 51 individuals, respectively, are threatened by ORV use, and lack long-term protection and management, impacts to these two colonies will not have a significant effect on the status of the species, as they represent less than one percent of the Vesta population. Delisting *Echinacea tennesseensis* is not likely to weaken TDEC's commitment to the conservation of these DSNAs, several of which harbor one or more federally listed plant species other than *E. tennesseensis.*

We have identified five colonies on public lands outside of DSNAs that we consider secure and that contribute to

the improved status of this plant (*i.e.,* colonies 1.2, 1.4, 3.9, 5.4, and 5.6). These colonies are described under Recovery Action (5) in the Recovery Plan Implementation section, above.

However, illegal ORV activity remains a threat to this species at three colonies on public lands (colonies 2.4, 2.7, and 4.3), which we have not counted among the 19 secure, self-sustaining colonies. TDEC has worked to reduce this threat in several DSNAs by constructing barbed wire fences and limestone barriers. The COE has also extended efforts in the form of constructing fences and/or earthen berms near three colonies on lands at J. Percy Priest Reservoir to reduce this threat. Damage from ORV activity was noted by TDEC (1996, Appendix I) at only one of the 9 colonies located exclusively on private lands that are not under recovery protection agreements, none of which were counted among the 19 secure, self-sustaining colonies in this rule. While illegal ORV use remains a potential threat in certain colonies of *Echinacea tennesseensis* (TDEC 1996, p. 21 and Appendix I), we do not have data to suggest that such activity is occurring at a magnitude to cause *E. tennesseensis* to meet the definition of either an endangered or a threatened species throughout its range.

The threat of habitat loss or modification in the form of ORV activity has been observed at a total of four colonies. Three of the colonies (colonies 2.4, 2.7, and 4.3) are located on public land, and the fourth colony is located on private land (TDEC 1996, Appendix I). Recovery protection agreements are lacking at nine colonies that exist solely on private lands, leaving them vulnerable to habitat disturbance. However, we believe that *Echinacea tennesseensis* is neither endangered nor threatened as a result of habitat loss or modification because there are 19 secure and self-sustaining colonies distributed among six geographically defined populations. TDEC coordinates management of these colonies to reduce threats to *E. tennesseensis* and its habitat in cooperation with other partners. Examples of these management activities were provided under Recovery Action (5) in the Recovery Plan Implementation section, above.

Summary of Factor A: Although ORV activity has the potential to negatively affect the habitat of four *Echinacea tennesseensis* colonies, we consider this to be a low-level threat and we do not have any information to indicate that this is currently, or likely to be, a significant threat that would cause *E. tennesseensis* to meet the definition of either an endangered or a threatened species. We expect that the lands containing the 19 secure and self-sustaining colonies, which accounted for approximately 83 percent of the total individuals estimated to exist in 2005, will remain permanently protected and that they will be managed to maintain cedar glade habitat. We anticipate that these conditions will remain essentially the same in the foreseeable future due to the adequate regulatory mechanisms in place to protect suitable habitat for *E. tennesseensis* in the majority of its range (see discussion under Factor D—Inadequacy of Existing Regulatory Mechanisms, below). In conclusion, we find that the present or threatened destruction, modification, or curtailment of its habitat or range is no longer a threat to the species throughout its range, both now and in the foreseeable future.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The final rule to list *Echinacea tennesseensis* as endangered (44 FR 32604; June 6, 1979) identified collection for commercial and recreational purposes as a threat to the species. Limited digging, presumably for horticultural purposes, has been historically observed at five colonies of *E. tennesseensis,* three (colonies 5.3, 5.5, and 5.6) of which are located in high visibility areas within Long Hunter State Park (TDEC 1996, p. 21). We do not consider these three colonies, or a fourth (colony 3.5) located on private land, to be secure for the purposes of this proposed rule. However, we do consider the fifth colony, colony 4.2, to be secure because it became a DSNA in 1998, and no evidence of digging at this site has been recorded since 1996.

Echinacea tennesseensis that originated from natural populations, but is now grown from seed or vegetative propagules produced in nurseries, is available for commerce from one nursery and for sale by multiple nurseries only within the State of Tennessee. Thus, a Service interstate permit under section 10(a)(1)(A) of the Act is not required. TDEC regulates commerce of plants listed as endangered by the State of Tennessee through issuance of State permits for this purpose, as authorized by the Tennessee Rare Plant Protection Act of 1985 (T.C.A. 11–26–201). There are also at least two cultivars of *E. tennesseensis,* which are of hybrid origin, now available for interstate commerce and easily found on the internet. As hybrids, the prohibitions on interstate commerce under section 9 of the Act do not apply to these cultivars, so a Service interstate permit under section 10(a)(1)(A) of the Act is not required. The prohibitions in the Tennessee Rare Plant Protection Act also do not apply to cultivars.

Native Americans have long used genus *Echinacea* for medicinal purposes and it is commercially available as a popular homeopathic supplement. However, *E. tennesseensis* is not included in the primary species used in commercial medicinal applications and studied for their medicinal properties (Senchina *et al.* 2006, p. 1). We are not aware of collections of this species being taken for this purpose and do not believe this poses a threat to this species currently or into the foreseeable future.

Summary of Factor B: Echinacea tennesseensis and hybrids displaying the attractive traits of the species are readily available commercially. Collection or intentional killing of specimens has been observed in the past at only five colonies, one of which we counted as secure in our analysis for this proposed delisting rule because this colony became a DSNA in 1998, and no evidence of digging at this site has been recorded since 1996.

In addition, *E. tennesseensis* is not among the primary species of *Echinacea* used for medicinal applications. In conclusion, we find that overutilization for commercial, recreational (*i.e.,* gardening), scientific, or educational purposes is no longer a threat to *E. tennesseensis* throughout its range, both now and for the foreseeable future.

Factor C. Disease or Predation

The June 6, 1979, listing rule for *Echinacea tennesseensis* (44 FR 32604) stated that light grazing occurred at colony 3.2 but acknowledged that the degree of threat, if any, posed by this grazing was uncertain. A robust population of *E. tennesseensis* remains at this site today, much of which TDEC acquired for addition to Tennessee's natural area system. Deer browse has been identified as a potential threat at the three colonies in Stones River National Battlefield (TDEC 1996, Appendix I, pp. XXXI–XXXIII) and at colony 5.5 (TDEC 2007, p. 5). However, we have no data to suggest that such browsing threatens these colonies, which have persisted since being established by introductions 10 or more years ago.

Summary of Factor C: Although grazing or deer browse do affect *Echinacea tennesseensis,* we have no data to suggest that either grazing or deer browse are a threat to any colonies of *E. tennesseensis* or that they will become a threat now or within the foreseeable future. In conclusion, we

find that neither disease nor predation is a threat to *E. tennesseensis* throughout its range, both now and for the foreseeable future.

Factor D. Inadequacy of Existing Regulatory Mechanisms

When *Echinacea tennesseensis* was listed, the State of Tennessee had no laws protecting rare plants. Therefore, the final rule to list *E. tennesseensis* as endangered (44 FR 32604; June 6, 1979) identified the lack of State protections as a threat to the species. *Echinacea tennesseensis* is now listed as endangered by the State of Tennessee and is protected under the Tennessee Rare Plant Protection Act of 1985 (T.C.A. 11–26–201), which forbids persons from knowingly uprooting, digging, taking, removing, damaging, destroying, possessing, or otherwise disturbing for any purpose, any endangered species from private or public lands without the written permission of the landowner. While this statute does not forbid the destruction of *E. tennesseensis* or its habitat, neither does the Act afford such protection to listed plants. Furthermore, those colonies located in DSNAs are afforded additional protection by the State of Tennessee's Natural Area Preservation Act of 1971 (T.C.A. 11–1701), which forbids removal of State endangered and threatened species from DSNAs but also protects these areas from vandalism.

While it is possible that the State of Tennessee could determine that *Echinacea tennesseensis* should be removed from their State endangered plant list if the species is removed from the Federal List of Endangered and Threatened Plants, we believe that the DSNA protected status of the lands where the 19 secure, self-sustaining colonies currently exist will continue to provide adequate regulatory protection for those colonies in the foreseeable future, including protection from threats due to habitat destruction and modification.

Summary of Factor D: We do not have any information to indicate that the existing regulatory mechanisms in absence of the Act's protection would be inadequate to address the remaining, low-level threats to the species from habitat destruction or modification (see Factor A discussion above). Therefore, we find that lack of regulatory protection is no longer a threat to *E. tennesseensis.* In conclusion, we find that the currently existing regulatory mechanisms described above are adequate, and they will remain adequate to protect *E. tennesseensis* and its habitat in the majority of its range now and within the foreseeable future.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

As discussed under the Factor A section above, the June 6, 1979, listing rule for *Echinacea tennesseensis* (44 FR 32604) identified vegetation succession as a threat to the species and the cedar glades it depends on for its survival. A status survey for the species, completed in 1996 (TDEC 1996, p. 22), did not address this threat in its analysis of factors affecting the survival of the species, but it did recommend controlling vegetation succession at some sites in the survey's appendix containing population and site status reports. TDEC has developed a program for managing vegetation succession and other threats to cedar glades on DSNAs inhabited by *E. tennesseensis* and two other federally listed species, and continues to work cooperatively with TDF, Tennessee State Parks, and COE to manage potential threats in habitats where colonies exist on properties belonging to these agencies. Further, we are not aware of any colonies of *E. tennesseensis* that have been lost to vegetation succession.

The TDEC (1996, p. 2) identified low levels of genetic variability in *Echinacea tennesseensis* as a threat but did not report any deleterious effects of diminished genetic variability, such as inbreeding depression, that would indicate this factor poses a threat to this species. Baskauf *et al.* (1994, p. 186) documented low levels of genetic variability in *E. tennesseensis,* but also observed that this species is not devoid of genetic variability and is evidently well adapted to its cedar glade habitat. They noted that given the relatively large sizes of many of the naturally occurring populations, random genetic drift should not erode genetic variability in *E. tennesseensis* very rapidly. They suggested that dramatic population fluctuations or extinction and colonization events could have occurred historically and eroded genetic variability (Baskauf *et al.* 1994, p. 186). However, it is possible that this species might never have possessed high levels of genetic variability (Walck *et al.* 2002, p. 62).

Reduction of genetic diversity could pose a threat to viability of the introduced colonies, as they could be subject to losses in genetic variability that result from establishing colonies from a subset of the total genetic structure found in the species (i.e., the founder effect) (Allendorf and Luikart 2007, p. 129). We have no information concerning the genetic structure of introduced colonies compared to naturally occurring ones, but this could be a factor to investigate if introduced colonies are found to be less stable than natural colonies through future monitoring. At this time, however, we do not believe that low genetic variability threatens the continued existence of *E. tennesseensis* now or within the foreseeable future.

Climate Change

The Intergovernmental Panel on Climate Change (IPCC) concluded that warming of the climate system is unequivocal (IPCC 2007a, p. 30). Numerous long-term changes have been observed including changes in arctic temperatures and ice; widespread changes in precipitation amounts, ocean salinity, and wind patterns; and occurrences of extreme weather including droughts, heavy precipitation, heat waves and the intensity of tropical cyclones (IPCC 2007b, p. 7). Based on scenarios that do not assume explicit climate policies to reduce greenhouse gas emissions, global average temperature is projected to rise by 2–11.5 °F by the end of this century (relative to the 1980–1999 time period) (Karl *et al.* 2009, p. 24). Species that are dependent on specialized habitat types, limited in distribution, or the extreme periphery of their range will be most susceptible to the impacts of climate change. Such species could currently be found at high elevations, at extreme northern/southern latitudes, dependent on delicate ecological interactions, or sensitive to nonnative competitors. While continued change is certain, the magnitude and rate of change is unknown in many cases.

As stated above, *Echinacea tennesseensis* is only found in limestone barrens and cedar glades habitats of the Central Basin, Interior Low Plateau Physiographic Province, in Davidson, Rutherford, and Wilson Counties in Tennessee. Within this ecosystem, *E. tennesseensis* inhabits both xeric (dry) communities, where there is no soil or soil depth less than 5 cm (2 in.), and subxeric (moderately dry) communities on soils deeper than 5 cm (2 in.).

Estimates of the effects of climate change using available climate models lack the geographic precision needed to predict the magnitude of effects at a scale small enough to discretely apply to the range of *Echinacea tennesseensis.* However, data on recent trends and predicted changes for the Southeast United States (Karl *et al.* 2009, pp. 111–116) provide some insight for evaluating the potential threat of climate change to *E. tennesseensis.* Since 1970, the average annual temperature of the region has increased by about 2 °F, with

the greatest increases occurring during winter months. The geographic extent of areas in the Southeast region affected by moderate to severe spring and summer drought has increased over the past three decades by 12 and 14 percent, respectively (Karl *et al.* 2009, p. 111). These trends are expected to increase.

Rates of warming are predicted to more than double in comparison to what the Southeast has experienced since 1975, with the greatest increases projected for summer months. Depending on the emissions scenario used for modeling change, average temperatures are expected to increase by 4.5 °F to 9 °F by the 2080s (Karl *et al.* 2009, pp. 111). While there is considerable variability in rainfall predictions throughout the region, increases in evaporation of moisture from soils and loss of water by plants in response to warmer temperatures are expected to contribute to increased frequency, duration, and intensity of droughts (Karl *et al.* 2009, pp. 112).

Despite the observations of Drew and Clebsch (1995, p. 66) that seedlings had an approximately 50-percent probability of dying during the drought conditions that occurred during their first year of study, we believe there is biological and historical evidence to suggest that *Echinacea tennesseensis* is well-adapted to endure predicted effects of climate change. First, Drew and Clebsch (1995, p. 66) found that stage-specific mortality rates during the drought conditions of their first year of study for non-reproductive *E. tennesseensis* plants with a cumulative leaf length greater than 30 cm (12 in) (*i.e.,* non-seedling, vegetative plants) and plants that were reproductively active ranged from 17 to 31 percent, considerably lower than rates observed in seedlings. Second, Hemmerly (1976, p. 12) found that mature plants possessed several roots averaging 38.4 cm (15.1 in.) in length and extending an average depth of 23.1 cm (9.1 in.) into the soil, often branching horizontally after reaching an impenetrable rock layer. These observations suggest that while seedlings face higher risks of mortality in drought conditions, this species possesses biological characteristics that increase drought resistance in later life-history stages. That non-seedling life stages of *E. tennesseensis* are more resilient to drought than seedlings is supported by Drew and Clebsch's (1995, p. 67) observation of demographic patterns in flowering individuals. During 1988, 41 percent of the plants that had flowered during 1987 failed to do so, presumably influenced by drought. However, 68 percent of the plants that failed to flower during 1988 produced flowers during 1989, when annual rainfall levels increased. This ability to vary flower production in relation to annual rainfall levels, combined with its apparently long-lived habit (individual plants live up to at least 6 years, but the maximum lifespan is probably much longer (Baskauf 1993, p. 37)), should enable *E. tennesseensis* to remain viable through periods of drought.

Studies examining the influence of genetic, ecological, and physiological factors on the distribution of *Echinacea tennesseensis* have not found sufficient differences between this species and more widespread congeners (other species belonging to the genus *Echinacea*) to explain its endemism in the cedar glades of middle Tennessee based on these factors alone (Baskin *et al.* 1997, p. 385; Baskauf and Eickmeier 1994, p. 963; Snyder *et al.* 1994, p. 64). Rather, it has been suggested that historical and ecological factors contributed to the evolution of this species and its subsequent restriction to cedar glade habitats in middle Tennessee (Baskin *et al.* 1997, p. 385). Baskin *et al.* (1997, pp. 390–391) suggested that an ancestral form of *E. tennesseensis* migrated to and became established in middle Tennessee during the Hypsithermal Interval (*i.e.,* the period of greatest post-glacial warming, ca. 8,000 to 5,000 years before present), and that as temperatures became cooler, the only members of this ancestral taxon that survived were those growing in the cedar glades of the region—*i.e.,* the plants that eventually gave rise to *E. tennesseensis.*

While predictions of increased drought frequency, intensity, and duration suggest that seedling survival could be a limiting factor for *Echinacea tennesseensis,* the species possesses other biological traits (*i.e.,* long life span, interannual reproductive variability) to provide resilience to this threat. Further, predicted climate changes for the Southeast United States could, similar to what is believed to have taken place during the Hypsithermal Interval (Delcourt *et al.* 1986, p. 135), lead to an expansion of openings within forested areas of middle Tennessee, potentially increasing the area occupied by cedar glade communities. This presumably would increase the amount of suitable habitat available for *E. tennesseensis.* Based on these factors and the fact that we have no evidence that climate changes observed to date have had any adverse impact on *E. tennesseensis* or its habitat, we do not believe that climate change is a threat to *E. tennesseensis* now or within the foreseeable future.

Summary of Factor E: Because (1) Management activities take place to prevent the loss of 19 secure *Echinacea tennesseensis* colonies; (2) 31 colonies are considered self-sustaining, as measured by persistence and demographic stability over time (despite low levels of genetic variation within the species), and 19 of these 31 colonies are considered secure; (3) there is biological and historical evidence to suggest that *E. tennesseensis* is well-adapted to endure predicted effects of climate change; and (4) we have no evidence that climate changes observed to date have had any adverse impact on *E. tennesseensis* or its habitat, we find that the other natural or manmade factors considered here are no longer a threat to *E. tennesseensis* and are not likely to become so in the foreseeable future.

Conclusion of the 5-Factor Analysis

We have carefully assessed the best scientific and commercial data available and have determined that *Echinacea tennesseensis* is no longer endangered or threatened throughout all of its range. We must next determine if the threats to *E. tennesseensis* are non-uniformly distributed such that populations in one portion of its range experience higher level of threats than populations in other portions of its range. When considering the listing status of the species, the first step in the analysis is to determine whether the species is in danger of extinction or likely to become endangered throughout all of its range. For instance, if the threats on a species are acting only on a portion of its range, but the effects of the threats are such that they place the entire species in danger of extinction or likely to become endangered, we would list the entire species.

Significant Portion of the Range

Data indicate that numbers of *Echinacea tennesseensis* and protections for its habitat have significantly increased since it was listed under the Act. As identified above, only ORV use, illegal or otherwise, potentially poses a known threat to *E. tennesseensis.* While disturbance from ORV use has been observed in the past and remains unaddressed at 4 colonies on publicly and privately owned lands harboring *E. tennesseensis* (*i.e.,* colonies 2.4, 2.7, 4.3 and 1 privately owned colony), these 4 colonies accounted for only 2 percent of the species' total distribution in 2005. Most of the largest colonies are located in DSNAs and are protected from this

threat by fences or other barriers that TDEC has constructed and maintained. At the time the 1989 recovery plan was written, there were five extant populations ranging in size from approximately 3,700 to 89,000 plants and consisting of one to three colonies each (Clebsch 1988, p. 14; Service 1989, p. 2). There were an estimated total of 146,000 individual plants in 1989 (Drew and Clebsch 1995, p. 62). Recovery efforts have secured habitat for 19 colonies that are self-sustaining and distributed among six geographically defined populations. These 19 secured, self-sustaining colonies accounted for an estimated 761,055 individual plants in 2005, or approximately 83 percent of the total species' distribution; colonies that we do not consider secure accounted for 159,224 individual plants, or approximately 17 percent of the total species' distribution. Therefore, while there is potential for ORV use to impact certain colonies, should that threat materialize, it is not a significant impact to the species as a whole. The number of secured plants and colonies is adequate to ensure that Factor A is no longer a threat to the species overall. Thus, destruction and modification of habitat from ORV use is not a threat to the species throughout all or a significant portion of its range now or into the foreseeable future.

In conclusion, major threats to *Echinacea tennesseensis* have been reduced, managed, or eliminated. Although the potential threats to *E. tennesseensis* habitat are fairly uniform throughout the range of the species, they are more pronounced on privately owned lands where the species occurs. However, we do not consider threats to these unsecured colonies to affect a significant portion of the range of this species. Therefore, we have determined that none of the existing or potential threats, either alone or in combination with others, warrant listing *E. tennesseensis* as endangered in any significant portion of its range or that these threats are likely to cause *E. tennesseensis* to become endangered within the foreseeable future in any significant portion of its range.

On the basis of this evaluation, we believe *E. tennesseensis* no longer requires the protection of the Act, and we propose to remove *E. tennesseensis* throughout its range from the Federal List of Endangered and Threatened Plants (50 CFR 17.12(h)).

Effects of This Proposed Rule

This rule revises 50 CFR 17.12(h) to remove *Echinacea tennesseensis* from the Federal List of Endangered and Threatened Plants. This rule would not affect 50 CFR 17.95 because critical habitat was never designated for this species.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered plants. The prohibitions under section 9(a)(2) of the Act make it illegal for any person subject to the jurisdiction of the United States to import or export, transport in interstate or foreign commerce in the course of a commercial activity, sell or offer for sale in interstate or foreign commerce, remove and reduce *Echinacea tennesseensis* to possession from areas under Federal jurisdiction, or remove, cut, dig up, or damage or destroy *E. tennesseensis* on any other area in knowing violation of any State law or regulation such as a trespass law. Section 7 of the Act requires that Federal agencies consult with us to ensure that any action authorized, funded, or carried out by them is not likely to jeopardize the species' continued existence. If this proposed rule is finalized, it would revise 50 CFR 17.12 to remove (delist) *E. tennesseensis* from the Federal List of Endangered and Threatened Plants, and these prohibitions would no longer apply. Delisting *E. tennesseensis* is expected to have positive effects in terms of increasing management flexibility by State and Federal governments.

Post-Delisting Monitoring

Section 4(g)(1) of the Act requires the Secretary of the Interior, through the Service, to implement a system, in cooperation with the States, to monitor for not less than 5 years the status of all species that are delisted due to recovery. Post-delisting monitoring refers to activities undertaken to verify that a species delisted due to recovery remains secure from the risk of extinction after the protections of the Act no longer apply. The primary goal of post-delisting monitoring is to monitor the species to ensure that its status does not deteriorate, and if a decline is detected, to take measures to halt the decline so that proposing to list it as endangered or threatened is not again needed. If at any time during the monitoring period, data indicate that protective status under the Act should be reinstated, we can initiate listing procedures, including, if appropriate, emergency listing. At the conclusion of the monitoring period, we will review all available information to determine if relisting, the continuation of monitoring, or the termination of monitoring is appropriate.

Section 4(g) of the Act explicitly requires cooperation with the States in development and implementation of post-delisting monitoring programs, but we remain responsible for compliance with section 4(g) and, therefore, must remain actively engaged in all phases of post-delisting monitoring. We also seek active participation of other entities that are expected to assume responsibilities for the species' conservation after delisting. In August 2008, TDEC agreed to be a cooperator in the post-delisting monitoring of *Echinacea tennesseensis.*

We have prepared our Draft Post-Delisting Monitoring Plan for Tennessee Purple Coneflower (*Echinacea tennesseensis*) (Plan) (Service 2009). The draft plan:

(1) Summarizes the species' status at the time of delisting;

(2) Defines thresholds or triggers for potential monitoring outcomes and conclusions;

(3) Lays out frequency and duration of monitoring;

(4) Articulates monitoring methods, including sampling considerations;

(5) Outlines data compilation and reporting procedures and responsibilities; and

(6) Proposes a post-delisting monitoring implementation schedule, including timing and responsible parties.

Colonies of *Echinacea tennesseensis* selected for post-delisting monitoring are indicated with an asterisk in Table 1 of this proposed rule and in the draft plan.

Concurrent with this proposed delisting rule, we announce the draft plan's availability for public review. The draft post-delisting monitoring plan can be viewed in its entirety at: *http://www.fws.gov/cookeville/.* Copies can also be obtained from the U.S. Fish and Wildlife Service, Cookeville Field Office, Tennessee (see **FOR FURTHER INFORMATION CONTACT** section). We seek information, data, and comments from the public regarding *Echinacea tennesseensis* and the post-delisting monitoring strategy. We are also seeking peer review of this draft plan concurrently with the proposed rule comment period. We anticipate finalizing this plan, considering all public and peer review comments, prior to making a final determination on the proposed delisting rule.

Peer Review

In accordance with our policy published in the **Federal Register** on July 1, 1994 (59 FR 34270), and the OMB's Final Information Quality Bulletin for Peer Review, dated December 16, 2004, we will solicit the expert opinions of at least three appropriate and independent specialists regarding the science in this proposed

rule and the draft post-delisting monitoring plan. The purpose of such review is to ensure that we base our decisions on scientifically sound data, assumptions, and analyses. We will send peer reviewers copies of this proposed rule and the draft post-delisting monitoring plan immediately following publication in the **Federal Register**. We will invite peer reviewers to comment, during the public comment period, on the specific assumptions and conclusions in this proposed delisting and draft post-delisting monitoring plan. We will summarize the opinions of these reviewers in the final decision documents, and we will consider their input and any additional information we receive as part of our process of making a final decision on this proposal and the draft post-delisting monitoring plan. Such communication may lead to a final decision that differs from this proposal.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Paperwork Reduction Act of 1995

OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), require that Federal agencies obtain approval from OMB before collecting information from the public. The OMB regulations at 5 CFR 1320.3(c) define a collection of information as the obtaining of information by or for an agency by means of identical questions posed to, or identical reporting, recordkeeping, or disclosure requirements imposed on, 10 or more persons. Furthermore, 5 CFR 1320.3(c)(4) specifies that "ten or more persons" refers to the persons to whom a collection of information is addressed by the agency within any 12-month period. For purposes of this definition, employees of the Federal government are not included. The draft post-delisting monitoring plan does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act. It will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

National Environmental Policy Act

We have determined that we do not need to prepare an environmental assessment or environmental impact statement, as defined in the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), in connection with regulations adopted under section 4(a) of the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951), Executive Order 13175, and the Department of Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. We have determined that there are no tribal lands affected by this proposal.

References Cited

A complete list of references cited is available upon request from the Cookeville Field Office (see **FOR FURTHER INFORMATION CONTACT** section).

Author

The primary author of this document is Geoff Call, Cookeville Field Office (see **FOR FURTHER INFORMATION CONTACT** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we hereby propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

§ 17.12 [Amended]

2. Amend § 17.12 (h) by removing the entry for "*Echinacea tennesseensis*" under "FLOWERING PLANTS" from the List of Endangered and Threatened Plants.

Dated: July 29, 2010.

Wendi Weber,

Acting Deputy Director, Fish and Wildlife Service.

[FR Doc. 2010–19742 Filed 8–11–10; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FWS–R9–IA–2008–0121; [96100–1671–0000–B6]

Endangered and Threatened Wildlife and Plants; 90–Day Finding on a Petition to Delist the Tiger (Panthera tigris)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 90-day petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 90-day finding on a petition to remove the tiger (*Panthera tigris*) from the List of Endangered and Threatened Wildlife under the Endangered Species Act of 1973, as amended. We find that the petition does not present substantial scientific or commercial information indicating that removing the species from the List of Endangered and Threatened Wildlife may be warranted. Therefore, we will not initiate a status review in response to this petition. We ask the public to submit to us any new information that becomes available concerning the status of the tiger or threats to it or its habitat at any time. This information will help us monitor and encourage the conservation of this species.

DATES: The finding announced in this document was made on August 12,

2010. You may submit new information concerning this species for our consideration at any time.

ADDRESSES: This finding is available on the Internet at *http://www.regulations.gov.* Supporting documentation we used in preparing this finding is available for public inspection, by appointment, during normal business hours at the Branch of Foreign Species, Endangered Species Program, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Suite 400, Arlington, VA 22203; telephone, 703–358–2171; fax, 703–358–1735. Please submit any new information, materials, comments, or questions concerning this species or this finding to the above address.

FOR FURTHER INFORMATION CONTACT: Janine Van Norman, Chief, Branch of Foreign Species, Endangered Species Program (see **ADDRESSES**); telephone 703–358–2171; facsimile 703–358–1735. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(A) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*), requires that we make a finding on whether a petition to list, delist, or reclassify a species presents substantial scientific or commercial information indicating that the petitioned action may be warranted. We are to base this finding on information provided in the petition, supporting information submitted with the petition, and information otherwise available in our files. To the maximum extent practicable, we are to make this finding within 90 days of our receipt of the petition, and publish our notice of the finding promptly in the **Federal Register**.

Our standard for substantial scientific or commercial information within the Code of Federal Regulations (CFR) with regard to a 90-day petition finding is "that amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted" (50 CFR 424.14(b)). If we find that substantial scientific or commercial information was presented, we are required to promptly conduct a species status review, which we subsequently summarize in our 12-month finding.

Petition History

On March 5, 2005, we received a petition dated February 25, 2005, from Sarah L. Blaskey of Merrionette Park, Illinois, requesting that the tiger (*Panthera tigris*), currently listed as endangered under the Act, be removed from the List of Endangered and Threatened Wildlife. The petition clearly identifies itself as such and included the requisite identification information for the petitioner(s), as required in 50 CFR 424.14(a). This finding addresses the petition.

Previous Federal Actions

The tiger has been the subject of several Federal actions (Service 2006, pp. 1–2). In 1970, we proposed four subspecies, *Panthera tigris balica* (from Indonesia), *Panthera tigris sondaica* (from Indonesia), *Panthera tigris virgata* (from Russia, Afghanistan, and Iran), and *Panthera tigris sumatrae* (from Indonesia), as Appendix A species ("species and subspecies threatened with extinction in other countries") under the Endangered Species Conservation Act of 1969 (ESCA) (35 FR 6069, April 14, 1970). We finalized this action on June 2, 1970 (35 FR 8491), but actual implementation was delayed in the United States until August 3, 1970, in order to ensure the orderly implementation of these regulations. In 1972, and in recognition of the fact that by listing a species the law applies to subspecies as well, we delisted the four subspecies and listed *Panthera tigris* under Appendix A of the "U.S. List of Endangered Foreign Fish and Wildlife" (37 FR 6476, March 30, 1972).

Two lists of endangered wildlife were maintained under the ESCA: One for foreign species and one for species native to the United States. Approved on December 28, 1973, the Endangered Species Act of 1973 (16 U.S.C. 1531–1544) superseded the Endangered Species Conservation Act of 1969 (Service 2008d). On January 4, 1974, we categorized the tiger as endangered foreign wildlife under 50 CFR 17.11 (39 FR 1158). On September 26, 1975, the foreign and native lists were replaced by a single "List of Endangered and Threatened Wildlife" (40 FR 44412), on which the tiger remained categorized as endangered. Under the Act, "endangered" means, in part, "any species which is in danger of extinction throughout all or a significant portion of its range." Under section 9, the Act prohibits unauthorized taking, possession, sale, and transport of endangered species. The Endangered Species Act of 1973 also implemented the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES; T.I.A.S. 8249).

The tiger was included under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) in 1977 (42 FR 10462, February 22, 1977). *Panthera tigris altaica* (= *amurensis*) was categorized as an Appendix II species under CITES, while all other subspecies of *Panthera tigris* were categorized as Appendix I species. Species included in CITES Appendix I are considered to be threatened with extinction, and most international trade of these species for commercial purposes is banned. CITES Appendix II species are not necessarily considered to be threatened with extinction now but may become so unless trade in the species is regulated. On July 10, 1987, the Service announced a negotiating position to recategorize *Panthera tigris altaica* to Appendix I under CITES, which would mean that all tiger subspecies merited protection under Appendix I (52 FR 26043). The CITES Party countries agreed and adopted a measure that became effective on October 22, 1987. This measure was implemented in the United States effective December 28, 1987 (52 FR 48820). On August 23, 2007, we revised U.S. CITES regulations for 50 CFR parts 10, 13, 17, and 23 covering the period from 1979 to 2004 (72 FR 48402).

Two additional sets of Federal regulations are relevant to the tiger: the Captive Bred Wildlife (CBW) registration program under the Act and the Captive Wildlife Safety Act (CWSA). The Act and implementing regulations prohibit any person subject to the jurisdiction of the United States from conducting certain activities with endangered or threatened species of fish, wildlife, or plants. These activities include import, export, take, and interstate or foreign commerce. The Secretary of the Interior may permit such activities, under such terms and conditions as he will prescribe, for scientific purposes or to enhance the propagation or survival of the affected species, provided these activities are consistent with the Act (Service 2003, p. 1). Since 1976, the Service has been striving to achieve an appropriate degree of control over prohibited activities involving living wildlife of nonnative species born in captivity in the United States. The regulations that we published in 1998 (63 FR 48634, September 11, 1998) reflect the Service's interpretation of the appropriate degree of control for these species of captive bred wildlife.

The Service has determined that, under the CBW registration system, activities can be conducted without first registering with the Service for "generic" or inter-subspecific crossed tigers (63 FR 48634, September 11, 1998). The Service defines "generic" or inter-

subspecific crossed tigers as "*Panthera tigris* (i.e., specimens not identified as or identifiable as members of the Bengal, Sumatran, Siberian, or Indochinese subspecies (*Panthera tigris tigris, P.t. sumatrae, P.t. altaica,* and *P.t. corbetti,* respectively))" provided that 50 CFR 17.21(g)(6) applies. This determination reiterates the Service's philosophy on its approach to captive versus wild populations: "The Service considers the purpose of the Act to be best served by conserving species in the wild along with their ecosystems. Populations of species in captivity are, in large degree, removed from their natural ecosystems and have a role in survival of the species only to the extent that they maintain genetic integrity and offer the potential of restocking natural ecosystems where the species has become depleted or no longer occurs" (63 FR 48635, September 11, 1998). CBW regulations were amended and became effective on October 13, 1998. They apply to tigers that are identified as, or identifiable as, one of the four subspecies. If used in interstate commerce, these tigers must either be registered with the Service through CBW, or permitted via an enhancement of survival permit (section 10(a)(1)(A) of the Act). In addition, the majority of CBW registered tigers are managed in the United States under the Species Survival Plan Program of the Association of Zoos and Aquariums (AZA; see AZA 2008; Minnesota Zoo 2008).

The CWSA amended the Lacey Act and addressed concerns about public safety and the growing number of big cats in private hands in the United States. Under the CWSA, several prohibitions apply to the tiger, as well as several other species generically identified by the Service as "big cats." The CWSA regulations (72 FR 45938, August 16, 2007) apply to tigers at the species level, as well as subspecies and hybrids (Service 2007, pp. 1–2). Unless you are exempt, you may not move live big cats, including tigers, across State lines or the U.S. border. Prohibited activities include: Import into or export out of the United States; interstate sale and purchase; transport across State lines; and receiving or acquiring big cats if the animals are moved from one State to another (72 FR 45938, August 16, 2007). These prohibitions became effective on September 17, 2007.

In order to be exempt from CWSA prohibitions, you must be licensed by the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture (USDA) under the Animal Welfare Act; a State college, university, or agency; a State-licensed wildlife rehabilitator; a State-licensed veterinarian; or an accredited wildlife sanctuary that meets certain criteria. License holders typically include zoos, circuses, and those who conduct research with wild animals.

Panthera tigris is also a beneficiary of the Rhinoceros and Tiger Conservation Act of 1994 (16 U.S.C. 5306), as amended. This Act, in part, authorizes the Secretary of the Interior to assist in the conservation of rhinoceros and tigers by supporting the conservation programs of nations whose activities directly or indirectly affect these taxa (Service 2004, p. 11; Service 2008a,b). In addition, this Act directs the Secretary of the Interior to convene an advisory group of individuals to assist in carrying out the Act. In 1998, this Act was amended to prohibit the sale, importation, or exportation of products labeled or advertised as rhinoceros or tiger products (Pub. L. 105–312; 16 U.S.C. 5305a). As amended, the law states that a person shall not sell, import, or export, or attempt to sell, import, or export, any product, item, or substance intended for human consumption or application containing, or labeled or advertised as containing, any substance derived from any species of rhinoceros or tiger (16 U.S.C. 5305a(a)).

Species Information

The tiger is the largest species of the cat family (Felidae) and is the top predator throughout its range (Mazák 1981, pp. 1–2; Cat Specialist Group 2002; ITIS 2008). Tigers are quite muscular and have a large head. The teeth are very strong. Adults are usually about 2.2–3.0 meters (m) in length (7.2–9.8 feet (ft)). Females are usually smaller than males. Body weights of 258.2–306.5 kilograms (kg) (569–675 pounds (lbs)) have been reported, but males typically weigh about 170 kg (375 lbs), while females weigh about 113 kg (249 lbs).

Tigers originally ranged from eastern Turkey to southeastern Siberia and the Malay Peninsula, Sumatra, Java, and Bali (Mazák 1981, pp. 2–3). The current geographic distribution is greatly reduced, and tigers have been exterminated from most of their former geographic range. At the end of the 19th century, there may have been as many as 100,000 tigers in the wild (Nowak 1999, p. 828). Currently, tiger populations are smaller, increasingly more isolated, and progressively more fragmented than before. Based on estimates by species experts, extant tiger populations total about 7,700 individuals in the wild and occupy only about 7 percent of their original range in areas from India to Vietnam, as well as in Sumatra, China, and the Russian Far East (Dinerstein *et al.* 2006, p. ii). Tigers primarily occur in forested areas, but can also be found in grasslands and savannahs (Nowak 1999, p. 825). These areas increasingly are being converted to agricultural uses, leading to conflicts between tigers and farmers. Cover, water, and sufficient prey are the main habitat requirements of tigers (Mazák 1981, p. 4).

Females typically give birth to about one to four cubs per litter (Mazák 1981, p. 4). New litters are born about every 2–4 years after the young of the previous litter have become independent of the mother and have left the family unit (Nowak 1999, p. 827).

Except for the mating season, tigers are usually solitary. Some tigers are territorial, while others share home ranges. Shared home ranges are often occupied by litter mates or members of extended tiger families (Nowak 1999, p. 827). Territory sizes usually range from about 200 to 1,000 square kilometers (km^2) (77–386 square miles (mi^2)) in size, depending on habitat quality and prey availability.

Tigers, which hunt primarily at night, mainly prey upon larger mammals, especially ungulates (Nowak 1999, p. 826). Domestic livestock, such as cattle, water buffalos, goats, and dogs, are also frequently taken by tigers (Mazák 1981, p. 5). These attacks are a major cause of conflicts with local farmers. Tigers also attack and kill humans, especially in India (Nowak 1999, p. 827; Nowell and Jackson 1996, p. 57).

Conservation threats to tigers include being poisoned, shot, trapped, and snared, as well as loss or modification of habitat and reductions to natural prey populations (World Wildlife Fund International undated, p. 1). These threats are widespread and ongoing (*e.g.,* Environmental Investigation Agency 1998, 2006a, 2006b; Johnson *et al.* 2006, pp. 7–8; Poole and Johnson 2008; Ng and Nemora 2007, pp. vi–vii; Shepherd and Magnus 2004, pp. vi–vii).

Recent reports suggest that natural mortality of tigers is being replaced by mortality due to man. Historically, bears, wild pigs, and other large mammals were major predators of tigers; today, tigers increasingly are being killed by human hunters (Mazák 1981, p. 5). As a result, tiger populations in most areas are greatly reduced due to human activities.

International trade in tigers has been a source of concern to conservationists and species experts for many years. According to Inskipp and Wells (1979, p. 40), big cats already showed signs of becoming rare in the 1960s. Three tigers

were imported into the United States in 1968 (Jones 1970, p. 19). During 1968–1972, 17 living tigers were imported into the United States (McMahan 1986, p. 468). Following the ratification of CITES in the United States, during 1979–1980, a total of 103 live tigers were imported according to Service records. Overall, a total of 317 live Appendix I tigers were reported in international trade during 1979–1980 (McMahan 1986, p. 471).

More recently in the United States, more than 130 live tigers were either imported, exported, or re-exported legally during 2004–2006 (purpose of transaction: zoos, circuses and traveling exhibitions, and breeding in captivity; Service 2008c). About 6,000 illegally obtained items during that same time period were either abandoned at the port of entry or seized by U.S. law enforcement officials (primarily skins, teeth, trophies, and articles used for traditional medicine). At the international level during 1976–1990, the average annual trade in tigers reported to CITES was about 16 individuals per year (primarily trophies; Nowell and Jackson 1996, p. 226). Elsewhere, reports about India (Environmental Investigation Agency 1998, 2006a, 2006b; Wright 2007) and Indonesia (Sumatra Island; Ng and Nemora 2007; Shepherd and Magnus 2004) document an ongoing illegal commercial and recreational trade in those countries. Wright (2007, p. 10) reported 34–81 tigers poached per year in India during 1998–2006. Poaching and killing tigers to protect livestock are also reported rangewide (Nowell and Jackson 1996, pp. 180–195).

Little is known about the nature or extent of disease in wild tiger populations. According to Nowell and Jackson (1996, p. 58), tiger mortality during the second year of life is 17 percent, while infanticide is overall the most common cause of cub death. Furthermore, Nowell and Jackson (1996, pp. 64–65) suggest that natural mortality is being replaced with mortality due to human activities.

Tigers can live up to about 15 years of age in the wild and up to 26 years of age in captivity (Nowell and Jackson 1996, p. 58). Habitat loss and reductions in the size of tiger prey populations increasingly are becoming significant determinants in tiger population sizes and geographic distribution. According to species experts, large tracts of contiguous habitat are essential to assure the survival of wild tigers on a long-term basis; small, isolated reserves cannot be relied upon to conserve the species (Nowell and Jackson 1996, p. 65).

Tigers readily breed in captivity and often are included in the exhibitions of larger zoos (Mazák 1981, p. 6). The Leipzig Zoo has maintained the International Tiger Studbook since 1973 (Müller 2004), while the AZA coordinates the Species Survival Plan Program (AZA 2008; Minnesota Zoo 2008). Species experts have recently proposed designs for landscape conservation efforts (Wikramanayake *et al.* 2004), as well as conservation and recovery priorities for wild tigers (Dinerstein *et al.* 2006; Sanderson *et al.* 2006).

There is a relatively large population of tigers in captivity. According to Werner (2005, p. 24), there are approximately 264 tigers in AZA-registered institutions in the United States, 1,179 in assorted wildlife sanctuaries, 2,120 in USDA-registered institutions, and 1,120 in private ownership (approximate U.S. total = 4,692 tigers). An additional 5,000 tigers have been reported in captivity in China at sites popularly identified as tiger farms, with an annual production of 800 individuals (CITES 2007b, p. 4). The long-term status of these captive tigers, however, has been questioned by some as the Government of China is studying and assessing a suggestion to use the bones of captive specimens for domestic purposes in traditional Chinese medicine (CITES 2007c, p. 7; CITES 2007d, p. 7). While domestic trade in tiger bone has been prohibited in China since 1993, traditional Chinese medicine—based in part on the use of tiger bones—continues (Shepherd and Magnus 2004; Nowell 2007; Ng and Nemora 2007). Fewer than 1,000 tigers occur in public zoos in Europe and Japan (Ron Tillson, cited by Morell 2007, p. 1312), while data for the quantity of tigers in private collections in Europe and Japan are not readily available.

Evaluation of Information for This Finding

Section 4 of the Act (16 U.S.C. 1533), and implementing regulations at 50 CFR part 424, set forth the procedures for adding a species to, or removing a species from, the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act:

(A) Present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

We must consider these same five factors in delisting a species. We may delist a species according to 50 CFR 424.11(d) if the best available scientific or commercial data indicate that the species is neither endangered nor threatened for the following reasons:

(1) The species is extinct;

(2) The species has recovered and is no longer endangered or threatened; or

(3) The original scientific data used at the time the species was classified were in error.

In making this 90-day finding, we evaluated whether information regarding the threats to the tiger, as presented in the petition and other information available in our files, is substantial, thereby indicating that the petitioned action may be warranted. Our evaluation of this information is presented below.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Information Provided in the Petition

The petitioner provides no information that suggests that threats to the habitat or range of the tiger have been reduced or eliminated.

Evaluation of Information Provided in the Petition and Available in Service Files

The information in Service files as described in the Species Information section (above) suggests that, rather than improving, the habitat or range of the tiger is deteriorating in quantity and quality throughout its range. Given the lack of information in the petition addressing the threats to habitat or range, and information in our files that indicates these threats are ongoing and increasing, we have determined that the information provided in the petition, as well as other information in our files, does not present substantial scientific or commercial information indicating that the petitioned action may be warranted due to the reduction or elimination of threats to the tiger's habitat or range.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Information Provided in the Petition

The petitioner provides copies of documents that indicate that large numbers of tigers are held in captivity in the United States. According to the petition, up to 10,000 tigers are being

maintained as pets in the United States. In addition, the petitioner suggests that the total population of tigers in the world may be approximately 20,000 individuals, including those maintained as pets by private individuals and those tigers in zoos or wildlife sanctuaries. The petitioner asserts that, given the number of individuals in the wild and in captivity, the species is no longer at risk of extinction.

Evaluation of Information Provided in the Petition and Available in Service Files

Although the petitioner acknowledges the number of tigers in the United States held as pets, in zoos, and in sanctuaries, the petition does not address the threat of overutilization of tigers for commercial, recreational, scientific, or educational purposes, or whether these threats have been reduced or eliminated. As described in the Species Information section, the information in Service files indicates that tigers have been and continue to be widely used for commercial, recreation, scientific, or educational purposes. Although the Service is not aware of any scientific or commercial information indicating overutilization of tigers for scientific or educational purposes, information in Service files indicates that overutilization for commercial and recreational purposes is ongoing and widespread.

Given that the petition does not address the threat of overutilization of tigers, and information in our files indicates this threat is ongoing and widespread, we find that the information provided in the petition, as well as other information in our files, does not present substantial scientific or commercial information indicating that the petitioned action may be warranted due to the reduction or elimination of the threat of overutilization of the tiger for commercial, recreational, scientific, or educational purposes.

C. Disease and Predation

Information Provided in the Petition

The petitioner does not provide any information about tiger disease or predation.

Evaluation of Information Provided in the Petition and Available in Service Files

As described in the Species Information section, among the documents available in Service files, little mention is made of disease or predation as a conservation factor for tigers. The Service is not aware of any scientific or commercial information that indicates that the conservation status of the tiger with respect to disease or predation has improved. It does not appear, however, that disease or predation are important factors that negatively affect the conservation status of the tiger at this time. Because the petitioner provided no information about tiger disease or predation, and information in our files appears to indicate that disease or predation are not important factors negatively affecting the conservation status of the species, the information available to us does not support or oppose this petition to delist the species. As such, we have determined that the information provided in the petition, as well as other information in our files, does not present substantial scientific or commercial information indicating that the petitioned action may be warranted due to the reduction or elimination of tiger disease or predation.

D. The Inadequacy of Existing Regulatory Mechanisms

Information Provided in the Petition

The petitioner does not provide any information that suggests that existing regulatory mechanisms have resulted in a reduction or elimination of threats to the tiger. Several of the supporting documents presented by the petitioner generally describe that many tigers are maintained as pets, but the petition does not indicate how this information relates to delisting the tiger under this factor.

Evaluation of Information Provided in the Petition and Available in Service Files

Information in the Service's files, as described in the Species Information section, consists of several reports that make special mention of the positive conservation benefits to tigers as a result of their being listed under Appendix I of CITES. As a result of CITES and the associated regulatory mechanisms, according to these reports, international trade of live tigers, as well as tiger parts, products, and derivatives for commercial purposes has decreased, but persists (Environmental Investigation Agency 2006a; Klenzendorf undated; Ng and Nemora 2007; Nowell 2007; Poole and Johnson 2008; Shepherd and Magnus 2004; Wright 2007).

Within the context of CITES, the CITES Secretariat and the Standing Committee have compiled information on the status of wild and captive tiger populations, as well as the implementation of CITES decisions and resolutions by importing, exporting, and re-exporting countries (*e.g.,* CITES 2007b,c,d; CITES 2008a,b,c,d). Furthermore, the enforcement of CITES prohibitions relating to international trade of tigers has been made more effective through the adoption and implementation of several CITES resolutions that call for stricter controls of international trade (CITES 1997, 2000, 2002a, 2002b, 2007a).

While CITES regulatory mechanisms may have positive conservation impacts on tigers, a number of inherent limitations have been identified that may reduce the usefulness of these mechanisms at the international level as a conservation tool for tigers. According to Santagelo (2005, p. 119), CITES has several major limitations related to enforcement, permits, and reporting. The inability of CITES to remedy implementation failures at the national level, however, perhaps is the most serious weakness of this regulatory mechanism and directly affects conservation and research of the tigers. The issue of tiger farming within the context of CITES, especially in China if the use of tiger bones from captive specimens is legalized, has been identified as a potentially serious regulatory problem (Santagelo 2005, p. 126).

While several international regulatory mechanisms affect the conservation status of tigers, serious and specific threats to the species at the national level remain. Several reports suggest that appropriate regulatory mechanisms continue to be lacking in many range countries (Tiger Task Force 2005, pp. vi–x; Environmental Investigation Agency 1998, 2006a). Poaching occurs throughout the range of the tiger. The seizure or abandonment mentioned above of about 6,000 items (tiger parts, products, or derivatives) during 2004–2006 by U.S. law enforcement officials at ports of entry also underscores the inadequacy of existing regulatory mechanisms in several countries that export or re-export tigers or tiger parts, products, or derivatives.

Several reports have suggested potential problems associated with the possession or private ownership of tigers in captivity in the United States. According to these reports, the exact number of tigers in captivity is unknown; breeding and husbandry controls vary from State to State; and the disposal of tiger parts, products, and derivatives is not monitored at the Federal level (Williamson and Henry 2008, pp. 1–4; World Wildlife Fund-US 2008). This information, according to these reports, is critical to the effective management of tigers in the United States.

Captive tigers in the United States are regulated under the CBW and CWSA. Regulations adopted under the CBW reflect a determination by the Service to focus Federal activities on wild specimens where conservation benefits will be most effective (63 FR 48634, September 11, 1998). Regulations adopted under the CWSA address big cats, including tigers, and public safety issues in the United States (72 FR 45938, August 16, 2007; Service 2007). It is the Service's determination that these two regulatory mechanisms provide an adequate level of control of captive tigers in the United States despite the potential problems mentioned above. Beyond U.S. borders, the Service is not aware of any scientific or commercial information that indicates that existing regulatory mechanisms are adequate for all or most of the countries where tigers either occur in the wild or are maintained in captivity.

In summary, we have determined that the information provided in the petition, as well as other information in our files, does not present substantial scientific or commercial information indicating that the petitioned action may be warranted due to the reduction or elimination of the threat of inadequacy of existing regulatory mechanisms with respect to the tiger.

E. Other Natural or Manmade Factors Affecting Continued Existence

Information Provided in the Petition

The petitioner does not provide any information about other natural or manmade factors affecting the continued existence of the tiger.

Evaluation of Information Provided in the Petition and Available in Service Files

The information in Service files, as described in the Species Information section above, includes several reports by internationally recognized tiger experts. These reports cite the importance of reducing or eliminating poaching, reversing habitat conversion and fragmentation, stopping the loss of the tiger prey base (especially ungulates taken by subsistence hunters), and eliminating human-tiger conflicts due to livestock grazing (Nowell and Jackson 1996, pp. 64–65; Species Programme 2002; Dinerstein *et al.* 2006, pp. ii–iv; Johnson *et al.* 2005; Johnson *et al.* 2006; Sanderson *et al.* 2006, pp. iii–vi). Environmental Investigation Agency (2006a, p. 20) specifically cites the recent example of poisons being placed in the carcasses of dead livestock to kill tigers returning to the site of a kill. The Service is not aware of any scientific or commercial information suggesting that the conservation status of tigers in any range country has undergone significant improvement. The Service is aware of improvements in husbandry techniques for captive tiger populations in several zoos and wildlife sanctuaries (Müller 2004), but it is not clear if privately held tigers are also benefitting from those changes.

In conclusion, based on the documents available to the Service, information about other natural or manmade factors affecting the continued existence of the tiger does not support this petition to delist the species.

Finding

The key element of the petition to delist the tiger is an assertion by the petitioner that the tiger population has grown exponentially over the past 35 years (since listing under the Act) and that there are approximately 20,000 tigers in the wild or in zoos and sanctuaries worldwide. Information about tigers available to the Service and summarized above suggests that over the past century both the total population size and the extent of the geographic range of the species in the wild are much reduced from previous levels. Tiger habitat continues to be converted to agricultural purposes, while remaining patches of tiger habitat increasingly are becoming fragmented and isolated from each other. This loss directly affects tigers, as well as the prey on which they depend. Poaching and illegal trade of tigers, domestic as well as international, especially for traditional Chinese medicine, continue despite increased national and CITES controls (Bolze *et al.* 1998, pp. 2–3; Henry 2004, pp. 12–13; Nowell and Ling 2007, pp. v–vi).

The petitioner does not provide information related to the relevant factors that the Service considers when reviewing proposals to list or delist a species, including the factors provided under subsection 4(a)(1) of the Act. The information in Service files, including several rangewide reports by internationally recognized tiger experts, numerous national reports, and trade summaries involving the United States and other countries, suggest that conservation threats to the tiger remain widespread and ongoing. While there may be some success stories in terms of tiger conservation (*e.g.,* Phoenix Fund 2001, 2004; Save the Tiger Fund 2005, 2007; Gratwicke *et al.* 2007; World Wildlife Fund International undated), in general the conservation status of the species throughout its range is deteriorating. In conclusion, the data in our files do not support the petitioned action.

We have reviewed the petition, as well as the literature cited in the petition, and have evaluated that information in relation to information available to the Service. Based on this review and evaluation, we find that the petition does not present substantial scientific or commercial information to indicate that the delisting of the tiger may be warranted at this time. Although we will not commence a status review in response to this petition, we will continue to monitor the tiger's population status and trends, potential threats to the tiger, and ongoing management actions that might be important with regard to the conservation of the tiger across its range. We encourage interested parties to continue to gather data that will assist with the conservation of the species. If you wish to provide information regarding the tiger, you may submit your information or materials to the Chief, Branch of Foreign Species, Endangered Species Program (see **ADDRESSES**).

References Cited

A complete list of all references cited in this document is available, upon request, from the Branch of Foreign Species, Endangered Species Program (see **FOR FURTHER INFORMATION CONTACT**).

Author

The primary author of this notice is the Staff of the Branch of Foreign Species, Endangered Species Program, U.S. Fish and Wildlife Service (see **ADDRESSES**).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: August 3, 2010.

Wendi Weber,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2010–19895 Filed 8–11–10; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

RIN 0648–AW75

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Atlantic Herring Fishery; Amendment 4

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability (NOA) of a fishery management plan amendment; request for comments.

SUMMARY: NMFS announces that the New England Fishery Management Council (Council) has submitted Amendment 4 to the Atlantic Herring (Herring) Fishery Management Plan (FMP) (Amendment 4), incorporating the public hearing document and the Initial Regulatory Flexibility Analysis (IRFA), for review by the Secretary of Commerce and is requesting comments from the public.

DATES: Comments must be received on or before October 12, 2010.

ADDRESSES: An environmental assessment (EA) was prepared for Amendment 4 that describes the proposed action and other considered alternatives and provides a thorough analysis of the impacts of the proposed measures and alternatives. Copies of Amendment 4, including the EA, the Regulatory Impact Review (RIR), and the Initial Regulatory Flexibility Analysis (IRFA), are available from: Paul J. Howard, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950, telephone (978) 465–0492. The EA/RIR/IRFA is also accessible via the Internet at *http://www.nero.nmfs.gov*.

You may submit comments, identified by 0648–AW75, by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal e-Rulemaking portal *http://www.regulations.gov*;
- Fax: (978) 281–9135, Attn: Carrie Nordeen;
- Mail to NMFS, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope "Comments on Herring Amendment 4."

Instructions: No comments will be posted for public viewing until after the comment period has closed. 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) 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 formats only.

FOR FURTHER INFORMATION CONTACT: Carrie Nordeen, (978) 281-9272.

SUPPLEMENTARY INFORMATION:

Background

The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) was re-authorized in January 2007. As a result of the re-authorization, the Magnuson-Stevens Act requires the establishment of annual catch limits (ACLs) and (AMs) to end and/or prevent overfishing in all FMPs. This amendment is needed to bring the Herring FMP into compliance with new Magnuson-Stevens Act requirements by: Revising definitions and the specifications-setting process, consistent with ACL requirements; and establishing fishery closure thresholds, a haddock incidental catch cap, and overage paybacks as AMs. Because herring is not subject to overfishing, the Herring FMP is required to be in compliance with ACL and AM requirements by 2011.

A notice of intent (NOI) was published in the **Federal Register** (73 FR 26082, May 8, 2008) announcing the Council's intent to develop Amendment 4 to the Herring FMP and prepare an environmental impact statement (EIS) analyzing the impacts of the proposed management measures. In addition to bringing the Herring FMP into compliance with ACL and AM requirements, initially, Amendment 4 also considered: Catch monitoring and reporting, interactions with river herring, access by midwater trawl vessels to groundfish closed areas, and interactions with the Atlantic mackerel fishery.

In June 2009, the Council determined there was not sufficient time to develop and implement Amendment 4, in its entirety, by 2011, so it decided to split Amendment 4 into two separate actions. The Council determined that Amendment 4 would continue to address ACL and AM requirements, but that all other issues (e.g., catch monitoring and reporting, interactions with river herring and Atlantic mackerel, access to groundfish closed areas) would be considered in Amendment 5 to the Herring FMP. A supplemental NOI, announcing this change and notifying the public that an environmental assessment, rather than an EIS, was being prepared to analyze the impacts of Amendment 4, was published in the **Federal Register** on December 28, 2009 (74 FR 68577).

The Council held three public meetings on Amendment 4 during January 2010. Following the public comment period that ended on January 12, 2010, the Council adopted Amendment 4 on January 26, 2010.

This action proposes management measures that were recommended by the Council as part of Amendment 4. If implemented, these management measures would:

- Revise current definitions and the specification-setting process to include ACLs and AMs;
- Designate herring as a "stock in the fishery;"
- Establish an interim acceptable biological catch (ABC) control rule;
- Eliminate total foreign processing (JVPt), including joint venture processing (JVP) and internal waters processing (IWP), and reserve from the specifications process; and
- Eliminate the annual consideration of total allowable level of foreign fishing (TALFF).

Public comments are solicited on Amendment 4 and its incorporated documents through the end of the comment period stated in this NOA. A proposed rule that would implement Amendment 4 may be published in the **Federal Register** for public comment, following NMFS's evaluation of the proposed rule under the procedures of the Magnuson-Stevens Act. Public comments must be received by the end of the comment period provided in this NOA of Amendment 4 to be considered in the approval/disapproval decision on the amendment. Comments received after that date will not be considered in the decision to approve or disapprove Amendment 4. To be considered, comments must be received by close of business on the last day of the comment period provided in this NOA.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 6, 2010.

Carrie Selberg,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2010–19868 Filed 8–11–10; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 75, No. 155
Thursday, August 12, 2010

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

National Institute of Food and Agriculture

Administrative Guidance for Multistate Extension Activities and Integrated Research and Extension Activities

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Notice of interim guidance and request for comments.

SUMMARY: The National Institute of Food and Agriculture (NIFA) is issuing a revised Administrative Guidance for Multistate Extension Activities and Integrated Research and Extension Activities as interim with a 60-day comment period. The Administrative Guidance has been revised to address the findings and recommendations of the U.S. Department of Agriculture (USDA) Office of Inspector General (OIG) Audit Report no. 13001–3–Te: ''Cooperative State Research, Education, and Extension Service's Implementation of the Agricultural Research, Extension and Education Reform Act of 1998 (AREERA),'' and to clarify policies and procedures associated with these requirements. Section 105 of AREERA amended the Smith-Lever Act to require that a specified amount of agricultural extension formula funds be expended on multistate extension activities. Section 204 of AREERA amended the Hatch Act and Smith-Lever Act to require that a specified amount of agricultural research and extension formula funds be expended on integrated research and extension activities.

DATES: The interim Administrative Guidance is effective August 12, 2010. The Agency must receive comments by October 12, 2010 for them to be considered in the final Administrative Guidance.

ADDRESSES: You may submit comments identified by 2010–0025, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

E-mail: administrativeguidance@nifa.usda.gov. Include the Docket Number in the subject line of the message.

Fax: 202–401–7752.

Mail: paper, disk or CD–ROM submissions should be submitted to the National Institute of Food and Agriculture, U.S. Department of Agriculture, STOP 2299, 1400 Independence Avenue, SW., Washington, DC 20250–2299.

Hand Delivery/Courier: National Institute of Food and Agriculture, U.S. Department of Agriculture, Room 2247, Waterfront Centre, 800 9th Street, SW., Washington, DC 20024.

Instructions: All submissions received must include the agency name and the docket number 2010–0025. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mary Snieckus, Policy Specialist, Office of Extramural Programs, National Institute of Food and Agriculture, U.S. Department of Agriculture, STOP 2299, 1400 Independence Avenue, SW., Washington, DC 20250–2299; *Voice:* 202–720–3842; *Fax:* 202–401–7752; *E-mail: msnieckus@nifa.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

The Cooperative State Research, Education, and Extension Service (CSREES) (now NIFA), in response to Recommendation 1 of the USDA OIG Audit Report no. 13001–3–Te: ''Cooperative State Research, Education, and Extension Service's Implementation of the Agricultural Research, Extension and Education Reform Act of 1998'' (often referred to as the AREERA Audit) is requiring 1862 Land-Grant Institutions not computing their base percentages to select 25 percent as the target percentage for multistate extension activities and for integrated research and extension activities or to correctly determine their base percentages based on actual expenditures. In FY 2000, 1862 Land-Grant Institutions were provided four options for establishing a Target Percentage for these requirements: (A) Target 25 percent which will automatically waive the requirements to report on the FY 1997 expenditures for multistate extension activities; (B) Target a percentage which is two times the FY 1997 expenditures for multistate extension activities (commonly referred to as the FY 1997 baseline) but less than 25 percent; (C) Target a percentage that is less than 25 percent (usually selected when auditable expenditure data is not available); and (D) Phase-in Option C with a 3-year phase-in period. The USDA OIG determined during the audit that Options C and D did not meet the intent of the legislation and that the 1862 Land-Grant Institutions, if unable to determine their actual FY 1997 baseline expenditures for multistate extension and integrated research and extension activities, must select 25 percent, and thus, expend 25 percent of their Smith-Lever Act funds on multistate extension activities and 25 percent on integrated research and extension activities and expend 25 percent of Hatch Act funds on integrated research and extension activities. However, Federal funds that are used by the institution for a fiscal year for integrated activities may also be counted to satisfy the multistate activities requirement.

In the revised Administrative Guidance, NIFA is requesting that each 1862 Land-Grant Institution (in the 50 States and in the District of Columbia for Hatch Act funds only) review the table in Appendix A which identifies by State the total FY 1997 Hatch Act and Smith-Lever Act funds allocated, the FY 1997 expenditures reported for multistate extension activities and integrated activities, the Target Percentage selected, and whether the Target Percentages needed to be reset at 25 percent or to be based on the actual FY 1997 expenditures. Appendix A is available at *http://www.nifa.usda.gov/business/reporting/planrept/plansofwork.html.* Although some institutions had previously established 25 percent or a Target Percentage based on actual expenditures, NIFA is requesting that all institutions either reconfirm or reset their Target Percentages.

The revised Administrative Guidance also clarifies the criteria for AREERA section 105 and 204 waiver requests and

describes the waiver process in more detail. NIFA also seeks to clarify that for purposes of determining the actual multistate extension and integrated amounts, only the regular allocation under the Smith-Lever Act (*i.e.,* Smith-Lever Act sections 3(b)&(c)) and the Hatch Act allocations together (*i.e.,* the regular Hatch Act allocation according to the legislative formula and the amount used to identify the matching amount for the Hatch Multistate Research Fund allocation) should be used to identify the actual expenditures required for that fiscal year's formula grants (*i.e.,* formula funds).

In complying with the Government Paperwork Elimination Act (GPEA), NIFA is considering an electronic business process for collecting the annual Form NIFA–PLAN (Rev. 07/2010) and Form NIFA–REPT (Rev. 07/2010) data to ensure AREERA sections 105 and 204 compliance. NIFA plans to integrate these requirements as part of the update to the 5-Year Plan of Work and Annual Report of Accomplishments and Results which will be entered electronically through the AREERA State Plan of Work Information System.

Response to Stakeholder Input

CSREES provided a draft of the revised Administrative Guidance to the State Extension Directors on May 2, 2008, and provided a 60-day comment period. Fifteen comments were received during the comment period. Thirteen were from university officials and two were from USDA staff. Comment topics included the administrative burden associated with compliance, definition of integrated activities, the use of split appointments, use of non-Federal funds to meet these requirements, waivers, effective date of revised Administrative Guidance, and the use of intrastate activities to meet the multistate requirements. Three of the commenters felt that resetting and reconfirming the target percentages would be a significant burden to the institutions. While NIFA realizes this may be a significant burden to some institutions, institutions are required to either expend the lesser of 25 percent or twice the percentage amount they spent in FY 1997 of their Smith-Lever Act funds on multistate extension activities and the lesser of 25 percent or twice the percentage amount they spent in FY 1997 of their Hatch Act and Smith-Lever Act funds on integrated activities. Three commenters requested clarification if two staff people need to be working on an activity for it to be considered "integrated." Two people do not need to be working on an activity for it to be "integrated." The misleading text has been deleted from the Administrative Guidance. There were two comments about the effective date of the Administrative Guidance and the time period to which it applies. Although the Administrative Guidance is effective upon publication in the **Federal Register**, the approved revised and reconfirmed target percentages do not apply until FY 2011. Two commenters stated that although their institution may not meet the target percentages for multistate and extension activities with Federal funds, they would if the entire funding portfolio was considered (*e.g.,* state and local funds). They requested that non-Federal funds be used to meet these requirements. While NIFA can appreciate this, the legislation applies to the Federal funds only. Five respondents commented that the use of formal agreements to document multistate extension activities was overly burdensome. The Administrative Guidance does not require formal agreements to support eligible multistate extension activities. One commenter asked if they could use intrastate activities to meet the multistate extension requirements. Institutions may not use intrastate activities to meet these requirements as the legislation requires activities that involve more than one state. Finally, two commenters stated that the Administrative Guidance was clear and helpful.

Time Line for Implementation

Although this Interim Administrative Guidance is effective upon publication in the **Federal Register**, NIFA is requesting comments during a 60-day period. These comments will be considered and incorporated in the final version of the Administrative Guidance. NIFA is requesting that institutions either reset or reconfirm their target percentages for multistate extension and integrated activities by September 30, 2010. NIFA will review and approve these target percentages by October 29, 2010. These approved target percentages will be effective October 1, 2010.

Paperwork Reduction Act

In accordance with the Office of Management and Budget (OMB) regulations (5 CFR part 1320) that implement the Paperwork Reduction Act of 1995, as amended (44 U.S.C. Chapter 35), the information and recordkeeping requirements imposed by the implementation of this guidance were approved under OMB Information Collection No. 0524–0036, "Reporting Requirements for the State Plans of Work for Agricultural Research and Extension Formula Funds."

Pursuant to the requirements for multistate extension activities and integrated research and extension activities enacted in the Agricultural Research, Extension, and Education Reform Act of 1998, NIFA hereby implements the Administrative Guidance for Multistate Extension Activities and Integrated Research and Extension Activities:

Interim Administrative Guidance for Multistate Extension Activities and Integrated Research and Extension Activities

I. Preface and Authority

Section 105 of the Agricultural Research, Extension, and Education

Reform Act of 1998 (AREERA) amended the Smith-Lever Act to require that each institution receiving extension formula funds under sections 3(b) and (c) of the Smith-Lever Act expend for multistate activities in FY 2000 and thereafter a percentage that is at least equal to the lesser of 25 percent or twice the percentage of funds expended by the institution for multistate activities in FY 1997 (7 U.S.C. 343(h)). Section 204 of AREERA amended both the Hatch and the Smith-Lever Acts to require that each institution receiving agricultural research and extension formula funds under the Hatch Act and sections 3(b) and (c) of the Smith-Lever Act expend for integrated research and extension activities in FY 2000 and thereafter a percentage that is at least equal to the lesser of 25 percent or twice the percentage of funded expended by the institution for integrated research and extension activities in FY 1997 (7 U.S.C. 343(i) & 361c(i)). These sections also require that the institutions include in the plan of work a description of the manner in which they will meet these multistate and integrated requirements.

These applicable percentages apply to the Federal agricultural research and extension formula funds only. Federal formula funds that are used by the institution for a fiscal year for integrated activities may also be counted to satisfy the multistate activities requirement.

The multistate extension and the integrated research and extension activities do not apply to the formula funds received by American Samoa, Guam, Micronesia, Northern Marianas, Puerto Rico, and the Virgin Islands. Since the Smith-Lever Act is not directly applicable, the multistate and integrated extension requirements do not apply to extension funds received by the District of Columbia.

The amendments made by sections 105 and 204 of AREERA also provide that the Secretary of Agriculture may reduce the minimum percentage required to be expanded by the institution for multistate and integrated activities in the case of hardship, infeasibility, or other similar circumstance beyond the control of the institution.

II. Definitions

For the purposes of implementing sections 105 and 204 of AREERA, the following definitions are applicable:

Activities mean either research projects or extension programs.

Formula Funds means, for the purpose of the multistate extension activities and integrated activities guidance, the Federal mean formula funding provided to the 1862 Land-Grant Institutions under section 3 of the Hatch Act of 1887, as amended (7 U.S.C. 361c) and sections 3(b)(1) and (c) of the Smith-Lever Act, as amended (7 U.S.C. 343(b)(1) and (c)).

Integrated activities means jointly planned, funded, and interwoven activities between research and extension to solve problems. This includes the generation of knowledge and the transfer of information and technology.

Multistate activities means collaborative efforts that reflect the programs of institutions located in at least two or more States or territories.

Planned Programs means collections of research projects or activities and/or extension programs or activities.

III. Multistate Extension Activities

A. Reconfirm or Reset Target Percentages

By September 30, 2010, each 1862 Land-Grant Institution must reconfirm or reset their Target Percentage for multistate extension activities. Institutions have a choice of two options: (A) Target 25 percent which will automatically waive the requirement to report on the FY 1997 expenditures for multistate extensions activities; or (B) Target a percentage which is two times the FY 1997 expenditures for multistate extension activities (commonly referred to as the FY 1997 baseline) but less than 25 percent. Institutions will use Form NIFA–TARG (Rev. 07/2010), Establishment of Target Percentages for Multistate Extension Activities and Integrated Activities, to select their option. If an institution wishes to reconfirm their original Target Percentage, they should forward a copy of the original Form NIFA–TARG (Rev. 07/2010) and Form NIFA–BASE (Rev. 07/2010) to the NIFA Formula Grants Section, Awards Management Branch, with a memo that the 1862 Land-Grant Institution is reconfirming the original Target Percentages set in FY 2000. Institutions selecting Option B for the first time also are required to report by September 30, 2010, the amount of FY 1997 funds allocated under sections 3(b) and (c) of the Smith-Lever Act (i.e., the regular allocation only) and expended on multistate extension activities during the period from October 1, 1996, through September 30, 1997. These institutions will use Form NIFA–BASE (Rev. 07/2010), Establishment of Fiscal Year (FY) 1997 Baselines for Multistate Extension Activities and Integrated Activities. When completing this form, institutions may opt to report on the planned program level which is a collection of extension programs or activities. Please see Appendix A for the total amount of Smith-Lever Act sections 3(b) and (c) funds that were allocated to the 1862 Land-Grant Institutions in FY 1997. The requirement to submit Form NIFA–BASE (Rev. 07/2010) is automatically waived for those institutions selecting Option A. States who were unable to document FY 1997 baseline expenditures must select Option A which is 25 percent.

The term "Multistate activities" means collaborative efforts that reflect the programs of institutions located in at least two or more States or territories. Each participating State or territory must be a collaborator towards objectives and involved in the outcomes. Evidence of this collaboration should have been documented through the formal agreements, letters of memorandum, contracts, grants, or other documents that provide primary evidence that a multistate relationship exists. Please note that formal agreements are not required. As mentioned in the Preface, this requirement applies to the Federal formula funds only and will apply to the Smith-Lever Act section 3(b) and (c) funds (i.e., the regular allocation only). Examples of multistate extension activities may include committees, projects, training, workshops, centers, and meetings that involve more than one State or territory.

B. Submission of Supplement to the 5-Year Plan of Work Update

Each institution also is required to submit Form NIFA–PLAN (Rev. 07/2010), Supplement to the 5-Year Plan of Work, Multistate Extension Activities and Integrated Activities, for all multistate extension activities that will be supported by the Smith-Lever Act section 3(b) and (c) funds used to satisfy the AREERA section 105 requirement for multistate extension activities. This form should be completed each fiscal year to reflect the 5-Year Plan of Work updated and submitted in the AREERA State Plan of Work Information System. Institutions should use the prior fiscal year amount (*e.g.,* use the FY 2009 allocation amount for the FY 2011–2015 reporting requirement due in FY 2010) as a basis for planning programs and/or activities to meet the AREERA section 105 requirements. Please note that compliance with section 105 of AREERA will be determined by the institution meeting the Target Percentage of the actual formula allocation for the applicable fiscal year. This form (NIFA–TARG (Rev. 07/2010)) is due to the NIFA Formula Grants

Section, Awards Management Branch, by April 1st each fiscal year and should complement the 5-Year Plan of Work. A brief statement of each planned program or activity is required and must be attached to this form. However, in lieu of these brief statements, institutions may refer to information on multistate extension activities reported in the 5-Year Plan of Work, if such information clearly describes multistate extension planned programs and/or activities as listed on Form NIFA–PLAN (Rev. 07/2010).

C. Annual Report of Accomplishments and Results

Form NIFA–REPT (Rev. 07/2010), Supplement to the Annual Report of Accomplishments and Results, Multistate Extension Activities and Integrated Activities, will be due on April 1st each year and must be submitted as a summary of the multistate extension planned programs or activities that have been used to satisfy the requirements of AREERA section 105. The form has been designed so that each institution will submit only one form with attached brief summaries for each fiscal year. The form allows for the reporting on all three AREERA requirements: Hatch integrated; Smith-Lever multistate; and Smith-Lever integrated and includes a certification statement. One form should be submitted for each fiscal year; and current fiscal year funds should not be commingled with funds from prior fiscal years. If you are carrying over AREERA multistate and integrated requirements from a previous fiscal year and both requirements are satisfied in a later fiscal year, the Form NIFA–REPT (Rev. 07/2010) should be marked "Final" for that fiscal year. If you are carrying over these AREERA requirements into the next fiscal year, the Form NIFA–REPT (Rev. 07/2010) should be marked "Interim" for that fiscal year in which the funds were first allocated. Do not submit a "Final" report for any fiscal year until the full requirement has been met for all three AREERA requirements. If you know that you will be unable to meet your AREERA requirements for any fiscal year, please contact NIFA Formula Grants Section, Awards Management Branch, via email as soon as possible. NIFA may be required to reduce your allocation by the Target Percentage amount not met, as these costs will be disallowed. Brief statements or summaries describing the activities performed and the progress to date on each planned program or activity must be attached to this form. Although the Annual Report describes in detail the goals and accomplishments for an institution's entire program, a brief description of the Multistate Extension Activities for each program listed in the NIFA–REPT (Rev. 07/2010) form must be attached. Please note that amounts on these forms are subject to audit. This form is due each fiscal year on April 1st and should be submitted to the NIFA Formula Grants Section, Awards Management Branch.

D. Waivers

A waiver may be requested for failure to meet the AREERA section 105 requirement. Eligible institutions may request a waiver for this purpose when one of the following criteria is met: (1) Infeasibility, (2) hardship, or (3) other circumstances beyond control of the State. The waiver request and supporting documentation should be addressed to NIFA Director and forwarded to the NIFA Formula Grants Section, Awards Management Branch. Waivers can only be granted on an annual basis and may be processed as either a pre-waiver or a post-waiver. A pre-waiver must be submitted prior to October 1st of the fiscal year. A post-waiver must be submitted with the other AREERA Section 105 reporting requirements due April 1st. Institutions must use Form NIFA–WAIVER (07/2010), Request for Waiver from Target Percentage for Multistate Extension Activities and Integrated Activities, to request a reduction in the minimum percentage required to be expended for multistate extension activities. The waiver request should be signed by the appropriate institutional official (*i.e.,* Dean or Director). To expedite the consideration of the waiver request, the institution should include the following elements in the request letter:

(a) A request for the waiver by grant;

(b) A statement of the fiscal year for which the waiver is requested;

(c) A statement of the amount of the waiver being requested by fiscal year and how the amount was computed;

(d) A statement of why the waiver is required;

(e) Documentation supporting the need for a waiver; and

(f) The university's efforts to meet the AREERA section 105 requirements in the future. NIFA will approve or disapprove these waiver requests within 60 days of receipt. As stated above, waivers will be granted in cases of hardship, infeasibility, or other circumstances beyond the control of the States.

IV. Integrated Research and Extension Activities (Hatch Act Funds)

A. Reconfirm or Reset Target Percentages

By September 30, 2010, each 1862 Land-Grant Institution must reconfirm or reset their Target Percentage for integrated research and extension activities authorized under the Hatch Act. Institutions have a choice of two options: (A) Target 25 percent which will automatically waive the requirement to report on the FY 1997 expenditures for integrated research and extension activities; or (B) Target a percentage which is two times the FY 1997 expenditures for integrated research and extension activities (commonly referred to as the FY 1997 baseline) but less than 25 percent. Institutions will use Form NIFA–TARG (Rev. 07/2010), Establishment of Target Percentages for Multistate Extension Activities and Integrated Activities, to select their option. If an institution wishes to reconfirm their original Target Percentage, they should forward a copy of the original Form NIFA–TARG (Rev. 07/2010) and Form NIFA–BASE (Rev. 07/2010) to the NIFA Formula Grants Section, Awards Management Branch, with a memo that the 1862 Land-Grant Institution is reconfirming the original Target Percentages set in FY 2000. Institutions selecting Option B for the first time also are required to report by September 30, 2010, the amount of FY 1997 funds allocated under the Hatch Act and expended on integrated research and extension activities during the period from October 1, 1996, through September 20, 1997. These institutions will use Form NIFA–BASE (Rev. 07/2010), Establishment of Fiscal Year (FY) 1997 Baselines for Multistate Extension Activities and Integrated Activities. When completing this form, institutions may opt to report on the planned program level which is a collection of integrated research and extension programs or activities. Please see Appendix A for the total amount of the Hatch Act funds that were allocated to the 1862 Land-Grant Institutions in FY 1997. The requirement to submit Form NIFA–BASE (Rev. 07/2010) is automatically waived for those institutions selecting Option A. States who were unable to document FY 1997 baseline expenditures must select Option A which is 25 percent.

Integrated activities mean jointly planned, funded, and interwoven activities between research and extension to solve problems. This includes the generation of knowledge and the transfer of information and technology. As mentioned in the

Preface, this requirement applies to the Federal formula funds only and will apply to all funds authorized and allocated under the Hatch Act, including Hatch Multistate Research Fund. Examples of integrated activities include joint research and extension personnel appointments. In addition, integrated activities may include coordinating committees, workshops, training, centers, projects, and meetings as long as they meet the definition of "integrated activities."

B. Submission of Supplement to the 5-Year Plan of Work Update

Each institution also is required to submit Form NIFA–PLAN (Rev. 07/2010), Supplement to the 5-Year Plan of Work, Multistate Extension Activities and Integrated Activities, for all integrated research and extension activities that will be supported by the Hatch Act funds used to satisfy the AREERA section 204 requirement for integrated research and extension activities. This form should be completed each fiscal year to reflect the 5-Year Plan of Work updated and submitted in the AREERA State Plan of Work Information System. Institutions should use the prior fiscal year amount (*e.g.*, use the FY 2009 allocation amount for the FY 2011–2015 reporting requirement due in FY 2010) as a basis for planning programs and/or activities to meet the AREERA section 204 requirements. Please note that compliance with section 204 of AREERA will be determined by the institution meeting the Target Percentage of the actual formula allocation for the applicable fiscal year. This form (NIFA–TARG (Rev. 07/2010)) is due to the NIFA Formula Grants Section, Awards Management Branch, by April 1st each fiscal year and should complement the 5-Year Plan of Work. A brief statement of each planned program or activity is required and must be attached to this form. However, in lieu of these brief statements, institutions may refer to information on integrated activities reported in the 5-Year Plan of Work, if such information clearly describes integrated planned programs and/or activities as listed on Form NIFA PLAN (Rev. 07/2010).

C. Annual Report of Accomplishments and Results

Form NIFA–REPT (Rev. 07/2010), Supplement to the Annual Report of Accomplishments and Results, Multistate Extension Activities and Integrated Activities, will be due April 1st each year and must be submitted as a summary of the integrated research and extension planned programs or activities that have been used to satisfy the requirements of AREERA section 204. The form has been designed so that each institution will submit only one form with attached brief summaries for each fiscal year. The form allows for the reporting on all three AREERA requirements: Hatch integrated; Smith-Lever multistate; and Smith-Lever integrated and includes a certification statement. One form should be submitted for each fiscal year; and current fiscal year funds should not be commingled with funds from prior fiscal years. If you are carrying over AREERA multistate and integrated requirements from a previous fiscal year and both requirements are satisfied in a later fiscal year, the Form NIFA–REPT (Rev. 07/2010) should be marked "Final" for that fiscal year. If you are carrying over these AREERA requirements into the next fiscal year, the Form NIFA–REPT (Rev. 07/2010) should be marked "Interim" for that fiscal year in which the funds were first allocated. Do not submit a "Final" report for any fiscal year until the full requirement has been met for all three AREERA requirements. If you know that you will be unable to meet your AREERA requirements for any fiscal year, please contact the NIFA Formula Grants Section, Awards Management Branch, via email as soon as possible. NIFA may be required to reduce your allocation by the Target Percentage amount not met, as these costs will be disallowed. Brief statements or summaries describing the activities performed and the progress to date on each planned program or activity must be attached to this form. Although the Annual Report describes in detail the goals and accomplishments for an institution's entire program, a brief description of the Integrated Research and Extension Activities for each program listed in the NIFA–REPT (Rev. 07/2010) form must be attached. Please note that amounts on these forms are subject to audit. This form is due each fiscal year on April 1st and should be submitted to the NIFA Formula Grants Section, Awards Management Branch.

D. Waivers

A waiver may be requested for failure to meet the AREERA section 204 requirement. Eligible institutions may request a waiver for this purpose when one of the following criteria is met: (1) Infeasibility, (2) hardship, or (3) other circumstances beyond the control of the State. The waiver request and supporting documentation should be addressed to the NIFA Director and forwarded to the NIFA Formula Grants Section, Awards Management Branch. Waivers can only be granted on an annual basis and may be processed as either a pre-waiver or a post-waiver. A pre-waiver must be submitted prior to October 1st of the fiscal year. A post-waiver must be submitted with the other AREERA Section 204 reporting requirements due April 1st. Institutions must use Form NIFA–WAIVER (Rev. 07/2010), Request for Waiver from Target Percentage for Multistate Extension Activities and Integrated Activities, to request a reduction in the minimum percentage required to be expended for integrated research and extension activities. The waiver request should be signed by the appropriate institutional official (*i.e.,* Dean or Director). To expedite the consideration of the waiver request, the institution should include the following elements in the requested letter:

(a) A request for the waiver by grant;

(b) A statement of the fiscal year for which the waiver is requested;

(c) A statement of the amount of the waiver being requested by fiscal year and how the amount was computed;

(d) A statement of why the waiver is required;

(e) Documentation supporting the need for a waiver; and

(f) The university's efforts to meet the AREERA section 204 requirements in the future. NIFA will approve or disapprove these waiver requests within 60 days of receipt. As stated above, waivers will be granted in cases of hardship, infeasibility, or other circumstances beyond the control of the States.

V. Integrated Research and Extension Activities (Smith-Lever Act Funds)

A. Reconfirm or Reset Target Percentages

By September 30, 2010, each 1862 Land-Grant Institution must reconfirm or reset their Target Percentage for integrated research and extension activities authorized under the Smith-Lever Act. Institutions have a choice of two options: (A) Target 25 percent which will automatically waive the requirement to report on the FY 1997 expenditures for integrated research and extension activities; or (B) Target a percentage which is two times the FY 1997 expenditures for integrated research and extension activities (commonly referred to as the FY 1997 baseline) but less than 25 percent. Institutions will use Form NIFA–TARG (Rev. 07/2010), Establishment of Target Percentages for Multistate Extension Activities and Integrated Activities, to select their option. If an institution wishes to reconfirm their original Target

Percentage, they should forward a copy of the original Form NIFA–TARG (Rev. 07/2010) and Form NIFA–BASE (Rev. 07/2010) to the Formula Grants Section, Awards Management Branch, with a memo that the 1862 Land-Grant Institution is reconfirming the original Target Percentages set in FY 2000. Institutions selecting Option B for the first time also are required to report by September 30, 2010, the amount of FY 1997 funds allocated under the Smith-Lever Act and expended on integrated research and extension activities during the period from October 1, 1996, through September 30, 1997. These institutions will use Form NIFA–BASE (Rev. 07/2010), Establishment of Fiscal Year (FY) 1997 Baselines for Multistate Extension Activities and Integrated Activities. When completing this form, institutions may opt to report on the planned program level which is collection of integrated research and extension programs or activities. Please see Appendix A for the total amount of Smith-Lever Act funds that were allocated to the 1862 Land-Grant Institutions in FY 1997. The requirement to submit Form NIFA–BASE (Rev. 07/2010) is automatically waived for those institutions selecting Option A. States who were unable to document FY 1997 baseline expenditures must select Option A which is 25 percent.

Integrated activities means jointly planned, funded, and interwoven activities between research and extension to solve problems. This includes the generation of knowledge and the transfer of information and technology. As mentioned in the Preface, this requirement applies to the Federal formula funds only and will apply to all funds authorized and allocated under the Smith-Lever Act. Examples of integrated activities include joint research and extension personnel appointments. In addition, integrated activities may include coordinating committees, workshops, training, centers, projects, and meetings as long as they meet the definition of "integrated activities."

B. Submission of Supplement to the 5-Year Plan of Work Update

Each institution also is required to submit Form NIFA–PLAN (Rev. 07/2010), Supplement to the 5-Year Plan of Work, Multistate Extension Activities and Integrated Activities, for all integrated research and extension activities that will be supported by the Smith-Lever Act funds used to satisfy the AREERA section 204 requirement for integrated research and extension activities. This form should be completed each fiscal year to reflect the 5-Year Plan of Work updated and submitted in the AREERA State Plan of Work Information System. Institutions should use the prior fiscal year amount (*e.g.,* use the FY 2009 allocation amount for the FY 2011–2015 reporting requirement due in FY 2010) as a basis for planning programs and/or activities to meet the AREERA section 204 requirements. Please note that compliance with section 204 of AREERA will be determined by the institution meeting the Target Percentage of the actual formula allocation for the applicable fiscal year. This form (NIFA–TARG (Rev. 07/2010)) is due to the NIFA Formula Grants Section, Awards Management Branch, by April 1st each fiscal year and should complement the 5-Year Plan of Work. A brief statement of each planned program or activity is required and must be attached to this form. However, in lieu of these brief statements, institutions may refer to information on integrated activities reported in the 5-Year Plan of Work, if such information clearly describes integrated planned programs and/or activities as listed on Form NIFA PLAN (Rev. 07/2010).

C. Annual Report of Accomplishments and Results

Form NIFA–REPT (Rev. 07/2010) Supplement to the Annual Report of Accomplishments and Results, Multistate Extension Activities and Integrated Activities, will be due April 1st each year and must be submitted as a summary of the integrated research and extension planned programs or activities that have been used to satisfy the requirements of AREERA section 204. The form has been designed so that each institution will submit only one form with attached brief summaries for each fiscal year. The form allows for the reporting on all three AREERA requirements: Hatch integrated; Smith-Lever multistate; and Smith-Lever integrated and includes a certification statement. One form should be submitted for each fiscal year, and current fiscal year funds should not be commingled with funds from prior fiscal years. If you are carrying over AREERA multistate and integrated requirements from a previous fiscal year and both requirements are satisfied in a later fiscal year, the Form NIFA–REPT (Rev. 07/2010) should be marked "Final" for that fiscal year. If you are carrying over these AREERA requirements into the next fiscal year, the Form NIFA–REPT (Rev. 07/2010) should be marked "Interim" for that fiscal year in which the funds were first allocated. Do not submit a "Final" report for any fiscal year until the full requirement has been met for all three AREERA requirements. If you know that you will be unable to meet your AREERA requirements for any fiscal year, please contact NIFA Formula Grants Section, Awards Management Branch, via e-mail as soon as possible. NIFA may be required to reduce your allocation by the Target Percentage amount not met, as these costs will be disallowed. Brief statements or summaries describing the activities performed and the progress to date on each planned program or activity must be attached to this form. Although the Annual Report describes in detail the goals and accomplishments for an institution's entire program, a brief description of the Integrated Research and Extension Activities for each program listed in the NIFA–REPT (Rev. 07/2010) form must be attached. Please note that amounts on these forms are subject to audit. This form is due each fiscal year on April 1st and should be submitted to the NIFA Formula Grants Section, Awards Management Branch.

D. Waivers

A waiver may be requested for failure to meet the AREERA section 204 requirement. Eligible institutions may request a waiver for this purpose when one of the following criteria is met: (1) Infeasibility, (2) hardship, or (3) other circumstances beyond the control of the State. The waiver request and supporting documentation should be addressed to the NIFA Director and forwarded to the NIFA Formula Grants Section, Awards Management Branch. Waivers can only be granted on an annual basis and may be processed as either a pre-waiver or a post-waiver. A pre-waiver must be submitted prior to October 1st of the fiscal year. A post-waiver must be submitted with the other AREERA Section 204 reporting requirements due April 1st. Institutions must use Form NIFA–WAIVER (Rev. 07/2010), Request for Waiver from Target Percentage for Multistate Extension Activities and Integrated Activities, to request a reduction in the minimum percentage required to be expended for integrated research and extension activities. The waiver request should be signed by the appropriate institutional official (*i.e.,* Dean or Director). To expedite the consideration of the waiver request, the institution should include the following elements in the requested letter:

(a) A request for the waiver by grant;

(b) A statement of the fiscal year for which the waiver is requested;

(c) A statement of the amount of the waiver being requested by fiscal year and how the amount was computed;

(d) A statement of why the waiver is required;

(e) Documentation supporting the need for a waiver; and

(f) The university's efforts to meet the AREERA section 204 requirements in the future. NIFA will approve or disapprove these waiver requests within 60 days of receipt. As stated above, waivers will be granted in cases of hardship, infeasibility, or other circumstances beyond the control of the State.

VI. Submission of Forms

All forms collected under this Interim Administrative Guidance should be submitted electronically to *formulagrantforms@nifa.usda.gov* or via fax on (202) 401–7752.

Dated: Done at Washington, DC, this 2nd day of August 2010.

Roger Beachy,

Director, National Institute of Food and Agriculture.

[FR Doc. 2010–19629 Filed 8–11–10; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF AGRICULTURE

Forest Service

Sierra National Forest, Bass Lake Ranger District, California, Fish Camp Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Sierra National Forest, Bass Lake Ranger District is proposing to conduct a comprehensive series of treatments near a Wildland-Urban Interface area known as the community of Fish Camp. Strategically Placed Landscape Area Treatments (SPLATs) have been initially identified to provide a means to reduce the intensity and spread of wildland fires across the landscape and near communities. Additional treatments within these SPLATs have been identified where forest stands are densely stocked and thinning is needed. This thinning is needed to reduce inter-tree competition and improve tree vigor and increase stand resistance to drought conditions, insect and disease attack.

DATES: Comments concerning the scope of this analysis should be received no later than 30 days after the publication of this notice in the **Federal Register**. The draft environmental impact statement (DEIS) is expected in November 2010 and the final environmental impact statement (FEIS) is expected in March 2011.

ADDRESSES: Send written comments to U.S. Forest Service, Sierra National Forest, Bass Lake Ranger District, 57003 Road 225, North Fork, CA 93643, Attn: David Martin. Comments may also be sent via e-mail to *comments-pacificsouthwest-sierra@fs.fed.us* (use Rich Text format (.rtf) or Word format (.doc)) or via facsimile to (559) 877–3308.

It is important that reviewers provide their comments at such times and in such a way that they are useful to the Agency's preparation of the EIS. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. However comments submitted anonymously will be accepted and considered.

FOR FURTHER INFORMATION CONTACT: Mark Lemon, Interdisciplinary Team Leader, at Sierra National Forest, Bass Lake Ranger District, 57003 Road 225, North Fork, CA 93643. 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 Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background Information: The Fish Camp Project (Madera and Mariposa Counties, California) lies within the Big Creek watershed, where during the period before significant Euro-American influence, natural fires occurred frequently and were of low intensity with return intervals ranging from five to 10 years. During the past century, management activities (including harvesting operations, fire exclusion/suppression, *etc.*) and increased human habitation, have changed the composition of vegetation. Currently, vegetation within the Fish Camp Project has changed from one where frequent, low intensity fires occurred to one with increased susceptibility to moderate to high intensity wildland fire. Forest stand densities are above what can be sustained, with inter-tree competition increasing and tree vigor beginning to decline. Pockets of insect and disease attack are beginning to show in the stands as well as drought induced mortality.

The Fish Camp Project was originally to be documented in an Environmental Assessment (EA). The Fish Camp Project lies within the elevational bands for the Southern Sierra Fisher Conservation Area and the American marten. Public concern and management review surrounding the significance of potential impacts to the Pacific fisher, a candidate threatened and endangered species, the California spotted owl, a sensitive species, and American marten during past projects, has led to the decision to document the environmental analysis with an environmental impact statement (EIS) for this project.

Purpose and Need for Action

The Sierra National Forest Land and Resource Management Plan (as amended in January 2004) has identified Wildland-Urban Interface (WUI) areas as places where human habitation is mixed with areas of flammable wildland vegetation and has the highest priority for treatment. As directed in the Sierra Nevada Forest Plan Amendment (2004), national forests are to integrate fire and fuels management objectives with other resource management objectives and address the role of wildland fire in the ecosystem. The forest-wide standards and guidelines state that "vegetation within treatment areas should be modified to meet desired surface, ladder and crown fuel conditions as well as stand densities necessary for healthy forest during drought conditions". The community of Fish Camp (Mariposa County, California) lies in the western portion of the project area. On the northern portion of the project boundary is Yosemite National Park. Many of the homes in Fish Camp do not have sufficient clearance to protect them if a fast moving wildland fire were to move into the area.

Vegetation in the Fish Camp Project area includes mixed conifer stands with some small areas of True Fir. Insect and drought induced mortality is beginning to appear in pockets within both natural stands and conifer plantations. Scattered throughout the project area are pockets of heavy dead and down material (branches, limbs and logs) resulting from natural accumulation and past management activities. In lower to mid-elevations of the project area and on the steeper slopes, brush (manzanita/ceanothus) is the main vegetation cover.

Based on the current conditions described above the Fish Camp Project objectives are to: (1) Reduce fuel ladders and excessive ground fuels that pose a potential for the propagation and sustainability of a crown fire, (2) minimize the effects of wildland fire in

high risk (probability of ignition occurring), high hazard (availability of fuels to sustain a fire) wildland urban intermix area, (3) increase the vigor and health of mixed conifer stands and plantations, and (4) prevent and control the spread of noxious weeds.

Proposed Action

The proposed action includes vegetation treatment areas designed to create SPLATs to reduce the intensity and spread of wildland fire across the landscape and near communities and reduce inter tree competition to improve tree vigor and increase stand resistance to drought induced mortality, insect and disease attack. To accomplish the goals listed above, the Bass Lake Ranger District is proposing a 5700 acre project area with approximately 2,130 acres in vegetation treatment. The proposed action includes silvicultural and fuel reduction treatments used to accelerate the development of old forest characteristics and improve the resiliency of conifer stands and plantations to natural disturbances. In summary these treatments would include:

- Commercial thinning from below and mechanically treating approximately 45–50 year old pine plantations and 85–110 year old pine and mixed conifer forests to remove fuel ladders and reduce competition between remaining trees to maintain or improve forest resiliency and vigor.
- Mechanical treatment of brush/shrub patches and failed plantations to reduce wildland fire effects and to tie treatment areas together.
- Re-establish conifers in areas lacking appropriate stocking.
- Hand-pull noxious weeds, prior to project implementation, in order to minimize the likelihood of spread into recently treated forests (invasive weeds tend to spread opportunistically into freshly disturbed areas).

Estimated acre accomplishment of the gross vegetation treatment:

- Commercial thinning of approximately 1,250 acres of pine plantations (550+/−acres), pine and mixed conifer stands (700+/−acres).
- Masticating brush fields and pre-commercially thinning non-commercial size reproduction areas on approximately 215 acres;
- Treating slash concentrations on 1,450 acres by a combination of tractor and/or hand piling and burning. Of these 1,450 acres 1,000 may be available for under story burning.
- Prescribe burning approximately 200 acres.

Possible Alternatives

To comply with the National Environmental Policy Act, the Forest Service will evaluate additional alternatives to the proposed action developed based on public comments. A no action alternative to provide a baseline for comparison to the action alternatives will be included within the EIS. Each alternative will be explored and evaluated, or rationale will be given for eliminating an alternative from detailed study.

Responsible Official

The Responsible Official is Scott G. Armentrout, Forest Supervisor, Sierra National Forest, 1600 Tollhouse Road, Clovis, CA 93612.

Nature of Decision To Be Made

The Forest Supervisor will decide whether to implement the proposed action, take an alternative action that meets the purpose and need or take no action.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. The project is included in the Sierra National Forest's quarterly schedule of proposed actions (SOPA). Information on the proposed action will also he posted on the Sierra National Forests Web site, *http://www.fs.fed.us/r5/sierra/projects,* and will also be advertised in both the Fresno Bee and the Oakhurst Sierra Star. This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. Comments submitted during this scoping period should writing and should be specific to the proposed action. The comments should describe as clearly and completely as possible any issues the commenter has with the proposal. It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement.

Dated: August 4, 2010.

Scott G. Armentout,

Forest Supervisor.

[FR Doc. 2010–19797 Filed 8–11–10; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2010–0024]

Codex Alimentarius Commission: Meeting of the Codex Committee on Residues of Veterinary Drugs in Food

AGENCY: Office of the Acting Under Secretary for Food Safety, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Office of the Acting Under Secretary for Food Safety, U.S. Department of Agriculture (USDA), and the U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine, are sponsoring a public meeting on August 16, 2010. The objective of the public meeting is to provide information and receive public comments on agenda items and draft U.S. positions that will be discussed at the 19th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), which will be held in Burlington, Vermont, from August 30–September 3, 2010. The Acting Under Secretary for Food Safety and the FDA recognize the importance of providing interested parties the opportunity to obtain background information on the 19th CCRVDF session and to address items on the agenda.

DATES: The public meeting is scheduled for August 16, 2010, from 1 p.m.–4 p.m.

ADDRESSES: The public meeting will be held at USDA, J.L. Whitten Building, Room 107–A, 1400 Independence Avenue, SW., Washington, DC 20250.

Conference Call Information:

Call-In#: 1–866–692–3158.
Passcode: 5986642.

Documents related to the 19th Session of the CCRVDF will be accessible via the World Wide Web at the following address: *http://www.codexalimentarius.net/current.asp.*

The U.S. Delegate to the 19th Session of the CCRVDF, Dr. Kevin Greenlees, and the FDA invite U.S. interested parties to submit their comments electronically to the following e-mail address: *Brandi.Robinson@fda.hhs.gov.*

For further information about the 19th session of the CCRVDF contact: Dr. Kevin Greenlees, Senior Advisor for Science & Policy, Office of New Animal Drug Evaluation, HFV–100 USFDA Center for Veterinary Medicine, 7520 Standish Place, Rockville, MD 20855, *Telephone:* (240) 276–8214, *Fax:* (240) 276–9538, *e-mail: Kevin.Greenlees@fda.hhs.gov*

For further information about the public meeting, contact: Ken Lowery,

International Issues Analyst, USDA, Food Safety and Inspection Service, U.S. Codex Office, 1400 Independence Avenue, SW., Room 4861, Washington, DC 20250, *Telephone:* (202) 690–4042, *Fax:* (202) 720–3157, *e-mail: Kenneth.Lowery@fsis.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Codex was established in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers andensure fair practices in the food trade.

The CCRVDF is responsible for determining priorities for the consideration of residues of veterinary drugs in foods, recommending maximum levels of such substances, developing codes of practice as may be required, and considering methods of sampling and analysis for the determination of veterinary drug residues in foods.

The Committee is hosted by the United States.

Issues To Be Discussed at the Public Meeting

The following items on the agenda for the 19th Session of the CCRVDF will be discussed during the public meeting:

- Matters referred by the Codex Alimentarius Commission and other Codex committees and task forces.
- Matters arising from FAO/WHO.
- Report of the World Organization For Animal Health (OIE) activities, including the harmonization of technical requirements for registration of veterinary medicinal products.
- Draft Maximum Residue Limits (MRL) for veterinary drugs (at Step 7).
- Discussion paper on methods of analysis for residues of veterinary drugs in foods.
- Draft priority list of veterinary drugs requiring evaluation or re-evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- Factors related to the establishment of Acceptable Dietary Intake (ADI) and the process of recommending MRLs.
- Risk management recommendations for veterinary drugs for which no ADI and MRL has been recommended by JECFA.
- Discussion paper on veterinary drugs in honey production.
- Discussion paper on sampling plan for residue control for aquatic animal products and derived edible products of aquatic origin.

Public Meeting

At the August 16, 2010, public meeting, draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to the U.S. Delegate for the 19th Session of the CCRVDF, Dr. Kevin Greenlees (*see* **ADDRESSES**). Written comments should state that they relate to activities of the 19th Session of the CCRVDF.

USDA Nondiscrimination Statement

USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, or audiotape) should contact USDA's Target Center at 202–720–2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW., Washington, DC 20250–9410 or call 202–720–5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations/2010_Notices_Index/*. FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an electronic mail subscription service that provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/*. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC on: August 10, 2010.

Karen Stuck,

U.S. Manager for Codex Alimentarius.

[FR Doc. 2010–20011 Filed 8–10–10; 4:15 pm]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Notice of Meeting of the Agricultural Air Quality Task Force

AGENCY: Natural Resources Conservation Service (NRCS), United States Department of Agriculture.

ACTION: Notice of meeting; correction.

SUMMARY: The Natural Resources Conservation Service (NRCS) published in the **Federal Register** of July 28, 2010, Notice of a Meeting (75 FR 44214). This document corrects the location of the LPAES Workshop. The correct location is on the campus of the U.S. Environmental Protection Agency Headquarters, Room C111 A–B–C, located at 109 TW Alexander Drive, Research Triangle Park, North Carolina 27711; (919) 541–5400.

The Agricultural Air Quality Task Force (AAQTF) will meet to continue discussions on air quality issues relating to agriculture. Additionally, the Livestock and Poultry Subcommittee of the AAQTF will conduct a pre-meeting *Livestock and Poultry Air Emissions Standardization (LPAES) Workshop* discussing livestock and poultry air emissions monitoring data/research obtained from the National Animal Air Emissions Monitoring Study (NAAEMS), and other published research/data.

DATES: The LPAES workshop will convene at 2 p.m. on Monday September 27, 2010 and at 8 a.m. on Tuesday September 28, 2010 and will conclude at 6 p.m. September 27, 2010 and 5 p.m. September 28, 2010.

The AAQTF meeting will convene at 8 a.m. on Wednesday and Thursday

(September 29–30, 2010), and conclude at 5 p.m. each day. A public comment period for the AAQTF meeting will be held on September 30, 2010. Individuals making oral presentations should register in person at the AAQTF meeting site and must bring with them fifty copies of any materials they would like distributed.

ADDRESSES: The LPAES workshop and the AAQTF meetings will be held on the campus of the U.S. Environmental Protection Agency Headquarters, Room C111 A–B–C, located at 109 TW Alexander Drive, Research Triangle Park, North Carolina 27711; (919) 541–5400.

FOR FURTHER INFORMATION CONTACT: Questions and comments should be directed to Jeff Schmidt, (Acting) Designated Federal Official. Mr. Schmidt may be contacted at the USDA Natural Resources Conservation Service, 420 S State Road 7, Royal Palm Beach, Florida, 33414; (561) 242–5520 x3748; *jeff.schmidt@fl.usda.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2. Additional information for the AAQTF meeting may be found on the World Wide Web at *http://www.airquality.nrcs.usda.gov/AAQTF/.* Please be advised RSVPs are highly recommended for the LPAES workshop.

Signed August 6, 2010, in Washington, DC.

Teressa Davis,

Rulemaking Manager, Natural Resources Conservation Service.

[FR Doc. 2010–19893 Filed 8–11–10; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Project Waiver Granted to Custer County, South Dakota for the Purchase of Foreign Manufactured Heating, Ventilation, Air Conditioning (HVAC) Equipment

AGENCY: Rural Housing Service, USDA.

ACTION: Notice.

SUMMARY: The United States Department of Agriculture ("USDA") grants a project waiver of the Buy American Requirements of the American Recovery and Reinvestment Act of 2009 ("ARRA"), to Custer County, South Dakota ("County") for the purchase of foreign manufactured Heating, Ventilation, Air Conditioning ("HVAC") equipment for a Courthouse renovation and expansion project because the necessary manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality. This action permits the purchase of a Daikin VRV III HVAC unit and Tempeff Dual Core Technology unit of Japan and Canada respectively. These units address the operational requirement to heat and cool simultaneously, perform very efficiently, and are compatible and adaptable to the space restrictions created by the existing facility.

DATES: This action goes into effect August 12, 2010.

ADDRESSES: Address all comments concerning this notice to Dallas Tonsager, Under Secretary, Rural Development, U.S. Department of Agriculture, Room 205–W, 1400 Independence Avenue, SW., Washington, DC 20250–0107.

FOR FURTHER INFORMATION CONTACT: William Downs, 202–720–1499.

SUPPLEMENTARY INFORMATION: In accordance with section 1605 of Public Law 111–5, USDA hereby provides notice that it is granting a project specific waiver of the Buy American Requirements of the ARRA, to Custer Counter, South Dakota for the purchase of HVAC equipment, manufactured by Daikin of Japan and Tempeff of Canada for the Courthouse renovation and expansion project.

I. Background Information

Section 1605(a) of public law 111–5 requires that none of the appropriated funds may be used for the construction, alteration, maintenance, or repair of a public building or public work unless all of the iron, steel, and manufactured goods used in the project are produced in the United States. According to section 1605(b) of Public Law 111–5, a waiver may be granted if the head of the appropriate department or agency, in this case the Secretary of Agriculture, determines that (1) Applying these requirements would be inconsistent with public interest; (2) iron, steel, and manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality; or (3) inclusion of iron, steel, and manufactured goods produced in the United States will increase the cost of the overall project by more than 25 percent. Custer County has requested a waiver from the Buy American Requirement for the purchase of HVAC equipment suitable for the conditions of the existing facility and the expansion area. The purchase of the new HVAC equipment is intended to provide the specified conditioning for the existing Courthouse renovation and expansion. The estimated cost of the overall improvements to the County's Courthouse is $5.8 million. In designing the HVAC equipment the designers of record evaluated the various technologies based on the following factors:

- The project requirements include addressing the limitations of space for HVAC equipment and the associated accessories.
- The project requires a very high efficiency performance for the conditions presented by the region and the requirement for simultaneous heating and cooling.
- The project requires a frost resistant operating system.

As part of an exhaustive review and search for potentially viable HVAC units, the County and their consultants determined that there is no domestic manufacturer of HVAC equipment that provides the specified performance and technical features required for this project.

According to the County, the only HVAC equipment that meets the technical specifications is manufactured only by Daikin and Tempeff, of Japan and Canada respectively. As a result, the County requested a waiver of the ARRA Buy American provisions on the basis of non-availability of a United States manufactured product that will meet the design and performance criteria specified for this HVAC system.

II. Non-Availability Finding

The Secretary has determined that, based on the information available, and to the best of USDA's knowledge, there do not appear to be other HVAC systems manufactured in the United States that are available at this time to meet the County's design specifications and performance requirements for this project.

USDA's technical review team and architects reviewed a memorandum submitted by the County describing the foreign equipment that fits the technical specifications for the HVAC equipment and the process the County followed in adopting the HVAC design. USDA's technical review team and architects conducted a nationwide review of equipment vendors, manufacturers' representatives, and associated resources typically relied on by designers of HVAC equipment in order to determine whether there was any HVAC equipment manufactured in the United States that meet the County's design specifications and performance requirements. The evaluation by USDA's technical review team and architects supports the County's claim that a suitable HVAC system which meets the County's design specifications

and performance requirements for its Courthouse renovation and expansion project is not reasonably available in sufficient commercial quantities of a satisfactory quality that is manufactured in the United States.

III. The Waiver

Having established a proper basis that this manufactured good was not available from a producer in the United States, the County is hereby granted a waiver from the Buy American requirements. This waiver permits use of ARRA funds for the purchase of the specified Daikin VRV III heat recovery system and Tempeff Dual Core Technology documented in the County's waiver request submittal dated February 19, 2010, as part of its Courthouse renovation and expansion project. This supplementary information constitutes the detailed written justification required by section 1605(c) of Public Law 111–5 for waivers "based on a finding under subsection (b)."

This waiver only applies to the use of the specified product for the ARRA project being proposed. Any other ARRA recipient that wishes to use the same product must apply for a separate waiver based on project specific circumstances.

IV. Equal Opportunity and Non-Discrimination Requirements

The U.S. Department of Agriculture prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs). Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202–720–2600 (voice and TDD). To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, SW., Washington, DC 20250–9410, or call 800–795–3272 (voice), or 202–720–6382 (TDD). "USDA is an equal opportunity provider, employer, and lender."

Authority: Sec. 1605, Pub. L. 111–5, 123 STAT. 115.

Dated: August 5, 2010.

Thomas J. Vilsack,

Secretary of Agriculture.

[FR Doc. 2010–19894 Filed 8–11–10; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Trade Adjustment Assistance for Farmers

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

The Administrator of the Foreign Agricultural Service (FAS) today accepted and began a review of a petition for trade adjustment assistance filed under the Fiscal Year 2011 program by the Maine State Pomological Society on behalf of apple producers in Maine. The Administrator will determine within 40 days whether increasing imports of apples contributed importantly to a greater than 15-percent decrease in the average annual price of apples compared to the average of the three preceding marketing years. If the determination is affirmative, producers who produce and market apples in Maine will be eligible to apply to the Farm Service Agency for free technical assistance and cash benefits.

FOR FURTHER INFORMATION CONTACT: Trade Adjustment Assistance for Farmers Program Staff, FAS, USDA by *phone:* (202) 720–0638 or (202) 690–0633; or by *e-mail at: tradeadjustment@fas.usda.gov;* or visit the TAA for Farmers' *Web site: www.fas.usda.gov/itp/taa.*

Dated: July 30, 2010.

John D. Brewer,

Administrator, Foreign Agricultural Service.

[FR Doc. 2010–19794 Filed 8–11–10; 8:45 am]

BILLING CODE 3410–10–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Determination Under the Textile and Apparel Commercial Availability Provision of the Dominican Republic-Central America-United States Free Trade Agreement ("CAFTA–DR Agreement")

August 9, 2010.

AGENCY: The Committee for the Implementation of Textile Agreements.

ACTION: Determination to add a product in unrestricted quantities to Annex 3.25 of the CAFTA–DR Agreement.

DATES: *Effective Date:* August 12, 2010.

SUMMARY: The Committee for the Implementation of Textile Agreements ("CITA") has determined that certain woven yarn-dyed fabrics of lyocell and cotton, as specified below, is not available in commercial quantities in a timely manner in the CAFTA–DR countries. The product will be added to the list in Annex 3.25 of the CAFTA–DR Agreement in unrestricted quantities.

FOR FURTHER INFORMATION CONTACT: Maria Dybczak, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–3651.

For Further Information On-Line: http://web.ita.doc.gov/tacgi/CaftaReqTrack.nsf under "Approved Requests," Reference number: 145.2010.07.08.Fabric. SoriniSametforBWA.

SUPPLEMENTARY INFORMATION:

Authority: The CAFTA–DR Agreement; Section 203(o)(4) of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act ("CAFTA–DR Implementation Act"), Pub. Law 109–53; the Statement of Administrative Action, accompanying the CAFTA–DR Implementation Act; and Presidential Proclamations 7987 (February 28, 2006) and 7996 (March 31, 2006).

Background: The CAFTA–DR Agreement provides a list in Annex 3.25 for fabrics, yarns, and fibers that the Parties to the CAFTA–DR Agreement have determined are not available in commercial quantities in a timely manner in the territory of any Party. The CAFTA–DR Agreement provides that this list may be modified pursuant to Article 3.25(4)-(5), when the President of the United States determines that a fabric, yarn, or fiber is not available in commercial quantities in a timely manner in the territory of any Party. *See* Annex 3.25 of the CAFTA–DR Agreement; *see also* section 203(o)(4)(C) of the CAFTA–DR Implementation Act.

The CAFTA–DR Implementation Act requires the President to establish procedures governing the submission of a request and providing opportunity for interested entities to submit comments and supporting evidence before a commercial availability determination is made. In Presidential Proclamations 7987 and 7996, the President delegated to CITA the authority under section 203(o)(4) of CAFTA–DR Implementation Act for modifying the Annex 3.25 list. Pursuant to this authority, on September 15, 2008, CITA published modified procedures it would follow in considering requests to modify the Annex 3.25 list of products determined to be not commercially available in the territory of any Party to CAFTA–DR (Modifications to Procedures for Considering Requests Under the Commercial Availability Provision of

the Dominican Republic-Central America-United States Free Trade Agreement, 73 FR 53200) ("CITA's procedures").

On July 8, 2010, the Chairman of CITA received a Request for a Commercial Availability Determination ("Request") from Sorini, Samet & Associates ("SS&A") for BWA, Inc. ("BWA") Corporation for certain woven yarn-dyed fabrics of lyocell and cotton. On July 12, 2010, in accordance with CITA's procedures, CITA notified interested parties of the Request, which was posted on the dedicated Web site for CAFTA–DR Commercial Availability proceedings. In its notification, CITA advised that any Response with an Offer to Supply ("Response") must be submitted by July 22, 2010, and any Rebuttal Comments to a Response ("Rebuttal") must be submitted by July 28, 2010, in accordance with Sections 6 and 7 of CITA's procedures. No interested entity submitted a Response to the Request advising CITA of its objection to the Request and its ability to supply the subject product.

In accordance with section 203(o)(4)(C) of the CAFTA–DR Implementation Act, and Section 8(c)(2) of CITA's procedures, as no interested entity submitted a Response objecting to the Request and demonstrating its ability to supply the subject product, CITA has determined to add the specified fabric to the list in Annex 3.25 of the CAFTA–DR Agreement.

The subject product has been added to the list in Annex 3.25 of the CAFTA–DR Agreement in unrestricted quantities. A revised list has been posted on the dedicated Web site for CAFTA–DR Commercial Availability proceedings.

Specifications: Certain Woven Yarn-Dyed Fabrics of Lyocell and Cotton

HTS Subheading: 5516.13.0000, 5516.43.00

Fiber Content: 55–85% standard lyocell (Tencel) staple fiber; 15–45% cotton

Avg Yarn Size: 29.6/1 to 84.7/1 metric

Thread Count (warp): 19.7 to 78.7 warp ends per centimeter

Thread Count (weft): 11.8 to 59 filling picks per centimeter

Weave Type: Plain or twill or dobby or jacquard or oxford or satin

Fabric Weight: 101.7 to 298.3 grams per square meter

Fabric Width: 139.7 to 154.9 centimeters

Coloration: Yarns of different colors

Finishing Processes: Enzyme (bio) washed

Kim Glas,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 2010–19941 Filed 8–11–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Reporting Requirements for Sea Otter Interactions with the Pacific Sardine Fishery Coastal Pelagic Species Fishery Management Plan.

OMB Control Number: 0648–0566.

Form Number(s): NA.

Type of Request: Regular submission (extension of a currently approved information collection).

Number of Respondents: 2.

Average Hours per Response: 15 minutes.

Burden Hours: 30 minutes (rounded up to 1 hour).

Needs and Uses: This request is for extension of a currently approved information collection. In accordance with the regulations implementing the Endangered Species Act (ESA), National Marine Fisheries Service (NMFS) initiated an ESA section 7 consultation with the United States Fish and Wildlife Service (USFWS) regarding the possible effects of implementing Amendment 11 (71 FR 36999) to the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP). USFWS determined that formal consultation was necessary on the possible effects to the threatened southern sea otter. USFWS completed a biological opinion for this action and although it was concluded that fishing activities were not likely to jeopardize the continued existence of the southern sea otter there remained the potential to incidentally take southern sea otters. USFWS determined that certain measures should be put in place to ensure the continued protection of the species. Therefore on May 30, 2007, NMFS published a final rule (72 FR 29891) implementing new reporting requirements and conservation measures under the CPS FMP. This included the requirement to report any interactions that may occur between a CPS vessel and/or fishing gear and sea otters within 24 hours to the Regional Administrator (RA). With the exception of an entanglement, all other observations must be reported within 20 days to the RA.

Affected Public: Business or other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, FAX number (202) 395–7285, or *David_Rostker@omb.eop.gov*.

Dated: August 6, 2010.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2010–19862 Filed 8–11–10; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: 2008 Panel of the Survey of Income & Program Participation, Wave 8 Topical Modules.

OMB Control Number: 0607–0944.

Form Number(s): SIPP–28805(L) Director's Letter; SIPP/CAPI Automated Instrument; SIPP28003 Reminder Card.

Type of Request: Revision of a currently approved collection.

Burden Hours: 143,303.

Number of Respondents: 94,500.

Average Hours per Response: 30 minutes.

Needs and Uses: The U.S. Census Bureau requests authorization from the Office of Management and Budget (OMB) to conduct the Wave 8 interview for the 2008 Panel of the Survey of Income and Program Participation

(SIPP). The core SIPP and reinterview instruments were cleared under Authorization No. 0607–0944.

The SIPP represents a source of information for a wide variety of topics and allows information for separate topics to be integrated to form a single and unified database so that the interaction between tax, transfer, and other government and private policies can be examined. Government domestic policy formulators depend heavily upon the SIPP information concerning the distribution of income received directly as money or indirectly as in-kind benefits and the effect of tax and transfer programs on this distribution. They also need improved and expanded data on the income and general economic and financial situation of the U.S. population. The SIPP has provided these kinds of data on a continuing basis since 1983, permitting levels of economic well-being and changes in these levels to be measured over time.

The survey is molded around a central "core" of labor force and income questions that remain fixed throughout the life of a panel. The core is supplemented with questions designed to answer specific needs, such as estimating eligibility for government programs, examining pension and health care coverage, and analyzing individual net worth. These supplemental questions are included with the core and are referred to as "topical modules."

The topical modules for the 2008 Panel Wave 8 are as follows: Annual Income and Retirement Accounts; Taxes; Child Care; and Work Schedule. These topical modules were previously conducted in the SIPP 2008 Panel Wave 5 instrument. Wave 8 interviews will be conducted from January 1, 2011 through April 30, 2011.

The SIPP is designed as a continuing series of national panels of interviewed households that are introduced every few years, with each panel having durations of approximately 3 to 4 years. The 2008 Panel is scheduled for four years and four months and includes thirteen waves which began September 1, 2008. All household members 15 years old or over are interviewed using regular proxy-respondent rules. They are interviewed a total of thirteen times (thirteen waves), at 4-month intervals, making the SIPP a longitudinal survey. Sample people (all household members present at the time of the first interview) who move within the country and reasonably close to a SIPP primary sampling unit (PSU) will be followed and interviewed at their new address. Individuals 15 years old or over who enter the household after Wave 1 will be interviewed; however, if these people move, they are not followed unless they happen to move along with a Wave 1 sample individual.

The OMB has established an Interagency Advisory Committee to provide guidance for the content and procedures for the SIPP. Interagency subcommittees were set up to recommend specific areas of inquiries for supplemental questions.

The Census Bureau developed the 2008 Panel Wave 8 topical modules through consultation with the SIPP OMB Interagency Subcommittee. The questions for the topical modules address major policy and program concerns as stated by this subcommittee and the SIPP Interagency Advisory Committee.

Data provided by the SIPP are being used by economic policymakers, the Congress, State and local governments, and Federal agencies that administer social welfare or transfer payment programs, such as the Department of Health and Human Services and the Department of Agriculture.

Affected Public: Individuals or households.

Frequency: Every 4 months.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Section 182.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or e-mail (*bharrisk@omb.eop.gov*).

Dated: August 6, 2010.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2010–19885 Filed 8–11–10; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XX94

2010 Russian Export Certification for Fishery Products

AGENCY: Seafood Inspection Program (SIP), National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The National Oceanic and Atmospheric Administration Seafood Inspection Program (NOAA SIP), through this notice, is announcing the requirements for exportation of fish and fishery products to the Russian Federation as set forth in the Memorandum of Understanding between Rosselkhoznadzor (the responsible Russian government agency) and the United States Department of Commerce, National Oceanic and Atmospheric Administration, which became effective on February 25, 2010.

FOR FURTHER INFORMATION CONTACT: Mr. Steven Wilson, *Steven.Wilson@noaa.gov*, Chief Quality Officer, Seafood Inspection Program, NOAA National Marine Fisheries Service, 1315 East West Highway, Room 10840, Silver Spring, MD 20910, (301) 713–2355 EXT. 217

SUPPLEMENTARY INFORMATION:

Background

On February 25, 2010, a Memorandum of Understanding (MOU) was signed by Russian officials marking the completion of an agreement between the National Oceanic and Atmospheric Administration (NOAA) and Rosselkhoznadzor of the Russian Federation regarding the certification of seafood products exported from the United States to the Russian Federation. The purpose of the agreement is to establish the terms for cooperation on monitoring the quality and safety of seafood products exported from the United States to the Russian Federation. Pursuant to the MOU, NOAA, through its Seafood Inspection Program, will issue export health certificates only to those firms on the SIP List of Approved Establishments and approved by Rosselkhoznadzor for export of seafood products to Russia.

The Seafood Inspection Program of the National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce, operating under authority of the Agricultural

Marketing Act (7 U.S.C. 1621 *et seq.*) and the Fish and Wildlife Act (16 U.S.C. 742a *et seq.*), is responsible for the development and advancement of commercial grade standards for fishery products and better health and sanitation standards in the industry and for furnishing inspection, evaluation, analytical, grading, and certification services to interested parties. Its primary purpose is to encourage and assist the industry in improving the quality, wholesomeness, safety, proper labeling, and marketability of seafood products.

In 2006, Rosselkhoznadzor notified the U.S. Government through the U.S. Embassy in Moscow of a change in Russian domestic law which allows Russian officials to deny entry of products into the Russian Federation in the absence of an agreement between the exporting country and Russia regarding certification of the safety and sanitary condition of fish and fishery products for export to the Russian Federation. Russian and U.S. officials met several times and exchanged correspondence regarding the new requirements in 2008 and 2009. In March 2009, NOAA and U.S. Food and Drug Administration (FDA) officials met with representatives of Russia's Rosselkhoznadzor. The U.S. delegation clarified that FDA is the responsible agency for the safety of imported food products from the Russian Federation and NOAA will provide certification services to exporters shipping seafood to the Russian Federation. In August 2009, the U.S. agreed to allow officials of Rosselkhoznadzor to visit selected seafood processing firms during which time Russian officials could observe and determine the status of controls in place for approved establishments of the NOAA Seafood Inspection Program. During the course of that visit, the parties had a series of discussions to arrive at the agreements found in the MOU between the two agencies.

New Procedures for Export Health Certification to the Russian Federation

According to the terms of the MOU, U.S. seafood firms in the supply chain desiring to produce, pack, store, or ship fish and fishery products for export to the Russian Federation are required to meet the requirements of the NOAA Seafood Inspection Program to be approved establishments in accordance with the regulations and policies of the NOAA Seafood Inspection Program, including but not limited to being in regulatory good standing with the FDA. Only such establishments meeting the requirements and subsequently approved by Rosselkhoznadzor may receive certification from the NOAA Seafood Inspection Program for export of fish and fishery products to the Russian Federation. The NOAA Seafood Inspection Program will allow a 90 day grace period after which U.S. seafood firms must fully comply with the new requirements.

More specifically, each U.S. seafood firm in the supply chain for export to the Russian Federation must:

- Demonstrate through inspection by the NOAA Seafood Inspection Program that seafood products produced at each U.S. seafood firm in the supply chain and exported to the Russian Federation meet the applicable Codex Alimentarius Commission (Codex), and the Organization for International Epizootics (OIE) standards, and meet the food safety objectives of U.S. and Russian Federation laws and regulations for seafood products
- Maintain regulatory good standing with the FDA. Only those U.S. seafood firms with a unique firm identification number, either a Central File Number or Firm Establishment Identifier, issued by the FDA are eligible to receive an export health certificate from the Seafood Inspection Program for export of seafood products to Russia.
- Demonstrate through inspection by the NOAA Seafood Inspection Program that each U.S. seafood firm in the supply chain meets the Seafood Inspection Program requirements for inclusion on a List of Approved Establishments. Only those establishments on the *List of Approved Establishments* will be eligible to export seafood products to Russia. The NOAA Seafood Inspection Program will post the *List of Approved Establishments* on the its website. (*http://www.seafood.nmfs.noaa.gov/*) and submit to Rosselkhoznadzor all changes in the list of approved establishments for export to the Russian Federation, including changes resulting from audits by Rosselkhoznadzor or the NOAA Seafood Inspection Program. The establishment is not finally approved until notification is provided by Rosselkhoznadzor. Only firms approved by Rosselkhoznadzor will be eligible to receive export certificates from the NOAA Seafood Inspection Program.

In order to meet the Seafood Inspection Program requirements as an approved establishment, U.S. seafood firms must contract for inspection services by the Seafood Inspection Program, provide a guarantee of payment, pass an initial audit of the seafood firm, and continually pass audits on a minimum of a quarterly basis. Under the terms of the contractual agreement between the firm and the Seafood Inspection Program, the firm must allow the program to conduct random, periodic audits of the firm to ensure that the relevant veterinary and sanitary requirements of the Seafood Inspection Program are met. If an audit reveals that an approved establishment is not in substantial compliance with the appropriate regulations, the Seafood Inspection Program will cease issuing export certificates to this establishment and inform Rosselkhoznadzor. The Seafood Inspection Program will inform Rosselkhoznadzor when an establishment is once again eligible for exporting seafood to the Russian Federation.

Separate and apart from the terms of the MOU, Rozzelkhozdzor has informed the NOAA Seafood Inspection Program that it will request information from U.S. seafood firms on the *List of Approved Establishments* shipping product to the Russian Federation regarding the importer of record in the Russian Federation. If the firm refuses to provide this information, Rosselkhoznadzor has stated that it may not allow the import of product from the firm into Russia.

Dated: August 9, 2010.

Eric C. Schwaab,

Assistant Administrator For Fisheries, National Marine Fisheries Service.

[FR Doc. 2010–19955 Filed 8–11–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 100726313–0313–01]

RIN 0648–ZC19

Coral Reef Conservation Program Implementation Guidelines

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final Implementation Guidelines for the Coral Reef Conservation Program.

SUMMARY: This document provides NOAA's revised Grant Program Implementation Guidelines (Guidelines) for the Coral Reef Conservation Program (CRCP or Program) under the Coral Reef Conservation Act of 2000 (Act). The Act authorizes the Secretary of Commerce (Secretary), through the NOAA Administrator (Administrator) and subject to the availability of funds, to provide matching grants of financial assistance for coral reef conservation projects under the Act. NOAA revised the Implementation Guidelines for the

Grant Program, which were originally published in 2002, to be applicable to Fiscal Years (FY) 2011 through FY 2015 and published a draft of the revision in the **Federal Register** notice of January 19, 2010 (75 FR 3114–3120) for review and comment. NOAA proposes to utilize several existing grant programs and mechanisms to implement the Program. Specific information about each funding category, including available funding, dates, detailed application requirements and evaluation criteria, is published in separate **Federal Register** notices. In accordance with the Act, NOAA developed a National Coral Reef Action Strategy (Strategy) in 2002 to provide an implementation plan to advance coral reef conservation, including a basis for funding allocations to be made under the Program. In response to an external program review in 2007, a new program manager, development of a 'Roadmap' for the future of the Program, and publication in 2009 of the CRCP Goals and Objectives 2010–2015 and CRCP International Strategy, the Program revised its Implementation Guidelines for the Grant Program to align more closely with the Program's new direction. The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of February 11, 2008 (73 FR 7696), are applicable to solicitations under this Program. This document is not a solicitation for project proposals.

DATES: Effective August 12, 2010.

FOR FURTHER INFORMATION CONTACT: Jenny Waddell, Grants and External Funding Coordinator, OCRM/Coral Conservation Division, NOAA National Ocean Service, 1305 East-West Highway, Silver Spring, MD 20910; 301–713–3155 extension 150, E-mail: *Jenny.Waddell@noaa.gov;* or Jennifer Koss, NMFS Habitat Conservation, NOAA National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910; 301–713–3459 extension 195, E-mail: *Jennifer.Koss@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

The Coral Reef Conservation Act of 2000 (16 U.S.C. 6401 *et seq.*) was enacted on December 14, 2000, for the following purposes:

(1) To preserve, sustain and restore the condition of coral reef ecosystems;

(2) To promote the wise management and sustainable use of coral reef ecosystems to benefit local communities and the Nation;

(3) To develop sound scientific information on the condition of coral reef ecosystems and the threats to such ecosystems;

(4) To assist in the preservation of coral reefs by supporting conservation programs, including projects that involve affected local communities and non-governmental organizations;

(5) To provide financial resources for those programs and projects; and

(6) To establish a formal mechanism for the collecting and allocating of monetary donations from the private sector to be used for coral reef conservation projects. Under section 6403 of the Act, the Secretary, through the NOAA Administrator (Administrator) and subject to the availability of funds, is authorized to provide matching grants of financial assistance for coral reef conservation projects. Section 408(c) of the Act authorizes up to $8,000,000 annually for projects under the Program.

As required under section 6403(j) of the Act, NOAA developed Implementation Guidelines for the Grant Program in 2002 and revised and refined those Guidelines in 2009. The Guidelines published in this notice will update and replace the existing guidelines in order to shift focus toward implementation of the Program's 20-year Goals and Objectives and International Strategy in an effort to narrow and sharpen the focus of the Program.

Each fiscal year the Program will publish notices of funding availability in the **Federal Register** and make the associated Federal Funding Opportunity announcement available on Grants.gov, to describe the availability of funds under each grant category and solicit project proposals.

B. Comments and Responses, and Changes to the Proposed Guidelines

The following summarizes the comments submitted in response to the Draft Guidelines published in the **Federal Register** on January 19, 2010 (75 FR 3114–3120), and NOAA's responses.

Comment 1: A commenter representing a regional Fishery Management Council wanted to know how the legislative requirement that 40% of grant funding be provided to the Atlantic/Caribbean and 40% to the Pacific will affect each of the four funding categories individually. *Response:* The 40%–40% requirement in the Coral Reef Conservation Act of 2000 pertains to the Coral Reef Conservation Grants Program Overall and is not applied to any individual funding category. Selection of projects across the program will be based on the merit of the proposed activities, regardless of the funding category under which the proposal was submitted.

Comments from the four Fishery Management Councils eligible for funding under this program were also received in response to supplemental information provided to the councils about the funding category to which they will be eligible to apply. The comments received on both the Guidelines and the supplemental information were considered but did not result in alterations to the final Guidelines. Interested parties may obtain access to the supplemental information provided to the councils by contacting *Jennifer.Koss@noaa.gov.* Any comments received on the supplemental information will be considered during subsequent revisions, if any, to the Guidelines. In summary, the Guidelines were not changed from the Draft published in the **Federal Register** on January 19, 2010 based on comments received by the Program.

II. Electronic Access

The Coral Reef Conservation Act of 2000 can be found on the Internet at: *http://thomas.loc.gov/* (Select Bill Text, then select 106th Congress, search on Bill Number HR 1653, select H.R. 1653.EH). Information on the U.S. Coral Reef Task Force, established June 11, 1998 under Executive Order 13089, can be found at: *http://coralreef.gov.* The National Coral Reef Action Strategy, which was published in 2002, is available at: *http://coris.noaa.gov/activities/actionstrategy/.* The CRCP Goals and Objectives 2010–2015, which were published in 2009, can be found at: *http://coralreef.noaa.gov/aboutcrcp/strategy/currentgoals/resources/3threats_go.pdf* and the CRCP International Strategy, also published in 2009, is available at: *http://coralreef.noaa.gov/aboutcrcp/strategy/currentgoals/resources/intl_strategy.pdf* Coral reef management priorities identified by State and Territorial partner agencies can be found in the Jurisdictional Coral Reef Management Priorities documents available at: *http://coralreef.noaa.gov/aboutcrcp/strategy/reprioritization/managementpriorities.*

III. Coral Reef Conservation Program

The objective of the Grant Program is to provide financial assistance for coral reef conservation programs and projects consistent with the Act, the National Coral Reef Action Strategy, the CRCP Goals and Objectives 2010–2015 and CRCP International Strategy, which were published in June 2009. NOAA's role in administering the Grant Program

is to strengthen and support the development and implementation of sound coral reef conservation projects, as well as ensure that the most beneficial projects are recommended for funding.

IV. Applicant Eligibility Requirements

As per section 6403(c) of the Act, eligible applicants include: Any natural resource management authority of a state or other government authority with jurisdiction over coral reefs or whose activities directly or indirectly affect coral reefs or coral reef ecosystems, or educational or non-governmental institutions with demonstrated expertise in the conservation of coral reefs. Each category of funding under this Program, as described in Section VII of this document, encompasses a specific subgroup of eligible applicants.

As a matter of policy, funding of Federal agency activities under this Program will be a low priority unless such activities are an essential part of a cooperative project with other eligible governmental or non-governmental entities.

NOAA agencies are not eligible for funding under this Program, as funding for such activities is provided for under section 6406 of the Act (National Program).

V. Eligible Coral Reef Conservation Activities

As described in section 6403(g) of the Act, projects considered for funding under this Program must be consistent with the National Coral Reef Action Strategy. Concordance with the Program's 20-year Goals and Objectives and International Strategy guidance documents published in 2009 to narrow and sharpen the priorities included in the National Coral Reef Action Strategy will be an additional criterion in evaluating eligible projects and activities. In addition, coral reef management priorities identified in 2010 by states, territories and commonwealths containing coral reef ecosystems through a formal management priority setting process will be considered when evaluating and selecting proposals. Further, the Administrator may not approve a project proposal unless it will enhance the conservation of coral reefs by addressing at least one of the following:

(1) Implementing coral conservation programs which promote sustainable development and ensure effective, long-term conservation of coral reefs;

(2) Addressing the conflicts arising from the use of environments near coral reefs or from the use of corals, species associated with coral reefs, and coral products;

(3) Enhancing compliance with laws that prohibit or regulate the taking of coral products or species associated with coral reefs or regulate the use and management of coral reef ecosystems;

(4) Developing sound scientific information on the condition of coral reef ecosystems or the threats to such ecosystems, including factors that cause coral disease;

(5) Promoting and assisting to implement cooperative coral reef conservation projects that involve affected local communities, nongovernmental organizations, or others in the private sector;

(6) Increasing public knowledge and awareness of coral reef ecosystems and issues regarding their long term conservation;

(7) Mapping the location and distribution of coral reefs;

(8) Developing and implementing techniques to monitor and assess the status and condition of coral reefs;

(9) Developing and implementing cost-effective methods to restore degraded coral reef ecosystems; or

(10) Promoting ecologically sound navigation and anchorages near coral reefs.

VI. Program Funding and Distribution

Section 6408(c) of the Act authorizes $8,000,000 annually for financial assistance awards administered by the Coral Reef Conservation Grant Program. The number of individual awards to be made each year will depend on the total amount of funds appropriated for coral reef activities within NOAA and the portion of those funds that are allocated to the Grant Program. More information about each category of funding, including the anticipated amount of funding available, suggested ranges for funding requests, and specific funding categories under which an applicant may choose to apply, will be published in annual solicitations published in the **Federal Register**.

Program funding awarded during any given fiscal year will be distributed, per section 6403(d) of the Act, in the following manner:

(1) No less than 40 percent of funds available shall be awarded for coral reef conservation projects in the Pacific Ocean within the maritime areas and zones subject to the jurisdiction or control of the United States;

(2) No less than 40 percent of funds available shall be awarded for coral reef conservation projects in the Atlantic Ocean, Gulf of Mexico and the Caribbean Sea within the maritime areas and zones subject to the jurisdiction or control of the United States; and

(3) Remaining funds shall be awarded for projects that address emerging priorities or threats, including international priorities or threats, identified by the Administrator. When identifying emerging threats or priorities, the Administrator may consult with the U.S. Coral Reef Task Force.

The above allocation provision applies to the Grant Program as a whole and not necessarily to individual funding categories.

VII. Funding Categories and Mechanisms

In order to ensure adequate funding for each of the purposes envisioned under the Act and to provide for a balanced overall Program, existing NOAA programs will be used to award funds in the funding categories described below. Each of the categories described below references the general activity and applicant eligibility requirements associated with proposals submitted therein. Specific activity and applicant eligibility information and proposal evaluation criteria for each category will be published in annual solicitations for proposals, consistent with the Guidelines.

(1) CRCP State and Territorial Coral Reef Conservation Cooperative Agreements support U.S. state and territorial government coral reef conservation management and monitoring activities, as described in Section V (1–10) of this document (section 6403(g) of the Act) for the purposes of monitoring and comprehensively managing coral reef ecosystems and associated fisheries within their jurisdictions. Monitoring of coral reef ecosystems under this category includes the collection, analysis, and reporting of long-term coral reef monitoring data pursuant to scientifically valid methodologies and protocols. These awards are intended to fund activities that are consistent with the CRCP Goals and Objectives 2010–2015 (*http://coralreef.noaa.gov/aboutcrcp/strategy/currentgoals/resources/3threats_go.pdf*), the Jurisdictional Coral Reef Management Priorities documents (*http://coralreef.noaa.gov/aboutcrcp/strategy/reprioritization/managementpriorities*) or both. Eligibility to receive an award is limited to the agency that was designated by the respective governors as the official point of contact agency. These proposals will be reviewed and awarded by the National Ocean Service (NOS) Office of Ocean and Coastal

Resource Management (OCRM) under CFDA 11.482.

(2) CRCP Domestic Coral Reef Conservation Grants provide funding to non-governmental entities not eligible under other categories, for the purpose of implementing cooperative coral reef conservation, protection, restoration, or education projects, as described in Section V (1–10) of this document (section 6403(g) of the Act) and consistent with the CRCP Goals and Objectives 2010–2015), the Jurisdictional Coral Reef Management Priorities documents or both. These proposals will be reviewed and awarded by the National Ocean Service (NOS) Office of Ocean and Coastal Resource Management (OCRM) under CFDA 11.482.

(3) CRCP Fishery Management Council Coral Reef Conservation Cooperative Agreements support projects to conserve, protect and restore coral reef habitats and associated fishery populations within the U.S. Exclusive Economic Zone, with the overall goal of improving the management of coral reefs and associated organisms through the avoidance of fishing impacts, application of ecosystem management or similar approaches and practices, as described in Section V (3) of this document (section 6403(g)(3) of the Act) and consistent with the CRCP Goals and Objectives 2010–2015. Eligible applicants include the four Regional Fishery Management Councils with jurisdiction over coral reefs, as established under the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*). These proposals will be reviewed and awarded by the NMFS Office of Habitat Conservation under CFDA 11.441.

(4) CRCP International Coral Reef Conservation Cooperative Agreements will be awarded for the purpose of implementing cooperative coral reef conservation activities as described in Section V (1–10) of this document (section 6403(g) of the Act) and consistent with priorities identified in the Program's International Strategy published in June 2009. Eligible applicants include international governmental and non-governmental entities, including those in the Freely Associated States of the Pacific. These proposals will be reviewed and awarded by the National Ocean Service (NOS) Office of Ocean and Coastal Resource Management (OCRM) under CFDA 11.482.

Annual solicitations published in the **Federal Register** will establish the annual priorities for that funding category, the range of funds available and the specific evaluation criteria for each funding category. NOAA may add additional funding categories in the annual solicitation based on available funding and/or the Program's coral reef conservation priorities. Selected applications may be funded and awards administered by NOAA, through either NMFS or NOS. Generally, one award will be made for each proposal accepted for funding. NOAA will determine the most appropriate funding mechanisms (grant, cooperative agreement, or interagency agreement) for selected individual projects, in consultation with the applicant, and based on the degree of direct NOAA involvement with the project beyond the provision of financial assistance. Substantial federal involvement in cooperative agreements may include participation of NOAA/CRCP staff in the planning, development and implementation of projects and/or provision of technical assistance, and will vary based on the category of funding, type of project, and type and experience of the award recipient. Proposals from non-Federal applicants that are selected for funding will be funded either through a project grant or cooperative agreement. Selected Federal proposals will be funded through interagency agreements; however, under the Program, such agreements must include a local sponsor of the coral reef conservation project.

VIII. Matching Funds

As per section 6403(b)(1) of the Act, Federal funds for any coral conservation project funded under this Program may not exceed 50 percent of the total costs of such project, and NOAA strongly encourages applicants to leverage as much investment as possible. Matching funds may comprise a variety of public and private sources and can include in-kind contributions and other non-cash support, but all matching funds must be from non-Federal sources. Federal funds may not be considered as matching funds. Details regarding the proposed match will be specified in the notice of funding availability.

For applicants who cannot meet the match requirement, as per section 6403(b)(2) of the Act, the Secretary may waive all or part of the matching requirement if the Administrator determines that the project meets the following two requirements:

(1) No reasonable means are available through which an applicant can meet the matching requirement, and

(2) The probable benefit of such project outweighs the public interest in such matching requirement.

Notwithstanding any other provision herein, and in accordance with 48 U.S.C. 1469a(d), this Program shall waive any requirement for local matching funds for any project under $200,000 (including in kind contributions) to the governments of Insular Areas, defined as the jurisdictions of the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

IX. Application Process

NOAA will publish in the **Federal Register** annual notifications soliciting project proposals under the categories described above and pursuant to these Guidelines. Applications submitted in response to solicitation notices will be screened for eligibility and conformance with the Guidelines.

To submit a proposal, a complete NOAA standard grants application package must contain the elements listed in section 6403(e) of the Act, which is provided below. Applicants are directed to the annual solicitation/FFO for filing instructions and the Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements published in the **Federal Register** on February 11, 2008 (73 FR 7696) for award terms and conditions.

A more detailed description of specific application requirements will be published in the annual solicitation; however, pursuant to section 6403(e) of the Act, each application must include the following elements:

(1) A cover sheet with the name of the individual or entity responsible for conducting the project;

(2) A description of the qualifications of the individual(s) who will conduct the project;

(3) A succinct statement of the purpose(s) of the project, including the specific geographic location where the project will be carried out;

(4) An estimate of the funds and time required to complete the project including: a detailed breakdown by category of cost estimates as they relate to specific aspects of the project, with appropriate justification for both the Federal and non-Federal shares;

(5) Evidence of support for the project by appropriate representatives of states or other government jurisdictions in which the project will be conducted, including obtaining or proceeding to obtain all applicable State and/or Federal permits, consultations, and consistencies. U.S. state or territorial applicants must also provide evidence of coordination with all relevant state or territorial agencies, including a list of agencies consulted in developing the proposal;

(6) Information regarding the amount of matching funding available to the applicant. In the case of a waiver request, the applicant must provide a detailed justification explaining the need for the waiver including attempts to obtain sources of matching funds, how the benefit of the project outweighs the public interest in providing match, and any other extenuating circumstances preventing the availability of match;

(7) A description of how the project meets one or more of the goals and objectives stated in Section V of this document (section 6403(g) of the Act) and contributes to conservation needs identified in the CRCP Goals and Objectives 2010–2015 (*http://coralreef.noaa.gov/aboutcrcp/strategy/currentgoals/resources/3threats_go.pdf*), the Jurisdictional Coral Reef Management Priorities documents (*http://coralreef.noaa.gov/aboutcrcp/strategy/reprioritization/managementpriorities*) and/or the CRCP International Strategy (*http://coralreef.noaa.gov/aboutcrcp/strategy/currentgoals/resources/intl_strategy.pdf*) as appropriate; and

(8) Any other information the Administrator considers necessary for evaluating the eligibility of the project for funding under this title.

Applicants are requested to indicate under which category(s) (as described in Section VII of this document) they are seeking funds, and are encouraged to submit only one comprehensive application per solicitation.

X. Project Review

As per section 6403(f) of the Act, NOAA will review eligible coral reef conservation proposals using an external governmental review and merit-based peer review. After such reviews, NOAA will implement an internal ranking and selection process. The overall project review and selection process will include the following five steps:

(1) NOAA will request and consider written comments on the proposal from each Federal agency, state government, or other government jurisdiction, including the relevant regional Fishery Management Councils established under the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), or any National Marine Sanctuary, with jurisdiction or management authority over coral reef ecosystems in the area where the project is to be conducted. Pursuant to this requirement of the Act, NOAA will apply the following standard in requesting comments: (A) Proposals for projects in state or territorial waters, including Federal marine protected areas in such waters (*e.g.* National Marine Sanctuaries), will be submitted to that state or territorial government's designated U.S. Coral Reef Task Force point of contact for comment; (B) proposals for projects in Federal waters will be submitted to the relevant Fishery Management Council for comment; (C) proposals for projects which require Federal permits will be submitted to the Federal agency which issued the permit for comment; (D) proposals for projects in Federal marine protected areas managed by Federal agencies (*e.g.* National Wildlife Refuges, National Parks, National Marine Sanctuaries, *etc.*) will be submitted to the respective Federal management authority for comment; and (E) NOAA will seek comments from other government entities, authorities, and/or jurisdictions, including international entities for projects proposed outside of U.S. waters, as necessary based on the nature and scope of the proposed project.

(2) Each NOAA program office will provide for a merit-based peer review and standardized documentation of that review for proposals considered appropriate for funding under their respective category(s). Each proposal will be reviewed by a minimum of three individuals with knowledge of the subject of the proposal. Each reviewer will submit a separate and individual review, and reviewers will not provide a consensus opinion. The identities of the peer reviewers will be kept anonymous to the degree permitted by law. Specific evaluation criteria for projects submitted under each funding category will be published in the category's respective annual **Federal Register** solicitation.

(3) Each NOAA Coral Reef Conservation Program Office will subsequently implement an internal review process to rank each proposal that is appropriate for funding under their program based upon consideration of: comments and recommendations from the reviews under paragraphs (1) and (2), and their evaluation of each proposal consistent with the five criteria identified within the notice of funding availability.

(4) A NOAA review panel made up of representatives from each relevant Program office will review the project rankings from each program office and make consensus-based, final project selections and funding recommendations to be presented to the NOAA Administrator, or his designee, for final approval. The review panel and Administrator, or designee, will ensure that the Act requirements for geographic funding distribution and consistency with the overall Program goals have been met. NOAA reserves the right to consult with applicants, prior to making an award, to determine the exact amount of funds to be awarded, as well as the most appropriate funding category and mechanism under which to consider the project for funding; and

(5) NOAA will provide written notification of a proposal's approval or disapproval to each applicant within 6 months of submitting a coral reef conservation proposal. Similarly, NOAA will also provide written notification of a project's approval to each State or other government jurisdiction that provided comments and/or reviews.

Definitions

In this Program:

(1) Administrator means the Administrator of the National Oceanic and Atmospheric Administration.

(2) Conservation means the use of methods and procedures necessary to preserve or sustain corals and associated species as diverse, viable, and self-perpetuating coral reef ecosystems, including all activities associated with resource management, such as assessment, conservation, protection, restoration, sustainable use, and management of habitat; mapping; habitat monitoring; assistance in the development of management strategies for marine protected areas and marine resources consistent with the National Marine Sanctuaries Act (16 U.S.C. 1431 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*); law enforcement; conflict resolution initiatives; community outreach and education; and that promote safe and ecologically sound navigation.

(3) Cooperative Agreement means a legal instrument reflecting a relationship between the Department of Commerce (DoC) and a recipient whenever: (1) The principal purpose of the relationship is to transfer money, property, services or anything of value to accomplish a public purpose of support or stimulation authorized by Federal statute, and (2) substantial involvement (*e.g.* collaboration, participation, or intervention by DoC in the management of the project) is anticipated between DoC and the recipient during performance of the contemplated activity.

(4) Coral means species of the phylum Cnidaria, including—(A) all species of the orders Antipatharia (black corals), Scleractinia (stony corals), Gorgonacea (horny corals), Stolonifera (organpipe corals and others), Alcyanacea (soft corals), and Coenothecalia (blue coral),

of the class Anthozoa; and (B) all species of the order Hydrocorallina (fire corals and hydrocorals) of the class Hydrozoa.

(5) Coral Reef means any reefs or shoals composed primarily of corals.

(6) Coral Reef Ecosystem means coral and other species of reef organisms (including reef plants) associated with coral reefs, and the non-living environmental factors that directly affect coral reefs, that together function as an ecological unit in nature.

(7) Coral Products means any living or dead specimens, parts, or derivatives, or any product containing specimens, parts, or derivatives, of any species referred to in paragraph (4).

(8) Grant means a legal instrument reflecting a relationship between DoC and a recipient whenever: (1) The principal purpose of the relationship is to transfer money, property, services, or anything of value in order to accomplish a public purpose of support or stimulation authorized by Federal statute, and (2) no substantial involvement is anticipated between DoC and the recipient during the performance of the contemplated activity.

(9) Interagency Agreement, for the purposes of these Guidelines, means a written document containing specific provisions of governing authorities, responsibilities, and funding, entered into between NOAA and another Federal agency where NOAA is funding the other Federal agency, pursuant to the Act.

(10) Secretary means the Secretary of Commerce.

(11) State means any State of the United States that contains a coral reef ecosystem within its seaward boundaries, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands, and any other territory or possession of the United States, or separate sovereign in free association with the United States, that contains a coral reef ecosystem within its seaward boundaries.

Classification: This is a continuing Program and is currently included in the Catalog of Federal Domestic Assistance under the Coral Reef Conservation Program (11.482) and Regional Fishery Management Councils (11.441). The Program uses existing NOAA Federal assistance application package requirements per 15 CFR parts 14 and 24.

The program will determine NEPA compliance on a project by project basis.

This action has been determined to be not significant for purposes of Executive Order 12866.

The use of the standard grants application package referred to in this notice involves collection of information requirements subject to the Paperwork Reduction Act. The use of Standard Forms 424, 424A, 424B, and SF–LLL have been approved by OMB under the respective control numbers 0348–0043, 0348–0044, 0348–0040, and 0348–0046.

The collection of information related (1) requests for a waiver of matching funds and (2) comments related to project review as described in Section X of this document have been approved by the Office of Management and Budget (OMB), control number 0648–0448, under the Paperwork Reduction Act. The public reporting burden is estimated to average one hour per response for comments on a proposed project from each agency with jurisdiction over coral reef ecosystems in the area where the project is to be conducted and one hour per response for a request for a waiver of matching funds. This estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments on these or any other aspects of the collection of information to NOAA Office of Ocean and Coastal Resource Management at the address listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, and to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (*Attention:* NOAA Desk Officer).

Notwithstanding any other provision of 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 Paperwork Reduction Act, unless that collection displays a currently valid OMB control number.

Dated: August 6, 2010.

Donna Rivelli,

Deputy Associate Assistant Administrator for Management and CFO/CAO, Ocean Services and Coastal Zone Management.

[FR Doc. 2010–19889 Filed 8–11–10; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

International Trade Administration

National Superconducting Cyclotron Laboratory of Michigan State University; Notice of Decision on Applications for Duty-Free Entry of Scientific Instruments

This is a decision pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, as amended by Pub. L. 106–36; 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in Room 3720, U.S. Department of Commerce, 14th and Constitution Ave., NW., Washington, DC.

Docket Number: 10–043. *Applicant:* National Superconducting Cyclotron Laboratory of Michigan State University. *Instrument:* Radio Frequency Quadropole Accelerator (RFQ). *Manufacturer:* Institut fur Angewandte Physik, Germany. *Intended Use:* See notice at 75 FR 40775, July 14, 2010. *Comments:* None received. *Reasons:* Unique characteristics of this instrument pertinent for the intended purposes include the reachable power and electrode voltage level, simple tuning of rod-voltage flatness, and simple resonance frequency tuning in order to guarantee the required ion beam properties. No other RFQ structure can deliver these features in the according frequency range of 80.5 MHz. *Decision:* Approved. We know of no instruments of equivalent scientific value to the foreign instrument, for such purposes as this is intended to be used and with the unique characteristics described above, that was being manufactured in the United States at the time of its order.

Dated: August 6, 2010.

Gregory W. Campbell,

Acting Director, Subsidies Enforcement Office, Import Administration.

[FR Doc. 2010–19942 Filed 8–11–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–821]

Notice of Implementation of Determination Under Section 129 of the Uruguay Round Agreements Act and Partial Revocation of the Antidumping Duty Order on Polyethylene Retail Carrier Bags From Thailand

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On July 28, 2010, the U.S. Trade Representative (USTR) instructed the Department of Commerce (the Department) to implement its determination under section 129 of the Uruguay Round Agreements Act (URAA) regarding the investigation of polyethylene retail carrier bags from Thailand. The Department issued its determination on June 29, 2010, regarding the offsetting of dumped comparisons with non-dumped comparisons when making average-to-average comparisons of export price and normal value in the investigation challenged by Thailand before the World Trade Organization (WTO) in *United States—Antidumping Measure on Polyethylene Retail Carrier Bags from Thailand.* The Department is now implementing this determination.

DATES: *Effective Date:* July 28, 2010.

FOR FURTHER INFORMATION CONTACT: Thomas Schauer or Richard Rimlinger, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–0410, or (202) 482–4477, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 27, 2010, the Department informed interested parties that it was initiating a proceeding under section 129 of the URAA to issue a determination that would implement the findings of the WTO dispute settlement panel in *United States—Antidumping Measure on Polyethylene Retail Carrier Bags from Thailand,* WT/DS383/R (February 18, 2010). On April 27, 2010, the Department issued the memorandum entitled "Preliminary Results Under Section 129 of the Uruguay Round Agreements Act: Antidumping Measures on Polyethylene Retail Carrier Bags from Thailand" (Preliminary Results) in which it recalculated the weighted-average dumping margins from the antidumping investigation of polyethylene retail carrier bags from Thailand [1] by applying the calculation methodology described in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin During an Antidumping Investigation; Final Modification,* 71 FR 77722 (December 27, 2006). The Department also invited interested parties to comment on the Preliminary Results. After receiving comments and rebuttal comments from the interested parties, the Department issued its final results for the section 129 determination on June 29, 2010. *See* the June 29, 2010, memorandum entitled "Issues and Decision Memorandum for the Final Results of the Proceeding Under Section 129 of the Uruguay Round Agreements Act: Antidumping Measures on Polyethylene Retail Carrier Bags from Thailand" (Issues and Decision Memorandum).

In its July 28, 2010, letter, the USTR notified the Department that, consistent with section 129(b)(3) of the URAA, the USTR had held consultations with the Department and the appropriate congressional committees with respect to the June 29, 2010, determination. On July 28, 2010, in accordance with section 129(b)(4) of the URAA, the USTR directed the Department to implement this determination.

Nature of the Proceeding

Section 129 of the URAA governs the nature and effect of determinations issued by the Department to implement findings by WTO dispute settlement panels and the Appellate Body. Specifically, section 129(b)(2) of the URAA provides that, "notwithstanding any provision of the Tariff Act of 1930," within 180 days of a written request from the USTR, the Department shall issue a determination that would render its actions not inconsistent with an adverse finding of a WTO panel or the Appellate Body. *See* 19 U.S.C. 3538(b)(2). The Statement of Administrative Action, URAA, H. Doc. 316, Vol. 1, 103d Cong. (1994) (SAA), variously refers to such a determination by the Department as a "new," "second," and "different" determination. *See* SAA at 1025, 1027. After consulting with the Department and the appropriate congressional committees, the USTR may direct the Department to implement, in whole or in part, the new determination made under section 129 of the URAA. *See* 19 U.S.C. 3538(b)(4). Pursuant to section 129(c) of the URAA, the new determination shall apply with respect to unliquidated entries of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the date on which the USTR directs the Department to implement the new determination. *See* 19 U.S.C. 3538(c). The new determination is subject to judicial review separate and apart from judicial review of the Department's original determination. *See* 19 U.S.C. 1516a(a)(2)(B)(vii).

Analysis of Comments Received

The issues raised in the case and rebuttal briefs submitted by interested parties to this proceeding are addressed in the Issues and Decision Memorandum dated June 29, 2010, which is hereby adopted by this notice. The Issues and Decision Memorandum is on file in the Central Records Unit (CRU), room 1117 of the main Department of Commerce building, and can be accessed directly at *http://ia.ita.doc.gov/frn/index.html.* The paper copy and electronic version of the Issues and Decision Memorandum are identical in content. A list of the issues addressed in the Issues and Decision Memorandum is appended to this notice.

Final Antidumping Duty Margins

The recalculated margins, unchanged from the Preliminary Results, are as follows:

- The margin for Thai Plastic Bags Industries Co., Ltd., Winner's Pack Co., Ltd., and APEC Film Ltd. (collectively TPBI), decreases from 2.26 percent to zero.
- The margin for Advance Polybag Inc., Alpine Plastics Inc., API Enterprises Inc., and Universal Polybag Co., Ltd. (collectively Universal), decreases from 5.35 percent to 4.69 percent.
- The margins for Champion Paper Polybags Ltd., TRC Polypack, and Zip-Pac Co., Ltd., remain 122.88 percent.
- Because the margin for Universal is the only margin that is neither *de minimis* nor based wholly on adverse facts available, the all-others rate is based on the margin for Universal consistent with section 735(c)(5)(A) of the Tariff Act of 1930, as amended. Therefore, the all-others rate changes from 2.80 percent to 4.69 percent.

Implementation of Partial Revocation and Recalculated Margins

Upon recalculation, TPBI does not have a dumping margin. Therefore, the

[1] *See Notice of Final Determination of Sales at Less Than Fair Value: Polyethylene Retail Carrier Bags From Thailand,* 69 FR 34122 (June 18, 2004), as amended in *Notice of Amended Final Determination of Sales at Less Than Fair Value: Polyethylene Retail Carrier Bags From Thailand,* 69 FR 42419 (July 15, 2004).

Department is revoking the order with respect to TPBI effective July 28, 2010, the date upon which USTR directed the Department to implement its final results. Accordingly, we will instruct U.S. Customs and Border Protection (CBP) to liquidate without regard to antidumping duties entries of the subject merchandise manufactured and exported by TPBI which were entered, or withdrawn from warehouse, for consumption on or after that date and to discontinue the collection of cash deposits for estimated antidumping duties for merchandise manufactured and exported by TPBI.

We will instruct CBP to continue to suspend liquidation of all entries of subject merchandise from all other exporters or producers. We will instruct CBP to continue to require a cash deposit equal to the estimated amount by which the normal value exceeds the U.S. price. The suspension-of-liquidation instructions will remain in effect until further notice. The all-others rate of 4.69 percent established in this section 129 determination will be the new cash-deposit rate on or after July 28, 2010, for all exporters of subject merchandise for which the Department has not calculated an individual rate.

This determination is issued and published in accordance with section 129(c)(2)(A) of the URAA.

Dated: August 5, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

Appendix I

Issues Raised in the Issues and Decision Memorandum

1. Targeted Dumping.
2. All-Others Rate.
3. Effective Date.

[FR Doc. 2010–19943 Filed 8–11–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XY04

General Advisory Committee to the U.S. Section to the Inter–American Tropical Tuna Commission; Meeting Announcement

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: NMFS announces a meeting of the General Advisory Committee and the Scientific Advisory Subcommittee to the U.S. Section to the Inter–American Tropical Tuna Commission (IATTC) on September 17, 2010. Meeting topics are provided under the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: The meeting will be held on September 17, 2010, from 9 a.m. to 5 p.m. PDT (or until business is concluded).

ADDRESSES: The meeting will be held in the Large Conference Room (Room 370) at NMFS, Southwest Fisheries Science Center, 3333 North Torrey Pines Court, La Jolla, California, 92037–1023. Please notify Heidi Hermsmeyer prior to September 10, 2010, of your plans to attend the meeting, or interest in a teleconference option.

FOR FURTHER INFORMATION CONTACT: Heidi Hermsmeyer, Southwest Region, NMFS at *Heidi.Hermsmeyer@noaa.gov*, or at (562) 980–4036.

SUPPLEMENTARY INFORMATION: In accordance with the Tuna Conventions Act, as amended, the Department of State has appointed a General Advisory Committee (GAC) and a Scientific Advisory Subcommittee (SAS) to the U.S. Section to the IATTC. The U.S. Section consists of four U.S. Commissioners to the IATTC and a representative of the Deputy Assistant Secretary of State for Oceans and Fisheries. The advisory bodies support the work of the U.S. Section in an advisory capacity with respect to U.S. participation in the work of the IATTC, with particular reference to the development of policies and negotiating positions pursued at meetings of the IATTC. NMFS, Southwest Region, administers the GAC and SAS in cooperation with the Department of State.

Meeting Topics

The meeting topics will include, but are not limited to, the following: (1) updates from the IATTC scientific staff on issues such as the status of tropical tuna stocks and conservation recommendations; (2) updates on other international agreements in the Pacific Ocean such as the Western and Central Pacific Fisheries Commission; (3) regulatory changes that could affect tuna fisheries in the eastern Pacific Ocean; (4) the status of Antigua Convention implementing legislation; (5) input and advice from the advisory bodies on issues that may arise at the upcoming AIDCP/IATTC meetings in September 2010, including, but not limited to, potential U.S. proposals, potential proposals from other IATTC members, the potential for an albacore working group, and potential revisions to IATTC Resolution C–09–01; (6) relevant changes in personnel and responsibilities at NOAA and the U.S. Department of State; and (7) other issues as they arise.

Special Accommodations

The meeting location is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Heidi Hermsmeyer at (562) 980–4036 by September 10, 2010.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 6, 2010.

Carrie Selberg,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XY07

Takes of Marine Mammals Incidental to Specified Activities; Piling and Structure Removal in Woodard Bay Natural Resources Conservation Area, Washington

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; proposed incidental harassment authorization; request for comments.

SUMMARY: NMFS has received an application from the Washington State Department of Natural Resources (DNR) for an Incidental Harassment Authorization (IHA) to take marine mammals, by harassment, incidental to derelict creosote piling and structure removal within the Woodard Bay Natural Resources Conservation Area (NRCA). Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to the DNR to incidentally harass, by Level B Harassment only, harbor seals during the specified activity.

DATES: Comments and information must be received no later than September 13, 2010.

ADDRESSES: Comments on the application should be addressed to Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-

West Highway, Silver Spring, MD 20910–3225. The mailbox address for providing e-mail comments is *0648–XY07@noaa.gov.* NMFS is not responsible for e-mail comments sent to addresses other than the one provided here. Comments sent via e-mail, including all attachments, must not exceed a 10-megabyte file size.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.nmfs.noaa.gov/pr/permits/incidental.htm* 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.

A copy of the application containing a list of the references used in this document may be obtained by writing to the address specified above, telephoning the contact listed below (*see* **FOR FURTHER INFORMATION CONTACT**), or visiting *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.* Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address. NMFS is also preparing an Environmental Assessment (EA) for this action (see NEPA section at the end of this notice) and will also be made available at the above listed Web site when complete.

FOR FURTHER INFORMATION CONTACT: Jaclyn Daly, Office of Protected Resources, NMFS, (301) 713–2289, ext 151.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined "negligible impact" in 50 CFR 216.103 as "* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization.

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Summary of Request

On June 9, 2010, NMFS received an application from the WA DNR requesting authorization to take, by harassment, small numbers of marine mammals incidental to derelict creosote piling and structure removal associated with a habitat restoration project within the Woodard Bay NRCA, Washington. The specified activity includes removal of approximately 615 timber pilings and a trestle located in Woodard Bay and a portion of pier superstructure located at the mouth of Chapman Bay. Pilings would be removed by vibratory hammer extraction methods and structures would be removed via cable lifting. In addition, approximately 25 nest boxes for purple martins would be relocated from removed pilings to pilings that are retained for seal habitat and buffer, using a small boat if necessary and would require a battery powered drill. Activities would occur across 40 days between November 1, 2010, and February 28, 2011.

Harbor seals have been utilizing the remnant log boom structures at Woodard Bay NRCA as haul-out habitat for resting, pupping and molting for more than 30 years. These booms are situated among the piles and structure planned for removal. The WA DNR anticipates harbor seals will flush into the water upon crew arrival and onset of pile and structure removal activities; hence, harbor seals may be harassed during pile removal activities. The DNR is thus requesting an IHA to take harbor seals, by Level B harassment, incidental to the piling and structure removal project.

Description of the Specified Activity

The Woodard Bay NRCA, located within Henderson Inlet in southern Puget Sound, was designated by the Washington State Legislature in 1987 to protect a large, intact complex of nearshore habitats and related biological communities, and to provide opportunities for low-impact public use and environmental education for the people of Washington. The site includes the former Weyerhaeuser South Bay Log Dump, which operated from the 1920s until the 1980s. The remnant structures from the log dump, including several hundred creosoted pilings, and a trestle and pier, continue to negatively impact nearshore ecosystems protected by the conservation area. Therefore, the WA DNR has proposed to remove these dilapidated structures to enhance the processes, functions, and structures of the nearshore ecosystems. However, a few of the remnant log booms from dumping operations have supported a healthy population of harbor seals for more than 30 years by providing haulout habitat. However, seals concentrate themselves and primarily haul out at only two locations within the NRCA (see Figure 4 in application).

The proposed project involves the removal of 615 creosote treated wood pilings and overwater creosoted structures (*i.e.,* a trestle and pier superstructure) that are not associated with the booms seals use as a haulout (*i.e.,* not within 30 yards (27 m) of the booms). Pile and structure removal would be accomplished using vibratory extraction, direct pull, and/or diver cutting techniques. The vibratory hammer is a large steel device suspended by a cable from a crane that is stationed on a barge adjacent to the piling. The pile is then lifted out of the water and placed on a barge.

Approximately 615 12–24 inch diameter pilings would be removed near but not directly adjacent to haulouts. An average of 30 pilings removed per day would be removed via vibratory hammer extraction methods. Typically the hammer vibrates for less than one minute per pile, so there would be no more than 30 minutes of hammer vibration over an 8-hour period. After

vibration, a choker is used to lift the pile out of the water where it is placed on the barge for transport to an approved disposal site. If a pile breaks during extraction, ideally it would do so below the mudline; however, if a pile is broken above the water line, then a choker is set on the broken pile and a diver cuts the pile at the mud line with a chain saw so that it may be brought up to the barge by crane. Operations would begin on the pilings and structures that are furthest from the seal haul-out so that there is an opportunity for the seals to adjust to the presence of the contractors and their equipment. Actual vibratory extraction operations could occur for approximately 21 days over the 4-month work window (November 1 and February 28). Other work days would be spent removing pilings associated with the trestle, which is over 850 m from the haulout, and pier superstructure, which does not involve vibratory extraction. NMFS anticipates that the presence of crew and use of a vibratory hammer would result in behavioral harassment.

The portion of the Chapman Bay Pier that would be removed is more than 100 yards (91 m) from the closest haul-out area. This activity is expected to take a maximum of 10 days and, although does not involve vibratory extraction, has the potential to result in behavioral harassment due to the close proximity to working crew. In contrast, the Woodard Bay trestle is located on the other side of a peninsula that separates Woodard and Chapman Bays and is a distance of more than 850 yards (777 m) from the closest haulout area. Work here is expected to take a maximum of 10 days to complete. Because of the distance from the haul-outs, the WA DNR anticipates structure removal at the Woodard Bay trestle would not disturb the seals. As such, 10 out of the 40 work days are not expected to result in harbor seal harassment.

Approximately 25 purple martin nest boxes would be relocated from the removed piles to the pilings that support or surround the haul-out area. This activity would only require a battery powered drill, is expected to take 2 days, and could also result in flushing the seals from the haulout. Crew would be required to complete this activity during the days when they are already working within 100 yards (91 m) of the haulout, possibly using a separate boat, so that no additional work days near the haulout are necessary. Presence of crew relocating nest boxes may result in behavioral harassment of seals. However, because this would be completed in tandem with pile removal, no substantial additional harassment is anticipated.

There is a paucity of data on airborne and underwater noise levels associated with vibratory hammer extraction. As background, in-air noise levels are referenced to 20 microPascals (re: 20 microPa) while underwater noise levels are referenced to one microPascal (re: 1 microPa). Based on information on airborne source levels measured for vibratory hammer steel and concrete pile driving, removal of wood piles is unlikely to exceed 90 dB_{rms} re: 20 microPa (pers. comm., Miner-Zukerberg, 2010). The DNR and NMFS could not find hydroacoustic data on vibratory extraction of wood piles; however, it can be assumed that this activity does not result in SPLs above vibratory hammering. However, data is also lacking on vibratory hammering wood piles. NMFS could only find data on driving timber piles using an impact hammer and vibratory driving non-timber piles. For example, the California Department of Transportation (Caltrans) indicates impact driving 12- or 14-inch wood piles typically emits peak source levels of 177 dB re: 1 microPa (Caltrans, 2009). Vibratory pile driving 12–24 inch steel piles typically results in SPLs around 155–165 dB re: 1 microPa (root mean square) ten meters from the source (Caltrans, 2007). It should be noted driving steel piles likely results in higher SPLs than driving wood piles. Similarly, it is generally assumed that vibratory extraction emits lower SPLs than impact hammering wood piles or vibratory pile driving steel piles.

Description of Marine Mammals in the Area of the Specified Activity

Harbor seals are the only marine mammal found within the action area. Harbor seals within the Woodard Bay NRCA belong to the Washington Inland Waters stock, which was estimated around 14,612 individuals in 2003 (NMFS, 2003). Although the stock assessment report for this stock has not been updated since 2003, based on trends of other harbor seal stocks, this is likely an underestimate. Based on the analyses of Jeffries *et al.* (2003) and Brown *et al.* (2005), both the Washington and Oregon coastal harbor seal stock have reached carrying capacity and are no longer increasing. Harbor seals are not listed as depleted under the MMPA or as endangered or threatened under the ESA. They are considered the most abundant resident pinniped species in Puget Sound (Lance and Jeffries, 2009).

Harbor seals haul out on rocks, reefs, beaches, and drifting glacial ice and feed in marine, estuarine, and occasionally fresh waters. Harbor seals generally are non-migratory, with local movements associated with such factors as tides, weather, season, food availability, and reproduction. They display strong fidelity for haulout sites (Pitcher and Calkins, 1979; Pitcher and McAllister, 1981). The remnant log booms at the Woodard Bay NRCA support a year-round population of harbor seals, which use the boom structures for haulout habitat to rest, pup, and molt in two primary locations; to the east and to the north of the Chapman Bay Pier (see Figure 4 in application). Haulout behavior is shown to be affected by time of day and tide cycle, as well as seasonal and weather patterns such as air temperature, wind speed, cloud cover, and sea conditions (Buettner *et al.,* 2008). Annually, use of the log booms peaks from July, when females haul out to give birth to their pups, through October, during the late pupping season and molt (WA DNR, 2002).

The harbor seal population within the NRCA is considered one of the healthier ones in southern Puget Sound. Seal numbers have been monitored at the site since 1977, when there were less than 50 seals. In 1996, the highest count year, there were 600 seals. The average maximum annual count between 1977 and 2008 was 315 seals with 410 counted in August of 2008 (Buettner *et al.,* 2008).

Pinnipeds produce a wide range of social signals, most occurring at relatively low frequencies (Southall *et al.,* 2007), suggesting that hearing is keenest at these frequencies. Pinnipeds communicate acoustically both on land and in the water, but have different hearing capabilities dependent upon the medium (air or water). Based on numerous studies, as summarized in Southall *et al.* (2007), pinnipeds are more sensitive to a broader range of sound frequencies underwater than in air. Underwater, pinnipeds can hear frequencies from 75 Hz to 75 kHz. In air, the lower limit remains at 75 Hz but the highest audible frequencies are only around 30 kHz (Southall *et al.,* 2007).

Potential Effects on Marine Mammals

The WA DNR and other organizations, such as the Cascadia Research Collective, have been monitoring the behavior of harbor seals present within the action area since 1977. Past disturbance observations at Woodard Bay NRCA have shown that seal harassment occurs from non-motorized boats (*e.g.,* recreational kayaks and canoes), motorized vessels (*e.g.,* fishing boats), and people walking by the haulout (Calambokidis and Leathery, 1991; Buettner *et al.,* 2008). Calambokidis and Leathery (1991)

found that the mean distance that seals entered the water in response to any type of vessel was 56 m. Most commonly seals were disturbed when vessels were 26 to 50 m from the haulout; however, only above 125 m was there a sharp decrease in the proportion of groups disturbed. Seals entered the water in response to people on foot at up to 256 m although, on many occasions, people were able to pass less than 100 m from seals, while maintaining a low profile without causing disturbance (Calambokidis and Leathery, 1991). Furthermore, the distances that seals were disturbed varied significantly by vessel type; seals entered the water at a greater distance in response to kayaks and canoes compared to recreational motorboats and skiffs. It is hypothesized that because motor boats are more readily detectable than non-motorized boats, seals are more aware of their presence at greater distances and do not react (Buettner *et al.,* 2008). Buettner *et al.* (2008) reported the research boat used during their study caused the greatest amount of harbor seal disturbance reactions with the second and third highest causes being canoes and kayaks, respectively. The scientists theorized the most plausible reason for this is that the boats used for research came within the closest distance to the seals, often within 1 m of the floats where seals were hauled out.

Buettner *et al.* (2008) also noted the difference in vigilance of seals based on float location during pupping season. For example, seals on floats located on the outer edges of the log boom area, and thus subjected to greater amounts of vessel traffic, were indifferent to vessels unless they came right up to the log booms. Contrarily, seals on the floats located in the central area of the log booms, and hence not exposed to as much traffic, were more vigilant and more sensitive to disturbances. Not surprisingly, the inner floats contained the highest amount of pups. The DNR would conduct the habitat restoration project from November to February, well outside of the pupping (and molting) season; therefore no impacts to seals during these biologically important time periods.

The two studies discussed above indicate that seals are susceptible to anthropogenic disturbance but also may habituate to such disturbances. During emergency maintenance operations on the haulout in 2008, the seals present on the log booms flushed when the maintenance boat first entered the haulout area but quickly became accustomed to the contractor and the boat and would rest on the haulout during maintenance operations (pers. comm., Osborne-Zukerberg, 2008). Maintenance operations included bringing in log booms to restore habitat and included drilling through booms on a small barge. Seals initially flushed in response to onset of work but quickly acclimated to crew presence and would haulout on adjacent booms directly adjacent to the small barge used during maintenance (pers. comm., Zukerberg-Daly, June, 2010). Furthermore, Suryan and Harvey (1991) found that harbor seals hauled-out at Puffin Island, WA, were more tolerant to subsequent harassments than they were to the initial harassment. However, sudden presence of a disturbance source (*e.g.,* kayaker) can induce strong behavioral reactions.

To avoid inducing strong reactions, the WA DNR would conduct activities such that the piles farthest from the hauled out seals would be removed first; thereby avoiding a sudden disturbance and allowing seals time to acclimate to human activity. This would maximize the initial distance between maintenance crews and seals. The DNR believes that throughout the day, seals will become accustomed to crew presence of construction activities, as seen in previous disturbance studies within the Woodard Bay NRCA and other harbor seal populations.

In addition to crew and vessel presence, hammer operations may disturb seals in-water; however, it is anticipated that most seals would be disturbed initially by physical presence. As discussed above, the DNR and NMFS could not find information on sound levels produced by timber pile extraction using a vibratory hammer; however, it is reasonable to assume that extraction would not result in higher SPLs than vibratory hammering. That is, NMFS anticipates that source levels in water would not reach 155–165 dB (the average source SPL for driving 12–24 inch steel piles). NMFS' general in-water harassment thresholds for pinnipeds exposed to non-pulse noise, such as those produced by vibratory pile extraction, are 190 dB rms re: 1 microPa as the potential onset of Level A (injurious) harassment and 120 dB rms re: 1 microPa at the potential onset of Level B (behavioral) harassment. These levels are considered precautionary and NMFS is currently revising these thresholds to better reflect the most recent scientific data. Vibratory extraction would not result in sound levels near 190 dB re: 1 microPa; therefore, injury would not occur. However, noise from vibratory extraction would exceed 120 dB re: 1 microPa near the source and may induce responses in-water such as avoidance or alteration of behavioral states at time of exposure.

There are limited data available on the effects of non-pulse noise on pinnipeds in-water; however, field and captive studies to date collectively suggest that pinnipeds do not strongly react to exposures between 90–140 dB re: 1 microPa; no data exist from exposures at higher levels (Southall *et al.,* 2007). Jacobs and Terhune (2002) observed wild harbor seal reactions to high frequency acoustic harassment devices (ADH) around nine sites. Seals came within 44 m of the active ADH and failed to demonstrate any behavioral response when received SPLs were estimated at 120–130 dB re: 1 microPa. In a captive study (Kastelein, 2006), a group of seals were collectively subjected to data collection and communication network (ACME) non-pulse sounds at 8–16 kHz. Exposures between 80–107 dB re: 1 microPa did not induce strong behavioral responses; however, a single observation at 100–110 dB re: 1 microPa indicated an avoidance response at this level. The group returned to baseline conditions shortly following exposure. Southall *et al.* (2007) notes contextual differences between these two studies noting that the captive animals were not reinforced with food for remaining in the noise fields, whereas free-ranging subjects may have been more tolerant of exposures because of motivation to return to a safe location or approach enclosures holding prey items.

Hearing Impairment

Temporary or permanent hearing impairment is a possibility when marine mammals are exposed to very loud sounds. Hearing impairment is measured in two forms: temporary threshold shift (TTS) and permanent threshold shift (PTS). PTS is considered injurious whereas TTS is not as it is temporary and hearing is fully recoverable. There are no empirical data for onset of PTS in any marine mammal; therefore, PTS-onset must be estimated from TTS-onset measurements and from the rate of TTS growth with increasing exposure levels above the level eliciting TTS-onset. PTS is presumed to be likely if the hearing threshold is reduced by ≥ 40 dB (*i.e.,* 40 dB of TTS). Due to the low source levels produced by vibratory extraction, NMFS does not expect that marine mammals will be exposed to levels that could elicit PTS; therefore, it will not be discussed further.

Temporary Threshold Shift (TTS)

TTS is the mildest form of hearing impairment that can occur during

exposure to a loud sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises and a sound must be louder in order to be heard. TTS can last from minutes or hours to, in cases of strong TTS, days. For sound exposures at or somewhat above the TTS-onset threshold, hearing sensitivity recovers rapidly after exposure to the noise ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals. Southall *et al.* (2007) considers a 6 dB TTS (*i.e.,* baseline thresholds are elevated by 6 dB) sufficient to be recognized as an unequivocal deviation and thus a sufficient definition of TTS-onset. Because it is non-injurious, NMFS considers TTS as Level B harassment that is mediated by physiological effects on the auditory system; however, NMFS does not consider onset TTS to be the lowest level at which Level B harassment may occur.

Harbor seals within the action area are considered resident and may therefore be continually exposed to habitat restoration activities (however, recall that the vibratory hammer need only operate for approximately 1 minute to extract each pile). Sound exposures that elicit TTS in pinnipeds underwater have been measured in harbor seals, California sea lions, and northern elephant seals for broadband or octaveband (OBN) non-pulse noise ranging from approximately 12 minutes to several hours (Kastak and Schusterman, 1996; Finneran *et al.,* 2003; Kastak *et al.,* 1999; Kastak *et al.,* 2005). Collectively, Kastak *et al.* (2005) analyzed these data to indicate that in the harbor seal, a TTS of *ca.* 6 dB occurred with 25 minute exposure to 2.5 kHz OBN with SPL of 152 dB re:1 microPa; the California sea lion showed TTS-onset at 174 dB re: 1 microPa (as summarized in Southall *et al.,* 2007). Source levels emitted by vibratory pile extraction are low, intermittent, and would occur for a total of only 30 minutes per day. Further, seals may leave the area upon onset on vibratory pile extraction thereby reducing exposure duration. For these reasons, NMFS does not anticipate TTS would be induced.

In summary, it is anticipated that seals would be initially disturbed by crew and vessels associated with the habitat restoration project; however, given the short duration and low energy of vibratory extraction, PTS would not occur and TTS is not likely. Those animals hauled out on the log booms would likely flush into the water; however, DNR would start with removal of piles farthest from the haulout. This methodology is designed to minimize disturbance as seals would have ample time to become alerted to and habituated to crew and vessel presence. As demonstrated in 2008, seals initially flushed into the water upon maintenance crew presence; however, quickly became accustomed to the contractor and the boat and would rest on the haul-out during maintenance operations. It is anticipated that harbor seals would react in a similar manner to pile and structure removal operations. For these reasons, harbor seals are not expected to abandon the haulout.

Anticipated Effects on Habitat

Marine mammal habitat would be temporarily ensonified by low sound levels resulting from habitat restoration effort. The piles designated to be removed have been treated with creosote, a wood preservative that is also toxic to the environment. Removing these piles will have beneficial impacts to the NRCA, including marine mammal habitat, by preventing the leaching of creosote chemicals, including polycyclic aromatic hydrocarbons, into the marine environment. No log booms would be removed; therefore, no impacts to the physical availability of haulout structure would occur.

Proposed Mitigation

In order to issue an incidental take authorization (ITA) under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses.

The DNR has proposed mitigation measures designed to minimize disturbance to harbor seals within the action area in consideration of timing, location, and equipment use. Foremost, pile and structure removal would only occur between November and February, well outside harbor seal pupping and molting seasons. Therefore, no impacts to pups from the specified activity during these sensitive time periods would occur. The DNR would approach the action area slowly to alert seals to their presence from a distance and would begin pulling piles at the farthest location from the log booms used as harbor seal haulout areas. The contractor would be required to survey the operational area for seals before initiating activities, including cutting and removing pilings and structures, and to wait until the seals are at a sufficient distance from the activity so as to minimize the risk of direct injury from the piling or structure breaking free or equipment. DNR would also require the contractor to initiate a vibratory hammer "soft start" at the beginning of each work day. The "soft-start" method includes a reduced energy vibration from the hammer for the first 15 seconds and then a one minute waiting period. This method would be repeated twice before commencing with regular energy operations. Finally, the vibratory hammer power pack would be outfitted with a muffler to reduce in-air noise levels.

NMFS has carefully evaluated the applicant's proposed mitigation measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another: (1) The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals; (2) the proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and (3) the practicability of the measure for applicant implementation, including consideration of personnel safety, and practicality of implementation.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS or recommended by the public, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable adverse impacts on marine mammals species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an ITA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth "requirements pertaining to the monitoring and reporting of such taking". The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for IHAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present.

Seal monitoring and research has been occurring at Woodard Bay since the 1970s and has included seal

ecology, population dynamics and disturbance behavior (Newby, 1970; Calambokidis *et al.,* 1991; Buettner *et al.,* 2008; Lambourn *et al.,* 2009). DNR's proposed monitoring plan adheres to protocols already established for Woodard Bay to the maximum extent practical for the specified activity. Monitoring of both haul-outs would be performed by at least one NMFS approved protected species observer (PSO) the first 2 days of project activities when the contractors are mobilizing and starting the vibratory hammer, during the 2 days when activities are occurring within 100 yards (91 m) of the haulout area, during five of the days of work on the Chapman Bay Pier, and for six other days during the 40-day work period to be decided when the project schedule is provided by the contractor. Therefore, there would be at least 15 days where a designated observer would be on site over the course of 40 days of work. The PSO would be onset prior to crew and vessel arrival to determine the number of seals present pre-disturbance. The PSO would maintain a low profile during this time to minimize disturbance from monitoring.

Observational data collected would include monitoring dates, times and conditions, estimated number of take, which would be recorded as number of seals flushed from the haulout, and type of activity occurring at time of disturbance. This information would be determined by recording the number of seals using the haulout on each monitoring day prior to the start of restoration activities for that day and recording the number of seals that flush from the haulout or, for animals already in the water, display adverse behavioral reactions to vibratory extraction. A description of the disturbance source, the proximity in meters of the disturbance source, and reactions would also be noted. Within 30 days of the completion of the project, DNR would submit a monitoring report to NMFS that would include a summary of findings and copies of field data sheets and relevant daily logs from the contractor.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

During previous surveys, seal counts for the month of October, the last month that data is recorded each year, averaged 171 and ranged between 209 and 275 from 2006 to 2009 (Lambourn, 2010). Although the number of seals is expected to decline from October through February when restoration actions are scheduled to occur, there is no data for these months so the DNR considered a maximum of 275 seals could potentially be affected by the project per day. The DNR has proposed that Woodard Bay trestle removal operations are not expected to harass marine mammals as the trestle is located approximately 850 yards (777 m) from the closest haulout and vibratory extraction does not emit loud noise into the marine environment. Therefore, days spent removing the trestle have been removed from take calculations. In addition, the DNR has proposed that removal of pilings located at greater than 100 yards (91 m) from the harbor seal haulout would not result in harassment as NMFS has indicated that people at Woodard Bay should remain 100 yards from the seals to prevent disturbance. Therefore, the DNR is estimating only nine days of pile removal would result in harassment to seals within the action area. Seals may be behaviorally disturbed due to crew presence of pile removal operations. Given the maximum of 275 animals on a haulout at any given day, the DNR is requesting authorization to take, by Level B harassment, 2,475 seals (275 x 9) during the habitat restoration project with the inference that the individual number of seals harassed will be low but may be taken multiple times. Although NMFS does not discount that harassment from pile structure removal could occur at distances greater than 100 yards from work location, the conservative estimate of 275 seals present on the haulout per day is ample buffer to consider the amount of requested take reasonable.

Negligible Impact and Small Numbers Analysis and Determination

NMFS has defined "negligible impact" in 50 CFR 216.103 as "* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival." In making a negligible impact determination, NMFS considers a number of factors associated with the proposed action and affected species and stocks including, but not limited to, the number of anticipated mortalities; number and nature of anticipated injuries; number, nature, intensity, and duration of Level B harassment; and temporal and spatial scale of the proposed action with respect to the ecology and life history of potentially affected marine mammals (*e.g.,* would harassment occur on prime foraging grounds, during critical reproductive times, etc.).

For reasons described above, there is no potential for injury or mortality to occur from the specified activity; therefore, none is anticipated. However, there is potential for seals to behaviorally react (*e.g.,* as flush, avoid the area) in response to the presence of crew and equipment and vibratory extraction noise. The DNR would not conduct habitat restoration operations during the pupping and molting season; therefore, no pups would be affected by the proposed action and no impacts to any seals would occur as a result of the specified activity during these sensitive time periods. Harbor seals are not listed as endangered under the ESA or depleted under the MMPA (NMFS, 2003).

Mitigation measures (*e.g.* beginning work at the farthest distance to the haulout as possible, use of a muffler pack, *etc.*) would minimize onset of sudden, acute reactions and overall disturbance. In addition, it is not likely that seals at both haulouts would be disturbed simultaneously as work, for example, may affect the southern haulout but not the northern haulout based on location of the crew and barge. The DNR estimates work at any given location may take approximately 10 days; therefore, seals on those haulouts may be taken for 10 consecutive days or they may move to the other haulout farther from where work is taken place. Further, although seals may initially flush into the water, based on previous disturbance studies and maintenance activity at the haulouts, the DNR expects seals will quickly habituate to piling and structure removal operations. For these reasons no long term or permanent abandonment of the haulout is anticipated.

The seals at Woodard Bay are considered resident and make small daily movements to forage; however, exactly how far they transit is unknown. The mean count of the localized seal population from 1977–2008 was 315 animals during the pupping season with a maximum of 400 individuals counted in 2008 during this time. However, as described above, these numbers drop over the late fall and winter. The DNR has scheduled the project to occur from November–February, a time outside of

sensitive reproductive periods and during a time seal numbers are lowest. The DNR is requesting to take approximately 275 seals multiple times; therefore, the proposed authorized amount of take can be considered small when compared to the stock size of harbor seals within Woodard Bay (14,612).

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS preliminarily finds that piling and structure removal associated with the WA DNR's habitat restoration project will result in the incidental take of small numbers of marine mammals by Level B harassment only, and that the total taking from the specified activity would have a negligible impact on the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this action.

Endangered Species Act (ESA)

No marine mammals listed under the ESA occur within the action area. Therefore, Section 7 consultation under the ESA is not required.

National Environmental Policy Act (NEPA)

NMFS is currently preparing an Environmental Assessment analyzing environmental impacts associated with the issuance of an IHA to WA DNR authorizing the incidental take of marine mammals from pile and structure removal within the Woodard Bay NRCA. Because the EA is specific to NMFS' action of issuing an IHA, any comments received in response to this notice would also influence development of the EA. The EA would be finalized prior to issuing an IHA to the DNR.

Dated: August 6, 2010.

James H. Lecky,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2010–19953 Filed 8–11–10; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 10–40]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, DoD.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

SUPPLEMENTARY INFORMATION: The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 10–40 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: August 9, 2010.

Mitchell S. Bryman,

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

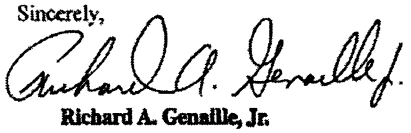
AUG 0 3 2010

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, DC 20515

Dear Madam 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. 10-40, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Oman for defense articles and services estimated to cost $3.5 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,



Richard A. Genaille, Jr.
Deputy Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

Transmittal No. 10-40

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: Oman

(ii) Total Estimated Value:

Major Defense Equipment*	$2.3 billion
Other	$1.2 billion
TOTAL	$3.5 billion

(iii) Description and Quantity or Quantities of Articles or Services under Consideration for Purchase: (18) F-16 Block 50/52 aircraft, (20) F100-PW-229 or F110-GE-129 Increased Performance Engines, (36) LAU-129/A Common Rail Launchers, (24) APG-68(V)9 radar sets, (20) M61 20mm Vulcan Cannons, (22) AN/ARC-238 Single Channel Ground and Airborne Radio Systems with HAVE QUICK I/II, (40) Joint Helmet Mounted Cueing Systems, (36) LAU-117 MAVERICK Launchers, (22) ALQ-211 Advanced Integrated Defensive Electronic Warfare Suites (AIDEWS) or Advanced Countermeasures Electronic Systems (ACES) (ACES includes the ALQ-187 Electronic Warfare System and AN/ALR-93 Radar Warning Receiver), Advanced Identification Friend or Foe (AIFF) Systems with Mode IV, (34) Global Positioning Systems (GPS) and Embedded-GPS/ Inertial Navigation Systems (INS), (18) AN/AAQ-33 SNIPER Targeting Pods or similarly capable system, (4) DB-110 Reconnaissance Pods (RECCE), (22) AN/ALE-47 Countermeasures Dispensing Systems (CMDS), and (35) ALE-50 Towed Decoys. Also included are the upgrade of the existing 12 F-16 Block 50/52 aircraft, site survey, support equipment, tanker support, ferry services, Cartridge Actuated Devices/Propellant Actuated Devices (CAD/PAD), conformal fuel tanks, construction, modification kits, repair and return, modification kits, spares and repair parts, construction, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical, engineering, and logistics support services, ground based flight simulator, and other related elements of logistics support.

* as defined in Section 47(6) of the Arms Export Control Act.

(iv) Military Department: Air Force (SAB)

(v) Prior Related Cases, if any: FMS case SDC-$701M-5Jun02

(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: AUG 0 3 2010

POLICY JUSTIFICATION

Oman – F-16 Aircraft

The Government of Oman has requested a possible sale of (18) F-16 Block 50/52 aircraft, (20) F100-PW-229 or F110-GE-129 Increased Performance Engines, (36) LAU- 129/A Common Rail Launchers, (24) APG-68(V)9 radar sets, (20) M61 20mm Vulcan Cannons, (22) AN/ARC-238 Single Channel Ground and Airborne Radio Systems with HAVE QUICK I/II, (40) Joint Helmet Mounted Cueing Systems, (36) LAU-117 MAVERICK Launchers, (22) ALQ-211 Advanced Integrated Defensive Electronic Warfare Suites (AIDEWS) or Advanced Countermeasures Electronic Systems (ACES) (ACES includes the ALQ-187 Electronic Warfare System and AN/ALR-93 Radar Warning Receiver), Advanced Identification Friend or Foe (AIFF) Systems with Mode IV, (34) Global Positioning Systems (GPS) and Embedded-GPS/Inertial Navigation Systems (INS), (18) AN/AAQ-33 SNIPER Targeting Pods or similarly capable system, (4) DB-110 Reconnaissance Pods (RECCE), (22) AN/ALE-47 Countermeasures Dispensing Systems (CMDS), and (35) ALE-50 Towed Decoys. Also included is the upgrade of the existing 12 F-16 Block 50/52 aircraft, site survey, support equipment, tanker support, ferry services, Cartridge Actuated Devices/Propellant Actuated Devices (CAD/PAD), conformal fuel tanks, construction, modification kits, repair and return, modification kits, spares and repair parts, construction, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical, engineering, and logistics support services, ground based flight simulator, and other related elements of logistics support. The estimated cost is $3.5 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 proposed sale will provide a significant increase in the Royal Air Force of Oman's (RAFO) capability to train with U.S. and coalition forces and augment coalition forces in a regional conflict. The F-16 Block 50/52 will enable Oman to support both its own air defense needs and coalition operations. Oman currently has 12 F-16s in its inventory and will have no difficulty absorbing these additional aircraft into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors will be:

BAE Advanced Systems	Greenlawn, New York
Boeing Company	Seattle, Washington
Boeing Integrated Defense Systems (three locations)	St Louis, Missouri Long Beach, California San Diego, California
Raytheon Company (two locations)	Lexington, Massachusetts Goleta, California
Raytheon Missile Systems	Tucson, Arizona
Lockheed Martin Aeronautics Company	Fort Worth, Texas
Lockheed Martin Missile and Fire Control	Dallas, Texas
Lockheed Martin Simulation, Training and Support	Fort Worth, Texas
Northrop-Grumman Electro-Optical Systems	Garland, Texas
Northrop-Grumman Electronic Systems	Baltimore, Maryland
Pratt & Whitney United Technology Company	East Hartford, Connecticut
General Electric Aircraft Engines	Cincinnati, Ohio
Goodrich ISR Systems	Danbury, Connecticut
L3 Communications	Arlington, Texas
ITT Defense Electronics and Services	McLean, Virginia
Symetrics Industries	Melbourne, Florida

There are no known offset agreements in connection with this proposed sale.

Implementation of this proposed sale will require multiple trips to Oman involving U.S. Government and contractor representatives for technical reviews/support, program management, and training over a period of 15 years.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 10-40

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. This sale will involve the release of sensitive technology to Oman. The F-16C/D Block 50/52 weapon system is classified up to Secret. The aircraft utilizes the F-16 airframe and features advanced avionics and systems. It contains the Pratt and Whitney F-100-PW-229 or the General Electric F-110-GE-129 engine, AN/APG-68(V)9 radar, digital flight control systems, internal electronic warfare equipment, Advanced IFF (with Mode IV), operational flight program, and software computer programs.

2. Sensitive and/or classified (up to Secret) elements of the F-16 aircraft proposed for sale include hardware, accessories, components, and associated software: AN/APG-68(V)9 Radar, Advanced Identification Friend or Foe (AIFF) with Mode IV, AN/ALE-47 Countermeasures (Chaff and Flare) set, SNIPER or similarly compatible system, DB-110 RECCE Pods, Embedded Global Positioning System/Inertial Navigation Systems, including Precise Positioning System enhanced navigation accuracy mode, Advanced Countermeasures Electronic System (ACES) or Advanced Integrated Defensive Electronic Warfare Suites (AIDEWS), Joint Helmet Mounted Cueing Systems, Advanced Interference Blanker Unit, Modular Mission Computer, Have Glass II, Digital Flight Control System, and F-100 or F-110 engines. Additional sensitive areas include operating manuals and maintenance technical orders containing performance information, operating and test procedures, and other information related to support operations and repair. The hardware, software, and data identified are classified to protect vulnerabilities, design and performance parameters, and other similar critical information.

3. The AN/APG-68(V)9 radar is the latest model of the APG-68 radar and was specifically designed for foreign military sales. This model contains the latest digital technology available for a mechanically scanned antenna, including higher processor power, higher transmission power, more sensitive receiver electronics, and a new capability, Synthetic Aperture Radar (SAR), which creates higher-resolution ground maps from a much greater distance than previous versions of the APG-68. The upgrade features a 30% increase in detection range of air targets, a five-fold increase in processing speed, a ten-fold increase in memory, as well as significant improvements in all modes, jam resistance and false alarm rates. Complete hardware is classified Confidential; major components and subsystems are

classified Confidential; software is classified Secret; and the technical data and documentation are classified up to Secret.

4. The AN/AAQ-33 SNIPER Targeting System is Unclassified but contains state-of-the-art technology. Information on performance and inherent vulnerabilities is classified Secret. The software (object code) is classified Confidential. Sensitive elements include the Forward Looking Infrared (FLIR) sensors, and the AGM-65 Missile Boresight Correlator.

5. The AN/ARC-238 radio is an Ultra High Frequency/Very High Frequency voice communication radio system and considered Unclassified without HAVE QUICK II.

6. The Advanced Identification Friend or Foe System is Unclassified unless MODE IV operational evaluator parameters are loaded into the equipment.

7. The AN/ALQ-211 Airborne Integrated Defensive Electronic Warfare Suite (AIDEWS) provided passive radar warning, wide spectrum radio frequency jamming, and control and management of the entire electronic warfare system. It is an internally mounted suite. The commercially developed system software and hardware is Unclassified. The system is classified Secret when loaded with a U.S. derived EW database.

8. The AN/ALQ-187 Advanced Countermeasures Electronic System (ACES) provides passive radar warning, wide spectrum radio frequency jamming, and control and management of the entire electronic warfare (EW) system. It is an internally mounted suite. The commercially developed system software and hardware is Unclassified. The system is classified Secret when loaded with a U.S. derived EW database.

9. The Joint Helmet Mounted Cueing System (JHMCS) is a modified HGU-55/P helmet that incorporates a visor-projected Heads-Up Display (HUD) to cue weapons and aircraft sensors to air and ground targets. This system projects visual targeting and aircraft performance information on the back of the helmet's visor, enabling the pilot to monitor this information without interrupting his field of view through the cockpit canopy. This provides significant improvement for close combat targeting and engagement. The JHMCS hardware is Unclassified.

10. 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. 2010–19929 Filed 8–11–10; 8:45 am]
BILLING CODE 5001–06–C

DEPARTMENT OF DEFENSE

Office of the Secretary

List of Institutions of Higher Education Ineligible for Federal Funds

AGENCY: Department of Defense (DoD).

ACTION: Notice.

SUMMARY: This document is published to identify institutions of higher education that are ineligible for contracts and grants by reason of a determination by the Secretary of Defense that the institution prohibits or in effect prevents military recruiter access to the campus, students on campus or student directory information. It also implements the requirements set forth in section 983 of title 10, United States Code, and 32 CFR part 216. The institutions of higher education so identified are the Vermont Law School, South Royalton, Vermont; and the William Mitchell College of Law, St. Paul, Minnesota.

ADDRESSES: Director for Accession Policy, Office of the Under Secretary of Defense for Personnel and Readiness, 4000 Defense Pentagon, Washington, DC 20301–4000.

FOR FURTHER INFORMATION CONTACT: Lieutenant Colonel Paul Nosek, (703) 695–5529.

Dated: August 9, 2010.

Mitchell S. Bryman,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2010–19930 Filed 8–11–10; 8:45 am]
BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of Proposed Information Collection Requests.

SUMMARY: The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: An emergency review has been requested in accordance with the Act (44 U.S.C. Chapter 3507 (j)), due to unanticipated events and the enactment of H.R. 1586, which authorizes the Education Jobs Fund Program. The Act requires awards to be made within a certain period from the date of enactment as specified under the "Additional Information" section. Approval by the Office of Management and Budget (OMB) has been requested by August 12, 2010.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, *Attention:* Education Desk Officer,

Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503, be faxed to (202) 395–5806 or e-mailed to *oira_submission@omb.eop.gov* with a cc: to *ICDocketMgr@ed.gov.*

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. 35) requires that the Director of OMB provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (OMB) may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.,* new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. ED invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner, (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected, and (5) how might the Department minimize the burden of this collection on respondents, including through the use of information technology.

Dated: August 10, 2010.

Darrin A. King,

Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management.

Office of Elementary and Secondary Education

Type of Review: New.

Title: Education Jobs Fund Program Application.

OMB #: 1810–NEW.

Agency Form(s) #: N/A.

Abstract: On August 10, 2010, President Barack Obama signed H.R. 1586, which authorizes the Education Jobs Fund Program. This economic recovery bill provides an investment in education to retain or create education jobs. It provides needed aid to school districts for the support of early childhood, elementary and secondary education. Under the Education Jobs Fund (Education Jobs), the U.S. Department of Education (Department) will award grants to Governors according to a formula based on their relative population of individuals aged 5 to 24 (sixty-one percent) and based on relative total population (thirty-nine percent).

Additional Information: In order to provide immediate assistance to help alleviate the substantial budget shortfalls that school districts are facing, the Department is committed to providing the Education Jobs allocations within a very short timeframe, necessitating emergency clearance of the Education Jobs program application. Specifically, the statute directs the Department to award each State the total amount that it is to receive within 45 days after the date of the enactment of the Act, if the governor submits an approvable application within 30 days after the date of enactment.

Frequency: One time.

Affected Public: State, Local, or Tribal Government, State Educational Agencies (SEAs) or Local Educational Agencies (LEAs).

Reporting and Recordkeeping Hour Burden:

Responses: 51.

Burden Hours: 107.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 4377. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to the Internet address *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2010–20049 Filed 8–11–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Arbitration Panel Decision Under the Randolph-Sheppard Act

AGENCY: Department of Education.

ACTION: Notice of arbitration panel decision under the Randolph-Sheppard Act.

SUMMARY: The U. S. Department of Education (Department) gives notice that on February 4, 2010, an arbitration panel rendered a decision in the matter of *Ohio Rehabilitation Services Commission, Bureau of Services for the Visually Impaired* v. *United States Department of Defense, Department of the Air Force, Case no. R–S/07–5.* This panel was convened by the Department under 20 U.S.C. 107d–1(b) after the Department received a complaint filed by the petitioner, the Ohio Rehabilitation Services Commission, Bureau of Services for the Visually Impaired.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the full text of the arbitration panel decision from Suzette E. Haynes, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5022, Potomac Center Plaza, Washington, DC 20202–2800. Telephone: (202) 245–7374. If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

Individuals with disabilities may obtain this document in an accessible format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: Under section 6(c) of the Randolph-Sheppard Act, 20 U.S.C. 107d–2(c), the Secretary publishes in the **Federal Register** a synopsis of each arbitration panel decision affecting the administration of vending facilities on Federal and other property.

Background

The Ohio Rehabilitation Services Commission, Bureau of Services for the Visually Impaired, the State licensing agency (SLA), alleged violations by the United States Department of Defense, Department of the Air Force (Air Force) of the Randolph-Sheppard Act (Act) and

the implementing regulations in 34 CFR part 395. Specifically, the SLA alleged that the Air Force violated the Act and its implementing regulations concerning the food services at Wright-Patterson Air Force Base in Montgomery County, Ohio.

According to the arbitration panel, the issues to be resolved were: (1) The Air Force's alleged failure to comply with the Act by denying the SLA's June 13, 2006, application for a permit to operate snack and beverage vending machines throughout the Wright-Patterson Air Force Base, and (2) the Air Force's alleged failure to properly report and pay the SLA or its designated vendors income from the vending machines at the Wright-Patterson Air Force Base pursuant to the Act and implementing regulations.

Arbitration Panel Decision

After hearing testimony and reviewing all of the evidence, the panel majority ruled as follows:

(1) The Air Force violated the Act by denying the SLA's vending machine permit application. The panel concluded that nothing in the Act or the implementing regulations authorizes a Federal agency to reject an SLA's vending permit application on the grounds that the Federal agency would lose income or prefer to tie the vending machine service to some other service. The panel declined, however, to prescribe a remedy for this violation based upon the requirement in 34 CFR 395.37(d) that it is the agency's responsibility to "cause such acts or practices to be terminated promptly and [to] take such other action as may be necessary to carry out the decision of the panel."

(2) The Air Force did not violate the Act or implementing regulations in 34 CFR 395.32 concerning the collection and distribution of vending machine income on Federal property by paying the two blind vendors at the Wright-Patterson Air Force Base fifty percent instead of 100 percent of vending machine income. Rather, the panel majority ruled that the evidence presented did not show that the Air Force's vending machines were located in an area of proximity that posed "direct competition" to either or both of the two blind vendors.

(3) The SLA failed to show that the Air Force's accounting of vending machine income varied from established procedures or that the vending machine income, which the Air Force reported quarterly to the SLA, was inaccurate.

(4) The Air Force did not violate the Act by failing to share vending machine income with the SLA when the vending machine income from each separate building did not exceed $3,000.

In drawing this conclusion, the panel majority noted that there was no evidence presented at the hearing that showed that any of the single buildings at the Wright-Patterson Air Force base were in close proximity to each other or that a majority of the Federal workers in any of the buildings regularly moved from one building to another in the course of official business during a normal work day. This is what is required to trigger the vending machine income sharing requirements under sections 395.1(h) and 395.32(i) of the regulations.

One panel member dissented from the panel majority regarding item one. The panel member concluded that the Air Force included both the food service operations and the vending machines as a package in the solicitation and thus denied the SLA's permit application on the basis that a vending machines "only" permit did not exist.

The views and opinions expressed by the panel do not necessarily represent the views and opinions of the Department.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

Note: The official version of this document is the document published in the **Federal Register.** Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: August 9, 2010.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2010–19947 Filed 8–11–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Arbitration Panel Decision Under the Randolph-Sheppard Act

AGENCY: Department of Education.

ACTION: Notice of arbitration panel decision under the Randolph-Sheppard Act.

SUMMARY: The Department of Education (Department) gives notice that on July 17, 2009, an arbitration panel rendered a decision in the matter of the *Illinois Department of Human Services, Division of Rehabilitation Services* v. *United States Postal Service, Case No. R–S/06–14.* This panel was convened by the Department under 20 U.S.C. 107d–1(b) after the Department received a complaint filed by the petitioner, the Illinois Department of Human Services, Division of Rehabilitation Services.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the full text of the arbitration panel decision from Suzette E. Haynes, U.S. Department of Education, 400 Maryland Avenue, SW., room 5022, Potomac Center Plaza, Washington, DC 20202–2800. Telephone: (202) 245–7374. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

Individuals with disabilities may obtain this document in an accessible format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: Under section 6(c) of the Randolph-Sheppard Act (the Act), 20 U.S.C. 107d–2(c), the Secretary publishes in the **Federal Register** a synopsis of each arbitration panel decision affecting the administration of vending facilities on Federal and other property.

Background

The Illinois Department of Human Services, Division of Rehabilitation Services, the State licensing agency (SLA) alleged violations by the United States Postal Service (USPS) of the Act and the implementing regulations in 34 CFR part 395. Specifically, the SLA alleged that USPS violated the Act, the implementing regulations, and the vending permits held by the SLA concerning a vending machine facility operated by a blind vendor at the USPS's Chicago Processing and Distribution Center.

According to the arbitration panel, the issues to be resolved were: (1) Whether the USPS cafeteria operations are exempt from the Act and whether the vending machines operated by a private vendor at the Chicago Processing and Distribution Center are in direct competition with the vending machines operated by the SLA's blind vendor; (2) Whether the no-commission contracts let by USPS for cafeteria vending violated the Act, and what compensatory damages, if any are due the SLA; and (3) Whether the SLA may amend its complaint against USPS to

address information which surfaced during settlement negotiations, namely, whether USPS violated the Act, its regulations, and the vending permits by closing Break Room A and removing the vending machines for 34 days, and what compensatory damages, if any, are due the SLA.

Arbitration Panel Decision

After hearing testimony and reviewing all of the evidence, the panel majority ruled that: (1) USPS cafeterias are not exempt from the protections of the Act, including the vending machine income sharing provisions; (2) The vending machines operated in the cafeteria at the Chicago Processing and Distribution Center by a private vendor are in direct competition with the blind vendor and are subject to the 100 percent income sharing provisions under the Act; and (3) The no-commission contracts let by USPS for cafeteria vending machines at the Chicago Processing and Distribution Center under its break-even policy violated the purpose and terms of the Act and implementing regulations.

Thus, the panel majority ruled that USPS must compensate the SLA 100 percent of vending machine income for all of the vending machines located in the rotunda and in the cafeteria at the Chicago Processing and Distribution Center in accordance with the income sharing provisions of the Act and implementing regulations at 34 CFR 395.32 as of September 21, 2006.

The panel majority further ruled that the USPS must pay interest at the Federal interest rate and the method of calculating interest should begin only at the end of the month in which the income originally would have been earned by the blind vendor and continue forward from that time. Additionally, the panel majority determined there was no need to allow the SLA to amend its complaint because those issues had already been resolved.

One panel member dissented to a portion of the decision regarding the monetary remedy award. Specifically, it was this panel member's belief that within 30 days following the date of the arbitration panel's decision, USPS should compensate the SLA the amount of $5,934.70 for income lost by the blind vendor from January 29 to March 3, 2007, resulting from violations of the Act. Also, this member believed that USPS should compensate the SLA the amount of $318,600 for income lost by the SLA and blind vendor as a consequence of vending machines operated by a private vendor in direct competition with the blind vendor in violation of the income sharing provisions of the Act and the relevant permits. Finally, this member believed that USPS should pay the SLA interest in the amount of $17,556.83 calculated at 5 percent per annum, compounded.

The views and opinions expressed by the panel do not necessarily represent the views and opinions of the Department.

Electronic Access to This Document

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To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register.** Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: August 9, 2010.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2010–19961 Filed 8–11–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Arbitration Panel Decision Under the Randolph-Sheppard Act

AGENCY: Department of Education.

ACTION: Notice of arbitration panel decision under the Randolph-Sheppard Act.

SUMMARY: The U.S. Department of Education (Department) gives notice that on April 27, 2009, an arbitration panel rendered a decision in the matter of *Jerry Manganello, et al.* v. *Pennsylvania Office of Vocational Rehabilitation, Case No. R–S/07–7.* This panel was convened by the Department under 20 U.S.C. 107d–1(a), after the Department received a complaint filed by the petitioner, *Jerry Manganello, et al.*

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the full text of the arbitration panel decision from Suzette E. Haynes, U.S. Department of Education, 400 Maryland Avenue, SW., room 5022, Potomac Center Plaza, Washington, DC 20202–2800. Telephone: (202) 245–7374. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free at 1–800–877–8339.

Individuals with disabilities may obtain this document in an accessible format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: Under section 6(c) of the Randolph-Sheppard Act (the Act), 20 U.S.C. 107–2(c), the Secretary publishes in the **Federal Register** a synopsis of each arbitration panel decision affecting the administration of vending facilities on Federal and other property.

Background

Jerry Manganello, et al. (Complainants) alleged violations of the Act and its implementing regulations in 34 CFR part 395 by the Pennsylvania Office of Vocational Rehabilitation, the State licensing agency (SLA). Specifically, Complainants alleged that the SLA improperly administered the Randolph-Sheppard Vending Facility Program as provided by the Act, implementing regulations, and State rules and regulations by failing to comply with a unanimous vote of the Committee of Blind Vendors (CBV) concerning unassigned vending machine income and the payment of set-aside fees to the SLA.

The SLA, in the overall operation and administration of Pennsylvania's Randolph-Sheppard vending program, established several funds to receive monies from various sources. Fund 33 receives monies paid by blind vendors from the net profits of vending facilities and vending machine income on Federal property. Fund 650 receives monies from vending machines operated by blind vendors at interstate highway rest areas.

In 1998, the CBV by referendum agreed to use 85 percent of the funds in Fund 650 for medical benefits and to permit the SLA to use the balance for programmatic purposes. However, the CBV alleged that, in practice, the SLA used 15 percent of the funds in Fund 650 to support SLA program staff salaries.

Conversely, the SLA alleged that between 1998 and 2005, it asked the CBV to approve the use of part of the accrued balance in Fund 650 for programmatic purposes and that whenever the SLA's request was not approved, the money remained in Fund 650.

In 2005, because of increased health insurance premiums, CBV unanimously

passed three referenda. The first referendum requested that the SLA forego its 15 percent of the annual revenue that accrued in Fund 650. Instead, the SLA would apply 100 percent of the revenue to the vendors' health insurance plan. The second referendum requested that the SLA transfer the unused balance of its 15 percent in Fund 650 to the vendors' health insurance account. The third referendum requested that the SLA transfer $650,000 from Fund 33 to the vendors' health insurance account so the money could be used to cover an impending shortage.

The Complainants alleged, however, that the SLA did not comply with the three referenda and actually transferred a substantial sum of the money to its own account to pay retroactive salaries of program staff.

A State fair hearing on this matter was held. On May 6, 2007, the hearing officer issued a decision affirming the CBV's complaint, finding that the SLA had violated CBV's right to actively participate in the SLA's administrative decision making concerning the collection and use of unassigned vending machine income and set-aside funds. The hearing officer ruled that (1) the SLA should return funds collected from the unassigned vending machine income used to pay for staff salaries, and (2) in all future major decisions, the SLA should allow active participation by the CBV.

Following the hearing officer's decision, the SLA filed a petition for review with the Commonwealth Court of Pennsylvania. On January 28, 2008, the court denied the SLA's appeal. The SLA then filed a motion for re-argument, which was denied by the court on March 14, 2008. Subsequently, the CBV requested review and enforcement by a Federal arbitration panel of the May 7, 2007, hearing officer's decision.

Arbitration Panel Decision

After a hearing at which all testimony was presented and following extensive negotiations, the panel majority and the parties were able to reach a settlement and entered into a Settlement agreement. The panel ruled that the Settlement Agreement would become the panel's final Decision and Award. Additionally, the parties have agreed that the terms of the Settlement Agreement should not be revealed or disclosed.

The views and opinions expressed by the panel do not necessarily represent the views and opinions of the Department.

Electronic Access to This Document

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Dated: August 9, 2010.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2010–19949 Filed 8–11–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services; Overview Information; Technology and Media Services for Individuals With Disabilities—Video Description Research and Development Center; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011

Catalog of Federal Domestic Assistance (CFDA) Number: 84.327J.

DATES: *Applications Available:* August 12, 2010.

Deadline for Transmittal of Applications: October 12, 2010.

Deadline for Intergovernmental Review: December 10, 2010.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of the Technology and Media Services for Individuals with Disabilities program are to: (1) Improve results for children with disabilities by promoting the development, demonstration, and use of technology; (2) support educational media services activities designed to be of educational value in the classroom setting to children with disabilities, and (3) provide support for captioning and video description of educational materials that are appropriate for use in the classroom setting. In the context of this notice, educational materials for use in the classroom setting include television programs, videos, and other materials, including programs and materials associated with new and emerging technologies, such as CDs, DVDs, and other forms of multimedia.

Priority: In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute or otherwise authorized in the statute (see sections 674(c) and 681(d) of the Individuals with Disabilities Education Act (IDEA), 20 U.S.C. 1474 and 1481(d)).

Absolute Priority: For FY 2011 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is: Technology and Media Services for Individuals with Disabilities—Video Description Research and Development Center.

Background

To ensure that children who are blind or visually impaired have access to all educational program content, the Office of Special Education Programs (OSEP) provides competitive grant funds to support the video description of educational television programs. (See *http://publicddb.tadnet.org.* Use the keyword search function with the term "video description".)

However, teachers are increasingly using the Internet and other technological devices (*e.g.,* cell phones, smart phones, digital video cameras) rather than television for instruction. Unfortunately, much of the educational program content provided via the Internet or through other technological devices is not accessible to children who are blind or visually impaired. While progress has been made in accessibility—through video description—for television programming that is appropriate for the classroom setting, there is currently no legal requirement or any OSEP-funded project for providing video description for educational program content delivered via the Internet (*e.g.,* YouTube, YouTube EDU, Second Life, and virtual on-line courses) or through technological devices (*e.g.,* smart phones, cell phones, and digital video cameras). The technology needed to provide description for educational program content delivered via the Internet or through other technological devices is either just beginning to emerge or yet to be developed.

It is essential to develop methods for providing video description that can be used in conjunction with the Internet and other technological devices in order to ensure that all students who are blind or visually impaired have access to educational program content delivered

through those methods. In addition, it is important to explore emerging alternatives to video description that could improve the accessibility of educational program content (*e.g.,* creating description by having sighted viewers verbally describe video content).

Priority

The purpose of this priority is to fund a cooperative agreement to support the establishment and operation of the Video Description Research and Development Center (Center). The purpose of the Center is to advance the research and development of video description, as well as alternative approaches to video description, to improve the accessibility of educational program content delivered via the Internet or through other technological devices (other than television) for students who are blind or visually impaired.

To be considered for funding under this absolute priority, applicants must meet the application requirements contained in this priority. Any project funded under this absolute priority also must meet the programmatic and administrative requirements specified in the priority.

Application Requirements. An applicant must include in its application the following:

(a) A detailed plan for implementing the activities described in the *Project Activities* and *Leadership and Coordination Activities* sections of this priority.

(b) A budget for attendance at the following:

(1) A one and one half-day kick-off meeting to be held in Washington, DC, within four weeks after receipt of the award, and an annual planning meeting held in Washington, DC, with the OSEP Project Officer during each subsequent year of the project period.

(2) A three-day Project Directors' Conference in Washington, DC, during each year of the project period; and

(3) A two-day technology Project Director's meeting in Washington, DC, during each year of the project period.

Project Activities. To meet the requirements of this priority, the Center, at a minimum, must conduct the following activities:

(a) Complete a systematic review and synthesis of existing research on technology that provides accessibility to educational program content that is delivered via the Internet or through other technological devices for children who are blind or visually impaired.

(b) Develop methods for providing video description that can be used in conjunction with the Internet and other technological devices in order to ensure that students who are blind or visually impaired have access to educational program content delivered through these methods.

(c) Conduct research on emerging alternatives to video description that could improve the accessibility of educational program content (*e.g.,* creating description by having sighted viewers verbally describe video content).

(d) Collaborate with researchers and technology experts to enhance or develop new open source technologies that make educational program content—appropriate for use in the classroom and delivered via the Internet or through other technological devices (*e.g.,* smart phones, cell phones, and digital video cameras)—accessible through video description.

(e) Systematically field-test and evaluate the efficacy of the technologies developed under paragraph (d) of this priority.

(f) Ensure that all technology developed under paragraph (d) will be available as open source materials (*i.e.,* the source codes for the developed technology are freely available to the public).

(g) Develop and implement—upon review and approval from OSEP—a strategy for disseminating research and development findings, in open source format, to key stakeholders including educators, technology developers, vendors, researchers, and federally-funded technical assistance and dissemination projects (*e.g.,* the National Center on Technology and Innovation and the Family Center on Technology and Disability).

Leadership and Coordination Activities

(a) Establish and maintain an advisory committee to review the activities and outcomes of the project and to provide programmatic support and advice throughout the project period. The committee membership must include technology experts, technical assistance providers, representatives of entities providing video description, educators, individuals with disabilities, parents of children with disabilities, and individuals from communities representing rural, low-income, urban, and English language learner populations. The names of proposed members of the advisory committee must be submitted to OSEP for approval within four weeks after receipt of the award.

(b) Conduct a summative evaluation of the Center in collaboration with the Center to Improve Project Performance (CIPP) as described in the following paragraphs. This summative evaluation must examine the outcomes or impact of the Center's activities in order to assess the effectiveness of those activities, specifically the degree to which the Center's activities contribute to changed practice and improved implementation of technologies that provide educational program content delivered via the Internet and through other technological devices accessible to children who are blind or visually impaired.

Note: The major tasks of CIPP are to guide, coordinate, and oversee the summative evaluations conducted by selected Technical Assistance, Personnel Development, Parent Training and Information Center, and Technology projects that individually receive $500,000 or more funding from OSEP annually. The efforts of CIPP are expected to enhance individual project evaluations by providing expert and unbiased assistance in designing evaluations, conducting analyses, and interpreting data.

To fulfill the requirements of the summative evaluation to be conducted under the guidance of CIPP, the Center must—

(1) Hire or designate, with the approval of the OSEP Project Officer, a project liaison staff person with sufficient dedicated time and knowledge of the Center to work with CIPP on the following tasks—

(i) Planning for the Center's summative evaluation (*e.g.,* selecting evaluation questions, developing a timeline for the evaluation, and locating sources of relevant data);

(ii) Developing the summative evaluation design and instrumentation (*e.g.,* determining quantitative or qualitative data collection strategies, selecting respondent samples, and pilot testing instruments);

(iii) Coordinating the evaluation timeline with the implementation of the Center's activities;

(iv) Collecting summative data; and

(v) Writing reports of summative evaluation findings;

(2) Cooperate with CIPP staff in order to accomplish the tasks described in paragraph (1) of this section; and

(3) Dedicate $55,000.00 per year of the annual budget request for this project to cover the costs of carrying out the tasks described in paragraphs (1) and (2) of this section and of implementing the Center's formative evaluation.

(c) Maintain ongoing communication with the OSEP Project Officer through regular teleconferences and e-mail communication.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the

opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1474 and 1481(d).

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $41,223,000 for the Technology and Media Services for Individuals with Disabilities program for FY 2011, of which we intend to use an estimated $1,000,000 for the competition announced in this notice. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2012 from this competition.

Maximum Award: We will reject any application that proposes a budget exceeding $1,000,000 for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

Estimated Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 24 months.

III. Eligibility Information

1. *Eligible Applicants:* State educational agencies (SEAs); local educational agencies (LEAs); public charter schools that are LEAs under State law; IHEs; other public agencies; private nonprofit organizations; outlying areas; freely associated States; Indian tribes or tribal organizations; and for-profit organizations.

2. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

3. *Other: General Requirements*—(a) The projects funded under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA (20 U.S.C. 1405)).

(b) Applicants and grant recipients funded under this competition must involve individuals with disabilities or parents of individuals with disabilities ages birth through 26 in planning, implementing, and evaluating the projects (see section 682(a)(1)(A) of IDEA (20 U.S.C. 1482(a)(1)(A))).

IV. Application and Submission Information

1. *Address to Request Application Package:* Education Publications Center (ED Pubs), U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *http://www.EDPubs.gov* or at its e-mail address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this competition as follows: CFDA number 84.327J.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to the equivalent of no more than 50 pages, using the following standards:

- A "page" is 8.5″ × 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, the references, or the letters of support. However, the page limit does apply to all of the application narrative section (Part III).

We will reject your application if you exceed the page limit; or if you apply other standards and exceed the equivalent of the page limit.

3. *Submission Dates and Times:*

Applications Available: August 12, 2010.

Deadline for Transmittal of Applications: October 12, 2010.

Applications for grants under this competition may be submitted electronically using the Electronic Grant Application System (e-Application) accessible through the Department's e-Grants site, or in paper format by mail or hand delivery. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under *For Further Information Contact* in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: December 10, 2010.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and Central Contractor Registry:* To do business with the Department of Education, (1) you must have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN); (2) you must register both of those numbers with the Central Contractor Registry (CCR), the Government's primary

registrant database; and (3) you must provide those same numbers on your application.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

7. *Other Submission Requirements:* Applications for grants under this competition may be submitted electronically or in paper format by mail or hand delivery.

a. *Electronic Submission of Applications.*

If you choose to submit your application to us electronically, you must use e-Application, accessible through the Department's e-Grants Web site at: *http://e-grants.ed.gov.*

While completing your electronic application, you will be entering data online that will be saved into a database. You may not e-mail an electronic copy of a grant application to us.

Please note the following:

- Your participation in e-Application is voluntary.
- You must complete the electronic submission of your grant application by 4:30:00 p.m., Washington, DC time, on the application deadline date. E-Application will not accept an application for this competition after 4:30:00 p.m., Washington, DC time, on the application deadline date. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the application process.
- The hours of operation of the e-Grants Web site are 6:00 a.m. Monday until 7:00 p.m. Wednesday; and 6:00 a.m. Thursday until 8:00 p.m. Sunday, Washington, DC time. Please note that, because of maintenance, the system is unavailable between 8:00 p.m. on Sundays and 6:00 a.m. on Mondays, and between 7:00 p.m. on Wednesdays and 6:00 a.m. on Thursdays, Washington, DC time. Any modifications to these hours are posted on the e-Grants Web site.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. You must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified in this paragraph or submit a password protected file, we will not review that material.
- Your electronic application must comply with any page limit requirements described in this notice.
- Prior to submitting your electronic application, you may wish to print a copy of it for your records.
- After you electronically submit your application, you will receive an automatic acknowledgment that will include a PR/Award number (an identifying number unique to your application).
- Within three working days after submitting your electronic application, fax a signed copy of the SF 424 to the Application Control Center after following these steps:

(1) Print SF 424 from e-Application.

(2) The applicant's Authorizing Representative must sign this form.

(3) Place the PR/Award number in the upper right hand corner of the hard-copy signature page of the SF 424.

(4) Fax the signed SF 424 to the Application Control Center at (202) 245–6272.

- We may request that you provide us original signatures on other forms at a later date.

Application Deadline Date Extension in Case of System Unavailability: If you are prevented from electronically submitting your application on the application deadline date because e-Application is unavailable, we will grant you an extension of one business day to enable you to transmit your application electronically, by mail, or by hand delivery. We will grant this extension if—

(1) You are a registered user of e-Application and you have initiated an electronic application for this competition; and

(2) (a) E-Application is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the application deadline date; or

(b) E-Application is unavailable for any period of time between 3:30 p.m. and 4:30:00 p.m., Washington, DC time, on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension or to confirm our acknowledgment of any system unavailability, you may contact either (1) the person listed elsewhere in this notice under *For Further Information Contact* (see VII. Agency Contact) or (2) the e-Grants help desk at 1–888–336–8930. If e-Application is unavailable due to technical problems with the system and, therefore, the application deadline is extended, an e-mail will be sent to all registered users who have initiated an e-Application.

Extensions referred to in this section apply only to the unavailability of e-Application. If e-Application is available, and, for any reason, you are unable to submit your application electronically or you do not receive an automatic acknowledgment of your submission, you may submit your application in paper format by mail or hand delivery in accordance with the instructions in this notice.

b. *Submission of Paper Applications by Mail.*

If you submit your application in paper format by mail (through the U.S. Postal Service or a commercial carrier), you must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.327J) LBJ Basement Level 1, 400 Maryland Avenue, SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you submit your application in paper format by hand delivery, you (or a courier service) must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.327J) 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this grant notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* In the past, the Department has had difficulty finding peer reviewers for certain competitions, because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The Standing Panel requirements under IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that, for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers, by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications. However, if the Department decides to select an equal number of applications in each group for funding, this may result in different cut-off points for fundable applications in each group.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *http://www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Technology and Media Services for Individuals with Disabilities program. These measures focus on the extent to which projects are of high quality, are relevant to improving outcomes of children with disabilities, and contribute to improving outcomes for children with disabilities. We will collect data on these measures from the projects funded under this competition.

Grantees will be required to report information on their projects' performance in their annual performance reports to the Department (34 CFR 75.590).

VII. Agency Contact

For Further Information Contact: Jo Ann McCann, U.S. Department of Education, 400 Maryland Avenue, SW., room 4076, Potomac Center Plaza (PCP), Washington, DC 20202–2550. Telephone: (202) 245–7434.

If you use a TDD, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.* To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: August 9, 2010.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2010–19959 Filed 8–11–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 516–467]

South Carolina Electric & Gas Company; Notice of Application for Amendment of License and Soliciting Comments, Motions to Intervene, and Protests

August 5, 2010.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Non-project use of project lands and waters.

b. *Project No:* 516–467.

c. *Date Filed:* July 27, 2010.

d. *Applicant:* South Carolina Electric & Gas Company.

e. *Name of Project:* Saluda Hydroelectric Project.

f. *Location:* The project is located on the Saluda River in Lexington, Newberry, Richland, and Saluda counties, South Carolina. The proposed action would occur on Lake Murray in Lexington County, South Carolina.

g. *Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Tommy Boozer, Manager, Lake Management Programs, SCE&G, 6248 Bush River Road, Columbia, SC 29212, telephone (803) 217–9007.

i. *FERC Contact:* Any questions on this notice should be addressed to Shana High at (202) 502–8674.

j. *Deadline for Filing Comments and or Motions:* September 7, 2010.

Comments, protests, and interventions may be filed electronically 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. The Commission strongly encourages electronic filings.

All documents (original and eight copies) filed by paper should be sent to: Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Please include the project number (P–516–467) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

k. *Description of Application:* The licensee proposes to permit the modification of Jakes Landing, an existing facility, by adding a 184-foot by 52-foot floating dock that would provide 30 slips. The new dock would be attached to the shoreline with an adjustable walkway, which would be secured to the ground.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also 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 (P–516) in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Any filings must bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers.

p. *Agency Comments:* Federal, State, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–19849 Filed 8–11–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

July 30, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1727–000.

Applicants: RRI Energy Florida, LLC.

Description: RRI Energy Florida, LLC submits tariff filing per 35.12: Baseline Filing to be effective 8/1/2010.

Filed Date: 07/07/2010.

Accession Number: 20100707–5077.

Comment Date: 5 p.m. Eastern Time on Friday, August 20, 2010.

Docket Numbers: ER10–1894–002.

Applicants: Wisconsin Public Service Corporation.

Description: Wisconsin Public Service Corporation submits tariff filing per 35: Compliance Filing for WPSR OATT to be effective 7/30/2010.

Filed Date: 07/30/2010.

Accession Number: 20100730–5037.

Comment Date: 5 p.m. Eastern Time on Friday, August 20, 2010.

Docket Numbers: ER10–1901–002.

Applicants: Upper Peninsula Power Company.

Description: Upper Peninsula Power Company submits tariff filing per 35: Compliance Filing for WPSR OATT to be effective 7/30/2010.

Filed Date: 07/30/2010.

Accession Number: 20100730–5039.

Comment Date: 5 p.m. Eastern Time on Friday, August 20, 2010.

Docket Numbers: ER10–1954–000.

Applicants: American Electric Power Service Corporation.

Description: AEP Texas Central Company et al. submits fully executed amended transmission interconnection agreements which are being filed as service agreement under the Open Access Transmission Service Tariff of the AEPS.

Filed Date: 07/23/2010.

Accession Number: 20100726–0204.

Comment Date: 5 p.m. Eastern Time on Friday, August 13, 2010.

Docket Numbers: ER10–1977–001.
Applicants: New York Independent System Operator, Inc.
Description: New York Independent System Operator submits tariff filing per 35.17(b): Errata Filing—IBRT—7/30/10 to be effective 9/30/2010.
Filed Date: 07/30/2010.
Accession Number: 20100730–5067.
Comment Date: 5 p.m. Eastern Time on Friday, August 20, 2010.

Docket Numbers: ER10–2035–000.
Applicants: Kansas City Power & Light Company.
Description: Kansas City Power & Light Company submits First Revised Rate Schedule FERC No. 129.
Filed Date: 07/29/2010.
Accession Number: 20100729–0209.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2036–000.
Applicants: Calpine Vineland Solar, LLC.
Description: Calpine Vineland Solar, LLC submits tariff filing per 35.12: Market-Based Rate Tariff in Compliance with Order No. 714 to be effective 7/29/2010.
Filed Date: 07/29/2010.
Accession Number: 20100729–5088.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2037–000.
Applicants: Calpine Philadelphia Inc.
Description: Calpine Philadelphia Inc. submits tariff filing per 35.12: Market-Based Rate Tariff in Compliance with Order No. 714 to be effective 7/29/2010.
Filed Date: 07/29/2010.
Accession Number: 20100729–5089.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2038–000.
Applicants: Entergy Services, Inc.
Description: Entergy Services, Inc submits Attachment A letter requesting termination of the executed interconnection and operating agreement and generator imbalance agreement.
Filed Date: 07/29/2010.
Accession Number: 20100729–0208.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2039–000.
Applicants: Calpine Newark, LLC.
Description: Calpine Newark, LLC submits tariff filing per 35.12: Market-Based Rate Tariff in Compliance with Order No. 714 to be effective 7/29/2010.
Filed Date: 07/29/2010.
Accession Number: 20100729–5090.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2040–000.
Applicants: Calpine New Jersey Generation, LLC.
Description: Calpine New Jersey Generation, LLC submits tariff filing per 35.12: Market-Based Rate Tariff in Compliance with Order No. 714 to be effective 7/29/2010.
Filed Date: 07/29/2010.
Accession Number: 20100729–5091.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2041–000.
Applicants: Calpine Mid Merit, LLC.
Description: Calpine Mid Merit, LLC submits tariff filing per 35.12: Market-Based Rate Tariff in Compliance with Order No. 714 to be effective 7/29/2010.
Filed Date: 07/29/2010.
Accession Number: 20100729–5092.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2042–000.
Applicants: Calpine Energy Services, L.P.
Description: Calpine Energy Services, L.P. submits tariff filing per 35.12: Market-Based Rate Tariff in Compliance with Order No. 714 to be effective 7/29/2010.
Filed Date: 07/29/2010.
Accession Number: 20100729–5093.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2043–000.
Applicants: Calpine Mid-Atlantic Generation, LLC.
Description: Calpine Mid-Atlantic Generation, LLC submits tariff filing per 35.12: Market-Based Rate Tariff in Compliance with Order No. 714 to be effective 7/29/2010.
Filed Date: 07/29/2010.
Accession Number: 20100729–5098.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2044–000.
Applicants: Zion Energy LLC.
Description: Zion Energy LLC submits tariff filing per 35.12: Market-Based Rate Tariff in Compliance with Order No. 714 to be effective 7/29/2010.
Filed Date: 07/29/2010.
Accession Number: 20100729–5100.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2045–000.
Applicants: New York Independent System Operator, Inc.
Description: New York Independent System Operator submits tariff filing per 35.13(a)(2)(iii): EDRP for STR—Allen—7/29/10 to be effective 9/30/2010.
Filed Date: 07/29/2010.
Accession Number: 20100729–5102.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2046–000.
Applicants: Calpine Bethlehem, LLC.
Description: Calpine Bethlehem, LLC et al. submits Notice of Succession notifying the Commission of a name change follow the recent consummation etc.
Filed Date: 07/29/2010.
Accession Number: 20100730–0202.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2047–000.
Applicants: Calpine Mid-Atlantic Generation, LLC.
Description: Calpine Bethlehem, LLC et al. submits Notice of Succession notifying the Commission of a name change follow the recent consummation etc.
Filed Date: 07/29/2010.
Accession Number: 20100730–0202.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2048–000.
Applicants: Calpine Mid Merit, LLC.
Description: Calpine Bethlehem, LLC et al. submits Notice of Succession notifying the Commission of a name change follow the recent consummation etc.
Filed Date: 07/29/2010.
Accession Number: 20100730–0202.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2049–000.
Applicants: Calpine New Jersey Generation, LLC.
Description: Calpine Bethlehem, LLC et al. submits Notice of Succession notifying the Commission of a name change follow the recent consummation etc.
Filed Date: 07/29/2010.
Accession Number: 20100730–0202.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2050–000.
Applicants: Calpine Vineland Solar, LLC.
Description: Calpine Bethlehem, LLC et al. submits Notice of Succession notifying the Commission of a name change follow the recent consummation etc.
Filed Date: 07/29/2010.
Accession Number: 20100730–0202.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2051–000.
Applicants: Calpine Bethlehem, LLC.
Description: Calpine Bethlehem, LLC submits tariff filing per 35.12: Market-Based Rate Tariff in Compliance with Order No. 714 to be effective 7/29/2010.
Filed Date: 07/29/2010.
Accession Number: 20100729–5132.
Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2052–000.
Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.12: G604 FCA Filing to be effective 12/31/9998.

Filed Date: 07/29/2010.

Accession Number: 20100729–5138.

Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2053–000.

Applicants: Southern California Edison Company.

Description: Southern California Edison Company submits tariff filing per 35: TOT Appendix 8 CWIP Settlement 072910 to be effective 6/1/2010.

Filed Date: 07/29/2010.

Accession Number: 20100729–5144.

Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2054–000.

Applicants: Pacific Gas and Electric Company.

Description: Pacific Gas and Electric Company submits tariff filing per 35.13(a)(2)(iii): Modifications to CAISO Interim Black Start Agreement to be effective 9/27/2010.

Filed Date: 07/29/2010.

Accession Number: 20100729–5145.

Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2055–000.

Applicants: Pacific Gas and Electric Company.

Description: Pacific Gas and Electric Company submits tariff filing per 35.13(a)(2)(iii): Modifications to CAISO Interim Dual Fuel Agreement to be effective 9/27/2010.

Filed Date: 07/29/2010.

Accession Number: 20100729–5147.

Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2056–000.

Applicants: California Independent System Operator Corporation.

Description: California Independent System Operator Corporation submits tariff filing per 35.13(a)(2)(iii): 2010–07–29 CAISO MSG Transition Costs Amendment to be effective 10/1/2010.

Filed Date: 07/29/2010.

Accession Number: 20100729–5152.

Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2056–000.

Applicants: California Independent System Operator Corporation.

Description: California Independent System Operator Corporation submits tariff filing per 35.13(a)(2)(iii): 2010–07–29 CAISO MSG Transition Costs Amendment to be effective 10/1/2010.

Filed Date: 07/29/2010.

Accession Number: 20100729–5153.

Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2057–000.

Applicants: American Electric Power Service Corporation.

Description: AEP Texas North Company submits unexecuted restated and amended transmission interconnection agreements etc.

Filed Date: 07/29/2010.

Accession Number: 20100730–0203.

Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2058–000.

Applicants: Southern Company Services, Inc.

Description: Southern Companies submits network integration transmission service agreement under the Open Access Transmission Tariff etc.

Filed Date: 07/29/2010.

Accession Number: 20100730–0201.

Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Docket Numbers: ER10–2059–000.

Applicants: Carolina Power & Light Company.

Description: Carolina Power & Light Company submits tariff filing per 35.13(a)(2)(iii): Service Agreement No. 321 under Carolina Power and Light OATT to be effective 8/1/2010.

Filed Date: 07/30/2010.

Accession Number: 20100730–5028.

Comment Date: 5 p.m. Eastern Time on Friday, August 20, 2010.

Docket Numbers: ER10–2060–000.

Applicants: Consolidated Edison Company of New York, Inc.

Description: Consolidated Edison Company of New York, Inc. submits tariff filing per 35.12: Baseline Filing of Con Edison OATT2 to be effective 7/30/2010.

Filed Date: 07/30/2010.

Accession Number: 20100730–5053.

Comment Date: 5 p.m. Eastern Time on Friday, August 20, 2010.

Docket Numbers: ER10–2061–000.

Applicants: Tampa Electric Company.

Description: Tampa Electric Company submits tariff filing per 35.13(a)(1): Wholesale Requirements Rate Case to be effective 10/1/2010.

Filed Date: 07/30/2010.

Accession Number: 20100730–5097.

Comment Date: 5 p.m. Eastern Time on Friday, August 20, 2010.

Docket Numbers: ER10–2062–000.

Applicants: New York Independent System Operator, Inc.

Description: New York Independent System Operator submits tariff filing per 35.13(a)(2)(iii): NYISO 205 Filing—RLS Schnell 7/30/10 to be effective 9/30/2010.

Filed Date: 07/30/2010.

Accession Number: 20100730–5105.

Comment Date: 5 p.m. Eastern Time on Friday, August 20, 2010.

Docket Numbers: ER10–2063–000.

Applicants: Otter Tail Power Company.

Description: Otter Tail Power Company submits tariff filing per 35.12: Baseline Electronic Tariff Filing to be effective 7/30/2010.

Filed Date: 07/30/2010.

Accession Number: 20100730–5110.

Comment Date: 5 p.m. Eastern Time on Friday, August 20, 2010.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES10–52–000.

Applicants: Southwestern Electric Power Company.

Description: Application of Southwestern Electric Power Company requesting authorization to issue securities Under Section 204 of the Federal Power Act.

Filed Date: 07/29/2010.

Accession Number: 20100729–5169.

Comment Date: 5 p.m. Eastern Time on Thursday, August 19, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets

other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–19882 Filed 8–11–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL10–80–000]

Ameren Services Company; Notice of Petition for Declaratory Order

August 5, 2010.

Take notice that on August 2, 2010, pursuant to section 207 of the Rules of Practice and Procedure of the Federal Energy Regulation Commission (Commission), 18 CFR 385.207, section 219 of the Federal Power Act, 16 U.S.C. 824s, and Order No. 679, *Promoting Transmission Investment Through Pricing Reform,* Order No. 679, 2006–2007 FERC Stats. & Regs., Regs. Preambles ¶ 31,222, *order on reh'g,* Order No. 679–A, 2006–2007 FERC Stats. & Regs., Regs. Preambles ¶ 31,236 (2006), *order on reh'g,* Order No. 679–B, 119 FERC ¶ 61,062 (2007), Ameren Services Company filed a Petition for Declaratory Order for Incentive Rate Treatments, requesting the Commission to approve certain incentive rate treatments for its affiliates, including Ameren Transmission Company, in connection with the first phase of the multi-year transmission development initiative, which consist of four major new transmission projects, totaling approximately $1.3 billion in cost.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* 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.

This filing is accessible online at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on August 31, 2010.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–19848 Filed 8–11–10; 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 Communications; Public Notice

August 5, 2010.

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.

Exempt:

Docket No.	File date	Presenter or requester
1. P–2106–000	8–3–10	Steve Nevares
2. P–12775–000	8–3–10	Michael Hilton, PhD

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–19850 Filed 8–11–10; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2010–0370; FRL–9188–2]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Air Emission Standards for Tanks, Surface Impoundments and Containers (Renewal), EPA ICR Number 1593.08, OMB Control Number 2060–0318

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before September 13, 2010.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2010–0370 to (1) EPA online using *http://www.regulations.gov* (our preferred method), or by e-mail to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 28221T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Compliance Assessment and Media Programs Division, Office of Compliance, Mail Code 2223A, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (202) 564–4113; fax number: (202) 564–0050; email address: *williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On June 2, 2010 (75 FR 30813), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2010–0370, which is available for public viewing online at *http://www.regulations.gov*, in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center 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 Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov*, to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select "docket search," then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper will be made available for public viewing at *http://www.regulations.gov*, as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov*.

Title: Air Emission Standards for Tanks, Surface Impoundments and Containers (Renewal).

ICR Numbers: EPA ICR Number 1593.08, OMB Control Number 2060–0318.

ICR Status: This ICR is scheduled to expire on October 31, 2010. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. 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. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, and displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This ICR contains recordkeeping and reporting requirements that are mandatory for compliance with 40 CFR part 264, subpart CC, and 40 CFR part 265, subpart CC. The Resource Conservation and Recovery Act (RCRA) subpart CC required control for minimizing release of volatile organic air emissions from tanks, surface impoundments, and containers holding hazardous waste. Records and reports are necessary in order for the EPA to determine that the standards are implemented and maintained, and to protect human health and the environment.

Organic air emissions from hazardous treatment, storage and disposal facilities (TSDFs) can contain toxic chemical compounds. Cancer and other adverse noncancerous human health effects can result from exposure to these emissions. Organic emissions from TSDFs react photochemically with other compounds in the atmosphere to form ground level ozone. Excessive ambient ozone concentrations are a major air quality problem in many cities throughout the United States. Nationwide organic emissions from TSDFs are estimated to be approximately one million megagrams per year. These organic

emissions are estimated to result in 48 excess incidences of cancer per year nationwide and a 3×10^{-2} maximum individual risk (MIR).

Information collected are needed by the EPA to determine: (a) Whether a hazardous waste contains sufficiently low concentrations of volatile organics to allow the waste to be managed in a tank, surface impoundment, or container without the use of emission controls; and (b) for units requiring emission controls, whether the controls are being properly operated and maintained. These notifications, reports, and records are essential in determining compliance with the applicable standards. Semiannual reports of excess emissions are also required.

Any owner or operator subject to the provisions of this part shall maintain a file of these measurements, and retain the records for at least three years following the date of such measurements, maintenance reports, and records. Performance tests reports are required as this is the Agency's record of a source's initial capability to comply with the emission standard, and they serve as a record of the operating conditions under which compliance was achieved.

All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the EPA regional office. This information is being collected to assure compliance with 40 CFR (part 264, subpart CC, and part 265, subpart CC) as authorized in sections 112 and 114(a) of the Clean Air Act. The required information consists of emissions data and other information that have been determined to be private.

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. The OMB Control Number for EPA regulations, listed in 40 CFR part 9 and 48 CFR chapter 15, are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 114 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose, and provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information. All existing ways will have to adjust to comply with any previously applicable instructions and requirements that have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Tanks, surface impoundments and containers.

Estimated Number of Respondents: 6,209.

Frequency of Response: Occasionally, annually, and semiannually.

Estimated Total Annual Hour Burden: 711,400.

Estimated Total Annual Cost: $80,708,869, which includes $68,290,869 in labor costs, no capital/startup costs, and $12,418,000 in operation and maintenance (O&M) costs.

Changes in the Estimates: There is no change in the number of affected facilities or the number of responses as compared to the previous ICR.

There is however, a small decrease in the estimated labor burden hours, as currently identified in the OMB Inventory of Approved Burdens. The decrease is not due to any program changes. The change in the labor burden hours occurred because the previous ICR rounded their calculations and this renewal did not. There is an increase in the cost estimates as compared to the previous ICR. The change in the cost estimates came about by the updated labor rates, which resulted in an increase in the labor costs.

Dated: August 5, 2010.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2010–19805 Filed 8–11–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9188–6]

Proposed Administrative Settlement Agreement Under Section 122(h) of the Comprehensive Environmental Response, Compensation, and Liability Act for the VIP Cleaners Superfund Site, Located in Morristown, Morris County, NJ

AGENCY: Environmental Protection Agency.

ACTION: Notice of Proposed Administrative Settlement and Opportunity for Public Comment.

SUMMARY: The United States Environmental Protection Agency ("EPA") is proposing to enter into an administrative settlement agreement ("Settlement Agreement") with Peter S. Austin, the William E. Austin Trust, and Austin & Austin Company, a partnership ("Respondents") pursuant to Section 122(h) of the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. 9622(h). The Settlement Agreement provides for Respondents' payment of certain past costs incurred at the VIP Cleaners Superfund Site, located in Morristown, Morris County, New Jersey ("Site").

In accordance with Section 122(i) of CERCLA, 42 U.S.C. 9622(i), this notice is being published to inform the public of the proposed Settlement Agreement and of the opportunity to comment. For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the proposed Settlement Agreement. EPA will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations that indicate that the proposed settlement is inappropriate, improper or inadequate. EPA's response to any comments received will be available for public inspection at EPA Region 2, 290 Broadway, 17th floor, New York, New York 10007–1866.

DATES: Comments must be provided by September 13, 2010.

ADDRESSES: Comments should reference the VIP Cleaners Superfund Site, EPA Docket No. CERCLA–02–2010–2025 and should be sent to the U.S. Environmental Protection Agency, Region 2, Office of Regional Counsel, New Jersey Superfund Branch, 290 Broadway—17th Floor, New York, NY 10007.

SUPPLEMENTARY INFORMATION: A copy of the proposed administrative settlement, as well as background information relating to the settlement, may be obtained from William C. Tucker, Assistant Regional Counsel, New Jersey Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, Region 2, 17th Floor, 290 Broadway, New York, New York 10007–1866. Telephone: 212–637–3139.

FOR FURTHER INFORMATION CONTACT: William C. Tucker, Assistant Regional Counsel, New Jersey Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, Region 2, 17th Floor, 290 Broadway, New York, New York 10007–1866. Telephone: 212–637–3139.

Dated: July 20, 2010.

Raymond Basso,

Acting Director, Emergency and Remedial Response Division.

[FR Doc. 2010–19927 Filed 8–11–10; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:45 a.m. on Tuesday, August 10, 2010, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision and resolution activities.

In calling the meeting, the Board determined, on motion of Director Thomas J. Curry (Appointive), seconded by Director John E. Bowman (Acting Director, Office of Thrift Supervision), concurred in by Director John C. Dugan (Comptroller of the Currency), Vice Chairman Martin J. Gruenberg, and Chairman Sheila C. Bair, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550-17th Street, NW., Washington, DC.

Dated: August 10, 2010.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2010–20009 Filed 8–10–10; 4:15 pm]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0313; 30-day notice]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–5806.

Proposed Project: National Blood Collection and Utilization Survey—Reinstatement without Change— OMB No. 0990–0313—The Office of the Advisory Committee on Blood Safety and Availability.

Abstract: The NBCUS is a biennial survey of the blood collection and utilization community to produce reliable and accurate estimates of national and regional collections, utilization and safety of all blood products.

The objective of the NBCUS is to produce reliable and accurate estimates of national and regional collections, utilization, and safety of all blood products—red blood cells, fresh frozen plasma, and platelets, as well as related cellular therapy products. This survey will significantly improve the federal government's capacity to understand the dynamics of blood supply, safety and availability, and to provide a quantitative basis for assessing strategic and regulatory agendas. An important purpose of the 2011 survey is to help the federal government continue to monitor trends in blood availability since a variety of factors have come to play that have reduced the number of people eligible to give blood and, as stated in the evolving National Strategic Plan for Blood, this information is critical to ensure an adequate supply of safe blood in the United States.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Hospitals, blood collection centers, cord blood banks	3,000	1	1	3,000

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

[FR Doc. 2010–19897 Filed 8–11–10; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0008; 30-day notice]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this

collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–5806.

Proposed Project: SF–424C (Budget Information—Construction Programs)—Reinstatement without Change—OMB No. 4040–0008—Grants.gov.

Abstract: The SF–424C (Budget Information—Construction Programs) form is being renewed without any proposed changes. This form could be utilized by up to 26 Federal grant making agencies. The SF–424C is used to provide budget information when applying for construction projects under Federal grants. The Federal awarding agencies use information reported on the form for the evaluation of award and general management of Federal assistance program awards.

ESTIMATED ANNUALIZED BURDEN TABLE

Agency	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
DOD	8	2.5	1.53	31
DOT	134	1	3	402
VA	163	1.24	38/60	128
HHS	540	1.73	2	1868
DOI	2535	1.31	136/60	7550
DOC	225	1	2	450
DHS	2608	1	1.5	3912
Total				14,341

Seleda M. Perryman,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

[FR Doc. 2010–19901 Filed 8–11–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0009; 30-day notice]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–5806.

Proposed Project: SF–424D (Assurances—Construction Programs)—Reinstatement without Change—OMB No. 4040–0009—Grants.gov.

Abstract: The Office of Grants.gov is requesting the approval of the SF–424D form. The form is being renewed with the following minor adjustments: The legal citations have been updated to reflect changes in location within the United States Code. The Trafficking Victims Protection Act of 2000 (Section 106), as amended (22 U.S.C. 7104(g) has been added in Section 19. This form can be utilized by up to 26 Federal grant making agencies. The SF–424D is used to provide information on required assurances when applying for construction projects under Federal grants. The Federal awarding agencies use information reported on the form for the evaluation of award and general management of Federal assistance program awards. The only information collected on the form are the applicant signature, title and date submitted.

ESTIMATED ANNUALIZED BURDEN TABLE

Agency	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
VA	163	1.24	26/60	88
DOT	134	1	49/60	109
DOD	3	1	18/60	1

ESTIMATED ANNUALIZED BURDEN TABLE—Continued

Agency	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
DHS	2,608	1	30/60	1,304
HHS	400	1.8	20/60	240
DOI	2,535	1.31	136/60	7,550
DOC	225	1	15/60	56
Total				9,348

Seleda M. Perryman,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

[FR Doc. 2010–19902 Filed 8–11–10; 8:45 am]

BILLING CODE 4150–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OS–4040–0007; 30-Day Notice]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–5806.

Proposed Project: SF–424B (Assurances—Non-Construction Programs)—Reinstatement without Change—OMB No. 4040–0007—Grants.gov.

Abstract: The Office of Grants.gov is requesting the approval of the SF–424B form. The form is being renewed with the following minor adjustments: The legal citations have been updated to reflect changes in location within the United States Code. The Trafficking Victims Protection Act of 2000 (Section 106), as amended (22 U.S.C. 7104 (g) has been added in Section 18. This form can be utilized by up to 26 Federal grant making agencies. The SF–424B is used to provide information on required assurances when applying for non-construction Federal grants. The Federal awarding agencies use information reported on this form for the evaluation of award and general management of Federal assistance program awards. The only information collected on the form is the applicant signature, title and date submitted.

ESTIMATED ANNUALIZED BURDEN TABLE

Agency	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total Burden hours
CNCS	6450	1	30/60	3225
DOD	107	1	9/60	16
DHS	4308	1	1	4308
DOL	780	1	45/60	585
VA	200	1	15/60	50
DOT	1157	1	49/60	945
SSA	175	1	20/60	58
HHS	8561	1.17	39/60	6511
EPA	3816	1	1	3816
DOC	3000	1	15/60	750
DOI	2535	1.3	136/60	7550
Total				27,814

Seleda M. Perryman

Paperwork Reduction Act Clearance Officer, Office of the Secretary.

[FR Doc. 2010–19900 Filed 8–11–10; 8:45 am]

BILLING CODE 4150–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0002]

30-Day Notice; *Agency Information Collection Request*

AGENCY: Office of the Secretary, HHS.

Agency Information Collection Request. 30-Day Public Comment Request.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–5806.

Proposed Project: SF–424 Mandatory—Reinstatement with Change-OMB No. 4040–0002-Grants.gov

Abstract: The SF–424 mandatory forms are the government-wide forms used for mandatory grant programs. The only proposed revision to the form includes making the fax number in block 17 optional. The revised form will assist agencies in collecting required data elements through the SF–424 applications. This form could be utilized by up to 26 Federal grant making agencies with mandatory grant programs.

ESTIMATED ANNUALIZED BURDEN TABLE

Agency	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
DOT	300	1	1	300
VA	363	1	1	363
Total				663

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

[FR Doc. 2010–19898 Filed 8–11–10; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0006; 30-day notice]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–5806.

Proposed Project: SF–424A (Budget Information—Non-Construction Programs)—Reinstatement with Change—OMB No. 4040–0006—Grants.gov.

Abstract: The Office of Grants.gov is requesting OMB approval for the SF–424A form. The proposed changes were made to the instructions only. In the "General Instructions" section, the following sentence is added as the last sentence: "In ALL cases total funding budgets should be reflected NOT only incremental budget request changes." Also, in the "Section B Budget Categories" section, the last sentence is revised as follows: "For each program, function or activity, fill in the total requirements for funds, Federal funding only, by object class categories." This form could be utilized by up to 26 Federal grant making agencies. The SF–424A is used to provide budget information when applying for non-construction Federal grants. The Federal awarding agencies use information reported on the form for the evaluation of award and general management of Federal assistance program awards.

ESTIMATED ANNUALIZED BURDEN TABLE

Agency	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
CNCS	6,450	1	4	25,800
DOD	108	1.6	50/60	144
DOL	2,130	1	1	2,130
VA	200	1	20/60	67
DOT	1,361	1	1.80	2,450
SSA	175	1.25	14	3,063
HHS	9,751	1.22	1.62	19,232
EPA	3,816	1	3	11,448
DOI	2,535	1.31	2.26	7,550
DOC	3,000	1	1	3,000
DHS	4,538	1	2	9,076
Total	.....	.....	.....	83,959

Seleda M. Perryman,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

[FR Doc. 2010–19899 Filed 8–11–10; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–10–0798]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Health Marketing (OMB No. 0920–0753 exp. 10/31/2010)—Extension—Office of the Associate Director for Communication (OADC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Since it was founded in 1946 to help control malaria, the Centers for Disease Control and Prevention (CDC) has remained at the forefront of public health efforts to prevent and control infectious and chronic diseases, injuries, workplace hazards, disabilities, and environmental health threats. Today, CDC is globally recognized for conducting research and investigations and for its action oriented approach. CDC applies research and findings to improve people's daily lives and responds to health emergencies—something that distinguishes CDC from its peer agencies.

As America has entered a new millennium, new health and safety challenges have emerged: Emerging infectious diseases (SARS, monkeypox, pandemic influenza); Terrorism; Environmental threats (hurricanes, wildfires, toxic chemical spills; Aging population; Lifestyle choices (tobacco use, poor nutrition, lack of physical fitness).

CDC is adapting to meet these new challenges. New strategies, new innovations, and new goals bring new focus to the agency's work, allowing CDC to do even more to protect and improve health. CDC is committed to achieving true improvements in people's health. To do this, the agency is defining specific *health protection goals* to prioritize and focus its work and investments and measure progress.

It is imperative that CDC provide high-quality timely information and programs in the most effective ways to help people, families, and communities protect their health and safety. Through continuous consumer feedback, prevention research, and public health information technology, we identify and evaluate health needs and interests, translate science into actions to meet those needs, and engage the public in the excitement of discovery and the progress being made to improve the health of the Nation. In our outreach to partners, we build relationships that model shared learning, mutual trust, and diversity in points of view and sectors of society.

OADC is requesting a 3-year extension of OMB 0920–0798, Health Marketing, to provide feedback on the development, implementation and satisfaction regarding public health services, products, communication campaigns and information. The information will be collected using standard qualitative and quantitative methods such as interviews, focus groups, and panels, as well as questionnaires administered in person, by telephone, by mail, by email, and online. More specific types of studies may include: User experience and user-testing; concept/product/package development testing; brand positioning/identity research; customer satisfaction surveying; ethnography/observational studies; and mystery shopping. The data will be used to provide input to the development, delivery and communication of public health services and information at CDC and to address emerging programmatic needs.

Every National Center and Office at CDC will have the opportunity to utilize this generic clearance. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
CDC Partners, Public Health Professionals, Health Care Professionals, General Public	25,000	1	27/60	11,250
Total	25,000			11,250

Dated: August 6, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–19911 Filed 8–11–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Information Collection Activities; Submission for OMB Review; Comment Request; National Survey of Older Americans Act Title III Service Recipients

AGENCY: Administration on Aging, HHS.

ACTION: Notice.

SUMMARY: The Administration on Aging (AoA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by September 13, 2010.

ADDRESSES: Submit written comments on the collection of information by fax 202.395.6974 to the OMB Desk Officer for AoA, Office of Information and Regulatory Affairs, OMB.

FOR FURTHER INFORMATION CONTACT: Valerie Cook 202–357–3583.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, AoA has submitted the following proposed collection of information to OMB for review and clearance.

The National Survey of Older Americans Act Title III Service Recipients information collection, which builds on earlier national pilot studies and surveys, as well as performance measurement tools developed by AoA grantees in the Performance Outcomes Measures Project (POMP), will include consumer assessment surveys for the Congregate and Home-delivered meal nutrition programs; Case Management, Homemaker, and Transportation Services; and the National Family Caregiver Support Program. This information will be used by AoA to track performance outcome measures; support budget requests; comply with Government Performance and Results Act (GPRA) reporting requirements; provide national benchmark information for POMP grantees; and inform program development and management initiatives. Descriptions of previous National Surveys of Older Americans Act Participants can be found under the section on Performance Outcomes on AoA's Web site at: *http://www.aoa.gov/AoARoot/Program_Results/OAA_Performance.aspx.* Copies of the survey instruments and data from previous National Surveys of OAA Participants can be found and queried using the AGing Integrated Database (AGID) at *http://www/agidnet.org/.*

AoA estimates the burden of this collection of information as follows: *Respondents:* Individuals; *Number of Respondents:* 6,250; *Number of Responses per Respondent:* one; *Average Burden per Response:* 6,000 at 30 minutes, 250 at 4 hours: Total Burden: 6,250 hours.

Dated: August 9, 2010.

Kathy Greenlee,

Assistant Secretary for Aging.

[FR Doc. 2010–19957 Filed 8–11–10; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Coordinating Center for Infectious Diseases: Notice of Charter Amendment

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Board of Scientific Counselors, Coordinating Center for Infectious Diseases, Department of Health and Human Services, has amended their charter to reflect the change in the name of the board to the Board of Scientific Counselors, Office of Infectious Diseases.

For information, contact Robin Mosely, M.A., Designated Federal Officer, Board of Scientific Counselors, Office of Infectious Diseases, CDC, 1600 Clifton Road, NE., Mailstop D10, Atlanta, Georgia 30333, telephone 404/639–4461 or fax 404/639–1255.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 4, 2010

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–19908 Filed 8–11–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0313]

Draft Guidance for Industry: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation" (the draft guidance). The draft guidance, when finalized, will provide guidance to egg producers on how to comply with certain provisions contained in FDA's final rule "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation" (the final rule), including how to implement *Salmonella*

Enteritidis (SE) prevention measures, how to sample for SE, and how to maintain records documenting compliance with the final rule.

DATES: Although you can comment on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))), to ensure that the agency considers your comments on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 12, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Plant and Dairy Food Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301–436–1070. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nancy Bufano, Center for Food Safety and Applied Nutrition (HFS–316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1493.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 9, 2009 (74 FR 33030), FDA issued the final rule requiring shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and requiring these producers to maintain records concerning their compliance with the final rule and to register with FDA. The final rule became effective September 8, 2009.

FDA is issuing the draft guidance as a level 1 draft guidance consistent with FDA's good guidance practices regulation (§ 10.115). The draft guidance, when finalized, will represent the agency's current thinking on how to comply with certain measures designed to prevent SE from contaminating eggs on the farm, as well as how to sample for SE and maintain records documenting compliance with the final rule. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 118.5, 118.6, 118.10, and 118.11 have been approved under OMB control number 0910–0660.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov*.

Dated: August 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19905 Filed 8–11–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Intent To Award Patient Protection and Affordable Care Act Funding to Approved But Unfunded Applications (ABU) Formerly Received in Response to the American Recovery and Reinvestment Act of 2009 (ARRA) Centers for Disease Control and Prevention Funding Opportunity DP09–912ARRA09, "Communities Putting Prevention to Work (CPPW)"

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice provides notice of CDC's intent to fund additional Approved but Unfunded (ABU) cooperative agreement applications previously received and competed in response to CDC Funding Opportunity, CDC–RFA–DP09–912ARRA09, "Communities Putting Prevention to Work" (CPPW). It is the intent of CDC to fund additional previously received applications with Patient Protection Affordable Care Act (PPACA), Section 4002, appropriations. To this end, CDC will remove the following ARRA–Specific Requirements published in the aforementioned funding opportunity announcement:

—Catalogue of Domestic Assistance Number 93.724

—*Recovery Act-Specific Reporting Requirements*

Recipients of Federal awards from funds authorized under Division A of the Recovery Act must comply with all requirements specified in Division A of the Recovery Act (Pub. L. 111–5), including reporting requirements outlined in Section 1512 of the Act and designated Recovery Act outcome and output measures as detailed at the end of this section. For purposes of reporting, Recovery Act recipients must report on Recovery Act sub-recipient (sub-grantee and sub-contractor) activities as specified below.

Not later than 10 days after the end of each calendar quarter, starting with the quarter ending _____; and reporting by _____, the recipient must submit quarterly reports to HHS that will posted to Recovery.gov, containing the following information:

a. The total amount of Recovery Act funds under this award;

b. The amount of Recovery Act funds received under this award that were obligated and expended to projects or activities;

c. The amount of unobligated award balances;

d. A detailed list of all projects or activities for which Recovery Act funds under this award were obligated and expended, including

- The name of the project or activity;
- A description of the project or activity;
- An evaluation of the completion status of the project or activity;
- An estimate of the number of jobs created and the number of jobs retained by the project or activity (see OMB Guidance M–09–21, June 22, 2009) and;
- For infrastructure investments made by State and local governments, the purpose, total cost, and rationale of the agency for funding the infrastructure investment with funds made available under this Act, and the name of the person to contact at the agency if there

are concerns with the infrastructure investment.

e. Detailed information on any sub-awards (sub-contracts or sub-grants) made by the grant recipient to include the data elements required to comply with the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282).

For any sub-award equal to or larger than $25,000, the following information:

- The name of the entity receiving the sub-award;
- The amount of the sub-award;
- The transaction type;
- The North American Industry Classification System code or Catalog of Federal Domestic Assistance (CFDA) number;
- Program source;
- An award title descriptive of the purpose of each funding action;
- The location of the entity receiving the award;
- The primary location of performance under the award, including the city, State, congressional district, and county.
- A unique identifier of the entity receiving the award and of the parent entity of the recipient, should the entity be owned by another entity;
- The date the sub-award was issued;
- The term of the sub-award (start/end dates);
- The scope/activities of the sub-award;
- The amount of the total sub-award that has been obligated or disbursed by the sub-recipient; and
- The amount of the total sub-award that remains unobligated by the sub-recipient.

f. All sub-awards less than $25,000 or to individuals may be reported in the aggregate, as prescribed by HHS.

g. Recipients must account for each Recovery Act award and sub-award (sub-grant and sub-contract) separately. Recipients will draw down Recovery Act funds on an award-specific basis. Pooling of Recovery Act award funds with other funds for drawdown or other purposes is not permitted.

h. Recipients must account for each Recovery Act award separately by referencing the assigned CFDA number for each award.

The definition of terms and data elements, as well as any specific instructions for reporting, including required formats, will be provided in subsequent guidance issued by HHS.

Buy American—Use of American Iron, Steel, and Manufactured Goods

Recipients may not use any funds obligated under this award for the construction, alteration, maintenance, or repair of a public building or public work unless all of the iron, steel, and manufactured goods used in the project are produced in the United States unless HHS waives the application of this provision. (Recovery Act Sec. 1605)

Wage Rate Requirements

[This term and condition shall not apply to tribal contracts funded with this appropriation. (Recovery Act Title VII—Interior, Environment, and Related Agencies, Department of Health and Human Services, Indian Health Facilities)] Subject to further clarification issued by the Office of Management and Budget, and notwithstanding any other provision of law and in a manner consistent with other provisions of Recovery Act, all laborers and mechanics employed by contractors and subcontractors on projects funded directly by or assisted in whole or in part by and through the Federal Government pursuant to this award shall be paid wages at rates not less than those prevailing on projects of a character similar in the locality as determined by the Secretary of Labor in accordance with subchapter IV of chapter 31 of title 40, United States Code. With respect to the labor standards specified in this section, the Secretary of Labor shall have the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (64 Stat. 1267; 5 U.S.C. App.) and section 3145 of title 40, United States Code. (Recovery Act Sec. 1606)

Preference for Quick Start Activities (Recovery Act)

In using funds for this award for infrastructure investment, recipients shall give preference to activities that can be started and completed expeditiously, including a goal of using at least 50 percent of the funds for activities that can be initiated not later than 120 days after the date of the enactment of Recovery Act. Recipients shall also use grant funds in a manner that maximizes job creation and economic benefit. (Recovery Act Sec. 1602)

Limit on Funds (Recovery Act)

None of the funds appropriated or otherwise made available in Recovery Act may be used by any State or local government, or any private entity, for any casino or other gambling establishment, aquarium, zoo, golf course, or swimming pool. (Recovery Act Sec. 1604)

Disclosure of Fraud or Misconduct

Each recipient or sub-recipient awarded funds made available under the Recovery Act shall promptly refer to the HHS Office of Inspector General any credible evidence that a principal, employee, agent, contractor, sub-recipient, subcontractor, or other person has submitted a false claim under the False Claims Act or has committed a criminal or civil violation of laws pertaining to fraud, conflict of interest, bribery, gratuity, or similar misconduct involving those funds. The HHS Office of Inspector General can be reached at *http://www.oig.hhs.gov/fraud/hotline/*

Recovery Act: One-Time Funding

Unless otherwise specified, Recovery Act funding to existent or new awardees should be considered one-time funding.

Schedule of Expenditures of Federal Awards

Recipients agree to separately identify the expenditures for each grant award funded under Recovery Act on the Schedule of Expenditures of Federal Awards (SEFA) and the Data Collection Form (SF–SAC) required by Office of Management and Budget Circular A–133, "Audits of States, Local Governments, and Non-Profit Organizations." This identification on the SEFA and SF–SAC shall include the Federal award number, the Catalog of Federal Domestic Assistance (CFDA) number, and amount such that separate accountability and disclosure is provided for Recovery Act funds by Federal award number consistent with the recipient reports required by Recovery Act Section 1512(c). (2 CFR 215.26, 45 CFR 74.26, and 45 CFR 92.26)

Responsibilities for Informing Sub-Recipients

Recipients agree to separately identify to each sub-recipient, and document at the time of sub-award and at the time of disbursement of funds, the Federal award number, any special CFDA number assigned for Recovery Act purposes, and amount of Recovery Act funds. (2 CFR 215.26, 45 CFR 74.26, and 45 CFR 92.26)

Reporting Jobs Creation

HHS' recipients of Recovery Act funding who are subject to Section 1512 reporting should report job-created data as prescribed in Section 5 of the Office of Management and Budget (OMB) guidance M–09–21. HHS will not accept statistical sampling methods to estimate the number of jobs created and retained. All recipients must report a direct and comprehensive count of jobs, as specified by OMB guidance M–09–21. See Section 5.3 of the OMB guidance for more information on calculating jobs,

including job estimation examples. For the full OMB guidance, please visit: *http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m09–21.pdf*.

Conclusion of Recovery Act-Specific Reporting Requirements

Recipient Reporting Requirements under PPACA

The removal of ARRA Section 1512 Reporting Requirements does not absolve the applicant from reporting project status as well as the other terms and conditions set forth in the above-referenced CPPW FOA and the Notice of Cooperative Agreement Award. Recipients funded with PPACA appropriations will be required to report project status on a semi-annual basis. Specific reporting requirements will be detailed in the Terms and Conditions of the Notice of Cooperative Agreement Award.

CFDA Number 93.520 is the PPACA-specific CFDA number for this initiative. It will replace CFDA Number 93.724 published in the above-referenced CPPW Funding Opportunity Announcement (FOA).

Award Information:

Approximate Current Fiscal Year Funding: $34,000,000.

Approximate Number of Awards: 11.

Approximate Average Award: $3,000,000.

Fiscal Year Funds: Patient Protection and Affordable Health Care Act of 2010.

Anticipated Award Date: 30 Sep 2010.

Budget Period: 24 months.

Project Period: 24 months.

Application Selection Process: CDC will apply the same selection methodology published in the CPPW FOA, CDC–RFA–DP09–912ARRA09.

Applications will be funded in order by score and rank determined by the previously held review panel.

In addition, as was referenced in the CPPW FOA, funding decisions may be made to ensure:

- Representation of tobacco and obesity/physical activity/nutrition across communities, including a varied type of interventions and evidence-based strategies.
- Geographic distribution of The Communities Putting Prevention to Work Initiative nationwide.
- Inclusion of communities of varying sizes, including rural, suburban, and urban communities.
- Inclusion of populations disproportionately affected by chronic disease and associated risk factors.

CDC will provide justification for any decision to fund out of rank order.

CDC will add the following Authority to that which is reflected in the published Funding Opportunity:

—Section 4002 of the Patient Protection and Affordability Care Act (Public Law 111–148.)

DATES: The effective date for this action is August 12, 2010 and remains in effect until the expiration of the project period of the PPACA funded applications.

FOR FURTHER INFORMATION CONTACT: Elmira Benson, Deputy Director, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341, telephone: (770) 488–2802, e-mail: *EBenson@cdc.gov*

SUPPLEMENTARY INFORMATION: On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (PPACA). PPACA is designed to improve and expand the scope of health care coverage for Americans. Cost savings through disease prevention is an important element of this legislation and PPACA has established a Prevention and Public Health Fund (PPHF) for this purpose. Specifically, the legislation states in Section 4002 that the PPHF is to "provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs". PPACA and the Prevention and Public Health Fund make improving public health a priority with investments to improve public health.

The PPHF states that the Secretary shall transfer amounts in the Fund to accounts within the Department of Health and Human Services to increase funding, over the fiscal year 2008 level, for programs authorized by the Public Health Services Act, for prevention, wellness and public health activities including prevention research and health screenings, such as the Community Transformation Grant Program, the Education and Outreach Campaign for Preventative Benefits, and Immunization Programs.

Both ARRA and PPACA legislation affords an important opportunity to advance public health across the lifespan and to reduce health disparities by supporting an intensive community approach to chronic disease prevention and control. Therefore, awarding cooperative agreements with PPACA funds under PPHF to ABUs to carry out CPPW objectives is consistent with the purpose of PPHF, as stated above, to provide for the expanded and sustained national investment in prevention and public health programs. Further, the Secretary allocated funds to CDC, pursuant to the PPHF, for the types of activities that the CPPW initiative is designed to carry out.

Therefore, the CPPW program activities CDC proposes to fund with PPACA appropriations are authorized by the amendment to the Public Health Services Act which authorized the Prevention and Wellness Program as embodied in CDC RFA DP09–912ARRA09.

Dated: August 5, 2010.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2010–19907 Filed 8–11–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, Epi R01s, Data Analysis R21s, and K99 Applications.

Date: August 23, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 1 Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: SAMUEL RAWLINGS, PhD, Chief, Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301–451–2020, *rawlings@nei.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Eye Institute Special Emphasis Panel, Clinical Trials.

Date: August 24–25, 2010.

Time: 8 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NEI Division of Extramural Research, 5635 Fishers Lane, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Daniel R. Kenshalo, PhD, Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301–451–2020, *kenshalod@nei.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: August 6, 2010.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19940 Filed 8–11–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee.

Date: September 7–8, 2010.

Time: September 7, 2010, 7 p.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Time: September 8, 2010, 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Camilla E. Day, PhD, Scientific Review Officer, CIDR, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4075, Bethesda, MD 20892, 301–402–8837, *camilla.day@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: August 5, 2010.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19939 Filed 8–11–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Liver Diseases.

Date: August 24, 2010.

Time: 2:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Najma Begum, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, MSC 7818, Bethesda, MD 20892. 301–435–1243. *begumn@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Program Project: Integrative Neuroscience.

Date: September 21–22, 2010.

Time: 7 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)

Contact Person: Brian Hoshaw, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC 7844, Bethesda, MD 20892. 301–435–1033. *hoshawb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Shared Instrumentation Grant Applications.

Date: September 22–23, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)

Contact Person: Patricia Greenwel, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892. 301–435–1169. *greenwep@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 5, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19938 Filed 8–11–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the AIDS Research Advisory Committee, NIAID.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: AIDS Research Advisory Committee, NIAID.

Date: September 20, 2010.

Time: 12:45 p.m. to 6 p.m.

Agenda: Reports from the Division Director and other staff.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Salon D, Bethesda, MD 20852.

Contact Person: Rona L. Siskind, Executive Secretary, AIDS Research Advisory Committee, Division of AIDS, NIAID/NIH, 6700B Rockledge Drive, Room 4139, Bethesda, MD 20892–7601, 301–435–3732.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: *August 6, 2010.*

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19937 Filed 8–11–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Advisory Allergy and Infectious Diseases Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Allergy and Infectious Diseases Council.

Date: September 20, 2010.

Open: 10:30 a.m. to 11:40 a.m.

Agenda: Report from the institute Director.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Salon D, Bethesda, MD 20852.

Closed: 11:40 a.m. to 12:40 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Salon D, Bethesda, MD 20852.

Contact Person: Marvin R. Kalt, PhD, Director, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7610, Bethesda, MD 20892–7610, 301–496–7291, *kaltmr@niaid.nih.gov*.

Name of Committee: National Advisory Allergy and Infectious Diseases Council, Acquired Immunodeficiency Syndrome Subcommittee.

Date: September 20, 2010.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Salon A, Bethesda, MD 20852.

Open: 12:45 p.m. to adjournment.

Agenda: Program advisory discussions and reports from division staff.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Salon D, Bethesda, MD 20852.

Contact Person: Marvin R. Kalt, PhD, Director, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7610, Bethesda, MD 20892–7610, 301–496–7291, *kaltmr@niaid.nih.gov*.

Name of Committee: National Advisory Allergy and Infectious Diseases Council, Allergy, Immunology and Transplantation Subcommittee.

Date: September 20, 2010.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Salon B, Bethesda, MD 20852.

Open: 1 p.m. to adjournment.

Agenda: Reports from the Division Director and other staff.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Salon B, Bethesda, MD 20852.

Contact Person: Marvin R. Kalt, PhD, Director, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7610, Bethesda, MD 20892–7610, 301–496–7291, *kaltmr@niaid.nih.gov*.

Name of Committee: National Advisory Allergy and Infectious Diseases Council, Microbiology and Infectious Diseases Subcommittee.

Date: September 20, 2010.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Salon C, Bethesda, MD 20852.

Open: 1 p.m. to adjournment.

Agenda: Reports from the Division Director and other staff.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Salon C, Bethesda, MD 20852.

Contact Person: Marvin R. Kalt, PhD, Director, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7610, Bethesda, MD 20892–7610, 301–496–7291, *kaltmr@niaid.nih.gov*.

Information is also available on the Institute's/Center's home page: *http://www.niaid.nih.gov/facts/facts.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 6, 2010.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19936 Filed 8–11–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; T-Cell Immunology.

Date: September 16, 2010.

Time: 12:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Wendy F. Davidson, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIH/NIAID/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–402–8399, *davidsonw@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: *August 6, 2010.*

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19935 Filed 8–11–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Date: September 28, 2010.

Open: 8:30 a.m. to 12 p.m.

Agenda: To discuss administrative details relating to the Council's business and special reports.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Closed: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Contact Person: Laura K. Moen, PhD, Director, Division of Extramural Research Activities, NIAMS/NIH, 6701 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301)–451–6515, *moenl@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: August 6, 2010.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19934 Filed 8–11–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Ischemia Trials.

Date: August 27, 2010.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Youngsuk Oh, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892–7924, 301–435–0277, *yoh@mail.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Conference Grants (R13's).

Date: August 31, 2010.

Time: 11 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert T. Su, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892–7924, 301–435–0297, *sur@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: *August 6, 2010.*

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19933 Filed 8–11–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Systems Technology on Agricultural Risk Assessment.

Date: August 16, 2010.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709, (Telephone Conference Call).

Contact Person: Leroy Worth, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, (919) 541–0670, *worth@niehs.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower

Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: August 6, 2010.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19932 Filed 8–11–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 75 FR 36104–36105 dated June 24, 2010).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice updates functional statement for the Maternal and Child Health Bureau (RM) by adding functions for programs authorized under the Affordable Care Act, and renames the Office of Data and Program Development (RM7) to the Office of Epidemiology, Policy and Evaluation (RM7).

Chapter RM—Maternal and Child Health Bureau

Section RM–10, Organization

Delete in its entirety and replace with the following:

The Office of the Associate Administrator (RM) is headed by the Associate Administrator, Maternal and Child Health Bureau (MCHB), who reports directly to the Administrator, Health Resources and Services Administration. MCHB includes the following components:

(1) Office of the Associate Administrator (RM);
(2) Office of Operation and Management (RM1);
(3) Division of Services for Children with Special Health Needs (RM2);
(4) Division of Child, Adolescent and Family Health (RM3);
(5) Division of Research, Training and Education (RM4);
(6) Division of Healthy Start and Perinatal Services (RM5);
(7) Division of State and Community Health (RM6); and
(8) Office of Epidemiology, Policy and Evaluation (RM7).

Section RM–20, Functions

(1) Delete the functional statement for the Maternal and Child Health Bureau (RM) and replace in its entirety; and (2) rename the Office of Data and Program Development (RM7) to the Office of Epidemiology, Policy and Evaluation (RM7).

Office of the Associate Administrator (RM)

Provides national leadership and policy direction for Maternal and Child Health Bureau (MCHB) programs. These programs are designed to improve the health of women of childbearing age, infants, children, adolescents and their families, children with special health needs, and persons with hemophilia. Specifically, MCHB: (1) Coordinates the planning, development, implementation, and evaluation of the programs and activities of the Bureau; (2) facilitates effective, collaborative relationships with other health and related programs; (3) establishes a program mission, goals, objectives, and policy with broad Administration guidelines; (4) serves as the focal point for managing the Bureau-wide strategic planning operation as it relates to long and short range programmatic goals and objectives for the Bureau; (5) arranges and provides technical assistance to assure that the grantees meet program expectations; (6) serves as principal contact point to HRSA, the Department, Office of Management and Budget (OMB), and the White House on matters concerning the health status of America's mothers and children; and (7) provides information and reports on the Bureau's programs to public, health, education and related professional associations, the Congress, other Federal agencies, OMB, and the White House.

Office of Operations and Management (RM1)

The Office of Operations and Management (OOM) plans, directs, coordinates, and evaluates Bureau-wide administrative and management activities; coordinates and monitors program and administrative policy implementation, and maintains close liaison with officials of HRSA and the Office of the Secretary on matters relating to these activities. Specifically, OOM: (1) Serves as the Associate Administrator's and Bureau's principal source for management and administrative advice and assistance; (2) provides or serves as liaison for program support services; (3) provides leadership on intergovernmental activities of the Bureau which requires administrative direction or intergovernmental activities of the Bureau, requiring central direction of cross-cutting administrative issues affecting program activities; (4) participates in the development of strategic plans, regulatory activities, policy papers, and legislative proposals relating to MCH programs; (5) plans, coordinates and facilitates the Bureau's Agency agreement activities; (6) coordinates human resource activities for the Bureau; (7) provides guidance to the Bureau on financial management activities; (8) determines State allocations of MCH Block Grant funds based on formula and current census data; (9) provides organization and management analysis, develops policies and procedures for internal operation, and interprets and implements the Administration's management policies, procedures and systems; (10) coordinates the Bureau's program and administrative delegations of authority activities; (11) provides staff services in operation planning and program analysis; (12) is responsible for paperwork management functions, including the development and maintenance of Bureau manual issuances; (13) provides direction regarding new developments in office management activities; and (14) coordinates Bureau funds and resources for grants, contracts and cooperative agreements.

Division of Services for Children With Special Health Needs (RM2)

The Division of Services for Children with Special Health Needs (DSCSHN) provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on the promotion of health and prevention of disease among children with special health care needs (CSHCN) and their families, with special emphasis on the development and implementation of family-centered, comprehensive, care-coordinated, community-based and culturally competent systems of care for such populations. Specifically, DSCSHN carries out the following activities: (1) Administers a program that supports the development of systems of care and services for CSHCN and their families; (2) develops policies and guidelines and promulgates standards for professional services and effective organization and administration of health programs for CSHCN and their families; (3) accounts for the administration of funds and other resources for grants, contracts and programmatic consultation and

assistance; (4) coordinates with other MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (5) provides consultation and technical assistance to State programs for CSHCN and to local communities, consistent with a Bureau-wide technical assistance consultation plan and in concert with other agencies and organizations; (6) provides liaison with public, private, professional and voluntary organizations on programs designed to improve services for CSHCN and their families; (7) develops and implements a national program for those at risk or living with genetic diseases, including a national program for persons with hemophilia, implementing a system of demonstration projects related to early identification, referral, treatment, education, and counseling information; (8) coordinates within this Agency and with other Federal programs (particularly Title XIX of the Social Security Act, Supplemental Security Income, Individuals with Disabilities Education Act, and others) to extend and improve comprehensive, coordinated services and promote integrated State-based systems of care for CSHCN, including those with genetic disorders, and their families; (9) promotes the dissemination of information on preventive health services and advances in the care and treatment of CSHCN, including those with genetic disorders, and their families; (10) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to health services for CSHCN, including those with genetic disorders, and their families; (11) provides a focus for international health activities of the Bureau for services for CSHCN and their families; (12) participates in the development of interagency agreements concerning Federal assignees to State MCHB programs; (13) carries out a national program on traumatic brain injury, and (14) administers funds and other resources for grants, contracts, and cooperative agreements.

Division of Child, Adolescent, and Family Health (RM3)

The Division of Child, Adolescent, and Family Health provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on the promotion of health and prevention of disease and injury among children, adolescents, young adults and their families with special emphasis on the development and implementation of family-centered, comprehensive, coordinated, community-based and culturally competent systems of care for such populations. Specifically, the Division: (1) Administers a program which supports the development of systems of care and services for children, adolescents, young adults and their families; (2) develops policies and guidelines and promulgates standards for professional services and effective organization and administration of health programs for children, adolescents, young adults and their families; (3) accounts for the administration of funds and other resources for grants, contracts, and programmatic consultation and assistance; (4) coordinates with MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (5) serves as the focal point within the Bureau in implementing programmatic statutory requirements for State programs for children, adolescents, young adults and their families; (6) provides consultation and technical assistance to State programs for children, adolescents, young adults and their families and to local communities, consistent with a Bureau-wide technical assistance consultation plan, working with other agencies and organizations; (7) provides liaison with public, private, professional and voluntary organizations on programs designed to improve services for children, adolescents, young adults and their families; (8) carries out a national program supporting Child Death Review systems; (9) carries out a national program on school health activities; (10) carries out a national program designed to improve the provision of emergency medical services for children; (11) carries out a national program designed to improve the provision of oral health services for children; (12) carries out a national program on injury prevention for children and adolescents; (13) coordinates within this Agency and with other Federal programs (particularly Title XIX of the Social Security Act) to extend and improve comprehensive, coordinated services and promote integrated State-based systems of care for children, adolescents, young adults and their families; (14) disseminates information on preventive health services and advances in the care and treatment of children, adolescents, young adults and their families; (15) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to health services for children, adolescents, young adults and their families; (16) provides a focus for international health activities for the Bureau for services for children, adolescents, and their families; (17) carries out, in collaboration with the Administration for Children and Families, a national program of maternal, infant and early childhood home visiting; and (18) administers funds and other resources for grants, contracts, and cooperative agreements.

Division of Research, Training and Education (RM4)

The Division of Research, Training and Education provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs related to research, professional and public education activities, and training, focusing on the promotion of health and prevention of disease among women of reproductive age, infants, children, adolescents and their families, with special emphasis on the development and implementation of family-centered, comprehensive, care-coordinated, community-based and culturally competent systems of care for such population. Specifically, the Division carries out the following activities: (1) Administers a program which supports the development of systems of care and services for children and their families; (2) develops policies and guidelines and promulgates standards through research, professional and public education and training activities for the Bureau; (3) accounts for the administration of funds and other resources for grants, contracts and programmatic consultation and assistance; (4) coordinates with other MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (5) provides liaison with public, private, professional and voluntary organizations on programs and activities; (6) disseminates information on research, professional and public education and training activities to States and localities; (7) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions; (8) provides a focus for international health activities of the Bureau relating to research, professional and public education and training activities for the Bureau; and (9) administers funds and other resources for grants, contracts, and cooperative agreements.

Division of Healthy Start and Perinatal Services (RM5)

The Division of Healthy Start and Perinatal Services provides national leadership in planning, directing,

coordinating, monitoring, and evaluating national programs focusing on maternal, infant, family, and women's health to improve and strengthen the awareness of, access, delivery, quality, coordination and evidence-based for services for targeted populations, especially for the vulnerable and those at high-risk for poor health and health outcomes. The Division strives to eliminate health disparities and provide high quality continuous health care, including health promotion and disease prevention, throughout the lifespan of women and their families from infancy to preconception, prenatal, postpartum, and inter-conception through support of local, State, and national innovative, evidenced-based projects of health promotion and risk reduction. Specifically, the Division is responsible for the following activities: (1) Administers local, State, and national programs on perinatal and women's health with an emphasis on infant mortality reduction and eliminating disparities in perinatal infant, maternal and women's health outcomes; (2) provides policy direction; technical assistance; national resource development and dissemination; professional consultation and development to address national trends in maternal, infant, family, and women's health status and gaps in the evidence-based of the healthcare services for these populations as well as Division programs; (3) accounts for the administration of funds and other resources for grants, contracts and programmatic consultation and assistance; (4) coordinates with Bureau, Agency, departmental, and Intra-Departmental initiatives in promoting Division programs' objectives and the mission of the Bureau; (5) serves as the focal point within the Agency and frequently the Department on programmatic infant, maternal, and women's health initiatives (6) coordinates the Advisory Committee on Infant Mortality, (7) provides liaison with public, private, professional and non-governmental organizations for Division programs; (8) disseminates information on Division programs to the local, State, national and international audiences; (9) participates in the development of strategic plans, health services research and evaluation, regulatory activities, policy papers, legislative proposals, and fiscal strategic planning, administration, and analysis relating to Division programs; (10) provides a focus for international health activities of the Bureau for Division programs in perinatal, infant, maternal and women's health; (11) provides leadership, technical assistance and professional consultation to Central and Regional Office staff of the Bureau, Agency, Department, other Federal agencies, students and allied groups to improve services; and (12) administers funds and other resources for grants, contracts, and cooperative agreements.

Division of State and Community Health (RM6)

In collaboration with MCHB Divisions and Offices, the Division of State and Community Health (DSCH) serves as the organizational focus for the administration of responsibilities related to the Maternal and Child Health (MCH) Block Grant to States Program. Specifically, DSCH: (1) Works in partnership with States, primarily through the Title V Block Grant, communities, and grantees to assure continued improvement in the health, safety and well-being of the MCH population; (2) provides national leadership, direction, coordination, and administrative oversight related to the development and management of the State MCH Block Grant applications and the annual reports; (3) based on independent and high quality evaluations and reviews, which includes the tracking of State progress in meeting performance objectives, develops, plans, manages, and monitors a Bureau-wide program of technical assistance and consultation in collaboration with other Bureau Divisions and related health programs; (4) develops and manages an online information system to facilitate in the collection, analysis and dissemination of national and State performance, program and financial State Title V information and data to various constituencies including the public, States, and Congress about the Block Grant to States Program; (5) coordinates within this Agency and with other Federal programs (particularly Title XIX of the Social Security Act) to extend and improve comprehensive, coordinated services in the Block Grant to States Program; (6) develops, plans, manages, and monitors the State Systems Development Initiative (SSDI) grant to the States' program; (7) develops, plans, manages and monitors contracts, grants, and cooperative agreements, including the Partnership for State Title V MCH Leadership Community, Partnership for Urban MCH Leadership Community and State Public Health Coordinating Center for Autism Cooperative Agreements; (8) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals and budget submissions relating to health services for women of childbearing age, infants, children, adolescents, children with special health care needs and their families; and (9) develops guidance and reporting forms for the State Title V MCH Block Grant Applications/Annual Reports and Five-Year Needs Assessments and other discretionary grants and cooperative agreements.

Office of Epidemiology, Policy and Evaluation (RM7)

The Office of Epidemiology, Policy and Evaluation provides leadership in the following two areas: (1) Identifies and analyzes data needs and utilizes and implements a data strategy and program focusing on the promotion of health and prevention of disease among women of reproductive age, infants, children, adolescents and their families with special emphasis on the development and implementation of family centered, comprehensive, coordinated care, community-based and culturally competent systems of care for such populations; (2) serves as the Bureau focal point for the management of the planning, evaluation, legislation, and legislative implementation activities, including the development, coordination, and dissemination of program objectives, policy positions, reports and strategic plans. Specifically, the Office carries out the following data functions: (1) Develops, coordinates, and maintains a data and information system designed to improve implementation of Title V and other Bureau programs; (2) develops, coordinates, and implements systematic technical assistance and consultation on data and information systems and evaluation approaches to State and local agencies and organizations or groups concerned with infants, children, adolescents, and CSHCN; (3) through grants and contracts, provides support for a broad range of data collection, analyses and projects designed to improve the health status of infants, children, adolescents, and CSHCN; (4) coordinates and provides professional consultation and technical assistance to State and local agencies and organizations; (5) develops, coordinates and disseminates data; (6) plans, implements and monitors a system of placement of Federal employees assigned to State health agencies; (7) coordinates and monitors the placement of Centers for Disease Control and Prevention sponsored epidemiologists in State agencies; and (8) provides for data program coordination at all levels of Bureau program operations through analyses of program data, trends and other issues concerning scientific and policy matters, the provision of health

services and data and information related to the promotion of health and prevention of disease among infants, children, adolescents, and CSHCN.

In addition, the Office carries out the following program development functions:

(1) Advises and assists the Associate Administrator for Maternal and Child Health and other Bureau staff in the development, coordination and management of strategic planning and policy documents, responses to departmental and HRSA initiatives, and information papers to support Bureau and Administration goals; (2) interprets evaluation requirements and develops, coordinates, and manages the preparation of the annual evaluation plans and activities, and conducts or contracts for specific evaluation projects related to the performance of MCHB programs; (3) develops, coordinates, and manages Bureau activities related to the development, clearance, and dissemination of **Federal Register** notices, guidelines, final grant reports, and periodic and annual reports to other Federal and non-Federal agencies; (4) participates in the development of budget submissions including the Government Performance Review Act annual performance plan and the Office of Management and Budget Program Assessment Review Tool; (5) coordinates activities closely and continuously with the Office of Planning, Analysis and Evaluation and the MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (6) provides liaison with public, private, professional, and voluntary organizations on programs related to MCHB planning and legislative issues; and (7) participates in international health activities of the Bureau.

Section RM–30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is upon date of signature.

Dated: August 5, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–19863 Filed 8–11–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2010–0062]

The Critical Infrastructure Partnership Advisory Council (CIPAC)

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Quarterly CIPAC membership update.

SUMMARY: The Department of Homeland Security (DHS) announced the establishment of the Critical Infrastructure Partnership Advisory Council (CIPAC) by notice published in the **Federal Register** (71 FR 14930–14933) dated March 24, 2006. That notice identified the purpose of CIPAC as well as its membership. This notice provides (i) the quarterly CIPAC membership update, (ii) instructions on how the public can obtain the CIPAC membership roster and other information on the Council, and (iii) information on recently completed CIPAC meetings.

FOR FURTHER INFORMATION CONTACT: Nancy J. Wong, Director, Partnership Programs and Information Sharing Office, Partnership and Outreach Division, Office of Infrastructure Protection, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane, SW., Mail Stop 0607, Arlington, VA 20598–0607, by telephone (703) 235–3999 or via e-mail at *CIPAC@dhs.gov.*

Responsible DHS Official: Nancy J. Wong, Director, Partnership Programs and Information Sharing Office, Partnership and Outreach Division, Office of Infrastructure Protection, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane, SW., Mail Stop 0607, Arlington, VA 20598–0607 by telephone (703) 235–3999 or via e-mail at *CIPAC@dhs.gov.*

SUPPLEMENTARY INFORMATION: *Purpose and Activity:* CIPAC facilitates interaction between government officials and representatives of the community of owners and/or operators for each of the critical infrastructure or key resources (CIKR) sectors defined by Homeland Security Presidential Directive 7 (HSPD–7) and identified in the National Infrastructure Protection Plan (NIPP). The scope of activities covered by CIPAC includes planning; coordinating among government and CIKR owner/operator security partners; implementing security program initiatives; conducting operational activities related to critical infrastructure protection security measures, incident response, recovery, infrastructure resilience, reconstituting CIKR assets and systems for both man-made as well as naturally occurring events; and sharing threat, vulnerability, risk mitigation, and infrastructure continuity information.

Organizational Structure: CIPAC members are organized into 18 CIKR sectors. Within all of the sectors containing CIKR owners/operators, there generally exists a Sector Coordinating Council (SCC) that includes CIKR owners and/or operators or their representative trade associations. Each of the sectors also has a Government Coordinating Council (GCC) whose membership includes a lead Federal agency that is defined as the Sector Specific Agency (SSA), and all relevant Federal, State, local, Tribal, and/or territorial government agencies (or their representative bodies) whose mission interests also involve the scope of the CIPAC activities for that particular sector.

CIPAC Membership: CIPAC Membership may include:

(i) CIKR owner and/or operator members of an SCC. CIKR owners and operators own and invest in infrastructure assets or in the systems and processes to secure them. CIKR owners and/or operators are held responsible by the public for CIKR operations and the response and recovery when their CIKR assets and systems are disrupted;

(ii) Trade association members who are members of an SCC representing the interests of CIKR owners and/or operators;

(iii) Each sector's Government Coordinating Council (GCC) members; and

(iv) State, local, Tribal, and territorial governmental officials comprising the DHS State, Local, Tribal, and Territorial GCC.

CIPAC Membership Roster and Council Information: The current roster of CIPAC membership is published on the CIPAC Web site *(http://www.dhs.gov/cipac)* and is updated as the CIPAC membership changes. Members of the public may visit the CIPAC Web site at any time to obtain current CIPAC membership as well as the current and historic list of CIPAC meetings and agendas.

Signed: August 2, 2010.

Nancy J. Wong,

Designated Federal Officer for the CIPAC.

[FR Doc. 2010–19866 Filed 8–11–10; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities: New information collection; Comment Request

ACTION: 60-Day Notice of New Information Collection for Review; Bond Worksheet; OMB Control No. 1653–NEW

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until October 12, 2010.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), Joseph M. Gerhart, Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, 500 12th Street, SW., Room 3138, Washington, DC 20024; (202) 732–6337.

Comments are encouraged and will be accepted for sixty days until October 12, 2010. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(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 agencies 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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New information collection.

(2) *Title of the Form/Collection:* Bond Worksheet.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* 71–022, U.S. Immigration and Customs Enforcement.

Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or households. This data collected on this worksheet is used by USICE for the purposes of ensuring the person or company posting a bond provides accurate written data for review and processing by USICE. It is a precursor for preparing the I–352.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 25,000 responses at 15 minutes (0.25 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 6,250 annual burden hours.

Requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be requested via e-mail to: *forms.ice@dhs.gov* with "ICE Form 71–022" in the subject line.

Dated: August 4, 2010.

Joseph M. Gerhart,

Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2010–19919 Filed 8–11–10; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1927–DR; Docket ID FEMA–2010–0002]

Idaho; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Idaho (FEMA–1927–DR), dated July 27, 2010, and related determinations.

DATES: *Effective Date:* July 27, 2010.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated July 27, 2010, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of Idaho resulting from severe storms and flooding during the period of June 2–10, 2010, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Idaho.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Willie G. Nunn, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Idaho have been designated as adversely affected by this major disaster:

Adams, Gem, Idaho, Lewis, Payette, Valley, and Washington Counties for Public Assistance.

All counties within the State of Idaho are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010–19886 Filed 8–11–10; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1922–DR; Docket ID FEMA–2010–0002]

Montana; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Montana (FEMA–1922–DR), dated July 10, 2010, and related determinations.

DATES: *Effective Date:* July 28, 2010.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Montana is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of July 10, 2010.

Chouteau County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010–19887 Filed 8–11–10; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5382–N–13]

Notice of Proposed Information Collection for Public Comment: 2011 American Housing Survey

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506 (c)(2)(A)). The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date: October 12, 2010.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW., Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: David A. Vandenbroucke at (202) 402–5890 (this is not a toll-free number), or Joe Huesman, Bureau of the Census, Demographic Surveys Division, Washington, DC 20233, (301) 763–4822 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (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; (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 collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: 2011 American Housing Survey.

OMB Control Number: 2528–0017.

Description of the need for the information and proposed use: The American Housing Survey (AHS) provides a periodic measure of the size and composition of the country's housing inventory. Title 12, United States Code, Sections 1701Z–1, 1701Z–2(g), and 1710Z–10a mandates the collection of this information.

Like the previous surveys, the 2011 AHS collects data on subjects such as the amount and types of changes in the inventory, the physical condition of the inventory, the characteristics of the occupants, housing costs, the persons eligible for and beneficiaries of assisted housing, and the number and characteristics of vacancies. The 2011 AHS will collect additional data on potential health and safety hazards in the home and modifications made to assist occupants living with disabilities. Selected neighborhood and journey to work questions will not be collected in the 2011 survey and the mortgage questions will be redesigned. There is no AHS–Metropolitan Sample in the 2011 survey. But, a supplemental sample of housing units will be selected for 30 metropolitan areas. The supplemental sample will be combined with existing sample in these areas in order to produce metropolitan estimates using the National data.

Policy analysts, program managers, budget analysts, and Congressional staff use AHS data to advise executive and legislative branches about housing conditions and the suitability of public policy initiatives. Academic researchers and private organizations also use AHS data in efforts of specific interest and concern to their respective communities.

The Department of Housing and Urban Development (HUD) needs the AHS data for two important uses.

1. With the data, policy analysts can monitor the interaction among housing needs, demand and supply, as well as changes in housing conditions and costs, to aid in the development of housing policies and the design of housing programs appropriate for different target groups, such as first-time home buyers and the elderly.

2. With the data, HUD can evaluate, monitor, and design HUD programs to improve efficiency and effectiveness.

Agency Form Numbers: Computerized Versions of AHS–21, AHS–22 and AHS–23.

Members of affected public: Households.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:

Number of Respondents	190,000.
Estimate Responses per Respondent	1 every 2 years.
Time (minutes) per Respondent	49.
Total hours to respond	155,167.

Respondent's Obligation: Voluntary.

Status of the proposed information collection: Pending OMB approval.

Authority: Title 13 U.S.C. Section 9(a), and Title 12, U.S.C., Section 1701z–1 *et seq.*

Dated: August 3, 2010.

Edward J. Szymanoski,

Acting Director, Division of Housing & Demographic Analysis.

[FR Doc. 2010–19876 Filed 8–11–10; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Vendor Outreach Workshop for Small Businesses in the National Capitol Region of the United States

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: The Office of Small and Disadvantaged Business Utilization of the Department of the Interior are hosting a Vendor Outreach Workshop for small businesses in the National Capitol region of the United States that are interested in doing business with the Department. This outreach workshop will review market contracting opportunities for the attendees. Business owners will be able to share their individual perspectives with Contracting Officers, Program Managers and Small Business Specialists from the Department.

DATES: The workshop will be held on August 31, 2010, from 9 a.m. to 1:30 p.m.

ADDRESSES: The workshop will be held at the U.S. Department of the Interior Main Auditorium, 1849 C Street, NW., Washington, DC 20240. Register online at: *http://www.doi.gov/osdbu.*

FOR FURTHER INFORMATION CONTACT: Mark Oliver, Director, Office of Small and Disadvantaged Business Utilization, 1951 Constitution Ave., NW., MS–320 SIB, Washington, DC 20240, telephone 1–877–375–9927 (Toll-Free).

SUPPLEMENTARY INFORMATION: In accordance with the Small Business Act, as amended by Public Law 95–507, the Department has the responsibility to promote the use of small and small disadvantaged business for its acquisition of goods and services. The Department is proud of its accomplishments in meeting its business goals for small, small disadvantaged, 8(a), woman-owned, HUBZone, and service-disabled veteran-owned businesses. In Fiscal Year 2009, the Department awarded 56 percent of its $2.6 billion in contracts to small businesses.

This fiscal year, the Office of Small and Disadvantaged Business Utilization are reaching out to our internal stakeholders and the Department's small business community by conducting several vendor outreach workshops. The Department's presenters will focus on contracting and subcontracting opportunities and how small businesses can better market services and products. Over 3,000 small businesses have been targeted for this event. If you are a small business interested in working with the Department, we urge you to register online at: *http://www.doi.gov/osdbu* and attend the workshop.

These outreach events are a new and exciting opportunity for the Department's bureaus and offices to improve their support for small business. Additional scheduled events are posted on the Office of Small and Disadvantaged Business Utilization website at *http://www.doi.gov/osdbu.*

Mark Oliver,

Director, Office of Small and Disadvantaged Business Utilization.

[FR Doc. 2010–19951 Filed 8–11–10; 8:45 am]

BILLING CODE 4210–RK–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Northwest Area Water Supply Project, North Dakota

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of intent to prepare a supplemental environmental impact statement.

SUMMARY: The Bureau of Reclamation (Reclamation) is commencing work under the National Environmental Policy Act of 1969 (NEPA) on a Supplemental Environmental Impact Statement (EIS) for the Northwest Area Water Supply Project (NAWS Project), a Federal reclamation project, located in North Dakota. A Final EIS and Record of Decision (ROD) for the NAWS Project were previously completed in December 2008 and January 2009, respectively. The Final EIS and ROD were challenged in U.S. District Court. A subsequent court order found the Final EIS to be insufficient in two areas. Therefore a supplement is being prepared to address those areas in more detail and any others that interested parties or the public may identify warranting additional analysis, as well as to re-examine and update, to the extent necessary, prior NEPA analysis that has been completed in connection with the NAWS Project to date. This notice is being published to inform the public about the preparation of the Supplemental EIS and to initiate a formal scoping period for obtaining public comment. The scoping period for the supplement will conclude 60 days following publication of this notice. Public meetings are scheduled as part of the scoping process.

Reclamation invites all interested parties to submit written comments or suggestions during the scoping period related to significant issues, environmental impacts, and reasonable alternatives to the proposed action. Reclamation will provide a separate project information document that describes the Supplemental EIS actions and how the public can become involved and participate. The project information document will provide details relative to the Supplemental EIS and is intended to assist the public in providing comments during the scoping period.

DATES: Public scoping meetings will be held during September 2010. See the Supplemental Information section for dates and locations of these meetings. Individuals who want to receive the additional project information document should contact Reclamation within 15 days following publication of this notice. Written or e-mailed comments on the scope of issues and alternatives should be received by October 12, 2010. Comments received

after that date will be considered to the extent practical.

ADDRESSES: Written comments should be submitted to: Bureau of Reclamation, Dakotas Area Office, Attention: Alicia Waters, P.O. Box 1017, Bismarck, ND 58502.

FOR FURTHER INFORMATION CONTACT: Alicia Waters, Northwest Area Water Supply Project EIS, Bureau of Reclamation, Dakotas Area Office, P.O. Box 1017, Bismarck, ND 58502; Telephone: (701) 221–1206; or facsimile (701) 250–4326. You may submit e-mail to *NAWS_EIS@usbr.gov*.

SUPPLEMENTARY INFORMATION:

Dates of Public Scoping Meetings

- September 13, 2010, 6:30 p.m.–8:30 p.m., Bottineau, ND
- September 14, 2010, 6:30 p.m.–8:30 p.m., Minot, ND
- September 15, 2010, 6:30 p.m.–8:30 p.m., New Town, ND
- September 16, 2010, 6:30 p.m.–8:30 p.m., Bismarck, ND

Locations of Public Scoping Meetings

- MSU–Bottineau, Nelson Science Center Room 125, 105 Simrall Boulevard, Bottineau, ND
- Sleep Inn—Inn and Suites, North Convention Center, 2400 10th Street NW., Minot, ND
- 4 Bears Casino, Mandan Room, 202 Frontage Room, New Town, ND
- Best Western Doublewood Inn, Congress Room, 1400 Interchange Avenue, Bismarck, ND

The meeting facilities are physically accessible to people with disabilities. People needing special assistance to attend and/or participate in the public meetings should contact Patience Hurley at 701–221–1204 as soon as possible. To allow sufficient time to process special requests, please call no later than one week before the public meeting of interest.

Background

The Garrison Diversion Unit's Municipal, Rural and Industrial Water Supply (MR&I) program was authorized by the U.S. Congress on May 12, 1986, through the Garrison Diversion Unit Reformulation Act of 1986. This act authorized the appropriation of $200 million of Federal funds for the planning and construction of water supply facilities throughout North Dakota. The NAWS Project is being constructed under this authorization.

The NAWS Project is designed as a bulk water distribution system that will service local communities and rural water systems in 10 counties in northwestern North Dakota including the community of Minot. The NAWS Project would convey water from Lake Sakakawea, in the Missouri River Basin in North Dakota, through a buried pipeline to Minot, surrounding communities and rural water systems in the Hudson Bay Basin. The Project would include a treatment plant in the Missouri River Basin to disinfect the water prior to it being delivered through the pipeline into the Hudson Bay Basin. An Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) were completed for the Project in 2001.

Construction on the project began in April 2002. In October 2002, the Province of Manitoba, Canada, filed a legal challenge in U.S. District Court in Washington, DC to compel the Department of the Interior to complete an EIS on the project. A court order dated February 3, 2005, remanded the case to Reclamation for completion of additional environmental analysis, but allowed construction to proceed on project features that would not preclude a future decision on water treatment to reduce the risk of transferring invasive species.

Project construction has continued as allowed by the court. Between 2002 and 2010, the entire 45 miles of main transmission pipeline for NAWS, from Lake Sakakawea to Minot, was completed along with several segments of the distribution system. The City of Minot is temporarily serving water to several communities and rural water systems with water from the city's ground water wells. This interim water supply is provided by the city through temporary water service contracts which expire in 2018 or sooner depending on the reliability of the water source.

Recently completed features of the NAWS Project include a high service pump station and 2 million gallon storage reservoir in Minot. Most of the other segments of the distribution system are being designed or constructed. The court also allowed the State of North Dakota to initiate design work on upgrades to the existing Minot water treatment plant which are necessary for the city to continue delivering the interim water supply to adjacent communities.

In March 2006, Reclamation initiated an EIS focused on different water treatment methods for the water from Lake Sakakawea. The analysis focused on environmental impacts that could occur due to pipeline leaks and failure of the water treatment systems. The Draft EIS was published on December 21, 2007 and the Final EIS on December 5, 2008 (documents available electronically at *http://www.usbr.gov/gp/dkao/*). Reclamation signed a Record of Decision (ROD) on January 15, 2009, selecting an alternative using chlorination and ultraviolet radiation to disinfect the water before it is delivered into the Hudson Bay Basin. Final treatment to drinking water standards would occur at the existing water treatment plant in Minot.

In February 2009, the Department of Justice notified the court that Reclamation had completed the Final EIS and ROD. Shortly thereafter, the Province of Manitoba filed a supplemental complaint contending the Final EIS was insufficient. Additionally, the State of Missouri filed a complaint against the Department of the Interior and the U.S. Army Corps of Engineers in the same District Court in Washington, DC. The State of Missouri alleged that Reclamation's Final EIS was insufficient and that the Corps of Engineers failed to complete a separate National Environmental Policy Act assessment for the NAWS Project. The court combined the Missouri suit with the Manitoba suit. On March 5, 2010, the court issued an order in favor of the Province of Manitoba and the State of Missouri. The case was remanded to Reclamation and the injunction imposed by the April 15, 2005, order remains in effect.

The Court found the EIS inadequately examined: (1) Cumulative impacts of water withdrawals on Lake Sakakawea and the Missouri River, and (2) consequences of transferring potentially invasive species into the Hudson Bay Basin.

Purpose of the Proposed Action

The purpose of the proposed action is to provide a reliable source of high quality treated water to northwestern North Dakota for MR&I uses.

Need for the Proposed Action

The NAWS Project is needed: (1) To provide high quality treated water because northwestern North Dakota has experienced water supply problems for many years, (2) to replace poor quality groundwater sources presently used for MR&I purposes, and (3) because the surface water supplies within the service area are insufficient from both a quality and quantity standpoint. This Supplemental EIS is needed to comply with the Court order of March 5, 2010, and fully satisfy NEPA. Reclamation will conduct additional analyses to address the Court's order regarding the consequences of transferring potentially invasive species into the Hudson Bay Basin and the cumulative impacts of water withdrawals on Lake Sakakawea and the Missouri River, in addition to

re-examining and updating all prior NEPA analysis that has been completed in connection with the NAWS Project to date.

The Proposed Action

Reclamation proposes to complete construction of the NAWS Project, including construction of a biota water treatment plant, to treat the source water from Lake Sakakawea before it is transported into the Hudson Bay drainage. As part of this proposed action, Reclamation would implement construction methods and operational measures to further reduce the risk of invasive species transfer that may occur as a result of an interruption in the treatment process and breach in the buried pipeline to the Minot water treatment plant.

Scope of the Proposed Action

The geographic scope of the Supplemental EIS will include areas and resources within the Missouri River Basin and Hudson Bay Basin that may be affected by water diversion and delivery for NAWS project purposes. This includes, but is not necessarily limited to: (1) The sites of NAWS Project features and facilities; (2) lands and waters that receive NAWS Project MR&I water supplies, including downstream areas in the Hudson Bay Basin; and (3) the Missouri River from Lake Sakakawea to its confluence with the Mississippi River.

The Supplemental EIS will review, and update, if necessary, the prior Environmental Assessment and Environmental Impact Statement. This Supplemental EIS will further evaluate the consequences of transferring potentially invasive species to the Hudson Bay Basin and the cumulative effects of water withdrawals from the Missouri River. Additional issues or concerns identified in the scoping process will be considered by Reclamation and evaluated in the Supplemental EIS as appropriate. Identification of known methods and technologies that can be used to assess potential consequences to resources will be considered as well.

Summary

Reclamation is preparing a Supplemental EIS to address the relevant issues related to final construction and operation of the NAWS Project. We are seeking comment from the public on the development of reasonable alternatives to the proposed action, information relative to new water treatment processes that could be considered, methods for evaluating the risks and potential consequences which may be associated with the proposed action, and concerns relative to the environmental effects that should be described in the supplement. We also seek identification of any issues in prior NEPA analyses for the NAWS Project to date that should be updated, and the identification of any other issues that should be addressed by the Supplemental EIS.

Public Disclosure Statement

Before including your name, address, telephone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

John F. Soucy,

Assistant Regional Director, Great Plains Region, Bureau of Reclamation.

[FR Doc. 2010–19903 Filed 8–11–10; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

National Park Service

Urban Park and Recreation Recovery Program Project Performance Reports, Conversion of Use Provisions, and Grant Agreements and Amendments

AGENCY: National Park Service, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, we (National Park Service, NPS) have sent three interrelated Information Collection Requests (ICRs) to OMB for renewal (OMB Control Numbers 1024–0028, 1024–0048, and 1024–0089). We summarize each ICR below and describe the nature of the collection and the estimated burden. These ICRs are scheduled to expire on August 31, 2010. We 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. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: Submit comments on any or all of these ICRs on or before September 13, 2010.

ADDRESSES: Send your comments and suggestions on these ICRs to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_DOCKET@OMB.eop.gov* (e-mail). Please provide a copy of your comments to Cartina Miller, Information Collection Clearance Officer, National Park Service, at 202–371–2049 (fax) or *Cartina_Miller@nps.gov* (e-mail). Please specify the appropriate OMB control number(s) in the subject line of your comment.

FOR FURTHER INFORMATION CONTACT: Laurie Heupel, Outdoor Recreation Planner, State and Local Assistance Programs, National Park Service, 1849 C Street NW., Mail Stop 2225, Washington, DC 20240 (mail) or phone: 202–354–6914. You are entitled to a copy of the ICR packages free of charge.

SUPPLEMENTARY INFORMATION: Congress passed the Urban Park and Recreation Recovery (UPARR) Act (16 U.S.C. 2501 *et seq.*) as Title X of the National Parks and Recreation Act of 1978. The UPARR Act authorized the Secretary of the Interior to establish a grant program to help physically and economically distressed urban areas improve recreation opportunities for their residents. We administer the UPARR program in accordance with regulations at 36 CFR 72. While the program has remained authorized, it has not been funded since Fiscal Year 2002. It may receive funding in the future, and we are seeking renewal of the following information collections associated with the UPARR program:

1. Performance Reports

Title: Urban Park and Recovery Project Performance Report, 36 CFR 72.

OMB Control Number: 1024–0028.

Type of Request: Extension of a currently approved collection of information.

Brief Description of Collection: Project Performance Reports include the scheduled completion date, percent completed to date, and percent to be completed at the end of next report period. We also ask for the percent of costs expended to date and the percent of costs to be expended by the end of the next reporting period. Reasons for delays or cost adjustments are described in the report. We use the information: (1) To monitor against possible waste, fraud, and abuse; (2) for billing and audit purposes; and (3) to prepare reports to Congress as necessary.

Affected Public: Local governments.

Obligation to Respond: Required to obtain or retain a benefit.

Frequency of Response: Annually for active grants.

Estimated Total Annual Responses: 1.

Estimated Completion Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 1 hour.

2. Conversion of Use Provisions

Title: Urban Park and Recovery Program Conversion of Use Provisions, 36 CFR 72.

OMB Control Number: 1024–0048.

Type of Request: Extension of a currently approved collection of information.

Brief Description of Collection: In accordance with Section 1010 of the UPARR Act and 36 CFR 72.72, no property improved or developed with UPARR assistance can be converted to other than public recreation uses without the advance approval of the NPS. The grant recipient (urban cities and counties) must submit a formal request to the appropriate NPS Regional Office documenting that: (a) All alternatives to the conversion have been evaluated and then rejected on a sound basis; (b) required replacement land being offered as a substitute is of reasonably equivalent location and recreational usefulness as the assisted site proposed for conversion; and (c) the property for substitution meets the eligibility requirements for UPARR assistance. Documentation must include maps identifying the assisted sites, the area to be converted, and the proposed replacement property.

Affected Public: Local governments.

Obligation to Respond: Required to obtain or retain a benefit.

Frequency of Response: On occasion.

Estimated Total Annual Responses: 1.

Estimated Completion Time per Response: 25 hours.

Estimated Total Annual Burden Hours: 25 hours.

3. Grant Agreement and Amendment

Title: Urban Park and Recovery Grant Agreement and Amendment, 36 CFR 72.

OMB Control Number: 1024–0089.

Service Form Numbers: 10–912 and 10–915.

Type of Request: Extension of a currently approved collection of information.

Brief Description of Collection: In order to receive financial assistance, grant respondents must complete and sign the UPARR Program Grant Rehabilitation and Innovation Agreement (Form # 10–912). To alter this agreement, they must complete and sign the Amendment to UPARR Grant Agreement (Form # 10–915). The forms set forth the obligations assumed by the grantee when accepting Federal assistance, including the rules and regulations applicable to the conduct of a project under the UPARR Act and any special terms and conditions established by the NPS and agreed to by the respondent.

Affected Public: Local governments.

Obligation to Respond: Required to obtain or retain a benefit.

Frequency of Response: On occasion.

Estimated Total Annual Responses: 2 (one for each form).

Estimated Completion Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 2 hours.

We published the following notices in the **Federal Register** announcing our intention to renew these ICRs and soliciting public comments for 60 days:

- OMB Control No. 1024–0028—notice published on April 5, 2010 (75 FR 17153) with public comment period open through June 4, 2010.
- OMB Control No. 1024–0048—notice published on April 21, 2010 (75 FR 20857) with public comment period open through June 21, 2010.
- OMB Control No. 1024–0089—notice published on March 18, 2010 (75 FR 13138) with public comment period open through May 17, 2010.

We did not receive any comments in response to the above notices. We again invite comments on: (1) The practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden to respondents, including the use of automated information collection techniques or other forms of information technology. Before including your address, phone number, e-mail, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

August 6, 2010.

Cartina Miller,

NPS Information Collection Officer.

[FR Doc. 2010–19864 Filed 8–11–10; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

U.S. Geological Survey

Federal Interagency Steering Committee on Multimedia Environmental Modeling

AGENCY: U.S. Geological Survey (USGS), Department of Interior (DOI).

ACTION: Notice of open meeting.

SUMMARY: The annual public meeting of the Federal Interagency Steering Committee on Multimedia Environmental Modeling (ISCMEM) will convene to discuss some of the latest developments in environmental modeling applications, tools and frameworks, as well as new operational initiatives for FY 2011 among the participating agencies. The meeting this year will emphasize ecosystem modeling and monitoring.

Dates of Meeting: September 13–16, 2010.

Place: U.S. Army Engineer Research and Development Center, 3909 Halls Ferry Road, Vicksburg, Mississippi 39180.

Time: 8 a.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Inquiries and notice of intent to attend the meeting may be e-mailed to: Pierre D. Glynn, ISCMEM Chair, U.S. Geological Survey, National Research Program, Branch of Regional Research, Eastern Region, 12201 Sunrise Valley Drive, Mail Stop 432, Reston, VA 20192. TEL 703–648–5823. *pglynn@usgs.gov.*

SUPPLEMENTARY INFORMATION:

Background: Nine Federal agencies have been cooperating under a Memorandum of Understanding (MOU) on the research and development of multimedia environmental models. The MOU, which was revised in 2006, continues an effort that began in 2001. It establishes a framework for facilitating cooperation and coordination among the following agencies (the specific research organization within the agency is in parentheses): National Science Foundation; U.S. Army Corps of Engineers (Engineer Research and Development Center); U.S. Department of Agriculture (Natural Resources Conservation Service); U.S. Department of Energy (Office of Biological and Environmental Research); U.S. Environmental Protection Agency; U.S. Geological Survey; U.S. National Oceanographic and Atmosphere Administration; U.S. Nuclear Regulatory Commission (Office of Nuclear Regulatory Research); and U.S. Bureau of Reclamation. These agencies are cooperating and coordinating in the research and development (R&D) of multimedia environmental models, software and related databases, including development, enhancements, applications and assessments of site specific, generic, and process-oriented multimedia environmental models as they pertain to human and environmental health risk assessment. Multimedia model development and

simulation supports interagency interests in risk assessment, uncertainty analyses, water supply issues and contaminant transport.

Purpose of the Public Meeting: The annual public meeting and workshop provides an opportunity for the scientific community, other Federal and State agencies, and the public to be briefed on ISCMEM activities and their initiatives for the upcoming year, and to discuss technological advancements in multimedia environmental modeling.

Proposed Agenda: The ISCMEM Chair will open the meeting with a brief overview of the goals of the MOU and an update on current activities of ISCMEM. This introduction will be followed by a series of invited presentations starting on Tuesday morning, Sept. 14, and ending on Thursday afternoon, Sept. 16. ISCMEM members, presenters and active participants are also invited to visit the U.S. Army Corps of Engineers ERDC facility on the afternoon of Monday, Sept. 13. A detailed agenda with presentation titles and speakers will be posted on the MOU public Web site: *http://www.environmental-modeling.org.* The topics covered this year focus on (1) ecosystem modeling frameworks, (2) ecosystem monitoring and modeling, (3) ecosystem variability, reference states and modeling, and (4) incorporating climate change into ecosystem models. Other topics also include modeling frameworks, databases and cyberinfrastructure, community modeling efforts, parameter estimation, uncertainty and sensitivity analyses, optimization modeling, reactive transport modeling, and watershed and distributed water quality modeling.

Meeting Access: To obtain access to the ISCMEM September 13–16 meeting and workshop, all interested attendees will need to pre-register by e-mailing Marilyn Butler (*Marilyn.L.Butler@usace.army.mil*) and La Tisa Osbourne (*losbourne@usgs.gov*), indicating their intent to attend the meeting and providing their full contact information and affiliation. Attendees will also need to present a valid photo-identification card in order to enter the ERDC facility.

Pierre D. Glynn,

Chair, Federal Interagency Steering Committee on Multimedia Environmental Modeling.

[FR Doc. 2010–19910 Filed 8–11–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Cape Cod National Seashore; South Wellfleet, MA; Cape Cod National Seashore Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Two Hundredth Seventy-Fifth Notice of Meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770, 5 U.S.C. App 1, Section 10) of a meeting of the Cape Cod National Seashore Advisory Commission.

DATES: The meeting of the Cape Cod National Seashore Advisory Commission will be held on September 13, 2010, at 1 p.m.

ADDRESSES: The Commission members will meet in the meeting room at Headquarters, 99 Marconi Station, Wellfleet, Massachusetts.

SUPPLEMENTARY INFORMATION: The Commission was reestablished pursuant to Public Law 87–126 as amended by Public Law 105–280. The purpose of the Commission is to consult with the Secretary of the Interior, or his designee, with respect to matters relating to the development of Cape Cod National Seashore, and with respect to carrying out the provisions of sections 4 and 5 of the Act establishing the Seashore.

The regular business meeting is being held to discuss the following:

1. Adoption of Agenda
2. Approval of Minutes of Previous Meeting
   (July 19, 2010)
3. Reports of Officers
4. Reports of Subcommittees
5. Superintendent's Report
   - Update on Dune Shacks
   - Improved Properties/Town Bylaws
   - Herring River Wetland Restoration
   - Wind Turbines/Cell Towers
   - Flexible Shorebird Management
   - Highlands Center Update
   - Alternate Transportation funding
   - Other construction projects
   - Land Protection
   - Cape Wide Bicycle Planning
   - Herring Cove Beach Facilities
   - Climate Friendly Parks
6. Old Business
7. New Business
8. Date and agenda for next meeting
9. Public comment and
10. Adjournment

The meeting is open to the public. It is expected that 15 persons will be able to attend the meeting in addition to Commission members.

Interested persons may make oral/written presentations to the Commission during the business meeting or file written statements. Such requests should be made to the park superintendent prior to the meeting. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

FOR FURTHER INFORMATION CONTACT: Further information concerning the meeting may be obtained from the Superintendent, Cape Cod National Seashore, 99 Marconi Site Road, Wellfleet, MA 02667.

Dated: August 4, 2010.

George E. Price, Jr.,

Superintendent.

[FR Doc. 2010–19865 Filed 8–11–10; 8:45 am]

BILLING CODE 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 Wind and Solar-Powered Light Posts and Street Lamps,* DN 2748; the Commission is soliciting comments on any public interest issues raised by the complaint.

FOR FURTHER INFORMATION CONTACT: Marilyn R. Abbott, 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 Duggal Dimensions LLC, Duggal Energy Solutions, LLC, and Duggal Visual Solutions, Inc. on August 6, 2010. 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 LUMI*SOLAIR Light Post. The complaint names as respondents Gus Power Incorporated of Mississauga, Ontario, Canada; Efston Science Inc. of Toronto, Ontario, Canada; King Luminaire, Inc. of Jefferson, Ohio; and The StressCrete Group of Burlington, Ontario, Canada.

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. 2748") 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)).

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 2010–19867 Filed 8–11–10; 8:45 am]

BILLING CODE 7020–02–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 Flash Memory Chips and Products Containing the Same,* DN2749; the Commission is soliciting comments on any public interest issues raised by the complaint.

FOR FURTHER INFORMATION CONTACT: Marilyn R. Abbott, 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 Spansion, LLC on August 6, 2010. 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 Flash Memory Chips and Products Containing the Same. The complaint names as respondents Samsung Electronics Co., Ltd., Seoul, South Korea; Samsung Electronics America, Inc., Ridgefield Park, NJ; Samsung International, Inc., San Diego, CA; Samsung Semiconductor, Inc., San Jose, CA; Samsung Telecommunications America, LLC, Richardson, TX; Apple, Inc., Cupertino, CA; BenQ Corp., Taipei, Taiwan; BenQ America Corp., Irvine, CA; Qisda Corp., Taoyuan, Taiwan; Kingston Technology Company Inc., Fountain Valley, CA; Kingston Technology (Shanghai) Co., Ltd., Shanghai, China; Kingston Technology Far East Co., Hsin-Chu, Taiwan; Kingston Technology Far East (Malaysia) Sdn Bhd, Bayan Legas, Malaysia; MiTAC Digital Corporation (aka Magellan), Santa Clara, CA; MiTAC International Corporation, Hsin-Chu Hsien, Taiwan; Nokia Corp., Espoo, Finland; Nokia Inc., Irving, TX; PNY Technologies Inc., Parsippany, NJ; Research In Motion Ltd., Waterloo, Ontario, Canada; Research In Motion Corporation, Irving, TX; Sirius XM Radio, Inc., New York, NY; Transcend

Information Inc., Taipei, Taiwan; Transcend Information Inc. (US), Orange, CA; and Transcend Information Inc., Shanghai, China.

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. 2749") 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: August 6, 2010.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 2010–19892 Filed 8–11–10; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

Notice is hereby given that on August 6, 2010, a proposed Consent Decree in the case of *U.S.* v. *Mascot Mines, Inc., et al.,* Civil Action No. 08–383–EJL, with Defendant Zanetti Brothers, Inc., was lodged with the United States District Court for the District of Idaho.

The United States filed a complaint in September 2008, on behalf of the Environmental Protection Agency (EPA), alleging that Defendant Zanetti Brothers, Inc., is liable pursuant to Section 107(a) of CERCLA for response costs incurred and to be incurred by the United States in connection with Operable Unit Three of the Bunker Hill Mining and Metallurgical Complex Superfund Site in northern Idaho. The proposed Consent Decree grants the Defendant a covenant not to sue for response costs, as well as natural resource damages, in connection with the Site. The United States Department of the Interior, the United States Department of Agriculture, and the Coeur d'Alene Tribe are trustees of injured natural resources at the Site, and the Tribe is a party to the proposed Consent Decree. The settlement requires, among other things, that the Defendant pay $150,000, provide $50,000 worth of construction materials to EPA, and grant an easement to the State of Idaho. The settlement also requires the Defendant to assign its interest in applicable insurance policies to the Coeur d'Alene Basin Insurance Recovery Trust, established for the benefit of EPA and the natural resource trustees.

For thirty (30) days after the date of this publication, the Department of Justice will receive 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. In either case, the comments should refer to *U.S.* v. *Mascot Mines, Inc., et al.,* D.J. Ref. No. 90–11–3–128/7.

During the comment period, the Consent Decree may 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 $22.00 (25 cents per page reproduction cost) payable to the United States Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2010–19913 Filed 8–11–10; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0033]

Baseline Safety and Health Practices; Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comment.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is soliciting public comments concerning the collection of information about the safety and health practices of private sector establishments in agriculture (with 10 or more workers) and non-agriculture industries, as well as public sector establishments in those states with OSHA-approved safety and health programs (State Plan states).

DATES: Comments must be submitted (postmarked, sent, or received) by October 12, 2010.

ADDRESSES: *Electronically:* You may submit comments and attachments electronically at *http://www.regulations.gov*, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit three copies of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2010–0033, U.S. Department of Labor, Occupational Safety and Health Administration, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., *e.t.*

Instructions: All submissions must include the Agency name and OSHA docket number for the Information Collection Request (ICR) (OSHA–2010–0033). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov*. For further information on submitting comments *see* the "Public Participation" heading in the section of this notice titled "Supplementary Information."

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may contact Todd Owen or Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Todd Owen or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The Occupational Safety and Health Administration (OSHA) is undertaking a rulemaking effort directed toward requiring employers to establish injury and illness prevention programs to monitor and more effectively implement practices to mitigate workplace hazards, thereby reducing the incidence of employee injuries and illnesses. OSHA believes that widespread implementation of such programs will substantially improve overall workplace safety and health conditions.

To gain information needed to support this rulemaking effort, OSHA is proposing to conduct a statistical survey of private sector establishments in non-agricultural industries. The goal of the survey is to develop industry-specific, statistically accurate estimates of the current prevalence of a variety of baseline safety and health practices that may be elements of injury and illness prevention programs among establishments. OSHA also proposes to conduct case study interviews in two sectors: (1) establishments in the agriculture sector to assess the prevalence of safety and health practices among farms with more than 10 workers; and (2) interviews with government officials in State Plan states to assess safety and heath practices among agencies and departments operated by state and local governments in State Plan states.

In addition to the statistical survey (Baseline Safety and Health Practices) described above—which also includes "case studies" in two industry sectors that could not be adequately sampled by the survey methodology—the Agency is proposing to conduct as many as 50 site visits to employers. These employers could potentially be affected by a new standard that could require a management program or system to address workplace hazards. Site visits would collect information on current employer practices (much like the information collected in the "case studies" and the survey questionnaire itself), but also solicit information from employers on how they would comply with such a regulation and what time or costs would be required to do so. Site visit reports capture much richer detail about employer conditions than the survey instrument, reflecting variations of employer size and industry sector. These site visits would be conducted either by OSHA personnel or a contractor under the agency's direction.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting OMB approval of the collection of information (paperwork) requirements contained in the Baseline Safety and Health Practices Survey. The hour burden of the

information collection effort for the study is 4,177 hours. The burden hour estimates are based on tests of the length of time each type of respondent is likely to need to respond to the survey questions. The total cost to respondents is $213,153. This is a one-time data collection effort.

OSHA will summarize the comments submitted in response to this notice, and will include this summary in its request to OMB to approve the information collection requirements in the Baseline Safety and Health Practices Survey.

Type of Review: New Collection.

Title: Baseline Safety and Health Practices.

OMB Number: 1218–0NEW.

Affected Public: Private businesses; state and local government entities in State plan states.

Number of Respondents: Statistical Survey—14,202; Case Studies—85 (agriculture and government sectors combined); Site visits—50.

Frequency: Nonrecurring.

Estimated Time Per Response: Statistical Survey—30 minutes (0.5 hour); Case Studies—30 minutes (0.5 hour) for agricultural establishments, 60 minutes (1 hour) for state and local governments; Site visits—2 hours.

Total Burden Hours: Statistical Survey—4,022; Case Studies—55; Site Visits—100.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on this Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other materials must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA–2010–0033). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (*see* the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (e.g. copyrighted material) is not publically available to read or download through this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available through the Web site's "User Tips" link. Contact the OSHA Docket Office for information about materials not available through the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 5–2007 (72 FR 31160).

Signed at Washington, DC, on this 6th day of August 2010.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2010–19869 Filed 8–11–10; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. They authorize the preservation of records of continuing value in the National Archives of the United States and the destruction, after a specified period, of records lacking administrative, legal, research, or other value. Notice is published for records schedules in which agencies propose to destroy records not previously authorized for disposal or reduce the retention period of records already authorized for disposal. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

DATES: Requests for copies must be received in writing on or before September 13, 2010. Once the appraisal of the records is completed, NARA will send a copy of the schedule. NARA staff usually prepare appraisal memorandums that contain additional information concerning the records covered by a proposed schedule. These, too, may be requested and will be provided once the appraisal is completed. Requesters will be given 30 days to submit comments.

ADDRESSES: You may request a copy of any records schedule identified in this notice by contacting the Life Cycle Management Division (NWML) using one of the following means:

Mail: NARA (NWML), 8601 Adelphi Road, College Park, MD 20740–6001.

E-mail: request.schedule@nara.gov.

FAX: 301–837–3698.

Requesters must cite the control number, which appears in parentheses after the name of the agency which submitted the schedule, and must provide a mailing address. Those who desire appraisal reports should so indicate in their request.

FOR FURTHER INFORMATION CONTACT: Laurence Brewer, Director, Life Cycle Management Division (NWML), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001. *Telephone:* 301–837–1539. *E-mail: records.mgt@nara.gov.*

SUPPLEMENTARY INFORMATION: Each year Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval, using the Standard Form (SF) 115, Request for Records Disposition Authority. These schedules provide for the timely transfer into the National Archives of historically valuable records and authorize the disposal of all other records after the agency no longer needs

them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

The schedules listed in this notice are media neutral unless specified otherwise. An item in a schedule is media neutral when the disposition instructions may be applied to records regardless of the medium in which the records are created and maintained. Items included in schedules submitted to NARA on or after December 17, 2007, are media neutral unless the item is limited to a specific medium. (*See* 36 CFR 1225.12(e).)

No Federal records are authorized for destruction without the approval of the Archivist of the United States. This approval is granted only after a thorough consideration of their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and whether or not they have historical or other value.

Besides identifying the Federal agencies and any subdivisions requesting disposition authority, this public notice lists the organizational unit(s) accumulating the records or indicates agency-wide applicability in the case of schedules that cover records that may be accumulated throughout an agency. This notice provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction). It also includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it too includes information about the records. Further information about the disposition process is available on request.

Schedules Pending

1. Department of Agriculture, Office of the Secretary (N1–16–10–5, 7 items, 6 temporary items). Records relating to disaster response, including continuity of operations plans and directives, records relating to continuity of operations exercises, and files relating to agency responses to disasters. Proposed for permanent retention are files relating to disasters of extraordinary significance that the President declares major disasters.

2. Department of Agriculture, Food and Nutrition Service (N1–462–09–9, 1 item, 1 temporary item). Master files of an electronic information system that contains data concerning the food stamp program, including redemptions, retailers authorized to accept food stamps, and compliance matters involving retailers.

3. Department of Agriculture, Office of Security Services (N1–16–09–5, 1 item, 1 temporary item). Master files of an electronic information system that contains employee emergency notification information.

4. Department of Agriculture, Risk Management Agency (N1–258–09–7, 5 items, 5 temporary items). Records relating to legal matters, including such records as appeals and litigation case files, witness request files, sanctions case files, insurance provider litigation cases, and special litigation documentation.

5. Department of the Army, Agency-wide (N1–AU–10–66, 1 item, 1 temporary item). Master files of an electronic information system that relates to continuing education programs and includes such data as soldier contact information, education plans, and tuition assistance status.

6. Department of the Army, Agency-wide (N1–AU–10–67, 1 item, 1 temporary item). Master files of an electronic information system that contains data concerning GI Bill of Rights benefits for Army reserve personnel.

7. Department of the Army, Agency-wide (N1–AU–10–78, 1 item, 1 temporary item). Master files of an electronic information system used to update and certify pay for retired reserve members.

8. Department of the Army, Agency-wide (N1–AU–10–79, 1 item, 1 temporary item). Master files of an electronic information system used to forecast workload at supply storage and distribution facilities.

9. Department of the Army, Agency-wide (N1–AU–10–82, 1 item, 1 temporary item). Master files of an electronic information system used in connection with substance abuse programs to identify and prevent high risk behaviors.

10. Department of Health and Human Services, Centers for Medicare & Medicaid Services (N1–440–09–9, 1 item, 1 temporary item). Master files of an electronic information system that contains enrollment eligibility and paid claims information concerning beneficiaries and is used to detect fraud, waste, and abuse.

11. Department of Health and Human Services, Centers for Medicare & Medicaid Services (N1–440–10–7, 4 items, 4 temporary items). Master files of an electronic information system used to verify beneficiary eligibility and conduct prepayment reviews.

12. Department of Homeland Security, U.S. Immigration and Customs Enforcement (N1–567–09–8, 2 items, 2 temporary items). Master files of an electronic information system that contains data concerning immigration, law enforcement, incidents and similar matters that is also maintained elsewhere as well as legacy data concerning students who entered the United States, legacy criminal investigations data, and agency generated intelligence reports.

13. Department of the Interior, Office of the Secretary (N1–48–10–9, 1 item, 1 temporary item). Master files of an electronic information system that allows the public to submit ideas regarding the agency's role as custodian of public lands.

14. Department of Justice, Executive Office for U.S. Attorneys (N1–118–09–5, 1 item, 1 temporary item). Master files of an electronic information system used to track crack cocaine re-sentencing actions.

15. Department of Justice, Executive Office of U.S. Trustees (N1–60–09–35, 1 item, 1 temporary item). Master files of an electronic information system used to track bankruptcy criminal enforcement efforts and referrals.

16. Department of Justice, Federal Bureau of Investigation (N1–65–10–21, 6 items, 6 temporary items). Issues files, communications files, committee files and other records of the Ombudsman.

17. Department of Justice, Federal Bureau of Investigation (N1–65–10–24, 5 items, 5 temporary items). Records, including electronic data, relating to security risk assessments of individuals and entities with access to biological agents and toxins.

18. Department of Justice, Federal Bureau of Investigation (N1–65–10–27, 4 items, 4 temporary items). Training materials, course registration information, and other records relating to training investigative and surveillance support staff.

19. Department of Labor, Bureau of Labor Statistics (N1–257–09–1, 1 item, 1 temporary item). Copies of collective bargaining agreements that cannot be made public by the agency or donated to a non-Federal depository in accordance with Section 211 of the Labor Management Relations Act of 1947.

20. Department of Labor, Employment Standards Administration (N1–271–06–

1, 23 items, 20 temporary items). Records relating to the Energy Employees Occupational Illness Compensation Program. Included are such records as administrative subject files, Congressional correspondence, legislative and legal subject files, case files, accountability review reports, financial files, and electronic information systems relating to such matters as payments, case management, and records access. Proposed for permanent retention are training records, bulletins, and circulars.

21. Department of Transportation, Federal Highway Administration (N1–406–09–19, 21 items, 20 temporary items). Records of Federal Aid Divisions field offices relating to engineering and operations. Included are such records as access interchange requests, defense access road proposals, reports relating to contract bids, contract administration files, safety and health records, continuity of operations files, and files relating to Federal Aid projects. Proposed for permanent retention are files relating to policies and procedures.

22. Department of Transportation, Federal Highway Administration (N1–406–09–20, 11 items, 10 temporary items). Records of Federal Aid Divisions field offices relating to environmental programs. Included are such records as construction and maintenance records, files relating to cooperation with other agencies, environmental controls records, files relating to policies and procedures, and project files lacking significance. Proposed for permanent retention are project files that relate to significant projects, including projects that attracted widespread public attention, established precedents, or have a significant economic impact.

23. Department of Transportation, Federal Highway Administration (N1–406–09–24, 10 items, 10 temporary items). Records of Federal Aid Divisions field offices relating to planning and program development. Included are such records as Federal land transfer files, general correspondence, records relating to the scenic byways program, records relating to controls on outdoor advertising, utility project files, and records relating to maintenance reviews and the review of state and local right-of-way functions.

24. Department of the Treasury, Internal Revenue Service (N1–58–10–10, 2 items, 2 temporary items). Outputs and documentation of an electronic information system used for monitoring compliance.

25. Department of Veterans Affairs, Veterans Health Administration (N1–15–08–1, 2 items, 2 temporary items). Case files relating to complaints of violations of the Privacy Act and the Health Insurance Portability and Accountability Act and a related electronic tracking system.

26. Administrative Office of the U.S. Courts, U.S. District Court (N1–21–10–2, 7 items, 1 temporary item). All post-1969 non-trial civil cases relating to litigation concerning contracts, torts, personal property, forfeiture, social security and other routine matters. Also included are post-1969 non-trial civil cases that do not progress to the "issue joined" stage that relate to such matters as prisoner petitions, stockholders suits, foreclosures, torts to land, medical malpractice, product liability, asbestos liability, civil rights—employment, civil rights—housing/accommodations, civil rights—welfare, civil rights—Americans with Disabilities Act, agriculture—forfeiture, agricultural acts, and Freedom of Information Act. Proposed for permanent retention are all cases that go to trial and all non-trial cases predating 1969. Also proposed for permanent retention are post-1969 non-trial class action suits and multi-district litigation and post-1969 non-trial cases relating to such matters as Federal employee liability, land condemnation, airplane personal injury, airplane product liability, truth in lending, state reapportionment, antitrust, banks and banking, civil rights, voting civil rights, deportation, death penalty prisoner petitions, patents, selective service, black lung litigation, environmental matters, and the constitutionality of state statutes. Also proposed as permanent are post-1969 non-trial civil cases that progress to or pass the "issue joined" stage before closing and relate to such matters as prisoner petitions, stockholders suits, foreclosures, torts to land, medical malpractice, product liability, asbestos liability, civil rights—employment, civil rights—housing/accommodations, civil rights—welfare, civil rights—Americans with Disabilities Act, agriculture—forfeiture, agricultural acts, and Freedom of Information Act. District of Columbia cases relating to domestic relations, adoption, mental incompetence, and probate are also proposed for permanent retention.

27. Export-Import Bank of the United States, Agency-wide (N1–275–10–2, 1 item, 1 temporary item). Master files of an electronic information system used to track financial instruments with renegotiated terms or payment schedules.

28. Export-Import Bank of the United States, Agency-wide (N1–275–10–4, 2 items, 2 temporary items). Master files of an electronic information system used to monitor and evaluate the risk associated with Bank financial products.

Dated: August 6, 2010.

Michael J. Kurtz,

Assistant Archivist for Records Services—Washington, DC.

[FR Doc. 2010–20043 Filed 8–11–10; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

National Science Board; Sunshine Act Meetings; Notice

The National Science Board's Committee on Audit & Oversight, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of a meeting for the transaction of National Science Board business and other matters specified, as follows:

DATE AND TIME: August 20, 2010 at 2 p.m. to 2:30 p.m.

SUBJECT MATTER: Discussion and Recommendation of the OIG Future year budget.

STATUS: Closed.

LOCATION: This meeting will be held at National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

UPDATES & POINT OF CONTACT: Please refer to the National Science Board website *http://www.nsf.gov/nsb* for additional information and schedule updates (time, place, subject matter or status of meeting) may be found at *http://www.nsf.gov/nsb/notices/.* Point of contact for this meeting is: Kim Silverman, National Science Board Office, 4201Wilson Blvd., Arlington, VA 22230. *Telephone:* (703) 292–7000.

Daniel A. Lauretano,

Counsel to the National Science Board.

[FR Doc. 2010–19946 Filed 8–10–10; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2010–0276]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and

Budget (OMB) and solicitation of public comment.

SUMMARY: The NRC invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR part 35 Medical Use of Byproduct Material.

2. *Current OMB approval number:* 3150–0010.

3. *How often the collection is required:* Reports of medical events, doses to an embryo/fetus or nursing child, or leaking sources are reportable on occurrence. A certifying entity desiring to be recognized by the NRC must submit a one-time request for recognition and revise the information on occurrence.

4. *Who is required or asked to report:* Physicians and medical institutions holding an NRC license authorizing the administration of byproduct material or radiation therefrom to humans for medical use.

5. *The number of annual respondents:* 8,610 (1,148 for NRC Licenses and 7,462 for Agreement States).

6. *The number of hours needed annually to complete the requirement or request:* 1,173,785 hours (156,538 for NRC Licenses and 1,017, 247 for Agreement States).

7. *Abstract:* 10 CFR Part 35, "Medical Use of Byproduct Material," contains NRC's requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The 10 CFR part 35 contains mandatory requirements that apply to NRC licensees authorized to administer byproduct material or radiation therefrom to humans for medical use.

The information in the required reports and records is used by the NRC to ensure that public health and safety is protected, and that the possession and use of byproduct material is in compliance with the license and regulatory requirements.

Submit, by October 12, 2010, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, Maryland 20852. OMB clearance requests are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. 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. Comments submitted should reference Docket No. NRC–2010–0276. You may submit your comments by any of the following methods. Electronic comments: Go to *http://www.regulations.gov* and search for Docket No. NRC–2010–0276. Mail comments to NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at 301–415–6258, or by e-mail to *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland on August 5, 2010.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2010–19923 Filed 8–11–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2010–0278]

NUREG–1946, "Inservice Testing of Pumps and Valves, and Inservice Examination and Testing of Dynamic Restraints (Snubbers) at Nuclear Power Plants, Draft Report for Comment"

AGENCY: Nuclear Regulatory Commission.

ACTION: Announcement of issuance for public comment, availability.

SUMMARY: The Nuclear Regulatory Commission has issued for public comment a document entitled: NUREG–1946, "Inservice Testing of Pumps and Valves, and Inservice Examination and Testing of Dynamic Restraints (Snubbers) at Nuclear Power Plants, Draft Report for Comment."

DATES: Please submit comments by January 20, 2011. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID NRC–2010–0278 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, 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.

Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2010–0278. Address questions about NRC dockets to Carol Gallagher 301–492–3668; e-mail *Carol.Gallagher@nrc.gov.*

Mail comments to: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: TWB–05–

B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by fax 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, Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room 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 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 NUREG–1946, "Inservice Testing of Pumps and Valves, and Inservice Examination and Testing of Dynamic Restraints (Snubbers) at Nuclear Power Plants, Draft Report for Comment" is available electronically under ADAMS Accession Number ML102100236.

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–2010–0278.

FOR FURTHER INFORMATION CONTACT: Gurjendra S. Bedi, Division of Component Integrity, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone: 301–415–1393, e-mail: *Gurjendra.Bedi@nrc.gov.*

SUPPLEMENTARY INFORMATION: NUREG–1946, "Inservice Testing of Pumps and Valves, and Inservice Examination and Testing of Dynamic Restraints (Snubbers) at Nuclear Power Plants, Draft Report for Comment" provides updated information on applicable regulations for testing of pumps and valves. The information in NUREG–1482, "Guidelines for Inservice Testing at Nuclear Plants," Revision 0, issued April 1995, and Revision 1, issued January 2005, has described these topics in the past. This NUREG report replaces Revision 0 and Revision 1 of NUREG–1482, and is applicable, unless stated otherwise, to all editions and addenda of the American Society of Mechanical Engineers Code of Operation and Maintenance of Nuclear Power Plants (OM Code), which Title 10 of the Code of Federal Regulations (10 CFR) 50.55a(b) incorporates by reference. NUREG–1946 also includes information related to inservice examination and testing of dynamic restraints (snubbers). In addition, the NUREG discusses other inservice test program topics such as the NRC process for review of the OM Code, conditions on the use of the OM Code, and interpretations of the OM Code.

Dated at Rockville, Maryland, August 2, 2010.

For the Nuclear Regulatory Commission.

Anthony C. McMurtray,

Chief, Component Performance and Testing Branch, Division of Component Integrity, Office of Nuclear Reactor Regulation.

[FR Doc. 2010–19945 Filed 8–11–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–034 and 52–035; NRC–2010–0277]

Notice of Availability of the Draft Environmental Impact Statement for the Combined Licenses for Comanche Peak Nuclear Power Plant; Units 3 and 4

Notice is hereby given that the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Army Corps of Engineers (Corps), Fort Worth District, have published NUREG–1943, "Environmental Impact Statement for the Combined Licenses (COLs) for Comanche Peak Nuclear Power Plant Units 3 and 4: Draft Report for Comment." The site is comprised of approximately 7,950 acres in Hood and Somervell Counties, Texas on the Squaw Creek Reservoir approximately 5.2 miles (mi) north of Glen Rose, Texas. Luminant Generation Company LLC (Luminant) submitted its application, including the Environmental Report (ER), to the NRC by letter dated September 19, 2008, pursuant to Title 10 of the Code of Federal Regulations (10 CFR) part 52. A notice of acceptance for docketing of the application for the COLs was published in the **Federal Register** on December 10, 2008 (73 FR 75141). A notice of intent to prepare a draft environmental impact statement (DEIS) and to conduct the scoping process was published in the **Federal Register** on December 18, 2008 (73 FR 77076). A COL is an authorization to construct and (with specified conditions) operate a nuclear power plant at a specific site, in accordance with established laws and regulations.

The purpose of this notice is to inform the public that NUREG–1943, "Environmental Impact Statement for the Combined Licenses (COLs) for Comanche Peak Nuclear Power Plant Units 3 and 4: Draft Report for Comment," is available for public inspection. The DEIS can be accessed online at *http://www.nrc.gov/reactors/new-reactors/col/comanche-peak.html* in the U.S. NRC Public Document Room (PDR) located at One White Flint North, 11555 Rockville Pike (first floor), Public File Area O1–F21, Rockville, Maryland 20852, or from the NRC Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html.* The accession numbers for the DEIS are ML102170030 and ML102170036. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the PDR reference staff at 1–800–397–4209, or 301–415–4737 or by e-mail to *pdr.resource@nrc.gov.* In addition, the Somervell County Library, located at 108 Allen Drive, Glen Rose, Texas 76043 and the Hood County Library, located at 222 North Travis Street, Granbury, Texas 76048 have agreed to maintain a copy of the DEIS and make it available for public inspection. Interested parties may submit comments on the DEIS for consideration by the NRC staff. Comments may be accompanied by additional relevant information or supporting data. This draft report is being issued with a 75-day comment period. The comment period begins on the date that the U.S. Environmental Protection Agency publishes a Notice of Filing in the **Federal Register** which is expected to be August 13, 2010. Such notices are published every Friday. The notice will identify the end date of the comment period. Members of the public may submit comments on the DEIS by e-mail, mail, or during the public meeting on the DEIS. Comments submitted via e-mail should be sent to *Comanche.COLEIS@nrc.gov.* Electronic submissions should be sent no later than the end date of the comment period. Written comments on the DEIS should be mailed to the Chief, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration, Mailstop TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 or by fax at 301–492–3446 and should cite the publication

date and page number of this **Federal Register** Notice. 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. To be considered, written comments should be postmarked by the end date of the comment period. Any comments of any Federal, State, and local agencies, Indian tribes or other interested persons will be made available for public inspection when received.

The NRC and Corps staff will hold two public meetings to present an overview of the DEIS and to accept public comments on the document on Tuesday, September 21, 2010, at the Glen Rose Expo Center, 202 Bo Gibbs Blvd., Glen Rose, Texas 76043. The first meeting will convene at 1 p.m. and will continue until 4:00 p.m. as necessary. The second meeting will convene at 7 p.m., with a repeat of the overview portions of the first meeting, and will continue until 10 p.m., as necessary. The meetings will be transcribed and will include a presentation of the contents of the DEIS and the opportunity for interested government agencies, organizations, and individuals to provide comments on the draft report. To be considered, comments must be provided during the transcribed public meeting either orally or in writing. Additionally, the NRC and Corps staff will host informal discussions one hour before the start of each meeting during which members of the public may meet and talk with NRC and Corps staff members on an informal basis. No formal comments on the DEIS will be accepted during these informal discussions.

Persons may pre-register to attend or present oral comments at the meeting by contacting Mr. Michael Willingham by telephone at 1–800–368–5642, extension 3924 or by e-mail to *Comanche.COLEIS@nrc.gov* no later than October 27, 2010. Members of the public may also register to speak at the meeting within 15 minutes of the start of the meeting. Individual oral comments may be limited by the time available depending on the number of persons who register. Members of the public who have not registered may also have an opportunity to speak, if time permits. Mr. Willingham will need to be contacted no later than September 14, 2010, if special equipment or accommodations are needed to attend or present information at the public meeting, so that the NRC staff can determine whether the request can be accommodated.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Willingham, Environmental Projects Branch 1, U.S. Nuclear Regulatory Commission, Mail Stop T7–E30, Washington, DC 20555–0001. Mr. Willingham may also be contacted at the aforementioned telephone number or e-mail address.

Dated at Rockville, Maryland, August 6, 2010.

For the Nuclear Regulatory Commission.

Scott Flanders,

Director, Division of Site and Environmental Reviews, Office of New Reactors.

[FR Doc. 2010–19956 Filed 8–11–10; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 29378; File No. 813–00375]

The Blackstone Group, LP; Notice of Application

August 5, 2010.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of application for an order under sections 6(b) and 6(e) of the Investment Company Act of 1940 (the "Act") granting an exemption from all provisions of the Act, except section 9, and sections 36 through 53, and the rules and regulations under the Act. With respect to sections 17 and 30 of the Act, and the rules and regulations thereunder, and rule 38a–1 under the Act, the exemption is limited as set forth in the application.

SUMMARY: *Summary of Application:* Applicant requests an order to exempt certain future partnerships, limited liability companies and other investment vehicles that it and/or its affiliates sponsor ("Partnerships") formed for the benefit of eligible employees of The Blackstone Group, LP and its affiliates from certain provisions of the Act. Each Partnership will be an "employees' securities company" within the meaning of section 2(a)(13) of the Act.

APPLICANT: The Blackstone Group LP ("Company").

DATES: *Filing Dates:* The application was filed on October 16, 2008 and amended on May 14, 2009 and May 27, 2010. Applicant has 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 applicant 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 30, 2010 and should be accompanied by proof of service on applicant, 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; Applicant, The Blackstone Group LP, 345 Park Avenue, New York, NY 10154.

FOR FURTHER INFORMATION CONTACT: Laura L. Solomon, Senior Counsel, at (202) 551–6915, or Julia Kim Gilmer, 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.

Applicant's Representations

1. The Company is a Delaware limited partnership. The Company and its "Affiliates," as defined in rule 12b–2 under the Securities Exchange Act of 1934 (the "Exchange Act"), are referred to collectively as "Blackstone." Blackstone is a global alternative asset manager and provider of financial advisory services. The alternative asset management businesses include the management of corporate private equity funds, real estate funds, funds of hedge

funds, credit-oriented funds, collateralized loan obligation vehicles, and publicly-traded closed-end mutual funds. Blackstone also provides various financial advisory services, including corporate and mergers and acquisitions advisory, restructuring and reorganization advisory and fund placement services.

2. Each of the Partnerships will be a limited partnership, limited liability company, corporation, business trust or other entity organized under the laws of the state of Delaware or any other U.S. or non-U.S. jurisdiction. Each Partnership will be identical in all material respects (other than investment objectives and strategies, form of organization and related structural and operative provisions contained in the constitutive documents of such Partnerships). The Partnerships will be formed as an "employees' securities company" within the meaning of section 2(a)(13) of the Act and will operate as a diversified or non-diversified, closed-end management investment company, provided that the governing documents of a Partnership may provide for periodic subscriptions and redemptions.[1] The Partnerships will be established primarily for the benefit of Eligible Employees (defined below) of the Company or of any Affiliate of the Company as part of a program designed to create capital building opportunities that are competitive with those at other financial services firms and to facilitate the recruitment of high caliber professionals.

3. The general partner of each Partnership will be an Affiliate of the Company ("General Partner"). Any partner, member of, or other investor in a Partnership (collectively, the "Partners") other than a General Partner is a "Limited Partner" or "Participant." The General Partner of each Partnership will manage, operate, and control that Partnership. The General Partner will be authorized to delegate investment management responsibility to a Blackstone entity or a group of Blackstone employees (the "Investment Manager"). The ultimate responsibility for the Partnerships' investments delegated to an Investment Manager will remain with the General Partner. Any Blackstone entity that is delegated the responsibility of making investment decisions for a Partnership will be registered as an investment adviser under the Investment Advisers Act of 1940 (the "Advisers Act") (or, in the case of a group of Blackstone employees, be reflected in the Form ADV of the applicable Blackstone entity) if required under applicable law.

4. The General Partner, Blackstone or any employee of the General Partner or Blackstone may be entitled to receive a performance-based fee (such as a "carried interest") based on the gains and losses of the investment program or of the Partnership's investment portfolio.[2] All Partnership investments are referred to herein collectively as "Portfolio Investments."

5. Ownership interests in the Partnerships ("Interests") will be offered without registration in reliance on section 4(2) of the Securities Act of 1933 (the "Securities Act"), or Regulation D under the Securities Act, and will be sold only to "Eligible Employees" and "Qualified Participants," in each case as defined below, or to Blackstone entities.[3] Prior to offering Interests to an Eligible Employee, the General Partner must reasonably believe that the Eligible Employee will be a sophisticated investor capable of understanding and evaluating the risks of participating in the Partnership without the benefit of regulatory safeguards.

6. An "Eligible Employee" is (a) an individual who is a current or former employee, officer, director, or current "Consultant" of Blackstone and, except for certain individuals who manage the day-to-day affairs of the Partnership in question ("Managing Employees")[4] and a limited number of other employees of Blackstone[5] (collectively, "Non-Accredited Investors"), meets the standards of an accredited investor under rule 501(a)(5) or 501(a)(6) of Regulation D under the Securities Act, or (b) an entity that is a current "Consultant" of Blackstone and meets the standards of an accredited investor under rule 501(a) of Regulation D.[6] A Partnership may not have more than 35 Non-Accredited Investors.

7. A "Qualified Participant," is an individual or entity (a) that is an Eligible Family Member or Qualified Investment Vehicle (in each case as defined below) of an Eligible Employee, and (b) purchasing an Interest from a Partnership (except as discussed below) and comes within one of the categories of an "accredited investor" under rule 501(a) of Regulation D. An "Eligible Family Member" is a spouse, parent, child, spouse of child, brother, sister, or grandchild of an Eligible Employee, including step and adoptive relationships. A "Qualified Investment Vehicle" is (a) a trust of which the trustee, grantor and/or beneficiary is an

[1] Applicant also may implement a pretax plan arrangement ("Pretax Plan"). In this case, no investment vehicle will be formed with respect to such Pretax Plan. Pursuant to a Pretax Plan, Blackstone will enter into arrangements with certain Eligible Employees, as defined below, of Blackstone, which will generally provide that (a) an Eligible Employee will defer a portion of his or her compensation payable by Blackstone, (b) such deferred compensation will be treated as having been notionally invested in investments designated for these purposes pursuant to the specific compensation plan, and (c) an Eligible Employee will be entitled to receive cash, securities or other property at the times and in the amounts set forth in the specific compensation plan, where the aggregate amount received by such Eligible Employee would be based upon the investment performance of the investments designated for these purposes pursuant to such compensation plan. The Pretax Plan will not actually purchase or sell any securities. Blackstone expects to offer, through Pretax Plans, economic benefits comparable to what would have been offered in an arrangement where an investment vehicle is formed. For purposes of the application, a Partnership will be deemed to be formed with respect to each Pretax Plan and each reference in the application to "Partnership," "capital contribution," "General Partner," "Limited Partner," "loans," and "Interest" will be deemed to refer to the Pretax Plan, the notional capital contribution to the Pretax Plan, Blackstone, a participant of the Pretax Plan, notional loans, and participation rights in the Pretax Plan, respectively.

[2] A "carried interest" is an allocation to the General Partner, a Limited Partner, or an Investment Manager based on net gains in addition to the amount allocable to such entity in proportion to its invested capital. A General Partner, Limited Partner or Investment Manager that is registered as an investment adviser under the Advisers Act may charge a carried interest only if permitted by rule 205–3 under the Advisers Act. Any carried interest paid to a General Partner, Limited Partner or Investment Manager that is not registered under the Advisers Act may be paid only if permitted by rule 205–3 as if such General Partner, Limited Partner or Investment Manager were registered under the Advisers Act.

[3] If applicant implements a Pretax Plan, participation rights in such Pretax Plan will only be offered to Eligible Employees who are current employees or Consultants, as defined below, of Blackstone.

[4] A Managing Employee may invest in a Partnership if he or she meets the definition of "knowledgeable employee" in rule 3c–5(a)(4) under the Act with the Partnership treated as though it were a "Covered Company" for purposes of the rule.

[5] Such employees must meet the sophistication requirements set forth in rule 506(b)(2)(ii) of Regulation D under the Securities Act and may be permitted to invest his or her own funds in the Partnership if, at the time of the employee's investment in a Partnership, he or she (a) has a graduate degree in business, law or accounting, (b) has a minimum of five years of consulting, investment banking or similar business experience, and (c) has had reportable income from all sources of at least $100,000 in each of the two most recent years and a reasonable expectation of income from all sources of at least $140,000 in each year in which such person will be committed to make investments in a Partnership. In addition, such an employee will not be permitted to invest in any year more than 10% of his or her income from all sources for the immediately preceding year in the aggregate in such Partnership and in all other Partnerships in which he or she has previously invested.

[6] A "Consultant" is a person or entity whom Blackstone has engaged on retainer to provide services and professional expertise on an ongoing basis as a regular consultant or as a business or legal adviser and who shares a community of interest with Blackstone and Blackstone employees.

Eligible Employee, (b) a partnership, corporation or other entity controlled by an Eligible Employee, or (c) a trust or other entity established solely for the benefit of Eligible Family Members of an Eligible Employee.[7] A Qualified Investment Vehicle that is not an accredited investor will be counted in accordance with Regulation D toward the 35 person limit for Non-Accredited Investors.

8. The terms of a Partnership will be fully disclosed to each Eligible Employee and, if applicable, to a Qualified Participant of the Eligible Employee, in the offering materials, including a copy of the partnership agreement or other organizational document (the "Partnership Agreement"), which will be furnished prior to the time such person or entity is admitted to the Partnership. The General Partner of each Partnership will send its Partners audited financial statements within 120 days after the end of its fiscal year of the Partnership or as soon as practicable thereafter, except for any Partnership that was formed to make a single portfolio investment (in which case audited financial statements will be prepared for either the Partnership or the entity that is the single portfolio investment).[8] In addition, as soon as practicable after the end of each tax year of a Partnership, each Partner will receive a report showing the Partner's share of income, credits, deductions, and other tax items.

9. Interests in a Partnership will be non-transferable except with the prior written consent of the General Partner.[9] No person or entity will be admitted into a Partnership unless such person or entity is an Eligible Employee, a Qualified Participant of an Eligible Employee, or a Blackstone entity. No sales load will be charged in connection with the sale of Interests.

10. An Eligible Employee's interest in a Partnership may be subject to repurchase or cancellation in certain circumstances as described in the offering documents related to the relevant Partnership. Upon repurchase or cancellation, the General Partner will at a minimum pay to the Eligible Employee the lesser of (a) the amount actually paid by the Eligible Employee to acquire the Interest plus interest less prior distributions, and (b) the fair market value of the Interest as determined at the time of repurchase or cancellation by the General Partner. The terms of any repurchase or cancellation will apply equally to any Qualified Participant of an Eligible Employee.

11. Subject to the terms of the applicable Partnership Agreement, a Partnership will be permitted to enter into transactions involving (a) a Blackstone entity, (b) a portfolio company, (c) any Partner or person or entity affiliated with a Partner, (d) an investment fund or separate account that is organized for the benefit of investors who are not affiliated with Blackstone and over which a Blackstone entity will exercise investment discretion or which is sponsored by a Blackstone entity ("Blackstone Third Party Fund"), or (e) any person or entity who is not affiliated with Blackstone and is a partner or other investor in a Blackstone Third Party Fund or a "Third Party Sponsored Fund"[10] (each a "Third Party Investor"). Prior to entering into any of these transactions, the General Partner or board of directors (or similar body) of the General Partner or any committee serving similar functions of the General Partner ("Board") must determine that the terms are fair to the Partners.

12. A Blackstone entity (including the General Partner) acting as agent or broker may receive placement fees, advisory fees, or other compensation from a Partnership or a portfolio company in connection with a Partnership's purchase or sale of securities, provided that such placement fees, advisory fees, or other compensation can be deemed to be "usual and customary." Such fees or other compensation will be deemed "usual and customary" only if (a) the Partnership is purchasing or selling securities (directly or indirectly) alongside other unaffiliated third parties, including Blackstone Third Party Funds or Third Party Investors, who are similarly purchasing or selling securities, (b) the fees or other compensation being charged to the Partnership (directly or indirectly) are also being charged to the unaffiliated third parties, including Blackstone Third Party Funds or Third Party Investors (directly or indirectly), and (c) the amount of securities being purchased or sold by the Partnership does not exceed 50% of the total amount of securities being purchased or sold by the Partnership and the unaffiliated third parties, including Blackstone Third Party Funds and Third Party Investors. A Blackstone entity, including the General Partner, also may be compensated for services to entities in which the Partnerships invest and to entities that are competitors of these entities, or from other unaffiliated persons or entities.

13. The investment objective of each Partnership will be set forth in the offering documents relating to the specific Partnership. A Partnership may invest directly or through investment pools (including private funds relying on sections 3(c)(1) and 3(c)(7) of the Act)[11] and registered investment companies sponsored or managed by Blackstone or by third parties. A Partnership will not acquire any security issued by a registered investment company if immediately after the acquisition the Partnership will own more than 3% of the outstanding voting stock of the registered investment company.

14. The Partnerships may borrow from a General Partner or a Blackstone entity. The interest rate on such loans will be no less favorable to the Partnerships than the rate that could be obtained on an arm's length basis. A Partnership will not borrow from any person if the borrowing would cause any person not named in section 2(a)(13) of the Act to own outstanding securities of the Partnership (other than short-term paper). Any indebtedness of a Partnership will be non-recourse to

[7] The inclusion of partnerships, corporations, or other entities controlled by an Eligible Employee in the definition of "Qualified Investment Vehicle" is intended to enable Eligible Employees to make investments in the Partnerships through personal investment vehicles over which they exercise investment discretion or other investment vehicles the management or affairs of which they otherwise control. In the case of a partnership, corporation, or other entity controlled by a Consultant entity, individual participants will be limited to senior level employees, members, or partners of the Consultant who will be required to qualify as an "accredited investor" under rule 501(a)(5) or 501(a)(6) of Regulation D and who will have access to the directors and officers of the General Partner.

[8] If applicant implements a Pretax Plan, Eligible Employees participating in such Pretax Plan will be furnished with a copy of the Pretax Plan, which will set forth at a minimum the same terms of the proposed investment program as those that would have been set forth in a Partnership Agreement for a Partnership. Blackstone will prepare an audited informational statement with respect to the investments deemed to be made by such Pretax Plan, including, with respect to each investment, the name of the portfolio company and the amount deemed invested by such Pretax Plan in the portfolio company. Blackstone will send each participant of such Pretax Plan a separate statement based on the audited informational statement within 120 days after the end of the fiscal year of Blackstone or as soon as practicable thereafter.

[9] If applicant implements a Pretax Plan, an Eligible Employee's participation rights in such Pretax Plan may not be transferred, other than to a Qualified Participant in the event of the Eligible Employee's death.

[10] "Third Party Sponsored Fund" is an investment fund or pooled investment vehicle for which entities or persons unaffiliated with Blackstone are the sponsors or investment advisers.

[11] Applicant is not requesting any exemption from any provision of the Act or any rule thereunder that may govern a Partnership's eligibility to invest in a Portfolio Investment relying on section 3(c)(1) or 3(c)(7) of the Act or the Portfolio Investment's status under the Act.

the Limited Partners of the Partnership, except indebtedness incurred specifically on behalf of a Limited Partner where such Limited Partner has agreed to guarantee the loan or act as co-obligor on the loan.

Applicant's Legal Analysis

1. Section 6(b) of the Act provides, in part, that the Commission will exempt employees' securities companies from the provisions of the Act to the extent that the exemption is consistent with the protection of investors. Section 6(b) provides that the Commission will consider, in determining the provisions of the Act from which the company should be exempt, the company's form of organization and capital structure, the persons owning and controlling its securities, the price of the company's securities and the amount of any sales load, how the company's funds are invested, and the relationship between the company and the issuers of the securities in which it invests. Section 2(a)(13) defines an employees' securities company, in relevant part, as any investment company all of whose securities (other than short-term paper) are beneficially owned (a) by current or former employees, or persons on retainer, of one or more affiliated employers, (b) by immediate family members of such persons, or (c) by such employer or employers together with any of the persons in (a) or (b).

2. Section 7 of the Act generally prohibits investment companies that are not registered under section 8 of the Act from selling or redeeming their securities. Section 6(e) of the Act provides that, in connection with any order exempting an investment company from any provision of section 7, certain provisions of the Act, as specified by the Commission, will be applicable to the company and other persons dealing with the company as though the company were registered under the Act. Applicant requests an order under sections 6(b) and 6(e) of the Act exempting applicant and any Partnerships from all provisions of the Act, except section 9 and sections 36 through 53 of the Act, and the rules and regulations under the Act. With respect to sections 17 and 30 of the Act, and the rules and regulations thereunder, and rule 38a–1 under the Act, the exemption is limited as set forth in the application.

3. Section 17(a) generally prohibits any affiliated person of a registered investment company, or any affiliated person of an affiliated person, acting as principal, from knowingly selling or purchasing any security or other property to or from the company. Applicant requests an exemption from section 17(a) to permit: (a) a Blackstone entity or a Blackstone Third Party Fund (or any affiliated person of the Blackstone Third Party Fund), acting as principal, to engage in any transaction directly or indirectly with any Partnership or any company controlled by the Partnership; (b) any Partnership to invest in or engage in any transaction with any Blackstone entity or Blackstone Third Party Fund, acting as principal, (i) in which the Partnership, any company controlled by the Partnership, or any Blackstone entity or Blackstone Third Party Fund has invested or will invest, or (ii) with which the Partnership, any company controlled by the Partnership, or any Blackstone entity or Blackstone Third Party Fund is or will become affiliated; and (c) any Third Party Investor, acting as principal, to engage in any transaction directly or indirectly with a Partnership or any company controlled by the Partnership.

4. Applicant states that an exemption from section 17(a) is consistent with the protection of investors and is necessary to promote the purpose of each Partnership. Applicant states that the Participants in each Partnership will be fully informed of the possible extent of the Partnership's dealings with Blackstone. Applicant also states that, as professionals with experience in financial services businesses, Participants in each Partnership will be able to understand and evaluate the attendant risks. Applicant asserts that the community of interest among the Participants in each Partnership and Blackstone will provide the best insurance against any risk of abuse.

5. Section 17(d) of the Act and rule 17d–1 under the Act prohibit any affiliated person of a registered investment company, or any affiliated person of such person, acting as principal, from participating in any joint arrangement with the company unless authorized by the Commission. Applicant requests relief to permit affiliated persons of each Partnership, or affiliated persons of any of these persons, to participate in or effect any transaction in connection with, any joint enterprise or other joint arrangement or profit sharing plan in which the Partnership or a company controlled by the Partnership is a participant.

6. Applicant asserts that compliance with section 17(d) would cause the Partnerships to forego investment opportunities simply because a Participant or other affiliated person of the Partnerships (or any affiliate of the affiliated person) made or is concurrently making a similar investment. Applicant also states that because certain attractive investment opportunities often require that each participant make available funds in an amount substantially greater than that available to one Partnership alone, there may be attractive opportunities that a Partnership may be unable to take advantage of except by co-investing with other persons, including affiliated persons. Applicant notes that each Partnership will primarily be organized for the benefit of the employee Participants, as an incentive for them to remain with Blackstone and for the generation and maintenance of goodwill. Applicant asserts that the flexibility to structure co-investments and joint investments will not involve abuses of the type section 17(d) and rule 17d–1 were designed to prevent.

7. Co-investments with a Blackstone Third Party Fund, or by a Blackstone entity pursuant to a contractual obligation to a Blackstone Third Party Fund, will not be subject to condition 3 below. Applicant notes that it is common for a Blackstone Third Party Fund to require that Blackstone invest its own capital in Blackstone Third Party Fund investments, and that Blackstone investments be subject to substantially the same terms as those applicable to the Blackstone Third Party Fund. Applicant believes it is important that the interests of the Blackstone Third Party Fund take priority over the interests of the Partnerships, and that the Blackstone Third Party Fund not be burdened or otherwise affected by activities of the Partnerships. In addition, applicant asserts that the relationship of a Partnership to a Blackstone Third Party Fund is fundamentally different from a Partnership's relationship to Blackstone. Applicant contends that the focus of, and the rationale for, the protections contained in the requested relief are to protect the Partnerships from any overreaching by Blackstone in the employer/employee context, whereas the same concerns are not present with respect to the Partnerships and a Blackstone Third Party Fund.

8. Section 17(e) of the Act and rule 17e–1 under the Act limit the compensation an affiliated person may receive when acting as agent or broker for a registered investment company. Applicant requests an exemption from section 17(e) to permit a Blackstone entity (including the General Partner) that acts as an agent or broker to receive placement fees, advisory fees, or other compensation from a Partnership in connection with the purchase or sale by the Partnership of securities, provided that the fees or other compensation can

be deemed "usual and customary." Applicant states that for the purposes of the application, fees or other compensation will be deemed "usual and customary" only if (a) the Partnership is purchasing or selling securities alongside other unaffiliated third parties, including Blackstone Third Party Funds or Third Party Investors, who are similarly purchasing or selling securities, (b) the fees or other compensation being charged to the Partnership are also being charged to the unaffiliated third parties, including Blackstone Third Party Funds and Third Party Investors, and (c) the amount of securities being purchased or sold by the Partnership does not exceed 50% of the total amount of securities being purchased or sold by the Partnership and the unaffiliated third parties, including Blackstone Third Party Funds or Third Party Investors. Applicant asserts that, because Blackstone does not wish it to appear as if it is favoring the Partnerships, compliance with section 17(e) would prevent a Partnership from participating in transactions where the Partnership is being charged lower fees than unaffiliated third parties. Applicant asserts that the fees or other compensation paid by a Partnership to a Blackstone entity will be the same as those negotiated at arm's length with unaffiliated third parties.

9. Rule 17e–1(b) under the Act requires that a majority of directors who are not "interested persons" (as defined in section 2(a)(19) of the Act) take actions and make approvals regarding commissions, fees, or other remuneration. Rule 17e–1(c) under the Act requires each Partnership to comply with the fund governance standards defined in rule 0–1(a)(7) under the Act. Applicant requests an exemption from rule 17e–1 to the extent necessary to permit each Partnership to comply with the rule without having a majority of the Board who are not interested persons take actions and make determinations as set forth in paragraph (b) of the rule, and without having to satisfy the standards set forth in paragraph (c) of the rule. Applicant states that because all the Board members will be affiliated persons, without the relief requested, a Partnership could not comply with rule 17e–1. Applicant states that each Partnership will comply with rule 17e–1 by having a majority of the Board members take actions and make approvals as are set forth in rule 17e–1. Applicant states that each Partnership will comply with all other requirements of rule 17e–1.

10. Section 17(f) of the Act designates the entities that may act as investment company custodians, and rule 17f–1 under the Act imposes certain requirements when the custodian is a member of a national securities exchange. Applicant requests an exemption from section 17(f) and rule 17f–1 to permit a Blackstone entity to act as custodian of Partnership assets without a written contract. Applicant also requests an exemption from the rule 17f–1(b)(4) requirement that an independent accountant periodically verify the assets held by the custodian. Applicant states that, because of the community of interest of all the parties involved and the existing requirement for an independent audit, compliance with these requirements would be unnecessary. Each Partnership will otherwise comply with all the provisions of rule 17f–1.

11. Applicant also requests an exemption from rule 17f–2 to permit the following exceptions from the requirements of rule 17f–2: (a) A Partnership's investments may be kept in the locked files of the General Partner (or a Blackstone entity) for purposes of paragraph (b) of the rule; (b) for purposes of paragraph (d) of the rule, (i) employees of the General Partner (or a Blackstone entity) will be deemed to be employees of the Partnerships, (ii) officers or managers of the General Partner of a Partnership (or a Blackstone entity) will be deemed to be officers of the Partnership, and (iii) the Board will be deemed to be the board of directors of the Partnership and (c) in place of the verification procedure under paragraph (f) of the rule, verification will be effected quarterly by two employees of the General Partner (or a Blackstone entity). Applicant expects that some of the Partnerships' investments will be evidenced only by partnership agreements, participation agreements or similar documents, rather than by negotiable certificates that could be misappropriated. Applicant asserts that these instruments are most suitably kept in the files of the General Partner (or a Blackstone entity), where they can be referred to as necessary.

12. Section 17(g) of the Act and rule 17g–1 under the Act generally require the bonding of officers and employees of a registered investment company who have access to its securities or funds. Rule 17g–1 requires that a majority of directors who are not interested persons take certain actions and give certain approvals relating to fidelity bonding. Applicant requests exemptive relief to permit the Board, regardless of whether it is (or each of its members are) deemed interested persons, to take actions and make determinations set forth in the rule. Applicant states that, because the General Partner will be affiliated with the Partnership, a Partnership could not comply with rule 17g–1 without the requested relief. Applicant also states that each Partnership will comply with all other requirements of rule 17g–1, except that the Partnerships request an exemption from the requirements of paragraphs (g) and (h) or rule 17g–1 relating to the filing of copies of fidelity bonds and related information with the Commission and relating to this provision of notices to the board of directors, and an exemption from the requirements of paragraph (j)(3) of rule 17g–1 that the Partnerships comply with the fund governance standards defined in rule 0–1(a)(7).

13. Section 17(j) of the Act and paragraph (b) of rule 17j–1 under the Act make it unlawful for certain enumerated persons to engage in fraudulent or deceptive practices in connection with the purchase or sale of a security held or to be acquired by a registered investment company. Rule 17j–1 also requires that every registered investment company adopt a written code of ethics and that every access person of a registered investment company report personal securities transactions. Applicant requests an exemption from the provisions of rule 17j–1, except for the anti-fraud provisions of paragraph (b), because they are unnecessarily burdensome as applied to the Partnerships.

14. Applicant requests an exemption from the requirements in sections 30(a), 30(b), and 30(e) of the Act, and the rules under those sections, that registered investment companies prepare and file with the Commission and mail to their shareholders certain periodic reports and financial statements. Applicant contends that the forms prescribed by the Commission for periodic reports have little relevance to a Partnership and would entail administrative and legal costs that outweigh any benefit to the Participants. Applicant requests exemptive relief to the extent necessary to permit each Partnership to report annually to its Participants. Applicant also requests an exemption from section 30(h) of the Act to the extent necessary to exempt the General Partner of each Partnership, directors and officers of the General Partner and any other persons who may be deemed to be members of an advisory board of a Partnership from filing Forms 3, 4, and 5 under section 16(a) of the Exchange Act with respect to their ownership of Interests in the Partnership. Applicant asserts that, because there will be no trading market and the transfers of Interests will be severely restricted, these filings are unnecessary for the protection of

investors and burdensome to those required to make them.

15. Rule 38a–1 requires investment companies to adopt, implement and periodically review written policies reasonably designed to prevent violation of the Federal securities law and to appoint a chief compliance officer. Each Partnership will comply with rule 38a–1(a), (c) and (d), except that (a) because the Partnership does not have a board of directors, the board of directors or other governing body of the General Partner will fulfill the responsibilities assigned to the Partnership's board of directors under the rule, (b) since the board of directors or other governing body of the General Partner does not have any disinterested members, approval by a majority of the disinterested board members required by rule 38a–1 will not be obtained, and (c) since the board of directors or other governing body of the General Partner does not have any independent directors, the Partnerships will comply with the requirement in rule 38a–1(a)(4)(iv) that the chief compliance officer meet with the independent directors by having the chief compliance officer meet with the board of directors or other governing body of the General Partner as constituted.

Applicant's Conditions

Applicant agrees that any order granting the requested relief will be subject to the following conditions:

1. Each proposed transaction otherwise prohibited by section 17(a) or section 17(d) and rule 17d–1 to which a Partnership is a party (the "Section 17 Transactions") will be effected only if the Board determines that:

(a) The terms of the Section 17 Transaction, including the consideration to be paid or received, are fair and reasonable to the Partners of the participating Partnership and do not involve overreaching of such Partnership or its Partners on the part of any person concerned; and

(b) The Section 17 Transaction is consistent with the interests of the Partners of the participating Partnership, such Partnership's organizational documents and such Partnership's reports to its Partners.

In addition, the Board will record and will preserve a description of all Section 17 Transactions, the Board's findings and the information or materials upon which the Board's findings are based and the basis for the findings. All such records will be maintained for the life of the Partnership and at least six years thereafter, and will be subject to examination by the Commission and its staff. Each Partnership will preserve the accounts, books and other documents required to be maintained in an easily accessible place for the first two years.

2. The Board will adopt, and periodically review and update, procedures designed to ensure that reasonable inquiry is made, prior to the consummation of any Section 17 Transaction, with respect to the possible involvement in the transaction of any affiliated person or promoter of or principal underwriter for such Partnership, or any affiliated person of such a person, promoter or principal underwriter.

3. The General Partner will not make on behalf of a Partnership any investment in which a "Co-Investor" with respect to any Partnership (as defined below) has acquired or proposes to acquire the same class of securities of the same issuer, where the investment involves a joint enterprise or other joint arrangement within the meaning of rule 17d–1 in which such Partnership and the Co-Investor are participants, unless any such Co-Investor, prior to disposing of all or part of its investment, (a) gives such General Partner sufficient, but not less than one day's notice of its intent to dispose of its investment; and (b) refrains from disposing of its investment unless the participating Partnership holding such investment has the opportunity to dispose of its investment prior to or concurrently with, on the same terms as, and on a *pro rata* basis with the Co-Investor. The term "Co-Investor" with respect to any Partnership means any person who is: (a) An "affiliated person" (as defined in section 2(a)(3) of the Act) of such Partnership (other than a Blackstone Third Party Fund); (b) a Blackstone entity; (c) an officer, director or partner of a Blackstone entity; or (d) an entity (other than a Blackstone Third Party Fund) in which the Company or an Affiliate acts as a general partner or has a similar capacity to control the sale or other disposition of the entity's securities. The restrictions contained in this condition, however, shall not be deemed to limit or prevent the disposition of an investment by a Co-Investor: (a) To its direct or indirect wholly-owned subsidiary, to any company (a "Parent") of which such Co-Investor is a direct or indirect wholly-owned subsidiary, or to a direct or indirect wholly-owned subsidiary of its Parent; (b) to immediate family members of such Co-Investor, including step and adoptive relationships, or to a trust or other investment vehicle established for any such immediate family member; (c) when the investment is comprised of securities that are listed on any exchange registered as a national securities exchange under section 6 of the Exchange Act; (d) when the investment is comprised of securities that are NMS securities pursuant to section 11A(a)(2) of the Exchange Act and rule 600(a) of Regulation NMS thereunder; (e) when the investment is comprised of securities that are listed on or traded on any foreign securities exchange or board of trade that satisfies regulatory requirements under the law of the jurisdiction in which such foreign securities exchange or board of trade is organized similar to those that apply to a national securities exchange or a national market system for securities; or (f) when the investment is comprised of securities that are government securities as defined in section 2(a)(16) of the Act.

4. Each Partnership and its General Partner will maintain and preserve, for the life of such Partnership and at least six years thereafter, such accounts, books, and other documents as constitute the record forming the basis for the audited financial statements that are to be provided to the Participants in such Partnership, and each annual report of such Partnership required to be sent to such Participants, and agree that all such records will be subject to examination by the Commission and its staff. Each Partnership will preserve the accounts, books and other documents required to be maintained in an easily accessible place for the first two years.

5. The General Partner of each Partnership will send to each Participant in that Partnership, at any time during the fiscal year then ended, Partnership financial statements audited by such Partnership's independent accountants, except under certain circumstances in the case of a Partnership formed to make a single Portfolio Investment. In such cases, the Partnership may send unaudited financial statements, but each Participant will receive financial statements of the single Portfolio Investment audited by such entity's independent accountants. At the end of each fiscal year, the General Partner will make a valuation or have a valuation made of all of the assets of the Partnership as of such fiscal year end in a manner consistent with customary practice with respect to the valuation of assets of the kind held by the Partnership. In addition, within 120 days after the end of each fiscal year of each Partnership or as soon as practicable thereafter, the General Partner will send a report to each person who was a Participant at any time during the fiscal year then ended, setting forth such tax information as shall be necessary for the preparation by the Participant of his, her or its U.S.

Federal and State income tax returns and a report of the investment activities of the Partnership during that fiscal year.

6. If a Partnership makes purchases or sales from or to an entity affiliated with the Partnership by reason of an officer, director or employee of Blackstone (a) serving as an officer, director, general partner or investment adviser of the entity, or (b) having a 5% or more investment in the entity, such individual will not participate in the Partnership's determination of whether or not to effect the purchase or sale.

For the Commission, by the Division of Investment Management, under delegated authority.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–19854 Filed 8–11–10; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Appiant Technologies, Inc., Cobalis Corp., FutureLink Corp., STM Wireless, Inc., Supermail International, Inc. (n/k/a PBHG, Inc.), and Women First Healthcare, Inc.; Order of Suspension of Trading

August 10, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Appiant Technologies, Inc. because it has not filed any periodic reports since the period ended September 30, 2002.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Cobalis Corp. because it has not filed any periodic reports since the period ended December 31, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of FutureLink Corp. because it has not filed any periodic reports since the period ended March 31, 2001.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of STM Wireless, Inc. because it has not filed any periodic reports since the period ended September 30, 2002.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Supermail International, Inc. (n/k/a PBHG, Inc.) because it has not filed any periodic reports since the period ended December 31, 1997.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Women First Healthcare, Inc. because it has not filed any periodic reports since the period ended December 31, 2003.

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 August 10, 2010, through 11:59 p.m. EDT on August 23, 2010.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2010–20002 Filed 8–10–10; 4:15 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Geotec, Inc., InnoPet Brands Corp., Marbledge Group, Inc. (n/k/a AR Growth Finance Corp.), Phlo Corp., Pliant Systems, Inc., Southeast Banking Corp., TNX Television Holdings, Inc., and WestPoint Stevens, Inc.; Order of Suspension of Trading

August 10, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Geotec, Inc. because it has not filed any periodic reports since the period ended March 31, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of InnoPet Brands Corp. because it has not filed any periodic reports since the period ended March 31, 1998.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Marbledge Group, Inc. (n/k/a AR Growth Finance Corp.) because it has not filed any periodic reports since the period ended November 30, 1996.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Phlo Corp. because it has not filed any periodic reports since the period ended December 31, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Pliant Systems, Inc. because it has not filed any periodic reports since the period ended June 30, 2001.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Southeast Banking Corp. because it has not filed any periodic reports since the period ended June 30, 1991.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of TNX Television Holdings, Inc. because it has not filed any periodic reports since the period ended September 30, 2004.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of WestPoint Stevens, Inc. because it has not filed any periodic reports since the period ended September 30, 2004.

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 August 10, 2010, through 11:59 p.m. EDT on August 23, 2010.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2010–20001 Filed 8–10–10; 4:15 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62657; File No. 4–274]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17d–2; Notice of Filing of an Amended 17d–2 Plan Between the Financial Industry Regulatory Authority, Inc. and the Chicago Stock Exchange, Inc.

August 5, 2010.

Pursuant to Section 17(d) of the Securities Exchange Act of 1934

("Act"),[1] and Rule 17d–2 thereunder,[2] notice is hereby given that on July 21, 2010, the Financial Industry Regulatory Authority, Inc. ("FINRA") and the Chicago Stock Exchange, Inc. ("CHX") (together with FINRA, the "Parties") filed with the Securities and Exchange Commission ("Commission" or "SEC") an amendment to their September 16, 1977 Agreement Between the National Association of Securities Dealers, Inc. (n/k/a FINRA) and the Midwest Stock Exchange Incorporated (n/k/a CHX) ("17d–2 Plan" or the "Plan") for the allocation of regulatory responsibilities. The Commission is publishing this notice to solicit comments on the amendment to the 17d–2 Plan from interested persons.

I. Introduction

Section 19(g)(1) of the Act,[3] among other things, requires every self-regulatory organization ("SRO") registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO's own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d) or Section 19(g)(2) of the Act.[4] Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO ("common members"). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

Section 17(d)(1) of the Act[5] was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.[6] With respect to a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d–1 and Rule 17d–2 under the Act.[7] Rule 17d–1 authorizes the Commission to name a single SRO as the designated examining authority ("DEA") to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO rules.[8] When an SRO has been named as a common member's DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d–1 deals only with an SRO's obligations to enforce member compliance with financial responsibility requirements. Rule 17d–1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17d–2 under the Act.[9] Rule 17d–2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect to their common members. Under paragraph (c) of Rule 17d–2, the Commission may declare such a plan effective if, after providing for appropriate notice and comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors; to foster cooperation and coordination among the SROs; to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system; and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17d–2 relieves an SRO of those regulatory responsibilities allocated by the plan to another SRO.

II. The Plan

On September 26, 1978, the Commission approved the Plan allocating regulatory responsibilities pursuant to Rule 17d–2 on a provisional basis.[10] Under the Plan, FINRA was responsible, in part, for conducting on-site examination of each dual member for which it was the DEA. On February 20, 1980, the Commission noticed for comment an amendment to the Plan, which provided, in part, for the handling of customer complaints, the review of dual members' advertising, and the arbitration of disputes under the Plan.[11] On May 30, 1980, the Commission approved the Plan, as amended.[12]

III. Proposed Amendment to the Plan

On July 21, 2010, the Parties submitted a proposed amendment to the Plan. The amended agreement would replace the previous Plan in its entirety. Accordingly, the proposed 17d–2 Plan is intended to reduce the duplication in the examination of common members[13] and in the filing and processing of certain registration and membership records. Pursuant to the proposed 17d–2 Plan, FINRA would assume certain examination and enforcement responsibilities for common members with respect to certain applicable laws, rules, and regulations.

The text of the Plan delineates the proposed regulatory responsibilities with respect to the Parties. Included in the proposed Plan is an exhibit (the "CHX Certification of Common Rules" referred to herein as the "Certification") that lists every CHX rule, and select federal securities laws, rules, and regulations, for which FINRA would bear responsibility under the Plan for examine and enforcing with respect to CHX members that are also members of FINRA and the associated persons therewith ("Dual Members").

Specifically, under the 17d–2 Plan, FINRA would assume examination and enforcement responsibility relating to compliance by Dual Members with the rules of CHX that are substantially similar to the applicable rules of FINRA, as well as certain provisions of the federal securities laws and the rules and regulations thereunder delineated in the Certification ("Common Rules").[14] Common Rules would not include the application of any CHX rule or FINRA rule, or any rule or regulation under the Act, to the extent that it pertains to

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[1] 15 U.S.C. 78q(d).

[2] 17 CFR 240.17d–2.

[3] 15 U.S.C. 78s(g)(1).

[4] 15 U.S.C. 78q(d) and 15 U.S.C. 78s(g)(2), respectively.

[5] 15 U.S.C. 78q(d)(1).

[6] *See* Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and Urban Affairs to Accompany S. 249, S. Rep. No. 94–75, 94th Cong., 1st Session 32 (1975).

[7] 17 CFR 240.17d–1 and 17 CFR 240.17d–2, respectively.

[8] *See* Securities Exchange Act Release No. 12352 (April 20, 1976), 41 FR 18808 (May 7, 1976).

[9] *See* Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976).

[10] *See* Securities Exchange Act Release No. 15191 (September 26, 1978), 43 FR 46093 (October 5, 1978).

[11] *See* Securities Exchange Act Release No. 16591 (February 20, 1980), 45 FR 12573 (February 26, 1980).

[12] *See* Securities Exchange Act Release No. 16858 (May 30, 1980), 45 FR 37927 (June 5, 1980).

[13] The proposed 17d–2 Plan refers to these members as "Dual Members." *See* Paragraph 1(c) of the proposed 17d–2 Plan.

[14] *See* paragraph 1(b) of the proposed 17d–2 Plan (defining Common Rules). *See also* paragraph 1(f) of the proposed 17d–2 Plan (defining Regulatory Responsibilities). Paragraph 2 of the Plan provides that annually, or more frequently as required by changes in either CHX rules or FINRA rules, the parties shall review and update, if necessary, the list of Common Rules. Further, paragraph 3 of the Plan provides that CHX shall furnish FINRA with a list of Dual Members, and shall update the list no less frequently than once each quarter.

violations of insider trading activities, because such matters are covered by a separate multiparty agreement under Rule 17d–2.[15] In the event that a Dual Member is the subject of an investigation relating to a transaction on CHX, the plan acknowledges that CHX may, in its discretion, exercise concurrent jurisdiction and responsibility for such matter.[16]

Under the Plan, CHX would retain full responsibility for surveillance, examination, investigation, and enforcement with respect to trading activities or practices involving CHX's own marketplace; registration pursuant to its applicable rules of associated persons (*i.e.,* registration rules that are not Common Rules); its duties and obligations as a DEA pursuant to Rule 17d–1 under the Act; and any CHX rules that are not Common Rules.[17]

The text of the proposed 17d–2 Plan is as follows:

AGREEMENT BETWEEN FINANCIAL INDUSTRY REGULATORY AUTHORITY, INC. AND CHICAGO STOCK EXCHANGE, INC. PURSUANT TO RULE 17d–2 UNDER THE SECURITIES EXCHANGE ACT OF 1934

This Agreement, by and between the Financial Industry Regulatory Authority, Inc. ("FINRA") and the Chicago Stock Exchange, Inc. ("CHX"), is made this 9th day of July, 2010 (the "Agreement"), pursuant to Section 17(d) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 17d–2 thereunder which permits agreements between self-regulatory organizations to allocate regulatory responsibility to eliminate regulatory duplication. FINRA and CHX may be referred to individually as a "party" and together as the "parties."

This Agreement amends and restates the agreement entered into between the parties on September 16, 1977, entitled "Agreement Between the National Association of Securities Dealers, Inc. and the Midwest Stock Exchange Incorporated Pursuant to SEC Rule 17d–2 Under the Securities Exchange Act of 1934," and any subsequent amendments thereafter.

WHEREAS, FINRA and CHX desire to reduce duplication in the examination of their Dual Members (as defined herein) and in the filing and processing of certain registration and membership records; and

WHEREAS, FINRA and CHX desire to execute an agreement covering such subjects pursuant to the provisions of Rule 17d–2 under the Exchange Act and to file such agreement with the Securities and Exchange Commission (the "SEC" or "Commission") for its approval.

NOW, THEREFORE, in consideration of the mutual covenants contained hereinafter, FINRA and CHX hereby agree as follows:

1. Definitions. Unless otherwise defined in this Agreement or the context otherwise requires, the terms used in this Agreement shall have the same meaning as they have under the Exchange Act and the rules and regulations thereunder. As used in this Agreement, the following terms shall have the following meanings:

(a) "*CHX Rules*" or "*FINRA Rules*" shall mean: (i) the rules of the CHX, or (ii) the rules of FINRA, respectively, as the rules of an exchange or association are defined in Exchange Act Section 3(a)(27).

(b) "*Common Rules*" shall mean the CHX Rules that are substantially similar to the applicable FINRA Rules and certain provisions of the Exchange Act and SEC rules set forth on *Exhibit 1* in that examination for compliance with such rules would not require FINRA to develop one or more new examination standards, modules, procedures, or criteria in order to analyze the application of such provisions or rule, or a Dual Member's activity, conduct, or output in relation to such rule; provided, however, Common Rules shall not include the application of SEC, CHX or FINRA rules as they pertain to violations of insider trading activities, which is covered by a separate 17d–2 Agreement by and among the American Stock Exchange LLC, BATS Exchange, Inc., Chicago Board Options Exchange, Inc., Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., International Securities Exchange, LLC, The NASDAQ Stock Market LLC, National Stock Exchange, Inc., New York Stock Exchange, LLC, NYSE Arca Inc., NYSE Regulation, Inc., NASDAQ OMX BX, Inc. and NASDAQ OMX PHLX, Inc. effective April 15, 2010, as may be amended from time to time.

(c) "*Dual Members*" shall mean those CHX members that are also members of FINRA and the associated persons therewith.

(d) "*Effective Date*" shall be the date this Agreement is approved by the Commission.

(e) "*Enforcement Responsibilities*" shall mean the conduct of appropriate proceedings, in accordance with the FINRA Code of Procedure (the Rule 9000 Series) and other applicable FINRA procedural rules, to determine whether violations of Common Rules have occurred, and if such violations are deemed to have occurred, the imposition of appropriate sanctions as specified under the FINRA Code of Procedure and sanctions guidelines.

(f) "*Regulatory Responsibilities*" shall mean the examination responsibilities and Enforcement Responsibilities relating to compliance by the Dual Members with the Common Rules and the provisions of the Exchange Act and the rules and regulations thereunder, and other applicable laws, rules and regulations, each as set forth on *Exhibit 1* attached hereto.

2. Regulatory and Enforcement Responsibilities. FINRA shall assume Regulatory Responsibilities and Enforcement Responsibilities for Dual Members. Attached as *Exhibit 1* to this Agreement and made part hereof, CHX furnished FINRA with a current list of Common Rules and certified to FINRA that such rules are substantially similar to the corresponding FINRA Rule (the "Certification"). FINRA hereby agrees that the rules listed in the Certification are Common Rules as defined in this Agreement. Each year following the Effective Date of this Agreement, or more frequently if required by changes in either the rules of CHX or FINRA, CHX shall submit an updated list of Common Rules to FINRA for review which shall add CHX Rules not included in the current list of Common Rules that qualify as Common Rules as defined in this Agreement; delete CHX Rules included in the current list of Common Rules that no longer qualify as Common Rules as defined in this Agreement; and confirm that the remaining rules on the current list of Common Rules continue to be CHX Rules that qualify as Common Rules as defined in this Agreement. Within 30 days of receipt of such updated list, FINRA shall confirm in writing whether the rules listed in any updated list are Common Rules as defined in this Agreement. Notwithstanding anything herein to the contrary, it is explicitly understood that the term "Regulatory Responsibilities" does not include, and CHX shall retain full responsibility for (unless otherwise addressed by separate agreement or rule) the following (collectively, the "Retained Responsibilities"):

(a) surveillance, examination, investigation and enforcement with respect to trading activities or practices involving CHX's own marketplace;

[15] *See* Securities Exchange Act Release No. 61919 (April 15, 2010), 75 FR 21051 (April 22, 2010) (File No. 4–566) (notice of filing and order approving and declaring effective the plan).

[16] *See* paragraph 6 of the proposed 17d–2 Plan.

[17] *See* paragraph 2 of the proposed 17d–2 Plan.

(b) registration pursuant to its applicable rules of associated persons (i.e., registration rules that are not Common Rules);

(c) discharge of its duties and obligations as a Designated Examining Authority pursuant to Rule 17d–1 under the Exchange Act, if applicable; and

(d) any CHX Rules that are not Common Rules.

3. Dual Members. Prior to the Effective Date, CHX shall furnish FINRA with a current list of Dual Members, which shall be updated no less frequently than once each quarter.

4. No Charge. There shall be no charge to CHX by FINRA for performing the Regulatory Responsibilities and Enforcement Responsibilities under this Agreement except as hereinafter provided. FINRA shall provide CHX with ninety (90) days advance written notice in the event FINRA decides to impose any charges to CHX for performing the Regulatory Responsibilities under this Agreement. If FINRA determines to impose a charge, CHX shall have the right at the time of the imposition of such charge to terminate this Agreement; provided, however, that FINRA's Regulatory Responsibilities under this Agreement shall continue until the Commission approves the termination of this Agreement.

5. Applicability of Certain Laws, Rules, Regulations or Orders. Notwithstanding any provision hereof, this Agreement shall be subject to any statute, or any rule or order of the Commission. To the extent such statute, rule or order is inconsistent with one or more provisions of this Agreement, the statute, rule or order shall supersede the provision(s) hereof to the extent necessary to be properly effectuated and the provision(s) hereof in that respect shall be null and void.

6. Notification of Violations.

(a) In the event that FINRA becomes aware of apparent violations of any CHX Rules, which are not listed as Common Rules, discovered pursuant to the performance of the Regulatory Responsibilities assumed hereunder, FINRA shall notify CHX of those apparent violations for such response as CHX deems appropriate.

(b) In the event that CHX becomes aware of apparent violations of any Common Rules, discovered pursuant to the performance of the Retained Responsibilities, CHX shall notify FINRA of those apparent violations and such matters shall be handled by FINRA as provided in this Agreement.

(c) Apparent violations of Common Rules shall be processed by, and enforcement proceedings in respect thereto shall be conducted by FINRA as provided hereinbefore; provided, however, that in the event a Dual Member is the subject of an investigation relating to a transaction on the CHX, CHX may in its discretion assume concurrent jurisdiction and responsibility.

(d) Each party agrees to make available promptly all files, records and witnesses necessary to assist the other in its investigation or proceedings.

7. Continued Assistance.

(a) FINRA shall make available to CHX all information obtained by FINRA in the performance by it of the Regulatory Responsibilities hereunder with respect to the Dual Members subject to this Agreement. In particular, and not in limitation of the foregoing, FINRA shall furnish CHX any information it obtains about Dual Members which reflects adversely on their financial condition. CHX shall make available to FINRA any information coming to its attention that reflects adversely on the financial condition of Dual Members or indicates possible violations of applicable laws, rules or regulations by such firms.

(b) The parties agree that documents or information shared shall be held in confidence, and used only for the purposes of carrying out their respective regulatory obligations. Neither party shall assert regulatory or other privileges as against the other with respect to documents or information that is required to be shared pursuant to this Agreement.

(c) The sharing of documents or information between the parties pursuant to this Agreement shall not be deemed a waiver as against third parties of regulatory or other privileges relating to the discovery of documents or information.

8. Statutory Disqualifications. When FINRA becomes aware of a statutory disqualification as defined in the Exchange Act with respect to a Dual Member, FINRA shall determine pursuant to Sections 15A(g) and/or Section 6(c) of the Exchange Act the acceptability or continued applicability of the person to whom such disqualification applies and keep CHX advised of its actions in this regard for such subsequent proceedings as CHX may initiate.

9. Customer Complaints. CHX shall forward to FINRA copies of all customer complaints involving Dual Members received by CHX relating to FINRA's Regulatory Responsibilities under this Agreement. It shall be FINRA's responsibility to review and take appropriate action in respect to such complaints.

10. Advertising. FINRA shall assume responsibility to review the advertising of Dual Members subject to the Agreement, provided that such material is filed with FINRA in accordance with FINRA's filing procedures and is accompanied with any applicable filing fees set forth in FINRA Rules.

11. No Restrictions on Regulatory Action. Nothing contained in this Agreement shall restrict or in any way encumber the right of either party to conduct its own independent or concurrent investigation, examination or enforcement proceeding of or against Dual Members, as either party, in its sole discretion, shall deem appropriate or necessary.

12. Termination. This Agreement may be terminated by CHX or FINRA at any time upon the approval of the Commission after one (1) year's written notice to the other party, except as provided in paragraph 4.

13. Arbitration. In the event of a dispute between the parties as to the operation of this Agreement, CHX and FINRA hereby agree that any such dispute shall be settled by arbitration in Washington, D.C. in accordance with the rules of the American Arbitration Association then in effect, or such other procedures as the parties may mutually agree upon. Judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction. Each party acknowledges that the timely and complete performance of its obligations pursuant to this Agreement is critical to the business and operations of the other party. In the event of a dispute between the parties, the parties shall continue to perform their respective obligations under this Agreement in good faith during the resolution of such dispute unless and until this Agreement is terminated in accordance with its provisions. Nothing in this Section 13 shall interfere with a party's right to terminate this Agreement as set forth herein.

14. Notification of Members. CHX and FINRA shall notify Dual Members of this Agreement after the Effective Date by means of a uniform joint notice.

15. Amendment. This Agreement may be amended in writing duly approved by each party. All such amendments must be filed with and approved by the Commission before they become effective.

16. Limitation of Liability. Neither FINRA nor CHX nor any of their respective directors, governors, officers or employees shall be liable to the other party to this Agreement for any liability, loss or damage resulting from or claimed to have resulted from any delays, inaccuracies, errors or omissions

with respect to the provision of Regulatory Responsibilities as provided hereby or for the failure to provide any such responsibility, except with respect to such liability, loss or damages as shall have been suffered by one or the other of FINRA or CHX and caused by the willful misconduct of the other party or their respective directors, governors, officers or employees. No warranties, express or implied, are made by FINRA or CHX with respect to any of the responsibilities to be performed by each of them hereunder.

17. Relief from Responsibility. Pursuant to Sections 17(d)(1)(A) and 19(g) of the Exchange Act and Rule 17d–2 thereunder, FINRA and CHX join in requesting the Commission, upon its approval of this Agreement or any part thereof, to relieve CHX of any and all responsibilities with respect to matters allocated to FINRA pursuant to this Agreement; provided, however, that this Agreement shall not be effective until the Effective Date.

18. Severability. Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

19. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and such counterparts together shall constitute one and the same instrument.

IN WITNESS WHEREOF, each party has executed or caused this Agreement to be executed on its behalf by a duly authorized officer as of the date first written above.

EXHIBIT 1

CHX CERTIFICATION OF COMMON RULES

CHX hereby certifies that the requirements contained in the rules listed below for CHX are identical to, or substantially similar to, the comparable FINRA (NASD) Rules, Exchange Act provision or SEC rule identified ("Common Rules").

CHX rule	FINRA (NASD) rule, Exchange Act provision, SEC rule
Article 6, Rule 2 Registration and Approval of Participant Personnel [18]	NASD Rule 1021(a) and (b) Registration Requirements; NASD Rule 1031(a) and (b) Registration Requirements; NASD Rule 1060(a)(1) and (2) Persons Exempt from Registration; and NASD Rule 3070 (a) Reporting Requirements.
Article 6, Rule 3 Training and Examination of Registrants [19]	NASD Rules 1031(a) and (b) Registration Requirements and 1032 Categories of Representative Registration.
Article 6, Rule 5(a) Supervision of Registered Persons and Branch and Resident Offices.	NASD Rule 3010(a)(2) and (b)(3) Supervision.*
Article 6, Rule 5(b) Supervision of Registered Persons and Branch and Resident Offices.	NASD Rule 3010(a)(2), (b)(1), (b)(4), and (d) Supervision.*
Article 6, Rule 5(c) Supervision of Registered Persons and Branch and Resident Offices.	NASD Rule 3010(a)(7) Supervision.*
Article 6, Rule 10(a) Fingerprinting	Exchange Act Rule 17f–2.
Article 6, Rule 11 Continuing Education for Registered Persons [20]	NASD Rule 1120(a)(1)–(5), 1120(b) Continuing Education Requirements.
Article 6, Rule 12 Anti-Money Laundering Compliance Program [21]	FINRA Rule 3310 Anti-Money Laundering Compliance Program.
Article 8, Rule 3 Fraudulent Acts	FINRA Rules 2010 Standards of Commercial Honor and Principles of Trade, 2020 Use of Manipulative, Deceptive or Other Fraudulent Devices and NASD IM 2310–2(b)(4) Fair Dealing with Customers.
Article 8, Rule 10 Customer Dealings—Account Transfers	NASD Rule 11870(a)(1) Customer Account Transfer Contracts.
Article 8, Rule 11 Customer Dealings—Suitability	NASD Rule 2310 Recommendations to Customers (Suitability) and IM–2310–2(b) Fair Dealing with Customers.
Article 8, Rule 12 Interest in Customer Accounts [22]	FINRA Rule 2150(b) Customers' Securities or Funds.
Article 8, Rule 13(a) Advertising and Promotion	NASD Rule 2210(d)(1)(B) Communications with the Public.
Article 8, Rule 13(b) Advertising and Promotion	NASD Rule 2210(a) Communications with the Public.
Article 9, Rule 2 Just and Equitable Trade Principles	FINRA Rule 2010 Standards of Commercial Honor and Principles of Trade.
Article 9, Rule 10 Prearranged Trades	Exchange Act Sections 9(a); 10(b) and Rule 10b–5 thereunder.*
Article 9, Rule 11 Price Manipulation	Exchange Act Sections 9(a); 10(b) and Rule 10b–5 thereunder.*
Article 9, Rule 12 Manipulative Operations	Exchange Act Sections 9(a); 10(b) and Rule 10b–5 thereunder.*
Article 9, Rule 21 Discretion of Employees Prohibited [23]	NASD Rule 2510(b), (c) and (d)(1) Discretionary Accounts.
Article 9, Rule 23(a) Short Sales	Regulation SHO.
Article 11, Rule 2 Maintenance of Books and Records [24]	NASD Rule 3110(a) Books and Records.*
Article 21, Rule 2 Book-Entry Settlement Requirements	NASD Rule 11310 Book-Entry Settlement.

* FINRA shall not have any Regulatory Responsibilities for these rules as they pertain to violations of insider trading activities, which is covered by a separate 17d–2 Agreement by and among the American Stock Exchange LLC, BATS Exchange, Inc., Chicago Board Options Exchange, Inc., Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., International Securities Exchange, LLC, The NASDAQ Stock Market LLC, National Stock Exchange, Inc., New York Stock Exchange, LLC, NYSE Arca Inc., NYSE Regulation, Inc., NASDAQ OMX BX, Inc. and NASDAQ OMX PHLX, Inc. effective April 15, 2010, as may be amended from time to time.

[18] FINRA shall not have any Regulatory Responsibilities for CHX Article 6 Rule 2 (a), (b)(7), (b)(10), (f), interpretation .01 or interpretation .03 and such sections shall not be considered Common Rules for purposes of this Agreement; responsibility for such requirements remain with CHX.

[19] FINRA shall not have any Regulatory Responsibilities for CHX Article 6 Rule 3 requirement regarding completion of a training course and interpretation .01 and such provisions shall not be considered Common Rules for purposes of this Agreement; responsibility for such requirements remain with CHX.

[20] FINRA shall not have any Regulatory Responsibilities for exercise of exemptive or other discretionary authority by CHX to the extent it makes the rule inconsistent with the corresponding FINRA rule.

[21] FINRA shall not have any Regulatory Responsibilities regarding the CHX rule to the extent it does not contain an exception to independent testing and requires notice to CHX.

[22] FINRA shall only have Regulatory Responsibilities for the first phrase of CHX Article 8 Rule 12 regarding guaranteeing customers against loss in their account and only the first phrase shall be considered a Common Rule for purposes of this Agreement; responsibility for the remainder of the CHX rule remains with CHX.

[23] FINRA shall not have any Regulatory Responsibilities regarding the CHX rule to the extent it does not contain an exception for time and price discretion.

[24] FINRA shall not have any Regulatory Responsibilities regarding maintaining books and records in conformity with CHX rules.

IV. Date of Effectiveness of the Proposed Plan and Timing for Commission Action

Pursuant to Section 17(d)(1) of the Act [25] and Rule 17d–2 thereunder,[26] after September 2, 2010, the Commission may, by written notice, declare the plan submitted by FINRA and CHX, File No. 4–274, to be effective if the Commission finds that the plan is necessary or appropriate in the public interest and for the protection of investors, to foster cooperation and coordination among self-regulatory organizations, or to remove impediments to and foster the development of the national market system and a national system for the clearance and settlement of securities transactions and in conformity with the factors set forth in Section 17(d) of the Act.

V. Solicitation of Comments

In order to assist the Commission in determining whether to approve the proposed 17d–2 Plan and to relieve CHX of the responsibilities which would be assigned to FINRA, interested persons are invited to submit written data, views, and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/other.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number 4–274 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number 4–274. 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/other.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed plan that are filed with the Commission, and all written communications relating to the proposed plan 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 the plan also will be available for inspection and copying at the principal offices of CHX and FINRA. 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 4–274 and should be submitted on or before September 2, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–19852 Filed 8–11–10; 8:45 am]

BILLING CODE 8010–01–P

[25] 15 U.S.C. 78q(d)(1).

[26] 17 CFR 240.17d–2.

[27] 17 CFR 200.30–3(a)(34).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62658; File No. SR–CBOE–2009–075]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Establish a Pilot Program to List P.M.-Settled End of Week and End of Month Expirations for Options on Broad-Based Indexes

August 5, 2010.

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 October 14, 2009, the Chicago Board Options Exchange, Incorporated ("Exchange" or "CBOE") 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 Exchange. On May 3, 2010, the Exchange filed Amendment 1 to the proposed rule change, and on July 30, 2010, the Exchange filed Amendment 2 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment Nos. 1 and 2, 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

CBOE requests approval to establish a pilot program that would permit P.M.-settled options on broad-based indexes that expire on: (a) Any Friday of the month, other than the third Friday-of-the-month ("End of Week Expirations"), and (b) the last trading day of the month ("End of Month Expirations"). The text of the rule proposal is available on the Exchange's Web site (*http://www.cboe.org/legal*), at the Exchange's Office of the Secretary, 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 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

Amendment 2 replaces Amendment 1 and the original filing in their entireties. The purpose of Amendment 2 is to broaden the definition of End of Week Expirations to include any Friday of the month, other than the third Friday-of-the-month.

The purpose of this filing is to establish a pilot program that would permit P.M.-settled options on broad-based indexes to expire on (a) any Friday of the month, other than the third Friday-of-the-month ("End of Week Expirations" or "EOWs"), and (b) the last trading day of the month ("End

[3] Amendment 2 replaces Amendment 1 and the original filing in their entireties.

of Month Expirations" or "EOMs").[4] For example, if EOWs and EOMs were currently listed, the expiration dates for October 2010 would be: October 1 (EOW), October 8 (EOW), October 15 (standard), October 22 (EOW) and October 29 (EOM).[5] Under the End of Week/End of Month Expirations Pilot Program ("Program"), EOWs and EOMs will be permitted on any broad-based index that is eligible for regular options trading. EOWs and EOMs will be cash-settled and have European-style exercise.

The proposal will become effective on a pilot basis for a period fourteen months to commence on the next full month after approval is received to establish the Program. If the Exchange were to propose an extension of the Program or should the Exchange to propose to make the Program permanent, then the Exchange would submit a filing proposing such amendments to the Program. Any positions established under the Program would not be impacted by the expiration of the Pilot. For example, if the Exchange lists an EOW or EOM expiration that expires after the Program expires (and is not extended) then those positions would continue to exist. However, any further trading in those series would be restricted to transactions where at least one side of the trade is a closing transaction.[6]

To implement the Pilot as described above, the Exchange is proposing to add new subparagraph (e) to Rule 24.9 to expressly provide the Exchange with the ability to list P.M.-settled EOWs and EOMs on broad-based indexes eligible for options trading. The amendment to Rule 24.9 will also set forth that the duration of the Program will be effective for a period of fourteen months from the next full month from approval.

EOMs and EOWs will be subject to the same rules that currently govern the trading of traditional index options, including sales practice rules, margin requirements, and floor trading procedures. Contract terms for EOWs and EOMs will be similar to regular index options, with one general exception: the exercise settlement value will be based on the index value derived from the closing prices of component stocks.

Since EOWs and EOMs will be a new type of series and not a new class, the Exchange proposes that EOWs and EOMs on the same broad-based index (*e.g.,* of the same class) shall be aggregated for position limits (if any) and any applicable reporting and other requirements.[7] The Exchange is proposing to add "EOWs" and "EOMs" to Rule 24.4(b) to reflect the aggregation requirement. This proposed aggregation is consistent the aggregation requirements for other types of option series (*e.g.,* QOS, QIXs) that are listed on the Exchange and which do not expire on the customary "third Saturday.[8]"

Annual Program Report:

As part of the Program, the Exchange will submit a Program report to the Securities and Exchange Commission ("Commission") at least two months prior to the expiration date of the Program (the "annual report"). As described below, the annual report will contain an analysis of volume, open interest and trading patterns. In addition, for series that exceed certain minimum open interest parameters, the annual report would provide analysis of index price volatility and, if needed, share trading activity. The annual report will be provided to the Commission on a confidential basis.

Analysis of Volume and Open Interest:

For EOW and EOM series, the annual report will contain the following volume and open interest data for each broad-based index overlying EOW and EOM options:

(1) Monthly volume aggregated for all EOW and EOM series,

(2) Volume in EOW and EOM series aggregated by expiration date,

(3) Month-end open interest aggregated for all EOW and EOM series,

(4) Month-end open interest for EOM series aggregated by expiration date and week-ending open interest for EOW series aggregated by expiration date,

(5) Ratio of monthly aggregate volume in EOW and EOM series to total monthly class volume, and

(6) Ratio of month-end open interest in EOM series to total month-end class open interest and ratio of week-ending open interest in EOW series to total week-ending open interest.

In addition, the annual report will contain the information noted above for standard Expiration Friday, AM-settled series, if applicable[9], for the period covered in the pilot report as well as for the six-month period prior to the initiation of the pilot.

Upon request by the SEC, CBOE will provide a data file containing: (1) EOW and EOM option volume data aggregated by series, and (2) EOW week-ending open interest for expiring series and EOM month-end open interest for expiring series.

Monthly Analysis of EOW & EOM Trading Patterns:

In the annual report, CBOE also proposes to identify EOW and EOM trading patterns by undertaking a time series analysis of open interest in EOW and EOM series aggregated by expiration date compared to open interest in near-term standard Expiration Friday A.M.-settled series in order to determine whether users are shifting positions from standard series to EOW and EOM series. Declining open interest in standard series accompanied by rising open interest in EOW and EOM series would suggest that users are shifting positions.

Provisional Analysis of Index Price Volatility and Share Trading Activity:

For each EOW and EOM Expiration that has open interest that exceeds certain minimum thresholds, the annual report will contain the following analysis related to index price changes and, if needed, underlying share trading volume at the close on expiration dates:

(1) A comparison of index price changes at the close of trading on a given expiration date with comparable price changes from a control sample. The data will include a calculation of percentage price changes for various time intervals and compare that information to the respective control sample. Raw percentage price change data as well as percentage price change data normalized for prevailing market volatility, as measured by the CBOE Volatility Index ("VIX"), will be provided; and

(2) if needed, a calculation of share volume for a sample set of the component securities representing an upper limit on share trading that could be attributable to expiring in-the-money EOW and EOM expirations. The data, if needed, will include a comparison of the calculated share volume for securities in the sample set to the

[4] If the last trading day of the month is a Friday, the Exchange will list an End of Month expiration series and not an End of Week expiration.

[5] *See* Rule 24.9(a)(2) for specific rule governing the expiration months that may be listed for index options. CBOE does not intend to list EOWs or EOMs that would expire on Exchange holidays.

[6] The Exchange intends to address this point in a circular to members should the Exchange receive approval to establish the Program.

[7] *See e.g.,* Rule 4.13, *Reports Related to Position Limits* and Interpretation and Policy .03 to Rule 24.4 which sets forth the reporting requirements for certain broad-based indexes that do not have position limits.

[8] As will be discussed in detail below, the Exchange trades structured quarterly and short term options. FLEX Options do not become fungible with subsequently introduced Non-FLEX structured quarterly and short term options. *See* Securities Exchange Act Release No. 59675 (April 1, 2009), 74 FR 15794 (April 7, 2009) (SR–OCC–2009–05). Because of the similarities between EOW and EOM expirations and existing structured quarterly and short term options, FLEX Options will similarly not become fungible with EOW and EOM expirations listed for trading.

[9] Standard OEX & XEO option series are P.M.-settled.

average daily trading volumes of those securities over a sample period.

The minimum open interest parameters, control sample, time intervals, method for selecting the component securities, and sample periods will be determined by the Exchange and the Commission.

Discussion:

In support of this proposal, the Exchange states that it trades other types of series and FLEX Options [10] that expire on different days than regular options and in some cases have P.M.-settlement. For example, since 1993 the Exchange has traded Quarterly Index Expirations ("QIXs") that are cash-settled options on certain broad-based indexes which expire on the first business day of the month following the end of a calendar quarter and are P.M.-settled.[11] The Exchange also trades Quarterly Option Series ("QOS") that overlie exchange traded funds ("ETFs") or indexes which expire at the close of business on the last business day of a calendar quarter and are P.M.-settled.[12] The Exchange has experience with these special dated options and has not observed any market disruptions resulting from the P.M.-settlement feature of these options. The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settlement EOM expirations, which will effectively permit the Exchange to fill in the remaining eight calendar months with series that expire on the last trading day of the month.

The Exchange trades Short Term Option Series that may overlie any security approved for listing and trading on the Exchange and which are opened for trading on any Friday that is a business day and that expire on the next Friday that is a business day.[13] These existing Short Term Option Series, however, are A.M.-settled and only have a contract duration of a single week. The Exchange seeks to introduce P.M.-settled EOW expirations to provide market participants with a tool to hedge special events and to reduce the premium cost of buying protection. Currently, the Exchange believes that market participants may be paying for more protection than needed if they are seeking to hedge weekend or special event risk that occurs. The Exchange believes that an EOW expiration would allow market participants to purchase an option based on their needed timing and allow them to tailor their investment or hedging needs more effectively. In addition, because P.M.-settlement permits trading throughout the day on the day the contract expires, the Exchange believes this feature will permit market participants to more effectively manage overnight risk and trade out of their positions up until the time the contract settles.

Finally, the Exchange considers this proposal to be a competitive rule filing. Specifically, a futures exchange has the ability to list options on broad-based index futures that expire on the first and second Fridays of the month. In addition, the same futures exchange lists end-of-month options on broad-based index futures that expire on the last trading day of the month.[14] As a result, that futures exchange is able to provide four expirations for each month for certain broad-based indexes, on which CBOE similarly trades security options.[15] The Exchange believes that the introduction of EOW and EOM expirations will enable the Exchange to compete more effectively with the futures markets.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act[16] and the rules and regulations thereunder and, in particular, the requirements of Section 6(b) of the Act.[17] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[18] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest interest [sic], by expanding the ability of investors to hedge risks against market movements stemming from economic releases or market events that occur throughout the month. Accordingly, the Exchange believes that EOWs and EOMs should create greater trading and hedging opportunities and flexibility, and provide customers with the ability to more closely tailor their investment objectives.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE 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

The Exchange neither solicited nor received comments on the proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate 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 No. SR–CBOE–2009–075 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 No. SR–CBOE–2009–075. 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/*

[10] *See* Securities Exchange Act Release No. 61439 (January 28, 2010), 75 FR 5831 (February 4, 2010) (SR–CBOE–2009–087) (order approving rule change to establish a pilot program to modify FLEX option exercise settlement values and minimum value sizes).

[11] *See* Rule 24.9(c).

[12] *See* Rules 5.5(e) and 24.9(a)(2)(B).

[13] *See* Rules 5.5(d) and 24.9(a)(2)(A).

[14] The options have European-style exercise and at expiration settle into a futures contract.

[15] Those indexes are the S&P 500 Index ("SPX") and the Mini-SPX Index.

[16] 15 U.S.C. 78s(b)(1).

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

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 CBOE. 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 No. SR–CBOE–2009–075 and should be submitted on or before September 2, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–19853 Filed 8–11–10; 8:45 am]

BILLING CODE 8010–01–P

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law (Pub. L.) 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions and extensions of OMB-approved information collections and a new information collection.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, e-mail, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer to the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA. Fax: 202–395–6974. E-mail address: *OIRA_Submission@omb.eop.gov.*

(SSA) Social Security Administration, DCBFM, Attn: Reports Clearance Officer, 1333 Annex Building, 6401 Security Blvd., Baltimore, MD 21235. Fax: 410–965–6400. E-mail address: *OPLM.RCO@ssa.gov.*

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than October 12, 2010. Individuals can obtain copies of the collection instruments by calling the SSA Reports Clearance Officer at 410–965–8783 or by writing to the above e-mail address.

1. Benefit Offset National Demonstration—0960–NEW. SSA is undertaking the Benefit Offset National Demonstration (BOND), a demonstration and evaluation of policy changes and services in the Social Security Disability Insurance (SSDI) program, to obtain strong evidence about the effectiveness of potential solutions that would improve the historically very low rate of return to work among SSDI beneficiaries. Under current law, Social Security beneficiaries lose their SSDI benefit if they have earnings and/or work activity above the threshold of Substantial Gainful Activity (SGA) after completing the Trial Work Period and two-month grace period. The benefit-offset component of this demonstration will reduce benefits by $1 for every $2 in earnings above the BOND threshold, gradually reducing benefits as earnings increase.

The experimental design for BOND will test a benefit offset alone and in conjunction with enhanced work incentives counseling. The central research questions include:

- What is the effect of the benefit offset alone on employment and other outcomes?
- What is the effect of the benefit offset in combination with enhanced work incentives counseling on employment and other outcomes?

The proposed public survey data collections will have four components: An impact study, a cost-benefit analysis, a participation analysis, and a process study. The data collections are a primary source for data to measure the effects of a more generous benefit offset and the provision of enhanced work incentives counseling on SSDI beneficiaries' work efforts and earnings. Ultimately, these data will provide information for researchers, policy analysts, policy makers and the United States Congress on a wide range of program areas. The effects of BOND on the well-being of SSDI beneficiaries could manifest in many dimensions and could be relevant to an array of other public programs. This project offers the first opportunity to obtain reliable measures of these effects based on a nationally representative sample. The long-term indirect benefits of this research are likely to be substantial. Respondents are SSDI beneficiaries, and concurrent SSDI and Supplemental Security Income (SSI) recipients whom we randomly assign to the study (Stage 1), and SSDI beneficiaries who agree to participate in the study (Stage 2).

Type of Request: Request for a new information collection.

Survey	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Total annual burden (hours)
Baseline Survey	12,600	1	12,600	41	8,610
Interim Survey	10,080	1	10,080	29	4,872
Stage 1 36-month Survey	8,000	1	8,000	49	6,533
Stage 2 36-month Survey	10,080	1	10,080	60	10,080
Key Informant Interviews	100	7	700	60	700
Stage 2 Participant Focus Groups	600	1	600	90	900
Totals	41,460	.....	42,060	.....	31,695

[19] 17 CFR 200.30–3(a)(12).

2. Private Printing and Modification of Prescribed Application and Other Forms—20 CFR 422.527—0960–0663. 20 CFR 422.527 of the Code of Federal Regulations requires a person, institution, or organization (third-party entities) to obtain approval from SSA prior to reproducing, duplicating, or privately printing any application or other form established by the agency. SSA collects the information to ensure requests comply with the law and regulations. We also use the information to process requests from third-party entities who want to reproduce, duplicate, or privately print any SSA application or other form owned by SSA. To obtain SSA's approval, entities must make their requests in writing, using their company letterhead, providing the required information set forth in the regulation. SSA employees review the requests and provide approval via e-mail or mail to the third-party entities. The respondents are third-party entities who submit a request to SSA to reproduce, duplicate, or privately print an SSA-owned form.

Type of Request: Extension of an OMB-approved information collection.

Number of Respondents: 10.

Frequency of Response: 15.

Number of Responses: 150.

Average Burden per Response: 8 minutes.

Estimated Annual Burden: 20 hours.

II. SSA has submitted the information collections listed below to OMB for clearance. Your comments on the information collections would be most useful if OMB and SSA receive them within 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than September 13, 2010. You can obtain a copy of the OMB clearance packages by calling the SSA Reports Clearance Officer at 410–965–8783 or by writing to the above email address.

1. Certificate of Coverage Request—20 CFR 404.1913—0960–0554. The United States has agreements with 24 foreign countries to eliminate double Social Security coverage and taxation where, except for the provisions of the agreement, a worker would be subject to coverage and taxes in both countries. These agreements contain rules for determining the country under whose laws the worker's period of employment is covered, and to which country the worker will pay taxes. The agreements further dictate that, upon the request of the worker or employer, the country under whose system the period of work is covered will issue a certificate of coverage. The certificate serves as proof of exemption from coverage and taxation under the system of the other country. The information we collect assists us in determining a worker's coverage and in issuing a U.S. certificate of coverage as appropriate. Respondents are workers and employers wishing to establish exemption from foreign Social Security taxes.

Type of Request: Revision of an OMB-approved information collection.

Type of respondent	Number of respondents	Frequency of response	Average burden per response (minutes)	Total annual burden (hours)
Individuals	30,000	1	30	15,000
Private Sector	20,000	1	30	10,000
Totals	50,000			25,000

2. Request to Decision Review Board To Vacate the Administrative Law Judge Dismissal of Hearing—20 CFR 405.427—0960–0755. When an administrative law judge (ALJ) dismisses a hearing for a claim for Title II or Title XVI disability payments, the claimant may request to vacate or stop this decision by completing and submitting Form SSA–525 to the SSA Decision Review Board (Board). The Board uses this information to: (1) Establish the continued involvement of the requestor in the claim; (2) consider the requestor's arguments for vacating the dismissal; and (3) vacate or decline to vacate the ALJ's dismissal order. The respondents are SSDI or SSI claimants who are requesting the Board vacate their dismissal order.

Type of Request: Revision of an OMB-approved information collection.

Number of Respondents: 30,000.

Frequency of Response: 1.

Average Burden per Response: 10 minutes.

Estimated Annual Burden: 5,000 hours.

3. Request for Accommodation in Communication Method—0960–0777. In *American Council of the Blind, et al.* v. *Michael Astrue and Social Security Administration,* class plaintiffs representing Social Security applicants, beneficiaries, recipients, and representative payees who are blind or visually impaired challenged the adequacy of the communication methods SSA uses in its notices and other communications. Prior to the court's order of October 20, 2009 in *American Council of the Blind,* SSA offered three modes of communications for blind and visually impaired Social Security recipients: (1) A standard print notice by first-class mail; (2) a standard print notice by first-class mail with a follow-up telephone call; and (3) certified mail. In *American Council of the Blind,* the court required SSA to offer two additional modes of communication to blind or visually impaired applicants, beneficiaries, recipients, and representative payees: (4) Braille; and (5) Microsoft Word files (on data compact discs).

In *American Council of the Blind,* the court further ordered SSA to implement Section 504 through 45 CFR 85.51 of the Code of Federal Regulations, meaning SSA must "take appropriate steps to ensure effective communication with applicants, participants, personnel of other Federal entities, and members of the public." To meet the court's mandates, SSA uses Form SSA–9000, Request for Accommodation in Communication Method, to gather information from blind or visually impaired individuals about why their particular accommodation (other than the five accommodations already offered by the agency) will allow SSA to communicate effectively with them. This form asks respondents to describe the type of accommodation they want, to disclose the condition they have that necessitates the need for a different type of accommodation, and to explain why none of the five methods described above are sufficient for their needs. The respondents are Social Security applicants, beneficiaries, recipients, and representative payees who are blind or visually impaired and are asking SSA to send notices and other communications in an alternative method besides the five modalities we describe in this notice.

Type of Request: Revision of an OMB-approved information collection.

Method of information collection	Number of respondents	Frequency of response	Response time (minutes)	Burden (hours)
Personal Interview (over the phone or in-person)	2,250	1	10	375
Form (taken or mailed from field office)	250	1	15	63
Total	2,500			438

Dated: August 6, 2010.

Faye Lipsky,

Reports Clearance Officer, Center for Reports Clearance, Social Security Administration.

[FR Doc. 2010–19914 Filed 8–11–10; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[DOT Docket No. DOT–OST–2010–0074]

Future of Aviation Advisory Committee (FAAC); Notice of Meeting

AGENCY: U.S. Department of Transportation, Office of the Secretary of Transportation

ACTION: Notice of meeting.

SUMMARY: The Department of Transportation, Office of the Secretary of Transportation, announces the third meeting of the FAAC, which will be held in the Chicago area. This notice announces the date, time and location of the meeting, which will be open to the public. The purpose of FAAC is to provide advice and recommendations to the Secretary of Transportation to ensure the competitiveness of the U.S. aviation industry and its capability to effectively manage the evolving transportation needs, challenges, and opportunities of the global economy.

DATES: The meeting will be held on August 25, 2010, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: The meeting will be held at the offices of the Federal Aviation Administration's Great Lakes Region Headquarters Building, O'Hare Lake Office Center, 2300 East Devon Avenue, Des Plaines, IL 60018.

Agenda: A presentation on the Next Generation Air Transportation System (NextGen) as well as expert presentations and committee discussions on financing, safety, the environment, workforce/labor, and competition will take place. A copy of the detailed agenda will be posted at *http://www.dot.gov/faac.*

Public Access: The meeting is open to the public. (See below for registration instructions.)

Entering the FAA Building:

- A valid form of government issued ID with an expiration date is required.
- Registration is from 7:15 to 8:30 a.m.
- Only pre-registered attendees may attend the meeting.
- Attendees must be screened and pass through a metal detector.
- No firearms are allowed in the building, including with protection detail.
- Special accessibility requirements should be noted at time of email registration.
- Parking is available along the East (Tollway) entrance into O'Hare Lake Office Park Complex. Visitors will be required to park outside guard controlled area and walk to entrance of building.
- Those using public transportation may use Chicago Transit Authority (CTA) Blue Line River Road, Rosemont exit. PACE Bus Service, Route 230, picks up from River Road station and stops at O'Hare Lake Office Park. More information at: *http://www.pacebus.com/pdf/schedules/230sched.pdf*

Public Comments: The public will be provided the opportunity to submit written comments in advance of the meeting. Comments received by close of business on August 20, 2010, will be used to inform the day's presentations. Comments should address one or more of the five topics (competition, environment, finance, safety and workforce/labor) that were published in the Federal Advisory Committee Charter at *http://www.regulations.gov* (Docket DOT–OST–2010–0074). You may file comments identified by the docket number DOT–OST–2010–0074 using any of the following methods:

- *Federal eRulemaking Portal:* go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave., SE., Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave., SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *E-mail:* In addition, you may send a written copy of your comments and questions to *FAAC@dot.gov* and include one of the following in the subject line when making your e-mail submission; "Financing," "Safety," "Environment," "Workforce/Labor," "Competition," and/or "General comment."

SUPPLEMENTARY INFORMATION: The advisory committee will also meet on the following dates this year:

- October 20. Location: The Federal Aviation Administration, Western-Pacific Region, 15000 Aviation Boulevard, Hawthorne, CA 90250.
- December 15. Location: The Department of Transportation, Headquarters Building Atrium 1200 New Jersey Avenue, SE., Washington, DC 20590.

Members of the public may review the FAAC charter and minutes of FAAC meetings at *http://www.regulations.gov* in docket number DOT–OST–2010–0074 or the FAAC Web site at *http://www.dot.gov/faac.*

Registration

- Space is limited. Registration will be available first-come, first-serve. Once the maximum number of 150 registrants has been reached, registration will close. Requests to attend the meeting must be received by close of business on Friday, August 20.
- All foreign nationals must register and provide their date of birth and passport number by Wednesday, August 18.
- Persons with disabilities who require special assistance should advise the Department at *FAAC@dot.gov*, under the subject line of "Special Assistance" of their anticipated special needs as early as possible.
- To register: Send an email to *FAAC@dot.gov* with "Registration" in the subject line including the following information:
  - Last name, First name
  - Title (if any)
  - Company or affiliation (if any)
  - Address
  - Phone number
  - U.S. Citizen (Y/N)
  - E-mail address in order for us to confirm your registration
- The Federal Aviation Administration building is a secure Federal facility.
- Lunch will be available for purchase on-site (cash only).
- An e-mail will be sent confirming your registration along with details on

security procedures for entering the Federal Aviation Administration building.

- There is no Internet access.

FOR FURTHER INFORMATION CONTACT: Pamela Hamilton, Designated Federal Official, Future of Aviation Advisory Committee, 202–267–9677, *FAAC@dot.gov.*

Issued on: August 9, 2010.

Ray LaHood,

Secretary of Transportation.

[FR Doc. 2010–19986 Filed 8–10–10; 11:15 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35396]

County of Greenville, S.C.—Acquisition Exemption—Greenville County Economic Development Corporation

The County of Greenville, S.C. (County), a noncarrier political subdivision of the State of South Carolina, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire from Greenville County Economic Development Corporation (GCEDC) approximately 11.8 miles of rail line between milepost 0.0 in Greenville, S.C. and milepost 11.8 in Travelers Rest, S.C.[1]

Petitioners state that, as a result of the transaction, the County will acquire GCEDC's interest in the line, including the residual common carrier obligation. GCEDC will assign its interest in a trail agreement reached with the Greenville County Recreation District (GCRD) on September 26, 2006, and the County will assume all of GCEDC's rights and responsibilities under that agreement. GCRD will retain its leasehold interest in the line and will continue to be the trail owner and operator. The end result will be that all of GCEDC's ownership rights and responsibilities in the line will be transferred to the County. According to petitioners, the proposed acquisition will not involve any provision or agreement between GCEDC and the County that would limit future interchange with a third-party connecting carrier.

The transaction is scheduled to be consummated on or after August 25, 2010 (30 days after the notice of exemption was filed).

The County certifies that its projected annual revenues as a result of this transaction will not exceed those that would qualify it as a Class III rail carrier and further certifies that its projected annual revenue will not exceed $5 million.

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 to stay must be filed no later than August 18, 2010 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35396, must be filed with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, a copy must be served on William A. Mullins, 2401 Pennsylvania Ave., NW., Suite 300, Washington, DC 20037.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: August 6, 2010.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2010–19792 Filed 8–11–10; 8:45 am]

BILLING CODE 4915–01–P

[1] The line is railbanked in accordance with the National Trails System Act, 16 U.S.C. 1247(d). *See Greenville County Economic Development Corporation—Abandonment and Discontinuance Exemption—in Greenville County, S.C.,* Docket No. AB 490 (Sub-No. 1X) (STB served Oct. 12, 2005 and Nov. 13, 2006).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Public Availability of the Final Environmental Assessment (EA) and Finding of No Significant Impact/Record of Decision (FONSI/ROD) Signed August 2, 2010, for the Evaluation of the Potential Environmental Impacts Associated With the Proposed Relocation of the Bowman County Airport (Airport) in Bowman County, ND.

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

ACTION: Notice of availability of a final EA and FONSI/ROD for the evaluation of the potential environmental impacts associated with the proposed relocation of the Bowman County Airport in Bowman County, North Dakota.

SUMMARY: The FAA has made available the final EA and FONSI/ROD for the proposed relocation of the Bowman County Airport. The EA was prepared in accordance with the National Environmental Policy Act (NEPA) of 1969, as amended, FAA Orders 1050.1E, "Environmental Impacts: Policies and Procedures" and FAA Order 5050.4B, "NEPA Implementing Instructions for Airport Actions."

Point of Contact: Ms. Patricia Dressler, Environmental Protection Specialist, FAA Bismarck ADO, Building 23B, 2301 University Drive, Bismarck, North Dakota 58504. Telephone number (701) 323–7380.

SUPPLEMENTARY INFORMATION: The FAA has issued a final EA and FONSI/ROD that evaluated the potential environmental impacts associated with the proposed relocation of the Bowman County Airport located in Bowman County, North Dakota. Based on the analysis contained in the final EA, the FAA has determined that the selected alternative has no associated significant impacts to resources identified in accordance with FAA Order 1050.1E, Environmental Impacts: Policies and Procedures and FAA Order 5054.4B, National Environmental Policy Act Implementing Instructions for Airport Actions. Therefore, no environmental impact statement will be prepared. The current Bowman County Airport has deficiencies in meeting current and future large aircraft demand (60, 000 pounds or less with 75 percent of these large aircraft at 60 percent useful load), the Runway Protection Zone, Runway Objective Free Area, wind coverage, and surrounding incompatible land use. Eight alternatives were studied for airspace feasibility and meeting the purpose and need. Five of the eight alternatives (three on site and two new locations) were reviewed, analyzed, and discarded due to the degree of environmental impacts or not meeting airspace requirements. A detailed discussion is in the Alternatives Discarded Section of the FONSI/ROD. The selected alternative is one of three (a no action and two off site locations) considered in the final EA. The selected alternative consists of addressing the identified deficiencies and relocating the Bowman County Airport. The new airport location is approximately 3.5 miles east of Bowman and just south of US Highway 12. The Bowman County Airport Authority will construct, operate, and maintain the new airport. Decommissioning of the existing airport will occur upon activation of the new airport. The selected alternative includes the: (1) Unconditional approval of the Airport Layout Plan (ALP) for the development listed in the EA and the decision document. (2) Issue

final airspace determinations for the development on the ALP. (3) Eligibility for Federal grants-in-aid funds for eligible items. (4) FAA Finding of "No Historic Properties Affected" for the proposed action. (5) FAA Finding of "No Effect" to threatened and endangered species. (6) FAA Finding of "No Impact" to floodplains. (7) Wetland finding that there is no practicable alternative to such construction and the proposed action includes all practicable measures to minimize harm to wetlands. (8) Environmental clearance for disposal of land no longer needed for airport purposes. (9) Appropriate permits and mitigation will be needed before disbursing Federal funds.

These documents will be available for public review during normal business hours at Bldg. 23B, FAA Bismarck ADO, 2301 University Drive, Bismarck, North Dakota, Bowman Regional Public Library, 18 East Divide Street, Bowman, ND 58623, and at the Bowman County Airport Authority, 14686 Highway 12, Bowman, ND 58623.

Issued in Bismarck, North Dakota, August 2, 2010.

Steve Obenauer,

Manager, Bismarck Airport District Office FAA, Great Lakes Region.

[FR Doc. 2010–19920 Filed 8–11–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2010–0035]

America's Marine Highway Grant Notice of Funding Availability

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Grant Notice of Funding Availability.

SUMMARY: On October 28, 2009, the President of the United States signed the 2010 National Defense Authorization Act (NDAA). Section 3515 of the NDAA, titled America's Short Sea Transportation Grants for the Development of Marine Highways, amended Section 55601 of the 2007 Energy Independence and Security Act, titled Short Sea Transportation Program. Section 3515 of the NDAA directs the Secretary of Transportation (Secretary) to establish and implement a short sea transportation grant program to implement projects or components of a project designated under subsection (d) of Section 55601.

Marine Highway Projects are new waterborne transportation services, or expansions of existing services operating between U.S. ports or between U.S. ports and ports in Canada in the Great Lakes Saint Lawrence Seaway. Projects are proposed by a project sponsor and formally designated by the Secretary under the America's Marine Highway Program. Projects that reduce external cost and provide public benefit by transporting passengers and/or freight (container or wheeled) in support of all or a portion of a Marine Highway Corridor, Connector, or Crossing may receive support from DOT and are eligible to compete for Marine Highway grants under the program described in this notice. Marine Highway projects and their designation are described in detail in the final rule published on April 9, 2010, at 75 FR 18095.

It is neither the purpose nor the intent of these grants to shift passengers or freight currently moving by water to another water service, but rather to expand the use of marine transportation where landside transportation is currently being utilized and when the water option represents the best overall option. Therefore a project that directly competes with another, existing Marine Highway service will not be considered for a grant award.

In order to receive a grant under the program, applicants are required to: submit an application to the Secretary in such form and manner, at such time, and containing such information as the Secretary may require, and demonstrate to the satisfaction of the Secretary that the project is financially viable, the funds received will be spent efficiently and effectively, and a market exists for the services of the proposed project as evidenced by contracts or written statements of intent from potential customers. Applicants are required to provide at least 20 percent of the project costs from non-Federal sources. In awarding grants under the program, the Secretary shall give preference to those projects or components that present the most financially viable transportation services and require the lowest percentage Federal share of the costs. A plan is financially viable upon demonstration to the Secretary of Transportation that the project will be sustainable in a specified and reasonable timeframe. The Maritime Administration's Fiscal Year 2010 appropriations, signed by the President of the United States on December 16, 2009, included $7,000,000 to "designate and support specific projects that will create new or expanded services along designated Marine Highway Corridors." Funds for this purpose will be allocated through the Marine Highway Grant Program established in the NDAA and set forth in this notice.

This notice announces the availability of funding for Marine Highway grants, and establishes selection criteria and application requirements.

Marine Highway Grants will be awarded to applicants to implement projects or components of projects designated under America's Marine Highway Program as outlined in the final rule published on April 9, 2010. Eligible applicants must be sponsors of Marine Highway Projects formally designated by the Secretary.

Sponsors of designated Marine Highway Projects are eligible to apply for a Marine Highway Grant as described in this notice.

DATES: Grant applications must be received by 5 p.m., August 27, 2010. The Department of Transportation (DOT) will evaluate all applications and announce the projects that have been selected to receive grant funds as soon as possible after the Application Deadline.

ADDRESSES: Grant applications must be submitted electronically through Grants.gov. Only applications received through Grants.gov will be deemed properly filed. Instructions for submitting applications through Grants.gov are included in Section IV (Submission of Applications).

Paperwork Reduction Act: In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. Chapter 35), the America's Marine Highway (AMH) information collection was previously approved by the Office of Management and Budget (OMB) and was assigned the OMB control number 2133–0541.

FOR FURTHER INFORMATION CONTACT: Please contact the Marine Highway Grants program manager via e-mail at *MH.Projects@dot.gov*, or contact Michael Gordon at (202) 366–5468.

Table of Contents

I. Background

Three legislative actions in combination require implementation of a Marine Highway Program, including the designation of Marine Highway Projects, the authorization of Marine Highway grants, and the appropriation of funds for such grants. These are described below.

The Energy Independence and Security Act of 2007, Sections 1121, 1122, and 1123 of Public Law 110–140, enacted on December 19, 2007 (121 STAT. 1492), calls for the Secretary of Transportation to establish a short sea transportation (Marine Highway) program and designate short sea transportation projects to mitigate landside congestion. It encourages the development and expansion of the use of documented vessels, increased shipper utilization, port and landside infrastructure improvement, and development of marine transportation strategies by State and local governments.

As required by the Energy Independence and Security Act of 2007, the Maritime Administration published a final rule on April 9, 2010, establishing America's Marine Highway Program, 75 FR 18095 (April 9, 2010), including the designation of Marine Highway Projects (Section 393.4). The intent of Section 393.4 is to designate and provide support to projects that lead to Marine Highway services which, if successfully implemented, expanded, or otherwise enhanced, would reduce external costs and provide the greatest benefit to the public. In addition to reduced transportation delays, public benefits can include, but are not limited to, reduced emissions including greenhouse gases, reduced energy consumption, road or rail infrastructure maintenance savings, and improved safety. Additional consideration will be given to Marine Highway Projects that represent the most cost-effective option among other modal improvements or reduce border congestion. Some Marine Highway Projects can also provide public benefit by offering routes that are more resilient to incidents that interrupt surface transportation, or provide additional, redundant surface transportation options. Designation can help focus public and private investment on pre-identified projects that offer the maximum potential public benefit, may receive support from DOT, and are eligible to compete for Marine Highway grants under the program described in this notice. Enactment of section 3515 of the 2010 National Defense Authorization Act (Pub. L. 111–84) (NDAA) directs the Secretary to establish and implement a Marine Highway grant program to implement projects or components of projects designated as a Marine Highway Project. In order to receive a grant under this program, applicants must submit an application to DOT and demonstrate that the project is financially viable, the funds will be spent efficiently and effectively, and that a market exists for the services of the proposed project as evidenced by contracts or written statements of intent from potential customers. It also requires that applicants provide at least 20 percent of the project costs from non-Federal sources. It calls for DOT to give preference to projects that represent the most financially viable transportation services and require the lowest Federal cost share.

The 2010 NDAA directs DOT to establish and implement a short sea transportation grant program to implement projects or components of projects designated as a Marine Highway Project. The Fiscal Year 2010 DOT Appropriation includes $7,000,000 from the O&T funds for the Secure and Efficient Ports Initiative, which seeks to develop the Nation's intermodal freight infrastructure by linking coastal and inland ports to the highway and rail networks. It recognizes the important role that our ports and waterways can play in easing congestion and increasing mobility by moving both freight and passengers from our roads to waterways. The funding provided as part of this initiative will allow DOT to designate and support specific projects that will create new or expanded services along designated Marine Highway Corridors. In addition, the funding will allow for the collection of data to support the expanded use of a secure national marine highway. The intent of this grant program is to expand the use of water transportation.

II. Eligibility

Applicants eligible for Marine Highway Grants are project sponsors that have received designation by DOT for a specific Marine Highway Project under the America's Marine Highway Program. Project sponsors are public entities, including but not limited to, Metropolitan Planning Organizations, State governments (including State Departments of Transportation), and port authorities. Project sponsors are encouraged to develop coalitions and public/private partnerships that can include vessel owners and operators, third party logistics providers, trucking companies, shippers, railroads, port authorities, State, regional, and local transportation planners, environmental interests or any combination of entities working in collaboration under a single application. Components of projects that are eligible for grant funding include, but are not limited to, the following items, generally in order of priority:

—Port and terminal infrastructure (wharves, docks, terminals, paving, etc.),
—Cargo, passenger and/or vessel handling equipment,
—Efficiency or capacity improvements in ports, terminals, aboard vessels, intermodal connectors, etc.,
—Investments that improve environmental sustainability,
—New or used vessel purchase or vessel modifications, and
—Research, planning, or environmental analysis or review.

III. Selection Criteria

This section specifies the criteria that DOT will use to evaluate applications. Three criteria will be considered in the evaluation process, which were established in the final rule. This information will have been provided by applicants during the project designation process. No additional applicant input is required to address these criteria. These criteria establish the degree to which projects are expected to:

1. Reduce external cost and provide public benefit,

2. Offer a lower-cost alternative to increasing land-based capacity in the Corridor, and

3. Demonstrate the likelihood of financial viability.

Applicants may, however, opt to provide additional information specific to the above criteria if they desire. In evaluating this option, applicants should consider paragraph (g)(2)(B) of Section 3515 of NDAA of 2010, which requires that, in order to receive a grant under the program, the following factors must be taken into consideration:

1. Applicants demonstrate to the satisfaction of DOT that the funds received will be spent efficiently and effectively,

2. Applicants demonstrate to the satisfaction of DOT that a market exists for the services of the proposed project as evidenced by contracts or written statements of intent from potential customers,

3. Applicants provide at least 20 percent of the costs from non-Federal sources, and,

4. In awarding grants under the program, DOT give preference to those projects or components that present the most financially viable transportation services and require the lowest percentage Federal share of the costs.

While the criteria above were generally addressed in the original Marine Highway Project application requirements (Section 393.4(e)1(F)(vi), and Business Planning (vii); Proposed Project Timeline), these more specific

requirements may warrant submission of additional information in response to this Notice of Funding Availability. It is important that this information is available to DOT during the grant evaluation process.

All grant applications will be reviewed pursuant to the requirements of the National Environmental Policy Act (NEPA), 42 U.S.C. 4321, *et seq.*

IV. Submission of Applications

Applications must be submitted through *http://*www.grants.gov (grants.gov). To apply for funding through Grants.gov, applicants must be properly registered. Complete instructions on how to register and submit applications can be found on the Web site; registration must be completed before an application can be submitted. If interested parties experience difficulties at any point during the registration or application process, they should call the Grants.gov Customer Support Hotline at 1–800–518–4726, Monday–Friday from 7 a.m. to 9 p.m. Eastern Time. The Catalog of Federal Domestic Assistance (CFDA) number for this solicitation is 20.816, titled America's Marine Highway Grants. Additional information on applying through Grants.gov is available in *Appendix A,* attached hereto.

V. Evaluation Process

DOT will use the evaluation, weighting, and selection processes as set forth in Section 393.4(e)6 contained in the final rule implementing the Marine Highway Program (MARAD–2010–0035) to review and select Marine Highway Grant applications. In addition, an assessment of the overall project risk factors will be conducted and considered during the evaluation process.

VI. Contents of Application

An applicant for a Marine Highway Grant should include all of the information requested below in the application. DOT reserves the right to ask any applicant to supplement the data in its application, but expects applications to be complete upon submission. To the extent practical, DOT encourages applicants to provide data and evidence of project merits in a form that is verifiable.

A. *Length of Application.* The narrative portion of an application should not exceed 10 pages. Documentation supporting assertions made in the narrative portion may also be provided, but should be limited to relevant information. If possible, Web site links to supporting documentation should be provided instead of copies of these materials. At the applicant's discretion, relevant materials provided previously in support of a Marine Highway Project application may be referenced and described as unchanged. To the extent referenced, this information need not be resubmitted for the Marine Highway grant application.

B. *First Page of Application:* The first page of the application should provide the following items of information:

1. Marine Highway Project name (as stated in the Department's Letter of Designation).

2. Primary point of contact for applicant.

3. Amount in dollars, of Grant Funds the applicant is seeking, along with sources, and share of other matching funds.

4. Summary statement of how the grant funding will be applied.

5. Project parties.

6. Data Universal Numbering System (DUNS) number. Recipients of Marine Highway grants and their first-tier sub-awardees will be required to have DUNS numbers (*http://www.dnb.com*) and current registrations in the Central Contractor Registration (*http://www.ccr.gov*). While these items do not need to be provided as part of the application, a Marine Highway grant will not be awarded if a recipient or first-tier sub-awardee does not have these items.

C. *Contact Information.* An application should include the name, phone number, e-mail address, and organization address of the primary point of contact for the applicant. DOT will use this information to inform applicants of DOT's decision regarding selection of grantees, as well as to contact them in the event that DOT needs additional information about applications.

D. *Grant Funds and Sources and Uses of Project Funds.* An application should include specific information about the amount of grant funding requested, sources and uses of all project funds, total project costs, percentage of project costs that would be paid for with Marine Highway grant funds and the identity and percentage shares of all parties providing funds for the project (including Federal funds provided under other programs).

E. *Selection Criteria.* In general, applications will be evaluated based on the information provided in the original application for designation as a Marine Highway Project as set forth in the final rule implementing the Marine Highway Program (MARAD–2010–0035). However, as addressed in Section III (Selection Criteria) of this notice, applicants may provide additional information. This information should be provided in the order it was solicited in the final rule.

F. *National Environmental Policy Act (NEPA) Requirement.* An application must detail whether the project will significantly affect the human environment. Applicants should consult the Maritime Administration's Manual of Orders, MAO–600–1, Procedures for Considering Environmental Impacts, available at *http://www.marad.dot.gov/documents/mao_600-001-0.pdf* and 40 CFR Part 1500 to ensure that the proper environmental impact information is included with the grant application. If the NEPA, or comparable state NEPA, process has already been completed, an applicant must indicate the date of, and provide a Web site link or other reference to, the final environmental document(s). If the NEPA process is underway but not complete, the application must detail where the project is in the process, indicate the anticipated date of completion, and provide a Web site link or other reference to copies of any environmental documents prepared.

G. *Environmentally Related Federal, State, and Local Actions.* An application must indicate whether the proposed project is likely to require actions by other agencies (*e.g.,* permits), indicate the status of such actions, and provide a Web site link or other reference to materials submitted to the other agencies, and/or demonstrate compliance with other Federal, state, and local regulations and permits as applicable.

H. *Certification Requirements.* In order for an application to be considered for a grant award, the Chief Executive Officer of the applicant is required to certify, in writing, the following:

1. That, except as noted in this grant application, nothing has changed from the original application for formal designation as a Marine Highway Project.

2. The project sponsor will administer the project and any funds received will be spent efficiently and effectively.

3. Applicants will provide information, data, and reports as required by the grantor.

I. *Protection of Confidential Business Information.* All information submitted as part of or in support of an application shall use publicly available data or data that can be made public and methodologies that are accepted by industry practice and standards, to the extent possible. If the application includes information that the applicant considers to be a trade secret or confidential commercial or financial

information, the applicant should do the following: (1) Note on the front cover that the submission "Contains Confidential Business Information (CBI)"; (2) mark each affected page "CBI"; and (3) highlight or otherwise denote the CBI portions. DOT protects such information from disclosure to the extent allowed under applicable law. In the event DOT receives a Freedom of Information Act (FOIA) request for the information, DOT will follow the procedures described in its FOIA regulations at 49 CFR 7.17. Only information that is ultimately determined to be confidential under that procedure will be exempt from disclosure under FOIA.

VII. Grant Administration

All applicable Federal laws, rules, and regulations will apply to projects that receive Marine Highway grants. How soon after award a project is expected to expend grant funds and start construction, acquisition, or procurement will be considered on a case-by-case basis and will be specified in the project-specific grant agreement. DOT reserves the right to revoke any award of Marine Highway grant funds and to award such funds to another project to the extent that such funds are not expended in a timely manner and in accordance with the project schedule. DOT's ability to obligate funds for Marine Highway grants expires on September 30, 2010.

Appendix A

Additional Information on Applying Through Grants.gov. Applications for Marine Highway grants must be submitted through Grants.gov. To apply for funding through Grants.gov, applicants must be properly registered. Complete instructions on how to register and apply can be found at *http://www.grants.gov*. If interested parties experience difficulties at any point during the registration or application process, please call the Grants.gov Customer Support Hotline at 1–800–518–4726, Monday–Friday from 7 a.m. to 9 p.m. Eastern Time. Registering with Grants.gov is a one-time process; processing delays may occur for first-time registrants to receive confirmation and a user password. It is highly recommended that applicants start the registration process as early as possible to avoid delays that may preclude submitting an application by the deadline specified. Applications will not be accepted after the relevant due date; delayed registration is not an acceptable reason for extensions. In order to apply for a Marine Highway grant under this announcement and to apply for funding through Grants.gov, all applicants are required to complete the following:

1. *Acquire a Data Universal Numbering System Number.* A Data Universal Numbering System (DUNS) number is required for Grants.gov registration. The Office of Management and Budget requires that all businesses and nonprofit applicants for Federal funds include a DUNS number in their applications for a new award or renewal of an existing award. A DUNS number is a unique nine-digit sequence recognized as the universal standard for identifying and keeping track of entities receiving Federal funds. The identifier is used for tracking purposes and to validate address and point of contact information for Federal assistance applicants, recipients, and sub-recipients. The DUNS number will be used throughout the grant life-cycle. Obtaining a DUNS number is a free, one-time activity. Obtain a DUNS number by calling 1–866–705–5711 or by applying online at *http://www.dnb.com.*

2. *Acquire or Renew Registration with the Central Contractor Registration (CCR) Database.* All applicants for Federal financial assistance maintain current registrations in the Central Contractor Registration (CCR) database. An applicant must be registered in the CCR to successfully register in Grants.gov. The CCR database is the repository for standard information about Federal financial assistance applicants, recipients, and sub-recipients. Organizations that have previously submitted applications via Grants.gov are already registered with CCR, as it is a requirement for Grants.gov registration. Please note, however, that applicants must update or renew their CCR registration at least once per year to maintain an active status, so it is critical to check registration status well in advance of relevant application deadlines. Information about CCR registration procedures can be accessed at *http://www.ccr.gov.*

3. *Acquire an Authorized Organization Representative (AOR) and a Grants.gov Username and Password.* Complete your AOR profile on Grants.gov and create your username and password. You will need to use your organization's DUNS number to complete this step. For more information about the registration process, go to *http://www.grants.gov/applicants/get_registered.jsp.*

4. *Acquire Authorization for your AOR from the E–Business Point of Contact (E–Biz POC).* The E–Biz POC at your organization must log into Grants.gov to confirm your AOR. Please note that there can be more than one AOR for your organization.

5. *Search for the Funding Opportunity on Grants.gov.* Please use the following identifying information when searching for the Marine Highway grant opportunity on Grants.gov. The Catalog of Federal Domestic Assistance (CFDA) number for this solicitation is 20.816, which is titled America's Marine Highway Grants.

6. *Submit an Application Addressing All of the Requirements Outlined in this Funding Availability Announcement.* Within 24–48 hours after submitting your electronic application, you should receive an email validation message from Grants.gov. The validation message will tell you whether the application has been received and validated or rejected, with an explanation. You are urged to submit your application at least 72 hours prior to the due date of the application to allow time to receive the validation message and to correct any problems that may have caused a rejection notification.

Note: When uploading attachments please use generally accepted formats such as .pdf, .doc, and .xls. While you may imbed picture files such as .jpg, .gif, or .bmp, in your files, please do not save and submit attachments in these formats. Additionally, the following formats will not be accepted: .com, .bat, .exe, .vbs, .cfg, .dat, .db, .dbf, .dll, .ini, .log, .ora, .sys, and .zip.

Unforeseen Grants.gov Technical Issues. If you experience unforeseen Grants.gov technical issues beyond your control that prevent you from submitting your application by the deadline, you must contact Michael Gordon at 202–366–5468 or *Michael.Gordon@dot.gov* within 24 hours after the deadline and request approval to submit your application by alternate means. In that circumstance, Department staff will request that you email the complete grant application along with your DUNS number, and provide a Grants.gov Help Desk tracking number(s) obtained prior to the deadline. After Department staff review all of the information submitted as well as contact the Grants.gov Help Desk to validate the technical issues you reported, Department staff will contact you to either approve or deny your request to submit a late application. If the technical issues you reported cannot be validated, your application will be rejected as untimely. To ensure a fair competition for limited funds, the following conditions are not valid reasons to permit late submissions: (1) Failure to complete the registration process before the deadline date; (2) failure to follow Grants.gov instructions on how to register and apply as posted on its Web site; (3) failure to follow all of the instructions in the funding availability notice; and (4) technical issues experienced with the applicant's computer or information technology environment.

Dated: August 10, 2010.

By Order of the Maritime Administrator.

Christine Gurland,

Secretary, Maritime Administrator.

[FR Doc. 2010–20013 Filed 8–11–10; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2010–0106; Notice 1]

CFMOTO Powersports, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

CFMOTO Powersports, Inc. (CFMOTO),[1] agent for the Chunfeng Holding Group Hangshou Motorcycles Manufacturing Co., LTD. (formerly known as Zhejiang CFMOTO Power Co., Ltd. (CHG)) has determined that certain model year 2005–2009 CHG Model CF250T–3(V3) and CF250T–5(V5)

[1] CFMOTO Powersports, Inc., a Minnesota Corporation, is an importer of motor vehicles.

motorcycles that CFMOTO imported did not fully comply with paragraph S5.2.1 of 49 CFR 571.123 Federal Motor Vehicle Safety Standards (FMVSS) No. 123, *Motorcycle Controls and Displays.* CFMOTO has filed an appropriate report pursuant to 49 CFR Part 573, *Defect and Noncompliance Responsibility and Reports.*

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), CFMOTO has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of CFMOTO's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Affected are a total of 6,405 model year 2005–2009 CHG model CF250T–3(V3) and CF250T–5(V5) motorcycles,[2] produced January 1, 2005, through December 31, 2009.

Paragraph S5.2.1 of FMVSS No. 123 requires in pertinent part:

S5.2.1 *Control location and operation.* If any item of equipment listed in Table 1, Column 1, is provided, the control for such item shall be located as specified in Column 2, and operable as specified in Column 3. Each control located on a right handlebar shall be operable by the operator's right hand throughout its full range without removal of the operator's right hand from the throttle. Each control located on a left handlebar shall be operable by the operator's left hand throughout its full range without removal of the operator's left hand from the handgrip. If a motorcycle with an automatic clutch other than a scooter is equipped with a supplemental rear brake control, the control shall be located on the left handlebar. If a scooter with an automatic clutch is equipped with a supplemental rear brake control, the control shall be on the right side and operable by the operator's right foot. A supplemental control shall provide brake actuation identical to that provided by the required control of Table 1, Item 11, of this Standard. If a motorcycle is equipped with self-proportioning or antilock braking devices utilizing a single control for front and rear brakes, the control shall be located and operable in the same manner as a rear brake control, as specified in Table 1, Item 11, and in this paragraph.

Item 11 from:

TABLE 1—MOTORCYCLE CONTROL LOCATION AND OPERATION REQUIREMENTS

Equipment control—column 1	Location—column 2	Operation—column 3
11. Rear wheel brakes	Right foot control	Depress to engage.
	Left handlebar for a motor-driven cycle and for a scooter with an automatic clutch.	Squeeze to engage.

See S5.2.1 for requirements for vehicles with a single control for front and rear brakes, and with a supplemental rear brake control.

CFMOTO explains that the noncompliance is that, the rear wheel brake control is located on the left handlebar instead of as a right foot control as required by paragraph S5.2.1 FMVSS No. 123.

CFMOTO provided the following arguments to support their contention that the subject noncompliance is inconsequential to motor vehicle safety:

The subject vehicles were certified as scooter type motorcycles by the CHG. CHG believed that the vehicles met all of the requirements for a scooter under FMVSS No. 123. As a result of the scooter certification the rear wheel brake was placed on the left handlebar.

The placement of the rear brake on the left handlebar should be deemed by the NHTSA as an inconsequential noncompliance, based on the history and safety records of the vehicles. No consumer complaints and no warranty claims or incident reports have been received by CFMOTO or CHG that relate to the lack of a right foot actuated rear wheel brake.

One of the main reasons consumers have been attracted to the subject vehicles is that they have the appearance of a motorcycle and the operation or function of a scooter. Aside from a lack of pass-through leg area, the vehicles are scooters in all technical respects. It is the scooter functionality that has been the driving force behind consumer demand for the vehicles.

Individuals with disabilities prefer the left hand rear brake controls to those of a foot operated actuator. Similarly, many consumers want to upgrade from a scooter to a motorcycle without the complexities of operating a motorcycle and therefore choose the subject vehicles.

In summation, CFMOTO believes that the described noncompliance is inconsequential to motor vehicle safety. Therefore, CFMOTO requests that its petition, to exempt it from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

CFMOTO also stated that CHG has corrected the problem that caused these errors so that they will not be repeated in future production.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance.

Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted by any of the following methods:

a. By mail addressed to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

b. By hand delivery to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.

c. Electronically: by logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/.* Follow the online instructions for submitting comments. Comments may also be faxed to 1–202–493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If

[2] CFMOTO's petition, which was filed under 49 CFR Part 556, requests an agency decision to exempt CFMOTO as a manufacturer (motor vehicle importers are defined as manufacturers by 49 U.S.C. 30102(5)(B)) of motor vehicles from the notification and recall responsibilities of 49 CFR Part 573 for all 6,405 of the affected vehicles. However, the agency cannot relieve CFMOTO's distributors of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after CFMOTO recognized that the subject noncompliance existed. Those vehicles must be brought into conformance, exported, or destroyed.

comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

Comment closing date: September 13, 2010.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at CFR 1.50 and 501.8.

Issued on: August 6, 2010.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2010–19877 Filed 8–11–10; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35380]

San Luis & Rio Grande Railroad—Petition for a Declaratory Order

AGENCY: Surface Transportation Board, DOT.

ACTION: Institution of declaratory order proceeding; request for comments.

SUMMARY: In response to a petition filed by the San Luis & Rio Grande Railroad (SLRG), the Board is instituting a declaratory order proceeding under 5 U.S.C. 554(e) and 49 U.S.C. 721 to determine whether the Board's jurisdiction preempts the land use code of Conejos County, Colo. (County) that might otherwise apply to SLRG's proposed operation of a containerized truck-to-rail solid waste transload facility at Antonito, Colo. No responses to the petition have been filed. As discussed below, the Board will provide SLRG an opportunity to supplement its filing and will seek public comments in response, with a particular focus on, but not limited to, issues related to the Clean Railroads Act of 2008, 49 U.S.C. 10501(c)(2), 10908–10910 (CRA).

DATES: SLRG's opening statement is due August 27, 2010. Comments are due September 27, 2010. SLRG's reply to comments is due October 12, 2010.[1]

ADDRESSES: Filings may be submitted either via the Board's e-filing format or in traditional paper format. Any person using e-filing should attach a document and otherwise comply with the instructions at the E–FILING link on the Board's Web site at *http://www.stb.dot.gov.* Any person submitting a filing in the traditional paper format should send an original and 10 copies referring to Docket No. FD 35380 to: Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, one copy of each comment filed in this proceeding must be sent (and may be sent by e-mail only if service by e-mail is acceptable to the recipient) to SLRG's representative, John D. Heffner, 1750 K Street, NW., Suite 200, Washington, DC 20006. When SLRG files its reply to comments, one copy of that filing must be sent (and may be sent by e-mail only if service by e-mail is acceptable to the recipient) to each commenter.

Copies of written comments will be available for viewing and self-copying at the Board's Public Docket Room, Room 131, and will be posted to the Board's Web site. FOR FURTHER INFORMATION, CONTACT: Joseph H. Dettmar, (202) 245–0395. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at (800) 877–8339.]

SUPPLEMENTARY INFORMATION: SLRG's petition for declaratory order concerns its transload facility in the County. SLRG explains that it has hired a contractor, Alcon Construction, Inc. (Alcon), to operate the facility. According to SLRG, Alcon intends to transfer sealed containers or bags of contaminated dirt from trucks originating at Los Alamos National Laboratory in New Mexico to railcars. SLRG would then transport the dirt from Antonito to an interchange with Union Pacific Railroad at Walsenburg, Colo., for movement to its final destination at Clive, Utah. SLRG states that Alcon would function as its agent and that SLRG would be responsible for marketing, liabilities, expenses, safety, security, and compliance with applicable laws.

There has been citizen opposition to the facility, and SLRG's efforts to reach an agreement with the County have failed. According to SLRG, County officials have indicated that compliance with the local land use code could take an indefinite amount of time. The facility is ready, and SLRG had planned to begin operations there on May 25, 2010. The County, however, filed a complaint on May 24, 2010, in County Court, Conejos County, seeking to enjoin operations at the facility. That complaint has since been removed to Federal court, where it remains pending. In the complaint, the County claims that SLRG has violated the County's land use code.

SLRG seeks an order from the Board declaring that, due to Federal preemption under 49 U.S.C. 10501(b), the facility is not subject to the County's land use code. According to SLRG, the facility meets the requirements for § 10501(b) preemption because the proposed activities are transportation and they would be performed under the auspices of a rail carrier. SLRG argues that transportation includes activities integrally related to transportation, such as its plans here to load, unload, and temporarily store materials. Further, SLRG asserts that it is a rail carrier, as the Board authorized it to acquire and operate a line of railroad in 2003.

In addition, petitioner argues that the proposed operations at its facility are not subject to the CRA, which, if applicable, would restrict the Board's jurisdiction over the facility. *See* 49 U.S.C. 10501(c)(2)(B), 10908–10910. First, SLRG argues that the dirt would remain in its original shipping containers (sealed bags) and that the CRA only applies to activities outside of original shipping containers. 49 U.S.C. 10908(e)(1)(H)(i). Second, SLRG claims that the dirt is not subject to the CRA because it is "government-generated dirt" as opposed to industrial waste.

Under 5 U.S.C. 554(e), the Board has discretionary authority to issue a declaratory order to terminate a controversy or remove uncertainty. As there is a controversy here, a declaratory order proceeding is being instituted to obtain supplemental information from petitioner and to invite public comment on the issues. Filings should focus particularly on whether SLRG's containers are original shipping

[1] SLRG's petition included a proposed expedited schedule for presentation of evidence and legal argument. Because of the novel issues raised in this proceeding, however, the Board has chosen to seek public comment. A decision in the matter will be issued after thorough consideration of all submissions.

containers under § 10908(e)(1)(H)(i) and whether the dirt SLRG plans to transload and transport is subject to the CRA, but evidence and argument are not limited to those issues.

Board decisions, notices, and filings in this and other Board proceedings are available on our Web site at *http://www.stb.dot.gov.*

Decided: August 6, 2010.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Kulunie L. Cannon,

Clearance Clerk.

[FR Doc. 2010–19896 Filed 8–11–10; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

ACTION: Notice; correction.

SUMMARY: The Department of the Treasury published a document in the **Federal Register** on July 28, 2010, inviting comments on collections of information submitted to the Office of Management and Budget (OMB) for review. This document contained incorrect references.

Correction

In the **Federal Register** of July 28, 2010, in FR Doc. 2010–18522, make the following corrections:

- Page 44308, in the third column, under *OMB Number:* 1545–0047, *Estimated Total Burden Hours:* replace "4,126,068" with "25,710,979".
- page 44308, in the third column, under *OMB Number:* 1545–0092, *Estimated Total Burden Hours:* replace "27,478,960" with "375,066,475".
- Page 44310, in the second column, under *OMB Number:* 1545–1668, *Type of Review:* replace "Extension without change" with "Revision".
- Page 44310, in the second column, under *OMB Number:* 1545–1668, *Estimated Total Burden Hours:* replace "296,124" with "245,074".
- Page 44311, in the first column, under *OMB Number:* 1545–2042, *Type of Review:* replace "Extension without change" with "Revision".
- Page 44311, in the first column, under *OMB Number:* 1545–2042, *Estimated Total Burden Hours:* replace "2,025" with "2,635".

Dated: August 6, 2010.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2010–19915 Filed 8–11–10; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form TD F 90–22.1

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form TD F 90–22.1, Report of Foreign Bank and Financial Accounts.

DATES: Written comments should be received on or before October 12, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins, at (202) 622–6665, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION: *Title:* Report of Foreign Bank and Financial Accounts.

OMB Number: 1545–2038.

Form Number: TD F 90–22.1.

Abstract: This information is collected because of its high degree of usefulness in criminal, tax or regulatory investigations or procedures or in the conduct of intelligence of counterintelligence activities, including analysis, to protect against international terrorism. Respondents include all United States persons who have financial interest in or signature or other authority over foreign financial accounts with an aggregate value over $10,000.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit and not-for-profit institutions, farms, and state, local or tribal government.

Estimated Number of Responses: 281,762.

Estimated Time per Response: 20 min.

Estimated Total Annual Burden Hours: 93,921.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 3, 2010.

Gerald Shields,

Supervisory Tax Analyst.

[FR Doc. 2010–19871 Filed 8–11–10; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–143797–06]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed

and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning the existing final regulation, REG–143797–06 (TD 9393), Employer Comparable Contributions to Health Savings Accounts Under Section 4980G.

DATES: Written comments should be received on or before October 12, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Allan Hopkins at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–6665, or through the Internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Employer Comparable Contributions to Health Savings Accounts Under Section 4980G.

OMB Number: 1545–2090.

Regulation Project Number: REG–143797–06.

Abstract: This document contains final regulations providing guidance on employer comparable contributions to Health Savings Accounts (HSAs) under section 4980G in instances where an employee has not established an HAS by December 31st and in instances where an employer accelerates contributions for the calendar year for employees who have incurred qualified medical expenses. These final regulations affect employers that contribute to employees' HSAs and their employees.

Current Actions: The original NPRM has gone final.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,000,000.

Estimated Time per Respondent: 1 Hour 15 minutes.

Estimated Total Annual Burden Hours: 1,250,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 3, 2010.

Gerald Shields,

Supervisory Tax Analyst.

[FR Doc. 2010–19872 Filed 8–11–10; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8817

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8817, Allocation of Patronage and Nonpatronage Income and Deductions.

DATES: Written comments should be received on or before October 12, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–6665, or through the internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION: *Title:* Allocation of Patronage and Nonpatronage Income and Deductions.

OMB Number: 1545–1135.

Form Number: 8817.

Abstract: Form 8817 is filed by taxable farmers cooperatives to report their income and deductions by patronage and nonpatronage sources. The IRS uses the information on the form to ascertain whether the amounts of patronage and nonpatronage income or loss were properly computed.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and farms.

Estimated Number of Respondents: 2,750.

Estimated Time Per Respondent: 8 hours.

Estimated Total Annual Burden Hours: 22,006.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 3, 2010.

Gerald Shields,

Supervisory Tax Analyst.

[FR Doc. 2010–19878 Filed 8–11–10; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1120–L

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1120–L, U.S. Life Insurance Company Income Tax Return.

DATES: Written comments should be received on or before October 12, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins, at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–6665, or through the Internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: U.S. Life Insurance Company Income Tax Return.

OMB Number: 1545–0128.

Form Number: 1120–L.

Abstract: Life insurance companies are required to file an annual return of income and compute and pay the tax due. The data is used to insure that the companies have correctly reported taxable income and paid the correct tax.

Current Actions: There are no changes being made to this form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 4,440.

Estimated Time per Respondent: 145 hours, 5 minutes.

Estimated Total Annual Burden Hours: 644,138.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 3, 2010.

Gerald Shields,

Supervisory Tax Analyst.

[FR Doc. 2010–19879 Filed 8–11–10; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form W–11

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form W–11, Hiring Incentives to Restore Employment (HIRE) Act Employee Affidavit.

DATES: Written comments should be received on or before October 12, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of notice should be directed to Allan Hopkins, at (202) 622–6665, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Hiring Incentives to Restore Employment (HIRE) Act Employee Affidavit.

OMB Number: 1545–2173.

Notice Number: Form W–11

Abstract: This form was created in response to the Hiring Incentives to Restore Employment (HIRE) Act, which was signed on March 18, 2010. The form was developed as a template for the convenience of employers who must collect affidavits from qualifying employees. The form is not filed, rather an employer must retain the affidavit in order to justify claiming certain HIRE Act benefits.

Current Actions: Extension of currently approved collection. There are no changes being made to the notice at this time.

Type of Review: Extension of currently approved collection.

Affected Public: Businesses or other for-profit institutions.

Estimated Number of Respondents: 100,000.

Estimated Average Time per Respondent: 2 hrs., 16 mins.

Estimated Total Annual Burden Hours: 227,000 hrs.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information

displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 3, 2010.

Gerald Shields,

Supervisory Tax Analyst.

[FR Doc. 2010–19880 Filed 8–11–10; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[PS–276–76]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, PS–276–76 (TD 8586), Treatment of Gain From Disposition of Certain Natural Resource Recapture Property (Sections 1.1254–1(c)(3) and 1.1254–5(d)(2)).

DATES: Written comments should be received on or before October 12, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Allan Hopkins at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224 or at (202) 622–6665, or through the Internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Treatment of Gain From Disposition of Certain Natural Resource Recapture Property.

OMB Number: 1545–1352.

Regulation Project Number: PS–276–76.

Abstract: This regulation prescribes rules for determining the tax treatment of gain from the disposition of natural resource recapture property in accordance with Internal Revenue Code section 1254. Gain is treated as ordinary income in an amount equal to the intangible drilling and development costs and depletion deductions taken with respect to the property. The information that taxpayers are required to retain will be used by the IRS to determine whether a taxpayer has properly characterized gain on the disposition of section 1254 property.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of OMB approval.

Affected Public: Individuals and business or other for-profit organizations.

Estimated Number of Respondents: 400.

Estimated Time per Respondent: 5 hours.

Estimated Total Annual Burden Hours: 2,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 3, 2010.

Gerald Shields,

Supervisory Tax Analyst.

[FR Doc. 2010–19873 Filed 8–11–10; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8877

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8877, Request for Waiver of Annual Income Recertification Requirement for the Low-Income Housing Credit.

DATES: Written comments should be received on or before October 12, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins at Internal Revenue Service, room 6129,

1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–6665, or through the Internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Request for Waiver of Annual Income Recertification Requirement for the Low-Income Housing Credit.

OMB Number: 1545–1882.

Form Number: 8877.

Abstract: Owners of low-income housing buildings that are 100% occupied by low-income tenants may request a waiver from the annual recertification of income requirements, as provided by Code section 42(g)(8))(B).

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and individuals.

Estimated Number of Respondents: 200.

Estimated Time per Respondent: 7 hours, 59 minutes.

Estimated Total Annual Burden Hours: 1,598.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 3, 2010.

Gerald Shields,

Supervisory Tax Analyst.

[FR Doc. 2010–19875 Filed 8–11–10; 8:45 am]

BILLING CODE 4830–01–P

Federal Register

Thursday,
August 12, 2010

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 413 and 414

Medicare Program; End-Stage Renal Disease Prospective Payment System; Final Rule and Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 413 and 414

[CMS–1418–F]

RIN 0938–AP57

Medicare Program; End-Stage Renal Disease Prospective Payment System

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements a case-mix adjusted bundled prospective payment system (PPS) for Medicare outpatient end-stage renal disease (ESRD) dialysis facilities beginning January 1, 2011 (ESRD PPS), in compliance with the statutory requirement of the Medicare Improvements for Patients and Providers Act (MIPPA), enacted July 15, 2008. This ESRD PPS also replaces the current basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.

DATES: *Effective Date:* These regulations are effective on January 1, 2011, except for § 413.174(f)(6), which will be effective on January 1, 2014 and § 413.232(f) and § 413.239(b), which will be effective November 1, 2010.

FOR FURTHER INFORMATION CONTACT: William Cymer, (410) 786–4533. Lynn Riley, (410) 786–1286, (ESRD Quality Incentive Program).

SUPPLEMENTARY INFORMATION:

Table of Contents

Acronym List

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

Act The Social Security Act
ASC Ambulatory surgical center
AV Arteriovenous
BIPA Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554)
BMI Body mass index
BSA Body surface area
BLS Bureau of Labor Statistics
CAH Critical assess hospitals
CAPD Continuous ambulatory peritoneal dialysis
CBC Complete blood count
CBSA Core-Based Statistical Area
CCPD Continuous cycling peritoneal dialysis
CDC Centers for Disease Control and Prevention
CFC Conditions for Coverage
CFR Code of Federal Regulations
CKD Chronic kidney disease
CMS Centers for Medicare & Medicaid Services
COLA Cost of living allowance
CPM Clinical performance measure
CR Composite rate
CROWN Consolidated Renal Operations in a Web-Enabled Network
CY Calendar year
DFC Dialysis facility compare
DME Durable medical equipment
EDB Enrollment Data Base
EPO Epoetin alfa
ESA Erythropoiesis stimulating agent
ESRD End-stage renal disease
FI Fiscal intermediary
FY Fiscal year
GAO Government Accountability Office
GI Gastrointestinal
HD Hemodialysis
IDPN Intradialytic parenteral nutrition
IEF Isolated essential facility
IHS Indian Health Service
IPD Intermittent peritoneal dialysis
IPN Intraperitoneal parenteral nutrition
IPPS Inpatient prospective payment system
IQR Interquartile range
Kt/V A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
LDO Large dialysis organization
LPN Licensed practical nurse
LTC Long term care
MAC Medicare Administrative Contractor
MAP Medicare allowable payment
MBR Master beneficiary record
MCP Monthly capitation payment
MCR Medical cost reports
MedPAC Medicare Payment Advisory Commission
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)
MRSA Methylcyline resistance staphylococcus aurues
MSA Metropolitan Statistical Area
MUE Medically unbelievable edit
NAICS North American Industry Classification Systems
NIH National Institutes of Health
NKF–KDOQI National Kidney Foundation's Kidney Disease Quality Initiative Clinical Practice Guidelines
NOS Not otherwise specified
NQF National Quality Forum
OMB Office of Management and Budget
OPPS Outpatient prospective payment system
OSCAR Online State Certification and Reporting System
PD Peritoneal dialysis
PDE Prescription drug event
PFS Physician fee schedule
PPI Producer price index
PPS Prospective payment system
PRS Practice-related risk score
PVD Peripheral vascular disease
QIP Quality Incentive Program
REMIS Renal Management Information System
RN Registered nurse
RRB Railroad Retirement Board
RRT Renal replacement therapy
SAF Standard analytical file
SB Separately billable
SDO Small dialysis organization
SIMS ESRD Standard Information Management System
SSA Social Security Administration
UM–KECC University of Michigan, Kidney Epidemiology & Cost Center
URR Urea reduction ratio
USRDS United States Renal Data System
WAC Wholesale acquisition cost

I. Background

A. Overview of the Proposed ESRD PPS

On September 29, 2009, we published in the **Federal Register** a proposed rule entitled "End-Stage Renal Disease Prospective Payment System" (74 FR 49922). In that rule, we proposed that the ESRD PPS would combine payments for composite rate and separately billable services into a single base rate of $198.64 developed from CY 2007 claims data (74 FR 49944). Under the proposed rule, the base rate would be adjusted using patient-specific case-mix adjustment factors developed from separate equations for composite rate and separately billable services (74 FR 49949). The case-mix adjusters would include variables for age, body surface area (BSA), low body mass index (BMI), patient sex, eleven co-morbidity categories, and the onset of renal dialysis. The proposed adjustment factors were developed using standard techniques of multiple regression analysis to yield case-mix adjusted payments per treatment. The per treatment payment amounts would also be adjusted to reflect urban and rural differences in area wage levels using an area wage index developed from Core Based Statistical Area (CBSA) definitions (74 FR 49968). The proposed rule also provided that ESRD facilities treating patients with unusually high resource requirements as measured through their utilization of identified services beyond a specified threshold would be entitled to outlier payments, that is, additional payments beyond the otherwise applicable case-mix adjusted prospective payment amount (74 FR 49988). The proposed ESRD PPS also provided for special adjustments for pediatric patients (74 FR 49981) and for facilities treating a low-volume of ESRD patients) 74 FR 49969), as well as a 4-year transition (phase-in) period under which facilities would receive a blend of payments under the prior case-mix adjusted composite payment system and the new ESRD PPS (74 FR 50003). This final rule will implement a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis patients beginning January 1, 2011, in accordance with the statutory provisions set forth in section 153(b) of MIPPA.

B. Legislative History and Statutory Authority for the ESRD Prospective Payment System

Section 299I of the Social Security Amendments of 1972, Public Law 92–603, established the ESRD program under Medicare. That law extended Medicare coverage to individuals regardless of age who have permanent kidney failure, requiring either dialysis or kidney transplantation to maintain life, and meet certain other eligibility criteria.

The enactment of the Omnibus Budget Reconciliation Act of 1981, Public Law 97–35, resulted in changes to the ESRD payment system. Section 2145 of Public Law 97–35 amended section 1881 of the Act by requiring the Secretary to provide by regulation a method for determining prospectively

the amounts of payments for dialysis services furnished by providers of services and renal dialysis facilities to individuals in a facility, and to such individuals at home. In particular, the law required that such method be based on a single composite weighted formula (''composite rate'') (which takes into account the mix of patients who receive services at a facility or at home and the relative costs for furnishing such services) for hospital-based facilities and such a single composite rate for other renal dialysis facilities, or that payment be based on such other method or combination of methods which differentiate between hospital-based and other renal dialysis facilities, and which would more effectively encourage more efficient delivery of dialysis services and would provide greater incentives for increased use of home dialysis.

As a result of these statutory requirements, on February 12, 1982, we published a proposed rule on reimbursement for outpatient dialysis services (47 FR 6556) to implement section 1881 of the Act, as amended by section 2145 of Public Law 97–35. The regulations provided that each facility would receive a payment rate per dialysis treatment (''composite rate''), that is adjusted for geographic differences in area wage levels for the treatment furnished in the facility or at home. We refer to the methodology for payment of outpatient maintenance dialysis services on a per-treatment basis as the ''composite payment system''.

Final regulations implementing the composite payment system were published on May 11, 1983 (48 FR 21254). The initial payment rates, which were developed from Medicare cost reports for fiscal years ending in 1977, 1978, and 1979, were established at $127 per treatment for independent facilities and $131 for hospital-based facilities. The composite payment system was effective August 1, 1983. It was limited to payments for the costs incurred by dialysis facilities furnishing outpatient maintenance dialysis, including some routinely provided drugs, laboratory tests, and supplies, whether furnished by hospital-based and independent facilities in a facility or at home. We established separate rates for hospital-based and independent dialysis facilities, and provided a process under which facilities with costs in excess of their payment rates could seek exceptions to those rates under specified circumstances.

With regard to home dialysis, this system was the basis for reimbursing home dialysis furnished by hospital-based and independent facilities (Method I). (The other is Method II, under which the beneficiary works directly with a durable medical equipment (DME) supplier to obtain the supplies and equipment needed.) For further information on the distinctions between Method I and Method II, *see* section II.A.7. of this final rule.

The composite payment system implemented in 1983 was relatively comprehensive with respect to the renal dialysis services included as part of the composite payment bundle. However, over time a substantial portion of expenditures for renal dialysis services became excluded from the composite payment system and reimbursed in accordance with the respective fee schedules or other payment methodologies. For example, payments for erythropoiesis stimulating agents (ESAs) such as epoetin alfa (EPO, for example, Epogen®) and darbepoetin alfa (ARANESP®) used to treat anemia, and vitamin D analogues (paracalcitol, doxercalciferol, calcitriol), are made outside of the composite payment system as separately billable services. These separately billable services currently comprise about 40 percent of total spending for outpatient maintenance dialysis. Thus, the current payment for outpatient maintenance dialysis under Medicare represents a mix of prospective payment, fee-for-service, and other payment rules.

Subsequent inflation increases to the composite payment system occurred only in response to specific statutory directives. For example, between 1983 and 2001, the payment rates were increased only three times. A $1.00 increase per treatment was effective January 1, 1991 as a result of the enactment of the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508. The rates were not revised again until the enactment of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Public Law 106–113, which increased the payments by 1.2 percent effective January 1, 2000 and January 1, 2001, respectively.

During the last few years, policymakers and other interested parties, including the Medicare Payment Advisory Commission (MedPac) and the Government Accountability Office (GAO), have examined the Medicare outpatient maintenance dialysis payment system and suggested a bundled prospective payment approach. *See Medicare Payment Advisory Commission (MedPAC): Report to the Congress: Medicare Payment Policy,* March 2001, March 2005, and March 2007, and GAO Report GAO–07–77, *End Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility,* November 2006. The ESRD PPS would combine composite rate dialysis services with separately billable services under a single payment, adjusted to reflect patient differences in resource needs or case-mix. As in any PPS, dialysis facilities would keep the difference if Medicare payments exceeded costs for the bundled services, and would be liable for the difference if costs exceeded Medicare payments.

Aside from resulting in a single comprehensive payment for all services included in the bundle, we believe the ESRD PPS would meet several objectives. These include reducing incentives to overuse profitable separately billable drugs, particularly EPO, the targeting of greater payments to ESRD facilities with more costly patients to promote both equitable payment and access to services, and the promotion of operational efficiency. Because of the increased flexibility a bundled PPS would provide in the delivery of outpatient maintenance dialysis services, we believe that it could also increase desirable clinical outcomes, resulting in an enhanced quality of care.

The Congress has twice required studies on the bundling of additional services into the composite payment system. In section 422(c)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106–554, the Congress required the Secretary to issue a report on a bundled system that would include separately billable drugs and clinical laboratory services routinely used in furnishing dialysis. The Secretary submitted this report, *Toward a Bundled Outpatient Medicare End Stage Renal Disease Prospective Payment System,* to Congress in May 2003. That report contained three major findings that would form the basis for the subsequent development of the ESRD PPS:

1. Currently available administrative data are adequate for proceeding with the development of an expanded outpatient ESRD PPS.

2. Case-mix adjustment is potentially feasible based on available clinical information for ESRD patients in order to pay facilities appropriately for treating more costly resource intensive patients.

3. Current quality review initiatives provide a basis for monitoring the impact of a bundled ESRD PPS after implementation, to ensure quality of

care does not deteriorate in response to the system's efficiency incentives.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, also required the Secretary to submit to the Congress a report detailing the elements and features for the design and implementation of a bundled ESRD PPS. Section 623(f)(1) of the MMA specified that such a system should include the bundling of separately billed drugs, clinical laboratory tests, and other items "to the maximum extent feasible". That section also required the report to include a description of the methodology to be used to establish payment rates and that the report, detailing the design of an appropriate bundled payment system, be submitted to the Congress by October 1, 2005. Section 623(e) of the MMA also required a demonstration project testing the feasibility of using a fully bundled case-mix adjusted ESRD PPS.

In addition to requiring a report on a bundled ESRD PPS, section 623 of the MMA amended section 1881(b) of the Act, by requiring significant revisions to the composite payment system. Specifically, section 623 of the MMA required:

- An increase of 1.6 percent to the composite payment rates effective January 1, 2005.
- An add-on to composite rate payments to account for the difference in payments for separately billable drugs based on a revised drug pricing methodology compared to the previous method.
- A "basic" case-mix adjustment to an ESRD facility's composite payment rate reflecting a "limited number of patient characteristics."
- That total payments under the basic case-mix adjusted composite payment system be budget neutral.
- An annual increase to the basic case mix adjusted payment amounts based on projected growth in expenditures for separately billed drugs (the "growth update").
- That payment rates be adjusted by a geographic index, as determined appropriate by the Secretary (and phased-in to the extent such index differed from the previous payment system).
- Reinstatement of the composite rate exceptions process, eliminated for most dialysis facilities beginning December 31, 2000 under BIPA, for ESRD pediatric facilities, effective October 1, 2002.

On August 5, 2004 and November 15, 2004, we published a proposed rule and final rule (69 FR 47487 through 47730 and 69 FR 66235 through 66915), respectively, implementing the provisions affecting the composite payment system effective January 1, 2005, as set forth in section 623 of the MMA. We refer to the modified composite payment system as the "basic case-mix adjusted composite payment system". The development and application of the basic case-mix adjustments, using regression based adjustment factors for the patient variables of age, BMI, and low BMI, are explained in each of those rules. (For more information, we refer readers to 69 FR 47529 and 69 FR 66323, respectively.) The product of the specific adjusters for each patient, multiplied by the otherwise applicable composite payment rate, yielded the basic case-mix adjustment required by the MMA. The basic case-mix adjusted composite payment system was effective April 1, 2005, and was developed from research conducted by the University of Michigan Kidney Epidemiology and Cost Center (UM–KECC) and summarized in its report, *Methodology for Developing a Basic Case-Mix Adjustment for the Medicare ESRD Prospective Payment System* (May 19, 2004 report and April 1, 2005 addendum).

Subsequent to our implementation of the MMA requirements discussed above, UM–KECC continued its research to develop a case-mix adjusted ESRD PPS that would combine composite rate and separately billable services. UM–KECC reported its findings and recommendations in a final report submitted to CMS in February 2008, *End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle.* That report is available on the internet at: *http://www.sph.umich.edu/kecc/assets/documents/UM-KECC%20ESRD%20Bundle%20Report.pdf.* UM–KECC's final report formed the basis for the Secretary's February 2008 Report to Congress, *A Design for a Bundled End Stage Renal Disease Prospective Payment System,* mandated under section 623(f)(1) of the MMA.

The aspects of the basic case-mix adjusted composite payment system implemented as a result of section 1881(b)(12) of the Act are important because they provide a foundation for the development of the case-mix adjusted bundled ESRD PPS required under Public Law 110–275, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The basic case-mix adjustment mandated under the MMA is described in detail in the next section and only affects the composite rate. It does not reflect costs associated with separately billable services. Separately billable services, particularly injectable drugs, are a significant component of the total dialysis resources used for each patient.

The implementation of the basic case-mix adjustments to the composite payment system effective April 1, 2005, and the Secretary's February 2008 Report to Congress, suggested that a bundled ESRD PPS which combined composite rate and separately billable services to yield case-mix adjusted payments was technically feasible. The report defined a payment bundle of dialysis-related services, described the methodology used to develop the regression based case-mix adjusters and the base period payment rates to which the case-mix adjusters would be applied, and discussed numerous other issues relevant to the bundling of outpatient dialysis services under a system of prospective payments.

As a result of the July 15, 2008 enactment of MIPPA, section 153(b) of MIPPA amended section 1881(b) of the Act to require the implementation of an ESRD bundled payment system effective January 1, 2011 (herein referred to as the "ESRD PPS"). Consistent with the language under the statute, we will refer to hospital-based and independent renal dialysis facilities as "providers" and "facilities", respectively, and when addressing both types of facilities, we will collectively refer to such entities as "ESRD facilities", as set forth in § 413.171. Section 153(b) of MIPPA specifies the following:

- The Secretary must implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for "renal dialysis services" in lieu of any other payment, and for such services and items furnished for home dialysis and self-care home dialysis support services.
- A definition for the "renal dialysis services" that are included in the payment bundle.
- The estimated amount of total payments under the ESRD PPS for 2011 must be equal to 98 percent of the estimated total amount of payments for renal dialysis services paid under Medicare, including payments for drugs, that would have been made with regard to services in 2011 if the new system was not implemented. Such estimate must be made based on per patient utilization data from 2007, 2008, or 2009, whichever year has the lowest per patient utilization.
- The ESRD PPS must include adjustments for case-mix variables, high cost outlier payments, and low-volume facilities and provide for a four-year transition (phase-in) period, with all facilities transitioned into the ESRD PPS

on January 1, 2014. ESRD facilities may make a one-time election before January 1, 2011, to be paid under the ESRD PPS and not go through the transition period.

- The ESRD PPS may include other payment adjustments, as the Secretary determines appropriate, including the use of a geographic index, and potential adjustments for pediatric patients and rural ESRD facilities, and may provide for a unit of payment as the Secretary specifies (for example, per treatment or per unit of time).
- The ESRD PPS payment amounts must be annually increased by an ESRD bundled market basket beginning in 2012, and during the transition.
- Section 623(e) of the MMA, which requires a demonstration project of the use of a case-mix adjusted bundled ESRD PPS, was repealed.

Section 153(a)(1) of MIPPA also requires that the composite payment rates be increased by 1.0 percent effective for services furnished on or after January 1, 2009, and before January 1, 2010, and increased by 1.0 percent for services furnished on or after January 1, 2010. In addition, section 153(a)(2) of MIPPA requires that the payment rate for dialysis services furnished on or after January 1, 2009, by ESRD providers of services, be the same as the payment rate for such services furnished by renal dialysis facilities. On November 19, 2008, we published the CY 2009 Physician Fee Schedule final rule (73 FR 69754), implementing the site neutral composite rate for ESRD facilities and the CY 2009 1.0 percent increase to the composite rate. On November 25, 2009, we published in the **Federal Register** the CY 2010 1.0 percent increase to the composite rate in the CY 2010 Physician Fee Schedule final rule (74 FR 61901).

In the following sections of this final rule, we describe the ESRD PPS we are implementing effective January 1, 2011, in compliance with the statutory requirements of MIPPA, and in response to the comments received in connection with the proposed rule published September 29, 2009.

C. Existing Basic Case-Mix Adjustments

Resources required to furnish routine dialysis such as staff and equipment time vary by patient. Because of the variation in resources required to furnish routine dialysis to individuals with varying patient characteristics, facilities that treat a greater than average proportion of resource-intensive patients could be economically disadvantaged if they are paid a rate based on average resources. In addition, patients who are costlier than average to dialyze may face difficulties gaining access to care because a fixed composite payment rate could create a disincentive to treat such patients. The purpose of a case-mix adjustment based on patient characteristics is to make higher payments to ESRD facilities treating more resource-intensive patients, according to objective quantifiable criteria.

The costs of providing the routine maintenance dialysis services that are paid under the composite rate are reported on the Medicare cost reports for hospital-based and independent ESRD facilities (Forms CMS 2552–96 and CMS 265–94, respectively). In order to determine a basic case-mix adjustment that could be applied to each ESRD facility's composite rate, UM–KECC further examined the relationship between facility-level costs for composite rate services based on the Medicare cost reports for hospital-based and independent facilities, and the average characteristics of patients treated by the facility. The research used data from Medicare cost reports for 3,254 ESRD facilities for 2000 to 2002, patient characteristics/co-morbidity data from CMS's Medical Evidence Form 2728 (Form 2728) for 1995 through 2002, and Medicare claims for approximately 360,000 ESRD patients. Based on standard techniques of multiple regression analysis, UM–KECC found that age and body size had significant relationships to composite rate costs. The body size variables were BSA and low BMI, calculated based on a patient's height and weight which is reported on Medicare claims.

A BMI less than 18.5 kg/m^2 is considered a clinical measure of underweight status and is an indicator of patients who are malnourished or suffering from co-morbidities such as wasting syndrome. BSA is closely associated with the duration and intensity of dialysis required to achieve targets for dialysis adequacy. Facilities with a larger proportion of patients with a greater than average BSA, or with a BMI lower than 18.5, were found to have greater composite rate costs. The research also revealed a U-shaped relationship between age and composite rate costs, with the youngest and oldest age groups incurring greater costs for composite rate services due to resource needs.

The outcome of UM–KECC's research was a set of basic case-mix adjusters or multipliers for ESRD patients based on three variables. These variables were: (1) The patient's age (five groups), (2) BSA (a patient-specific value based on incremental differences from the national patient average), and (3) BMI category (two groups, value either less than, or equal to/greater than 18.5 kg/m^2). CMS also developed a special adjuster for pediatric patients outside of UM–KECC's research methodology based on analysis of a sample of Medicare cost reports. The adjuster for each of these three variables is multiplied by the facility's composite rate to yield the current "basic" case-mix adjustment for each ESRD patient according to the specified patient characteristics.

These adjusters are as follows:

Table 1: Basic Case-Mix Adjustments Used Under the Current Composite Payment System

Age group	Composite Rate Multiplier
< 18	*1.62
18-44	1.223
45-59	1.055
60-69 (reference group)	1.000
70-79	1.094
80+	1.174
Body Surface Area (BSA): (per 0.1m² change in BSA from national average of 1.84)	1.037
Low Body Mass Index (BMI): (<18.5kg/m²)	1.112

* Developed by CMS. The age, BSA, and BMI multipliers do not apply under the basic case-mix adjustments for patients under age 18.

The above multipliers were derived from the coefficients of the regression model used to predict facility differences in composite rate costs based on UM–KECC's research. For example, the case-mix adjuster for a 47 year old ESRD patient who is underweight (BMI < 18.5 kg/m²) and has a BSA of 2.0 m² would be calculated as follows:

Age Adjuster 1.055

BSA Adjuster $1.037^{(2.0-1.84)/0.1} = 1.060$

Low BMI Adjuster 1.112

Case-Mix Adjuster $1.055 \times 1.060 \times 1.112 = 1.244$

The resulting case-mix adjustment factor of 1.244 for this patient would be multiplied by the facility's otherwise applicable wage adjusted composite payment rate.

The basic case-mix adjustment mandated under the MMA only affects the composite rate. It does not reflect costs associated with separately billable services. Separately billable services, particularly injectable drugs, are a significant component of the total dialysis resources used for each patient. Prior to the enactment of MIPPA on July 15, 2008, however, CMS did not have authority to bundle those services into a case-mix adjusted PPS.

II. Summary of the Proposed Provisions and Responses to Comments on the Proposed Rule

The proposed rule was published in the **Federal Register** on September 29, 2009 with a comment period that ended on November 16, 2009 (74 FR 49922). We received approximately 1475 public comments, including comments resulting from a large write-in campaign regarding oral Part D drugs. Interested parties that submitted comments included numerous dialysis facilities, the national organizations representing dialysis facilities, nephrologists, and patients, the major chain facilities, clinical laboratories, pharmaceutical manufacturers, hospitals and their representatives, individual dialysis patients, and MedPAC. Following publication of the proposed rule, we received several requests to extend the comment period to allow time for stakeholders to understand the proposed ESRD payment changes and to formulate comments that would be meaningful to CMS. On November 4, 2009 we published a notice (74 FR 57127) in the **Federal Register** extending the public comment period an additional 30 days to December 16, 2009, to provide additional time for the public to examine the proposed rule and provide meaningful comments on its provisions. In this final rule we provide a summary of each proposed provision, a summary of the public comments received, our responses to them, and any changes to the proposed ESRD PPS we are implementing in this final rule as a result of comments received. Below we address general comments received regarding the proposed rule.

Comment: Clinicians, health systems, medical supply companies, patients, and hospital-based and independent ESRD facilities from small, medium, and large dialysis organizations requested that rather than proceeding by issuing a final rule, CMS issue its next public notice as an interim final rule with an additional opportunity for public comment prior to the implementation deadline. Commenters provided several reasons for this position including:

- A lack of clarity and specificity with regard to the proposals in the proposed rule will make implementation difficult and compromise ESRD facilities' viability. Specifically, operational questions remain unanswered such as the way in which billing for laboratory tests would occur during the transition, the way in which medical history would be retrieved for purposes of the co-morbidity adjustments, and the way in which ESRD facilities would provide patients with oral drugs. Commenters noted that absent additional clarification in these areas it would be difficult to implement the provisions of the ESRD PPS in the short timeframe between the expected publication of a final rule and its implementation on January 1, 2011.
- A lack of transparency with regard to the data used in developing the proposed rule. Specifically, some commenters noted that they did not have access to Part D data or CMS' rate setting data file that would have facilitated their ability to fully analyze the impact of the ESRD PPS.
- The absence of administrative or judicial reviews, a feature mandated by MIPPA, would mean there would be an inability to challenge payment making it

even more important that the provisions of the final ESRD PPS rule are correct.

- The additional time associated with issuing an interim final rule would help bring to light inequities between ESRD provider types and the level of owned service lines including laboratory, pharmacy, equipment and supplies.
- Concern about the potential for unintended patient and provider consequences that may result from the ESRD PPS and believed that issuing an interim final rule would reduce this risk by allowing additional time to address stakeholder concerns.

Response: We understand the commenters' interest in ensuring that potential unintended negative consequences associated with the new ESRD PPS are minimized. However, we believe that we have adequately reflected the essential elements of the ESRD PPS in the proposed rule including basic issues associated with implementing the system and have received a comprehensive collection of public comments from a wide array of stakeholders to which we have responded in this rule. Specifically, as noted in section II.K.2. of this final rule, we have clarified the way in which provider billing for laboratory tests would occur during the transition. We have also clarified our position with respect to co-morbidity adjustments and their associated administrative burden in section II.F.3. of this final rule. As noted in section II.K.2. of this final rule, we have addressed implementation issues associated with ESRD facility provision of oral drugs.

With regard to the lack of transparency in sharing the data that was used in developing the ESRD PPS proposed rule, we note that the files to which commenters refer contain patient-specific data. To maintain patient confidentiality and privacy we are unable to share such data. However, we posted detailed information by facility which was used for purposes of assessing facility-level impact.

In addition, we note that following publication of the ESRD PPS proposed rule, we posted the CY 2011 Proposed Rule ESRD PPS Facility Level Impact File to the ESRD Payment Web site (*http://www.cms.hhs.gov/ESRDPayment/PAY/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=4&sortOrder=descending&itemID=CMS1228517&intNumPerPage=10*). This file includes facility level data that was used by CMS to assess the impact of the proposed ESRD PPS.

Given that we have issued a proposed rule containing a detailed proposal for an ESRD PPS, allowed for an extended 90-day public comment period, and carefully considered the comments received, we believe that a final rule is appropriate. In addition, because of the January 1, 2011 implementation deadline mandated by MIPPA, we believe that finalizing the rule now will maximize the amount of time ESRD facilities will have to implement the provisions of this rule prior to the implementation deadline. For these reasons we are issuing this document as a final rule.

A. The Proposed ESRD PPS Bundle

Section 1881(b)(14)(A)(i) of the Act, as added by section 153(b) of MIPPA, specifies that the ESRD PPS must represent a single payment to ESRD facilities for "renal dialysis services" in lieu of any other payment, and home dialysis supplies, equipment, and support services furnished pursuant to section 1881(b)(4) of the Act. Section 1881(b)(14)(B) of the Act, which identifies the renal dialysis services that are to be included in the ESRD PPS payment bundle, provides the following:

> * * * the term "renal dialysis services" includes—
>
> (i) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;
>
> (ii) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;
>
> (iii) Other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was(before application of this [new ESRD PPS]) made separately under this title, and any oral equivalent form of such drug or biological; and
>
> (iv) Diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

1. Composite Rate Services

Section 1881(b)(14)(B)(i) of the Act requires that the ESRD PPS payment bundle include composite rate services. As we indicated in the proposed rule, the current case-mix adjusted composite payment system represents a limited PPS for a bundle of outpatient renal dialysis services that includes maintenance dialysis treatments and all associated services including historically defined dialysis-related drugs, laboratory tests, equipment, supplies and staff time (74 FR 49928). Therefore, consistent with the statute, we proposed to include the items and services included in the composite rate for renal dialysis services as of December 31, 2010, (including self-dialysis training services), such as labor, supplies, and equipment.

We proposed to define composite rate services at proposed § 413.171. We also proposed that the composite rate services would not only include payments for the costs of services directly related to dialysis, but would also include payments authorized in accordance with the composite payment rate exception provisions set forth in 42 CFR 413.180 through 413.186 (74 FR 49928). The costs for such composite rate services were included in our computation of the proposed ESRD PPS base rate, as explained in section II.E. of this final rule, as well as in the development of the proposed composite rate regression model used to create the two equation patient specific case-mix adjusters that would be applied to the base rate. We did not receive any public comments on our proposed inclusion of the renal dialysis services currently covered under the composite payment system for inclusion under the bundled ESRD PPS. Therefore, we are finalizing our definition of composite rate services as renal dialysis services as proposed in § 413.171.

2. ESAs and Their Oral Forms

Section 1881(b)(14)(B)(ii) of the Act requires that ESAs and any oral form of such agents that are furnished to individuals for the treatment of ESRD be included in the ESRD PPS payment bundle. We proposed that payments for injectable ESAs, (for example, Epoetin® and ARANESP®) would be included in the calculation of the proposed ESRD PPS base rate, as well as in the separately billable regression model used to create the two equation patient specific case-mix adjusters for the proposed ESRD PPS (74 FR 49928). Therefore, consistent with our interpretation of the statute, we proposed that no additional payment would be provided for ESAs and their oral forms outside of the bundle of renal dialysis services included in the ESRD PPS. We also noted that oral versions of ESAs do not currently exist, but we further proposed that to the extent oral forms are approved after the implementation of the ESRD PPS, those drugs would be paid under the ESRD PPS (74 FR 49928). We set forth provisions regarding the inclusion of ESAs and their oral forms as renal dialysis services in the ESRD PPS payment bundle at proposed § 413.171.

We received a few comments regarding our proposal to bundle ESAs and those comments are addressed below.

Comment: Some commenters expressed concern that bundling drugs

will restrict nephrologists' ability to prescribe necessary medications. One commenter stated that including medications like EPO and oral medications will limit nephrologists from prescribing what is necessary.

Response: We believe that the ESRD PPS will establish a bundled payment system based on the average cost of care with adjustments that target more payment to more resource intensive ESRD patients. In situations where costs for treating patients exceed an established threshold, the outlier policy would apply. The outlier policy is discussed in detail in section II.F.4. of this final rule. We expect that ESRD facilities and health care providers will continue to advocate on behalf of patients who require more than the average utilization of ESRD-related items and services. We note that the responsibility for determining the appropriateness of medical care resides with the ESRD facility, physicians, and the interdisciplinary team as stipulated by the ESRD Conditions for Coverage. Under § 494.90, an ESRD facility would be out of compliance if it did not meet the patient's documented needs as shown in the patient plan of care.

Comment: Several commenters expressed concern that the inclusion of ESAs in the payment bundle will result in dialysis facilities decreasing the amounts of EPO given to patients, resulting in an increase in blood transfusions for anemia management, and increased stress on the nation's blood supply.

Response: Section 1881(b)(14)(B)(ii) of the Act requires that ESAs be included in the ESRD PPS. While the inclusion of any item or dialysis service in the payment bundle provides an incentive for dialysis facilities to maximize profits by skimping on the provision of that item or service, we point out that an important part of our Quality Incentive Program (QIP) is the monitoring of hemoglobin levels among dialysis patients to ensure that target levels are met, and that anemia management does not deteriorate under the ESRD PPS (see section II.M. of this final rule). We also plan to monitor the incidence of transfusions among dialysis patients subsequent to the implementation of the PPS to ensure that blood transfusions do not replace effective anemia management with ESAs as a result of the system's payment incentives. More information about monitoring efforts planned due to the implementation of the ESRD PPS appears in section II.L. of this final rule and in future issuances.

Comment: A few commenters opposed the inclusion of EPO or intravenous iron in the bundle, claiming that if included, there will be a decrease in the use of these drugs resulting in decreased hemoglobin levels, necessitating more in-hospital blood transfusions. Another commenter stated that bundling would result in a shift to subcutaneous administration of ESAs with additional needle sticks, decreases in hemoglobin levels, and an increase in transfusions. Several commenters cited the USRDS 2008 Annual Data report as showing a large decrease in the use of red blood cell transfusions since 1992. One commenter questioned how patients will obtain EPO as it is expensive. One commenter referenced National Kidney Foundation (NKF) guidelines to support their statement that "intravenous iron is * * * more efficacious at helping patients maintain adequate iron levels in clinical studies of patients * * * undergoing hemodialysis and therefore is generally the preferred recommended therapy." Another commenter claimed, based on their analysis of two patients' reimbursement under the proposed ESRD PPS, that their facility would face significant financial loss, especially for those receiving large doses of EPO. Some commenters suggested that we include only intravenous ESAs. One commenter stated that ESRD-related intravenous drugs include those used in the treatment of anemia, and therefore, their oral equivalents should be included in the bundle.

Response: We have no authority to exclude ESAs from the ESRD PPS bundled payment. As we explained in the proposed rule (74 FR 49928), section 1881(b)(14)(B)(ii) of the Act requires that ESAs and any oral form of such agents that are furnished to individuals for the treatment of ESRD be included in the ESRD PPS payment bundle. We explained that the payments for injectable ESAs (for example Epoetin alfa (Epogen®) and darbepoetin (ARANESP®), which are separately payable outside of the current basic case-mix adjusted composite payment system, would be included in the calculation of the proposed ESRD PPS base rate. We also noted in the proposed rule that while we were currently unaware of any other injectable ESAs or oral forms of such ESAs used for the treatment of ESRD, if any such agents would become available subsequent to the implementation of the ESRD PPS on January 1, 2011, they would be considered renal dialysis services and subject to payment under the ESRD PPS (74 FR 49928). We are not aware that a shift to subcutaneous administration of ESAs from intravenous administration will lead to decreases in hemoglobin levels and increases in transfusions.

Although several commenters suggested that ESRD beneficiaries may be denied appropriate and necessary treatment because of the perceived negative financial impact of the ESRD bundled payment system, we point out that section 1881(b)(14)(B)(ii) is clear in requiring that ESAs and any oral forms of ESAs must be included in the ESRD PPS payment bundle. In addition, as discussed in section II.M. of this final rule, we will monitor anemia management as part of the ESRD QIP.

Comment: Several commenters expressed concern that the bundling of ESAs poses a financial disincentive for adequate anemia management, and will lead to the maintenance of hemoglobins at the lowest possible level, resulting in worse outcomes for patients.

Response: Section 1881(b)(14)(B)(ii) of the Act is very clear in requiring that ESAs and any oral equivalent forms of ESAs furnished for the treatment of ESRD must be included in the ESRD PPS payment bundle. We have no discretion with respect to their inclusion or exclusion.

We do not understand the commenters' conclusion that maintaining hemoglobins at the least possible level will result in worse patient outcomes. We expect ESRD facilities to provide the appropriate medications at the appropriate dosage to maintain patient hemoglobins at the required level. We note that we will be closely monitoring the anemia management of ESRD patients subsequent to the implementation of the ESRD PPS as part of CMS's QIP.

Therefore, after considering the public comments and for the reasons stated above, we are not making changes to the proposed Medicare regulation at § 413.171 and are finalizing the inclusion of ESAs and their oral forms as renal dialysis services in the ESRD PPS payment bundle.

3. Other Drugs and Biologicals and Their Oral Forms

Section 1881(b)(14)(B)(iii) of the Act specifies that other drugs and biologicals that were furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, prior to the implementation of the ESRD PPS, and their oral equivalent forms, must be included in the ESRD PPS payment bundle. In the proposed rule, we noted the reference to "this title," in the statutory language, and we interpreted clause (iii) as requiring the inclusion in the ESRD PPS payment bundle of all drugs and biologicals that were

separately payable under title XVIII of the Act prior to the implementation of MIPPA (74 FR 49928). We proposed at § 413.171 that drugs and biologicals used to treat ESRD that were separately payable prior to January 1, 2011, be included as part of the proposed ESRD PPS payment bundle (74 FR 50022). Accordingly, we proposed to include such drugs and biologicals in the development of the proposed patient-specific case-mix adjusters and in the calculation of the proposed ESRD base rate to which the adjusters would be applied. In the proposed rule, we identified the top eleven injectable drugs furnished to Medicare ESRD beneficiaries which we proposed to include in the payment bundle (*See* Table 8 at 74 FR 49940). Table 8 also contained a category of miscellaneous other injectable drugs, as well as a line item reflecting other services furnished by ESRD facilities. The identification and treatment of these other injectable drugs and services are addressed in later in this section.

We identified specific National Drug Codes (NDCs) for drugs and biologicals previously payable under Part D that we proposed to include in the payment bundle. However, we proposed that the ESRD PPS would apply, regardless of the emergence of new drugs or biologicals or different NDCs for the classes of drugs and biologicals included in the ESRD PPS bundle. Finally, we noted that section 1881(b)(14)(B) of the Act specifically excludes vaccines from the payment bundle and, therefore, we did not include vaccines in the proposed ESRD PPS. We requested comments on our proposals above.

We received numerous public comments related to inclusion of ESRD-related injectable drugs and biologicals; the inclusion of oral equivalents of ESRD injectable drugs; and the inclusion of oral-only ESRD-related drugs (that is, drugs for which there is no injectable equivalent or other form of administration) currently paid under Part D in the payment bundle. Most of the commenters were opposed to the inclusion of all oral drugs and biologicals, claiming that their inclusion would lead to poorer patient outcomes because the proposed amount per treatment of $12.47 reflected in the calculation of the base rate (Table 8 at 74 FR 49940) was claimed to be inadequate to cover the average cost of these drugs. The comments received are summarized below.

a. Oral-Only ESRD–Related Drugs

Comment: Several commenters agreed with CMS that clause (iii) of section 1881(b)(14)(B) of the Act can be interpreted broadly to encompass all drugs furnished to individuals for the treatment of ESRD, including oral drugs. In particular, the commenters did not interpret the subsequent reference to "any oral equivalent form of such drug or biological" as limiting the scope of oral drugs that may be included. Another commenter stated that one possible interpretation of MIPPA gives CMS authority to broaden the bundle to include former Part D oral drugs. Finally, another commenter strongly endorsed the agency's proposal to include all ESRD-related drugs and concurred with CMS's rationale and statutory interpretation set forth in the proposed rule. In particular, the commenter stated that the plain language of the statute with respect to clauses (iii) and (iv) gave CMS clear authority to include ESRD drugs, regardless of the route of administration, agreeing with the agency's interpretation of the reference to the word "title", and also noting that the phrase "other drugs and biologicals" included no qualifier that would limit clause (iii) to only separately reimbursable injectable drugs.

Response: We appreciate the comments on our proposal to bundle oral-only drugs, which support our interpretation of the statute.

Comment: One commenter suggested that CMS implement an expeditious appeals process for physicians to challenge payment for drugs that may be excluded from dialysis companies' formularies.

Response: ESRD facility formularies are beyond the scope of this final rule. However, we expect ESRD facilities to provide the appropriate medications, at the appropriate dosage, based upon individual patient needs. We expect the patient's nephrologist and the interdisciplinary team to identify medication needs in accordance with the individual patient's plan of care.

Comment: Many comments indicated that CMS's decision to include oral drugs with no injectable equivalent ("oral-only" drugs) within the statutory definition of "renal dialysis services" represents a misreading of statutory intent and violates principles of statutory construction. One commenter asserted that CMS's inclusion of oral-only drugs in the ESRD PPS appeared to hinge entirely on the reference to the words "this title" under section 1881(b)(14)(B)(iii) of the Act. The commenter stated that this interpretation represented too narrow a reading of the statute, and was inconsistent with the intended meaning of "this title" set forth elsewhere in section 1881 of the Act. Other commenters stated that CMS's reasoning that the use of "this title" in section 1881(b)(14)(B)(iii) of the Act means that all ESRD drugs payable under title XVIII of the Act must be included in the payment bundle, including drugs payable under Part D, represents a selective reading of the statute, and that the more appropriate approach is to read the language as a whole. The commenters asserted that the entirety of section 1881(b) of the Act focuses on payments to ESRD facilities, and that the four categories of renal dialysis services specified in section 1881(b)(14)(B) of the Act only pertain to services furnished for which payment is made to ESRD facilities.

A few commenters compared references to "this title" in other subparagraphs of section 1881(b) of the Act and argued that our prior implementation of payment to dialysis facilities did not include oral-only drugs when the same reference to "this title" was used, stating that the reference has been interpreted previously to mean separately billable Part B drugs (with separate payment to dialysis facilities). Consequently, commenters claimed that such oral-only products do not fall within clause (iii) because they are not separately billable Part B drugs (which are limited to those products that cannot be self-administered by a patient and must be furnished in the facility by staff), and are not oral equivalents of separately billable drugs. Commenters claimed that because the oral-only drugs (calcimemetics and phosphate binders) proposed for inclusion in the ESRD PPS payment bundle are currently dispensed by a pharmacy for home use, are not furnished by ESRD facilities, and are not the oral equivalent of an injectable drug under clause (iii), such drugs must be excluded from the bundle. Therefore, these commenters maintained that inclusion of such oral-only drugs in the expanded bundle under the proposed ESRD PPS is inappropriate. Although most commenters opposed the inclusion of former Part D drugs, several stated that there appeared to be sufficient statutory support for including them.

Response: We agree that section 1881(b) of the Act addresses payments to dialysis facilities for dialysis services furnished Medicare ESRD beneficiaries, either directly by the facility, by a supplier (for example, DMEPOS supplier), or under arrangement (for example, clinical laboratory). However, in our view, the intent of section 1881(b)(14)(B) of the Act was not to limit the renal dialysis services included in the ESRD PPS payment bundle to services for which only ESRD

facilities are currently paid. Clause (iii) of that section specifies that drugs and biologicals for which separate payment is made, and their oral equivalents, must be included in the bundle as renal dialysis services. We have interpreted clause (iii) as encompassing not only injectable drugs and biologicals (other than ESAs, which are included under clause (ii)) used for the treatment of ESRD, but also all non-injectable drugs furnished under Title XVIII. Under this interpretation, the "any oral equivalent form of such drug or biological" language pertains to the oral versions of injectable drugs other than ESAs. All other ESRD-related drugs and biologicals, regardless of the route of administration, are addressed by the "other drugs * * * under this title" portion of clause (iii). We disagree with the commenters' argument that we have incorrectly expanded the scope of clause (iii) to include drugs and biologicals based on an inconsistent interpretation of "this title" as used elsewhere in the Act. Accordingly, we continue to believe that the entirety of clause (iii) gives us sufficient statutory authority to include all ESRD-related drugs and biologicals, regardless of whether they are furnished by a dialysis facility, under the ESRD PPS payment bundle.

Another issue is whether the "other items and services" language in clause (iv) of section 1881(b)(14)(B) of the Act encompasses oral-only drugs furnished for the treatment of ESRD. Commenters argue that oral-only drugs would not be excluded from the definition of renal dialysis services under the reasoning that the scope of the bundle was intended to cover only services for which ESRD facilities currently are being paid, as payments for the oral equivalents of injectables are not made to ESRD facilities.

We do not believe that construing the "other items and services" language in clause (iv) as applying to oral-only drugs violates a principle of statutory construction, by making clauses (ii) and (iii) otherwise redundant. The language in clause (iv) does not mean all drugs currently available to Medicare beneficiaries for the treatment of ESRD as the commenters suggest. Rather, we believe that it can be interpreted as a residual or catch all category for drugs which do not fall under the scope of those specified renal dialysis services identified in clauses (ii) and (iii). Medicare regulation under § 400.202 defines "services" as follows in pertinent part:

Services means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, * * *

Thus, we are interpreting the use of the word services in clause (iv) consistent with how we interpret and define services under Medicare which supports including other oral-only drugs not specified in the preceding clauses in the bundle, not the exclusion of those drugs from the payment bundle. We believe that this interpretation of clause (iv) neither represents a selective reading of the statute, nor an overly expansive definition of the scope of the renal dialysis services intended to be included in the payment bundle.

Comment: Another commenter stated that the reference to "separate payment" under section 1881(b)(14)(B)(iii) of the Act would exclude Part D drugs because under Part D, Medicare is not making separate payment for drugs. The commenter reasoned that the Medicare program makes per beneficiary payments to plans, and plans use such payments to reimburse pharmacies that fill prescriptions for covered Part D drugs. The commenter argued that the focus of section 1881(b) of the Act is on payments to dialysis facilities for services furnished to beneficiaries. Therefore, the first part of clause (iii) pertains to Medicare payments separately made to dialysis facilities for separately payable Part B drugs and biologicals, and does not include Part D products.

Response: We disagree with the commenter with regard to the meaning of the language in clause (iii) of the statutory definition for renal dialysis services under section 1881(b)(14)(B) of the Act. We believe that such language was intended to be broadly interpreted given that all drugs are reimbursable under Medicare by virtue of being authorized for payment under Title XVIII. Therefore, drugs covered under Part B and formerly covered under Part D would be included regardless of whether payment was made directly by us or by a plan.

Comment: Several commenters agreed with CMS that clause (iv) of section 1881(b)(14)(B) of the Act is a catch all provision that permits inclusion of any additional products and services, including oral drugs furnished to treat individuals with ESRD, and agreed with the agency's interpretation and rationale that the inclusion of oral-only drugs in the bundle is supported by clause (iv). One commenter noted that the term "services" is used in clause (iv) of the definition for renal dialysis services, and that for purposes of Medicare such term is defined under § 400.202 as "medical care or other services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and the use of hospital, CAH, or SNF facilities [emphasis added]." The commenter noted that services and items encompass drugs and biologicals. The commenter further stated that a plain reading of clause (iv) leads to the conclusion that clause (iv) is inclusive of all other drugs and biologicals not reimbursed under the ESRD composite rate as of December 31, 2010, that are furnished to individuals for the treatment of ESRD.

Other commenters disagreed with our interpretation, stating that clause (iv) should not apply to oral-only drugs, as it would render the other clauses of the definition unnecessary. Those commenters claimed that an interpretation of clause (iv) that includes all drugs and biologicals fails to consider the entire context of the statute, and that this reading would negate clauses (ii) and (iii) of the statutory definition for renal dialysis services. Commenters stated that under rules of statutory construction, a statute should be construed to give meaning to all aspects of it, such that "other items and services" cannot be read to include drugs that are currently used for treatment of chronic renal failure, but are excluded from clauses (ii) and (iii).

Response: We believe that clause (iv) of the definition for renal dialysis services under section 1881(b)(14)(B) of the Act could include certain other items and services such as "oral-only" drugs. We agree with the commenter that the definition should be viewed as a whole when considering each of the four clauses, and particularly, clause (iv). With regard to the concerns of statutory interpretation that commenters have identified, we believe we have followed them when interpreting the statute. We note, however, that such rules must be taken into context based on the underlying statutory language at issue. In particular, we note that the definition for renal dialysis services has overlapping categories of services, and that certain clauses included arguably are unnecessary. For example, given that several clauses of the definition contain similar types (or categories) of items and services, we find unconvincing the commenter's suggestion that clause (iv) cannot include drugs or biologicals. We note that drugs and biologicals are not limited to clauses (ii) and (iii) of the definition. In particular, clause (i) covers the composite rate, which contains some drugs.

We also agree with the commenter who pointed to the Medicare definition for "services" that such term includes drugs and biologicals. Given that clause (iv) addresses laboratory tests and other items and services not described in clause (i) (that is, non-composite rate labs, items, services, etc.), we believe that a reasonable interpretation of clause (iv) is that certain non-composite drugs and biologicals are included. We agree with commenters, however, that to ensure that meaning is attached to the other clauses, such drugs and biologicals included in clause (iv) would not be the same as those included in clauses (ii) and (iii). Accordingly, if oral-only drugs are not considered to fall within clause (iii) of the statutory definition (or clause (ii) for that matter), we believe that such drugs would appropriately fall under clause (iv), and would constitute other items and services used for the treatment of ESRD that are not described in clause (i).

In addition, as we noted, several of the clauses of the definition could be viewed as superfluous. Therefore, we believe the definition as a whole must be considered when determining whether an item or service constitutes a "renal dialysis service." In particular, we note that clause (iii) would have been broad enough to include the erythropoiesis stimulating agents (ESAs) identified in clause (ii), given that such agents would constitute "drugs and biologicals that are furnished for the treatment of ESRD and for which payment was made (before the ESRD PPS) separately under this title, and any oral equivalent of such drug or biological." Hence, clause (ii) arguably is unnecessary. Congress decided, however, to nevertheless specifically identify these agents as a separate category under the definition. Given the structure of the definition, we do not believe Congress' identification of certain "other drugs and biologicals" in clause (iii), limits the definition such that it excludes other types of drugs or biologicals from clause (iv) of the definition, if such drugs otherwise meet that prong (and are not included in clause (iii) or clause (ii)).

Moreover, we believe that when the definition is viewed as a whole, it suggests a comprehensive definition that wraps in all items and services related to outpatient renal dialysis that are furnished to individuals for the treatment of ESRD. Although the definition is perhaps overlapping or redundant, we find clause (iv) to be a catchall category, and one that provides sufficient authority for bundling oral-only drugs (if such drugs do not fall under clause (iii)). For a discussion of the other items and services under clause (iv), please see the next section below.

Comment: One commenter pointed to recent legislative proposals and an analysis by the Congressional Budget Office as support that oral-only drugs are not included in the statutory definition for renal dialysis services. Another commenter pointed to legislative history by citing floor statements as evidence of Congressional intent behind the creation of a broad payment bundle, including all oral dialysis-related drugs, such as calcimimetics and phosphate binders.

Response: We are not persuaded by recent legislative proposals. We continue to interpret section 1881(b)(14)(B) of the Act as including in the ESRD PPS, all drugs and biologicals furnished for the treatment of ESRD, and we believe this interpretation reflects the intent of the statute. With regard to recent legislation, we note that the ESRD PPS proposed rule, in which we set forth our interpretation of the statute and our proposal for the scope of the bundle, was specifically noted and acknowledged by Congress in section 10336 of the Affordable Care Act passed on March 23, 2010 (Pub. L. 111–148), which requires a study by the GAO on the impact on Medicare beneficiaries of including oral-only drugs in the bundled ESRD PPS. Significantly, this new legislation imposes no restrictions or additional requirements with regard to our proposal to bundle such products.

Comment: Some commenters stated that the exclusion of oral-only drugs from the payment bundle would not make the bundle of services less comprehensive, nor would it defeat the purpose of the new payment system as CMS suggests. These commenters claim that the comprehensive bundle of renal dialysis services the Congress envisioned is a bundle of services furnished by ESRD facilities. Therefore, some commenters believed that since calcimimetics and phosphate binders are not furnished by ESRD facilities, their exclusion would not make the bundle less comprehensive than Congress intended. Commenters also stated that no cost shifting would occur between Part B and Part D, because these oral-only drugs have no Part B equivalent.

Response: We do not agree with the commenters' assertion that the intent of the payment bundle under the ESRD PPS was to include only those services furnished by dialysis facilities. For example, inclusion of diagnostic laboratory tests (which may be performed by laboratories under arrangements with dialysis facilities, for those facilities that do not have their own laboratories), and oral equivalent forms of injectable drugs, which are currently furnished by pharmacies under Part D, belie this interpretation. Therefore, we believe the exclusion of an item or service from the payment bundle solely because it is not furnished (or traditionally furnished) by ESRD facilities is inappropriate. We also disagree with the argument that excluding drugs from the bundle for which there currently is no injectable equivalent is acceptable because there is no issue of cost-shifting between Part B and Part D. Notwithstanding that there may not be injectable equivalents of certain drugs widely used for the treatment of ESRD currently that may not be the case in the future as new drugs and treatments are developed.

We also point out that apart from the goal of avoiding cost-shifting, we believe the purpose of a bundled payment system is to ensure that patient care is not skewed by financial incentives. We believe that access to and compliance with recommended care can be negatively impacted if certain drugs remain outside of the payment bundle. Although many Medicare beneficiaries may have oral-only drug coverage under Medicare Part D, others have private sources, and some lack reliable sources of coverage altogether. We do not wish to continue an uneven payment policy that favors certain types of drugs by permitting them to remain separately payable outside of the payment bundle.

Comment: Commenters indicated that several of the oral-only drugs which CMS proposes to include in the payment bundle are relatively expensive, and that the associated payment amount per treatment ($12.48 as calculated from Table 8 at 74 FR 49940) for these drugs was inadequate. Commenters stated that this will result in unintended clinical consequences for patients as ESRD facilities seek to maximize profits by resorting to cheaper but less effective alternatives.

Response: We believe that by including all drugs widely used for the treatment of ESRD in the payment bundle, we will be providing a level playing field that will benefit patient care. The purpose of a bundled payment system is to make available all treatment options under the same payment system. When drugs remain outside of the payment bundle, financial issues can influence both facility and patient behavior, as the over-utilization of EPO to the detriment of patient care in the past has demonstrated. We acknowledge

that the contrary effect can occur whereby drugs included in the payment bundle could also influence behaviors with potential underutilization. However, we expect ESRD facilities and monthly capitation payment (MCP) physicians will evaluate the potential use of less expensive equally effective alternatives for the treatment of conditions associated with ESRD, where those alternatives are available and not contraindicated by the patient's clinical status. Notwithstanding the availability of less expensive alternatives, we expect that patient care regimens will always be selected solely based on patient needs as identified in the patient's plan of care. We believe that we have developed the bundle, with the inclusion of all oral drugs, to account for the costs that ESRD facilities will incur in furnishing these drugs to patients.

Comment: Several commenters expressed concern that the inclusion of oral-only drugs in the ESRD PPS payment bundle could adversely impact beneficiaries through increased co-payments. Because the cost of these oral-drugs would be included in the payment for all of the renal dialysis services included in the bundle, commenters noted that the beneficiary would be responsible for 20 percent of the total bundled payment amount, and that this has the potential to increase the co-payment amount owed by the beneficiary. In addition, commenters stated that patients, who currently have Part D coverage and qualify for the low income subsidy, would be required to pay coinsurance on these drugs for the first time, as Part D coverage limits their financial responsibility at very low dollar amounts. The commenters believe that this will pose a financial hardship for these low income patients who will be unable to meet their new coinsurance obligation, caused by including these drugs under Part B. In addition, commenters stated that patients who are dually eligible for both Medicare and Medicaid would also see an increase in their coinsurance liability, as minimal prescription drug copayment amounts are replaced with a 20 percent coinsurance requirement under the ESRD PPS.

Response: It is inherent with the implementation of any PPS that patients who incur costs greater than the amount covered by the average PPS payment will benefit from the ESRD, because their coinsurance liability will be based on that lower average payment amount compared to the actual costs for resources consumed. Patients whose actual costs for services furnished are less than the PPS payment amount will see an increase in their coinsurance liability, because the actual payment exceeds the actual utilization of resources. Table 2 shows total Part D expenditures for drugs for CYs 2007, 2008, and the first nine months of 2009 currently available. The table reveals that the portion of these expenditures for ESRD drugs borne by the beneficiary, or otherwise paid on behalf of the beneficiary, ranges from 38 to 41 percent.

Table 2
Part D expenditures for Medicare ESRD beneficiaries undergoing dialysis

	2007	2008	Jan-Sept 2009
Total payments for Part D drugs for each year, including part of 2009	$1,108,514,200	$1,264,188,670	$1,009,761,143
Total payments for ESRD oral equivalents of injectables	$10,700,084	$15,038,895	$13,565,768
Payments made by/on behalf of beneficiary—all Part D drugs	$460,046,395	$509,917,138	$439,330,445
Payments made by/on behalf of beneficiary—ESRD drugs	$4,059,734	$5,762,986	$5,565,784
% of payments that were made by/on behalf of beneficiary—all Part D drugs	41.5%	40.3%	43.5%
% of payments that were made by/on behalf of beneficiary—ESRD drugs	37.9%	38.3%	41.0%

These amounts compare to the 20 percent coinsurance liability under Part B. We believe that this difference in coinsurance liability between Part B drugs and Part D drugs is largely caused by the beneficiary obligation incurred under the Part D "donut hole", and by various coinsurance amounts imposed by the drug plans because of formulary differences. Based on this comparison, some beneficiaries will be better off with a 20 percent coinsurance obligation under Part B compared to the range of 37.9 to 41.0 percent liability under Part D, particularly if their utilization of Part D drugs is high, and they have no low income subsidy. While there is no equivalent low income

subsidy under Part B for those patients who currently receive this benefit under Part D, we believe our interpretation of the statute is consistent with the statutory intent to bundle all renal dialysis services under Part B.

In addition, ESRD beneficiaries who currently have private market coverage of the ESRD drugs that would be included in the ESRD PPS and minimal copayments will see an increase in their copayments because of the classification of these drugs under Part B as renal dialysis services, for which the 20 percent coinsurance obligation applies. We would expect that the shift in coverage for oral drugs formerly Part D to Part B will result in drug plans and insurers modifying the scope of their drug coverage, formularies, premiums, and benefits to reflect this shift in coverage, in a competitive environment to maintain and attract beneficiaries. With respect to patients dually eligible for Medicare and Medicaid with minimal prescription drug copayment amounts under Part D, we expect that the 20 percent coinsurance for renal dialysis services included in the payment bundle under the ESRD PPS will be covered by the beneficiary's Medicaid benefit, just like other Part B coinsurance obligations. We will conduct outreach efforts to the States to ensure that States understand the changes due to the ESRD PPS, and their responsibility to process Medicare claims and determine their financial obligations under the new payment system.

Comment: One commenter proposed that oral equivalents of injectable drugs be included in the ESRD PPS effective January 1, 2011, and that CMS clearly indicate that the only currently available oral drugs with an injectable version are oral iron and oral vitamin D. The commenter suggested that if oral drugs without an injectable version are included in the payment bundle, their inclusion should not occur until the transition period expires in 2014, or later. The commenter proposed that the payment rate for oral drugs included in the bundle be set at the price which a small dialysis organization would need to pay to obtain the drug from a pharmacy under arrangements.

Response: Consistent with section 1881(b)(14)(B)(iii) of the Act, we are including the oral equivalents of ESRD injectable drugs in the payment bundle effective January 1, 2011. These drugs include the oral Vitamin D analogues (calcitriol, doxercalciferol, and paracalcitol) and levocarnitine. Oral iron is generally available over the counter and not covered under Parts B or D. Therefore, it is not included in the payment bundle. There are currently no oral versions of ESAs for inclusion in the ESRD PPS. For reasons set forth in greater detail response to the comment below, we have adopted the commenter's suggestion that the inclusion of oral-only drugs be delayed until after the end of the transition period, or until January 1, 2014.

Comment: Several commenters expressed concern that the inclusion of certain oral-only drugs and laboratory tests unrelated to dialysis in the payment bundle represented an inappropriate shifting of costs to dialysis facilities for services unrelated to the dialysis treatment.

Response: Oral-only drugs will not be implemented under the ESRD PPS until January 1, 2014 for reasons set forth in greater detail below. Neither will laboratory tests unrelated to the treatment of ESRD be included in the payment bundle. Laboratory tests ordered by a dialysis patient's MCP, nephrologist, or other practitioner for reasons unrelated to ESRD will be excluded from the ESRD PPS and will continue to be reimbursed separately.

Comment: One commenter urged CMS to implement its proposed policy to bundle all drugs January 1, 2011, as mandated by Congress, stating that statutory authority, sound public policy, and patient clinical needs support inclusion of such drugs in the bundle. The commenter stated that any delay would potentially create unintended financial incentives, leading to adverse clinical outcomes.

Other commenters stated that CMS lacks pricing data from all payers to accurately determine the payments for the inclusion of oral drugs in the bundle, and recommended that CMS should exercise its authority to delay the inclusion of oral drugs. Some commenters argued that expanding the bundle to include oral-only drugs when it had insufficient data and support would have the potential to hamper future bundling efforts. Many commenters cited various policy and operational reasons in support of a decision to delay the inclusion of oral drugs in the ESRD PPS bundle. In particular, several commenters asserted that if CMS determines that it has sufficient legal authority to include oral-only Part D drugs in the payment bundle, it should nonetheless delay the inclusion of these drugs to a subsequent year in order to permit an orderly implementation of the ESRD PPS. Commenters claimed that a delay would also give CMS the necessary time to ensure that its billing systems and software are appropriately developed and tested to make sure that the conversion of payment for Part D ESRD drugs to renal dialysis services under Part B goes smoothly for beneficiaries, facilities, and pharmacies.

Several commenters stated that CMS has the discretion to defer the inclusion of Part D oral drugs in the payment bundle and asserted various statutory bases. In particular, commenters stated that the requirement to implement the ESRD PPS on or after January 1, 2011, does not specifically state that CMS must include all drugs for which payment is made under Title XVIII prior to implementation of the ESRD PPS. Commenters pointed out that section 1881(b)(14)(B) of the Act does not time limit CMS's discretion to define renal dialysis services for the ESRD PPS, and argued that the definition of "renal dialysis services" under section 1881(b)(14)(B)(iv) provides discretion to the agency about what items and services to include in the ESRD PPS and when to include them, claiming that Congress likely would not have enacted a provision that did not allow new items and services to be added. Some commenters argued that the "breadth of the language in subparagraph (iv)" of the statutory definition suggested broad discretion to the agency in making this determination, such that we may define renal dialysis services to exclude oral drugs in 2011, while maintaining authority to define renal dialysis services as including oral drugs in a subsequent year.

Other commenters cited the 4-year phase-in (section 1881(b)(14)(E) of the Act) as permitting full implementation of that portion of the single payment at any time before January 1, 2014, provided the implementation occurs in equal increments. Commenters argued that implicit in our interpretation of section 1881(b)(14)(E) of the Act is our authority to delay inclusion of oral drugs in the new bundled payment system. Commenters maintained the position that the phase-in over equal increments relates to coverage and payment, and that if CMS interpreted the provision to include oral drugs entirely at the beginning, CMS could implement the inclusion of oral drugs in the ESRD PPS in the fourth year of the transition period and still comply with the statute, including the requirement to implement the payment system in "equal increments".

Finally, some commenters argued that CMS has a statutory obligation to defer inclusion of oral drugs in the bundle, claiming that there is an obligation to delay under section 1881(b)(14)(ii) of the Act, because it requires CMS to determine the total amount of payments for renal dialysis services. If the agency

cannot do so because of a lack of data, it would be improper to include those items and services in the definition until it is able to do so.

Response: As we stated above and in the proposed rule, we continue to believe that section 1881(b)(14)(B) of the Act supports our interpretation that ESRD drugs and biologicals, including oral-only ESRD drugs, used for the treatment of ESRD, meet the definition of "renal dialysis services" under section 1881(b)(14)(B) of the Act, and should be included under the ESRD PPS (74 FR 49928 through 49929). For this reason, we have specified that oral ESRD drugs, including oral-only ESRD drugs, are included in the ESRD PPS.

However, we disagree with commenter's claims that this statutory definition is not "time-limited" such that we could delay including under this definition certain items or services that are currently in existence. We believe that the statutory definition dictates what services constitute "renal dialysis services" and does not afford us discretion to postpone such a determination for purposes of implementing the ESRD PPS. This is not to say, as some commenters have suggested, that the definition is static with regard to new items and services. To the extent new renal dialysis items or services come onto the market in the future and meet the definition, such services would be considered "renal dialysis services" and bundled under the ESRD PPS. For example, as we pointed out in the proposed rule, if other types of injectable ESAs or new oral forms of ESAs become available subsequent to the implementation of the ESRD PPS on January 1, 2011, such agents would be considered renal dialysis services and be subject to the ESRD PPS (74 FR 49928). Accordingly, for the reasons we set forth above and in the proposed rule, and after careful consideration of the public comments, we are finalizing the proposed policy decision that ESRD drugs and biologicals, including oral drugs, be identified as renal dialysis services under section 1881(b)(14)(B) of the Act.

With regard to the issue of inadequate data to price for payment oral drugs and biologicals, including oral-only drugs used for the treatment of ESRD, we agree with the commenters in part. We have included the Part B injectable drugs and biologicals used for the treatment of ESRD in the calculation of the base rate. Total payments for these drugs and biologicals were divided by the total number of hemodialysis (HD) equivalent treatments to obtain the amount of the payment per treatment for these drugs and biologicals reflected in the base rate. Injectable drugs are priced at ASP + 6 percent. Oral drugs with an injectable version were included in the payment bundle by taking total payments for these drugs based on Part D claims, and dividing that total by the total number of HD-equivalent treatment for Medicare ESRD beneficiaries enrolled in Part D. As explained in section II.K. of this final rule, prices for these drugs will be based on the national average drug prices developed from the Medicare Prescription Drug Plan Finder. These prices reflect pharmacy dispensing and administration fees and will be applied to only a limited number of drugs (three vitamin D analogues and levocarnitine).

While this pricing mechanism is also available for oral-only ESRD drugs, we believe that before we consider its adoption in connection with pricing these drugs for payment, we should evaluate its potential impact on dialysis facilities, particularly small dialysis facilities who may not be able to obtain drugs and biologicals at prices similar to those of the larger chains with greater purchasing power. Because payments for oral ESRD drugs with an injectable version in 2007 was about $10.7 million, while total payments for all oral ESRD drugs was about $455.7 million, we believe a careful assessment of the use of the Medicare Prescription Drug Plan Finder as a basis for pricing oral-equivalent ESRD drugs is appropriate before extending its application to oral-only drugs. Accordingly, we are delaying the implementation of oral drugs with no injectable equivalent or other form of administration (oral-only drugs), pending this evaluation.

As we discuss in more detail below and in the section II.K.2. of this final rule, we also agree that commenters' concerns about operational and safety issues with regard to furnishing oral-only agents should be further examined. We believe a delay would allow time to examine such issues and address as appropriate. For example, we agree with the commenters that a delay in implementing the inclusion of oral-only drugs under the ESRD PPS would provide sufficient time for ESRD facilities to establish a pharmacy in accordance with state licensure requirements, or establish arrangements with pharmacies to provide oral-only drugs to their patients and ensure a smoother transition to the dispensing of these drugs under Part B.

We disagree with the commenters who have suggested that the 4-year phase-in under section 1881(b)(14)(E)(i) of the Act provides authority to delay inclusion of certain types of renal dialysis services such as oral-only drugs beyond January 1, 2014. We believe that section 1881(b)(14)(E)(i) of the Act requires a phase-in of payments under the new system for facilities that do not opt to go all-in under the new ESRD PPS, allows for a blended payment under the old and new payment systems in equal increments over a 4-year period to allow facilities opportunity to transition to the new payment under the ESRD PPS. It does not, however, authorize a phase-in of renal dialysis services.

We also do not agree that the requirement under section 1881(b)(14)(A)(i) of the Act that the ESRD PPS be implemented by January 1, 2011, affords the agency discretion to delay identification of renal dialysis services to be included in the ESRD PPS. Section 1881(b)(14)(A)(i) of the Act requires implementation of a payment system in which a single payment is made for home dialysis and renal dialysis services which, as we discussed above, represent a specific set of services currently in existence that must be identified as renal dialysis services for the payment bundle.

We agree, however, with commenters with regard to our obligations under section 1881(b)(14)(A)(ii) of the Act, which requires that we make certain estimates about total payments for renal dialysis services based on certain data (that is, per patient utilization data). We agree that we must perform an assessment of the use of the Medicare Prescription Drug Plan Finder as a basis for the pricing of oral equivalent ESRD drugs before that pricing mechanism is potentially extended to oral-only ESRD drugs in order to develop payment rates for those drugs. Therefore, it would not be appropriate to implement oral-only ESRD drugs in the ESRD PPS at this time.

We believe that there are several advantages to delaying the implementation of oral-only drugs. A delay would—

• Provide additional time to determine the propriety of the Medicare Prescription Drug Plan Finder for the pricing of oral-equivalent ESRD drugs, before we consider extending that pricing mechanism to include all oral ESRD drugs and biologicals. CY 2007 data reveal that expenditures for the oral equivalents of injectable ESRD drugs totaled $10,700,083 for Medicare ESRD beneficiaries enrolled in Part D. *See* Table 9. Subtracting this amount from the total figure of $455,683,740, the total payments for all ESRD Part D drugs identified in Table 8 of the proposed rule (74 FR 49940), reveals that the comparable figure for oral-only ESRD drugs was $444,983,657. Given the

potential impact on the oral drug component of the payment bundle, evaluating the Medicare Prescription Drug Plan Finder and other potential alternative data sources for the pricing of oral ESRD drugs is essential.

- Allow ESRD facilities additional time to develop the arrangements or infrastructure necessary to provide oral-only drugs and negotiate prices with drug companies.
- Provide additional time for CMS to thoroughly educate beneficiaries, ESRD facilities, and pharmacies on those aspects of the bundled ESRD PPS involving the furnishing of non-injectable drugs to ensure as smooth a transition as possible.
- Given that oral drugs with an injectable version are included in the payment bundle as of January 1, 2011, provide CMS an opportunity to assess potential problems which may arise in connection with the provision of oral drugs prior to the system's expansion to include oral-only ESRD drugs beginning January 1, 2014.
- Allow time for additional analysis regarding the ability of ESRD facilities to provide oral-only ESRD drugs.
- Provide additional time to evaluate the need for additional clinical indicators applicable to the monitoring of certain patient conditions treated with oral-only drugs, such as bone loss and mineral metabolism associated with the provision of calcimimetics and phosphate binders. This could assist in determining the impact of the fully bundled ESRD PPS, and any unintentional consequences that might ensue, on quality of care.
- Allow Part D plans sufficient time to prepare bids for 2014 that excludes those oral-only drugs identified as "ESRD related". CMS will specify the oral-only drugs that are for the treatment of ESRD in connection with a proposed rule Beneficiaries will have access to more accurate premium quotes to assist them in making decisions about their Part D coverage.
- Allow Part D plans and pharmacies additional time to establish, test, and modify the infrastructure necessary to identify ESRD patients, as the oral equivalents of injectable drugs are bundled beginning January 1, 2011. Part D sponsors will gain several years of experience in identifying ESRD patients within CMS systems in order to ensure that Part D payments are not made for ESRD related drugs.

Beginning January 1, 2011, 18 oral drugs (as discussed below), will be included in the ESRD PPS base rate. Specifically, facilities will furnish such oral drugs beginning January 1, 2011. Until comprehensive beneficiary protections can be developed in anticipation of the inclusion of all ESRD-related oral-only drugs in the payment bundle under the ESRD PPS beginning January 1, 2014, patients will have access to these drugs under Part D. After considering the public comments and for the reasons we discussed above, we are retaining the definition of renal dialysis services as proposed in § 413.171, including with respect to the inclusion of oral-only drugs and biologicals. However, we are revising the implementation date for oral-only ESRD drugs and biologicals to be January 1, 2014 in § 413.174(f)(2). We believe that the transition period will give us sufficient time to address the data/pricing issues identified above, and to evaluate and correct any potential concerns that may emerge as a result of the inclusion of the oral drugs and biologicals with other forms of administration in the payment bundle effective January 1, 2011.

b. Other Drugs and Biologicals

Below we discuss comments regarding drugs and biologicals other than oral-only drugs and biologicals (for example, injectable drugs, oral drugs with some other form of administration, etc.). Oral-only drugs are separately addressed above.

Comment: Most commenters who expressed opposition to our proposed inclusion of oral-only Part D drugs in the ESRD PPS payment bundle were careful to distinguish these drugs from oral equivalents of injectable drugs, for which they conceded statutory authority existed for their inclusion under section 1881(b)(14)(B) of the Act. Although the commenters maintained that the inclusion of any oral drugs in the payment bundle would pose administrative burdens on dialysis facilities, they generally did not challenge our authority to include in the payment bundle the oral equivalents of injectable drugs used to treat ESRD in order to prevent the shifting of costs from Medicare Part B to Part D. The commenters, however, stated that if such drugs and biologicals were included in the payment bundle, their inclusion should be adequately funded.

Response: We agree with the commenters that section 1881(b)(14)(B) of the Act specifically requires that oral equivalents of injectable drugs used in the treatment of ESRD must be considered renal dialysis services for inclusion in the payment bundle. Accordingly, we have included those drugs, as described later in this section of this final rule. We have also revised the methodology for calculating the average amount per treatment for these drugs and biologicals included in the base rate, as described elsewhere in this final rule.

Comment: One commenter pointed out that dialysis patients take numerous oral medications, many of which are not related to ESRD. The commenter stated that the inclusion of oral equivalent drugs with an injectable version in the payment bundle could result in the patient receiving these drugs from a pharmacy with which the dialysis facility has established a relationship for the dispensing of these drugs to its patients, while the other medications are received from a different pharmacy of the patient's choice. Because multiple pharmacies would be involved, this could result in less attention paid to potential adverse consequences resulting from drug interactions and less coordination of care.

Response: We agree that under the circumstances which the commenter has described, multiple pharmacies could be involved in the dispensing of drugs to dialysis patients. However, the prescriptions for these drugs are prepared by the patient's nephrologist, primary care physician, or specialist, each of whom should be aware of the patient's medications for potential adverse interactions. The dialysis facility should also be aware of the patient's oral medications as an additional safeguard and therefore, we expect dialysis facilities to collect comprehensive information on patients' oral medications to identify any potential drug interactions that might otherwise occur. Finally, patients can always advise their pharmacist of the oral drugs they take when filling a prescription, and inquire about potential drug interactions as well. Therefore, we believe that there are sufficient safeguards to ensure that the use of several pharmacies to obtain oral drugs does not result in adverse consequences for dialysis patients.

Comment: Many commenters expressed concern about what they believed would occur if drugs were included in the ESRD PPS. Some commenters were opposed to including oral drugs in the bundled payment, particularly vitamin D used for bone and mineral metabolism. Commenters cited negative effects on patients' health because ESRD facilities may consider cost saving measures such as purchasing less costly and less effective drugs (for example, over-the-counter calcium binders or vitamin D); limiting the use of the more expensive drugs; using oral drugs which they believe are not as effective as intravenous drugs; switching to generic drugs or to drugs used in the past, which the commenters believed are not as effective; and using

lower cost oral drugs instead of intravenous drugs resulting in various complications as vascular calcification, anemia, blood transfusions, and hospitalizations. Some commenters predicted an increase in the number of parathyroidectomies due to poor control of hyperparathyroidism. One commenter expressed concern that cost cutting changes in medication practices at his ESRD facility have already begun to occur in preparation for the implementation of the ESRD PPS.

Some commenters indicated that certain patients would be negatively affected by the inclusion of drugs in the ESRD PPS bundled base rate. The commenters believed that older patients would be discriminated against by being given less expensive and less effective medications. Others believed patients needing more medications than others would be unable to receive the appropriate dose of their medications. One commenter believed that patients receiving dialysis twice weekly or those who miss treatments will be considered financially undesirable because ESRD facilities will be responsible for the entire month for their medications while receiving payment for the dialysis treatments only.

Response: We are concerned by the issues raised by commenters who believe ESRD facilities would intentionally and knowingly deny medications or provide less effective drugs because of the inclusion of drugs in the ESRD PPS bundle. We do not agree that the inclusion of drugs in the ESRD PPS would result in facilities denying drugs to patients or necessarily using less effective drugs. In particular, we do not agree that the use of alternative less costly drugs necessarily constitutes the use of less effective drugs. We expect that ESRD facilities will continue to provide necessary care to patients with ESRD, and we will be monitoring the implementation of the ESRD PPS very closely.

As with any prospective payment system, there are patients whose medical treatment results in more costly care as well as those with less costly care. As we have discussed in other sections of this final rule, the ESRD PPS bundled base rate reflects Medicare payment for the average ESRD patient. We have incorporated payments under the current composite rate payment system as well as payments for separately billable items and services into the ESRD PPS base rate. As a result, we believe the ESRD PPS payments are sufficient and reflect the average cost of providing care to the average patient with ESRD and therefore, we expect that, on average, high cost patients would be offset by low cost patients. We have provided for higher acuity patients with patient case-mix adjusters as discussed in section II.F. and with outlier payments for high cost patients as discussed in section II.H. of this final rule.

Section 494.80(a)(5)of the regulations requires an ESRD patient's comprehensive assessment include an "[e]valuation of factors associated with renal bone disease." Section 494.80 outlines other requirements for assessing and reassessing patients, as well as creating and implementing an individual patient plan of care as described in § 494.90. Section 494.90(a)(3) requires all ESRD facilities to "* * * provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease." Patient rights, including the mechanisms for filing grievances, are established at § 494.70. This means that ESRD facilities are required to provide care necessary to treat patients. We are confident that ESRD facilities will act responsibly to provide appropriate care under the ESRD PPS and oversight activities will identify any ESRD facility that may not do so. Therefore, we plan to monitor utilization of renal dialysis items and services to ensure that quality care is being provided. We will discuss monitoring in the implementation section II.K. of this final rule and in the future.

Comment: One commenter believed that separating the dispensing of oral renal drugs from oral drugs used for non-renal conditions will cause confusion for patients, their families, and other providers that provide care to ESRD patients.

Response: We believe the commenter is referring to ESRD-related drugs and biologicals included in the ESRD PPS base rate. We do not agree that the bundling of ESRD-related drugs or biologicals will result in confusion. Currently patients may receive medications or prescriptions from multiple sources especially if they require medical specialists for non-ESRD conditions. We do not see any difference in this process under the ESRD PPS.

Comment: Some commenters believe patients will be involuntary discharged from ESRD facilities if the patients are noncompliant and drugs are included in the ESRD bundle.

Response: As discussed earlier in this section of the final rule, the statute requires that renal dialysis services included in the ESRD PPS include specified ESRD-related services including injectable and oral drugs and biologicals. Because ESRD-related drugs and biologicals are in the ESRD PPS bundle, ESRD facilities will be responsible for furnishing ESRD-related drugs and biologicals that their patients require. We appreciate the commenter's concern that patients may be involuntarily discharged. However, § 494.180 of the ESRD Conditions for Coverage explicitly addresses the discharge procedure, the acceptable circumstances for an involuntary discharge or transfer, the required actions that must be completed by the ESRD facility prior to ceasing treatment, as well as the requirement to inform patients of their rights and protections.

Comment: One commenter stated that because of the ESRD PPS, patients with vascular access dysfunction, who are currently treated in the ESRD facility, would instead be referred to the emergency department in order to be able to receive separate payment for drugs used to maintain vascular access. Other commenters indicated that patients would be referred to other health care settings such as infusion centers or other health care providers to administer medications such as antibiotics and thrombolytic agents, for the purpose of being reimbursed for medications.

Response: We believe that the commenter is implying that as a result of including anti-thrombolytic drugs and antibiotics in the bundled ESRD PPS base rate, ESRD facilities would refer patients with any difficulties with vascular access to the emergency department or to other settings rather than ensuring that vascular access patency is addressed in the ESRD facility at the time of dialysis (as is currently being done). We believe that maintaining vascular access is a renal dialysis service and therefore, would be included in the ESRD PPS and ESRD facilities would continue to be responsible for furnishing the service. In other words, as ESRD facilities have been maintaining vascular access sites under the current basic case-mix adjusted composite rate system and receiving separate payment for anti-thrombolytic drugs, we will expect that they would continue to maintain vascular access under the ESRD PPS, with payment for anti-thrombolytic agents included in the ESRD PPS base rate. Accordingly, we expect that ESRD facilities would not refer patients to another health care setting for the purpose of maintaining vascular access. We note, we would expect patients to be referred to another setting if medically necessary and we are not implying that ESRD facilities are expected to address any and all vascular access complications, if doing so would be

unsafe for the patient. We merely are indicating that we expect ESRD facilities to perform the same procedures to maintain vascular access that they currently perform, and not refer patients to other settings for the purpose of obtaining additional payment. We will monitor ESRD facilities to determine whether they are continuing to perform the same procedures to maintain vascular access that they currently perform.

Comment: Some commenters cited patient non-compliance for their opposition to including oral drugs in the bundle. The commenters believed that dialysis facilities could control intravenous drugs and dosing but could not determine patient compliance with pill taking; that inclusion of oral drugs would require patients to take responsibility for their own care; and that patient compliance in inner cities is already poor. Others stated that reverting to oral medications in place of their intravenous forms, would result in an increase in the number of pills patients with ESRD, who are already required to take multiple pills with limited daily fluid allowance, would be required to take. Other commenters were concerned that patients might not receive their medications if they forget to obtain them during their dialysis treatment. Several commenters claimed patient non-compliance would increase due to the bundling of oral drugs. The commenters believed there would be higher spending on hospitalizations and outpatient care because of decreased control of patient's anemia and bone disease.

Response: We appreciate the concerns about patient compliance and pill burden. We do not understand the commenter's statement indicating that inner city compliance is already poor and therefore, we regret that we are unable to respond to the comment.

We do not agree that including oral drugs in the bundle will result in increased patient compliance difficulties, increased pill burden or poor control of anemia and bone disease because under the ESRD PPS there is no requirement that drugs must be administered in any particular form or by any particular route. It is the responsibility of the ESRD facility, the patient's physician, and the ESRD interdisciplinary team to develop a plan of care that is appropriate and meets each patient's needs. That includes determining the most appropriate route of administration of a drug. Although we believe we are required by statute to include oral drugs and biologicals in the payment bundle, the use of oral equivalents remains a medical decision. Section 494.90 of the ESRD Conditions for Coverage requires the development of an individualized patient plan of care to address the patient's needs. Therefore, we believe ESRD facilities should make medical decisions based on patient needs and not solely on a financial basis.

As we discussed in several responses above, we believe that ESRD facilities will act responsibly to provide appropriate care under the ESRD PPS and that continued monitoring may serve to help identify the ESRD providers who do not. Therefore, we plan to monitor utilization of renal dialysis items and services to ensure the quality care continues to be provided. We will discuss monitoring in the implementation section II.K. of this final rule and in the future.

Comment: Commenters were divided in expressing their support or opposition to the inclusion of intravenous drugs and their oral equivalents in the ESRD PPS base rate. Some commenters expressed concern that bundling drugs will restrict nephrologists' ability to prescribe necessary medications. One commenter suggested removing all oral drugs from the bundle to allow nephrologists to decide what is in the best clinical interest of the patient without reimbursement concerns. Others expressed concern that physicians would not prescribe drugs that could put a facility at financial disadvantage or would be forced to use the "cheapest available therapy which might be harmful to patients and further increase their cardiovascular mortality." Another commenter believed that disparities in care will occur when physicians will need to determine which patients are "most deserving or have the greatest need for certain medications" placing physicians in an adversarial position with ESRD facilities. Several commenters believed physicians should have autonomy to prescribe the most appropriate drugs within classes of medications.

Some commenters supported inclusion of all drugs and biologicals used to treat ESRD regardless of the route of administration noting that oral and injectable drugs are routinely given during the course of dialysis treatment. Other commenters indicated that inclusion of all drugs, regardless of route of administration in the bundle was " * * * critical to achieving optimal patient care." These commenters believed that allowing certain drugs and biologicals to be unbundled while others are bundled would establish incentives to select treatment options contrary to patient's clinical needs and results in medications from different sources jeopardizing adherence to care regimens and undermining quality of care.

Response: We thank the commenters for their views of the impact of including ESRD-related drugs and biologicals in the bundle. The general premise of the ESRD PPS is that the ESRD payments reflect the average cost of furnishing renal dialysis items and services to patients. In situations where costs for treating patients exceed an established threshold under the ESRD PPS, the outlier policy would apply. The outlier policy is discussed in detail in section II.H. of this final rule.

We continue to believe that the responsibility for determining the appropriateness of medical care resides with the ESRD facility, physicians, and the interdisciplinary team as stipulated by the ESRD Conditions for Coverage. We also believe that physicians, the interdisciplinary team, and ESRD facilities should make medical decisions based on patient needs and not solely on a financial basis. We plan to monitor utilization of renal dialysis items and services to ensure the quality care continues to be provided. We will discuss monitoring in the implementation section II.K. of this final rule and in the future.

We note that we do not have the discretion to exclude services from the ESRD payment system that meet the statutory definition of a renal dialysis service. We discuss the definition of renal dialysis services earlier in this section and in section II.D. of this final rule. We also discuss the delay in implementation of oral-only drugs earlier in this section.

Comment: Several commenters expressed concern that there are no quality measures for calcium, phosphorus, and parathyroid control. Others recommended tracking changes in transfusion utilization. One commenter urged that necessary steps be taken to ensure access to drugs appropriate for patients and not the "least costly alternative." Another commenter suggested that MedPAC and other entities track drug utilization to avoid unintended consequences.

Response: We agree with the commenters that there needs to be overall monitoring, tracking measures to monitor utilization and measure outcomes, and specifically to eventually track and report patient levels of calcium, phosphorus and parathyroidism prior to implementing the oral-only drugs in the ESRD PPS in 2014. We are currently working to develop measures for the initial year of the QIP and beyond. We note that, as set

forth in section 1881(h)(2)(A) of the Act, additional measures are being considered and developed such as patient satisfaction, iron management, bone mineral metabolism, and vascular access.

We are currently developing a comprehensive monitoring plan which includes tracking drug utilization. We will discuss monitoring in the implementation section II.K. of this final rule and in the future. We also plan to ensure that patients are educated about the ESRD PPS including the mechanisms they can use to report grievances. We believe that other entities such as MedPAC, the GAO, and the OIG will be looking into the effects of the ESRD PPS. We note that quality measures are discussed in section II.M. of this final rule. Additionally, we will include a discussion of future QIP measures forecasting in the ESRD QIP proposed rule.

Comment: One commenter believed that if the concern is cost shifting from injectable vitamin D to the oral vitamin D analogs, it would be better to address that issue directly.

Response: We do not understand what the commenter is suggesting with the statement about addressing the issue of injectable versus the oral version of vitamin D directly. However, we believe that the ESRD PPS provides an opportunity for ESRD facilities to make financially sound decisions while providing necessary care recognizing that some patients may utilize less renal dialysis items and services while others may use more. In addition, under the QIP, we are working towards developing quality measures for bone and mineral metabolism. Further discussion on quality measures are found in section II.M. of this final rule.

Comment: One commenter stated that certain injectable drugs used to treat ESRD may not have oral equivalents. Therefore, the patient would not be able to afford obtaining these drugs outside of the payment bundle, resulting in a lower quality of care.

Response: We are not clear about the point the commenter was attempting to make, as ESRD-related injectable drugs without oral equivalents would be furnished by the dialysis facility. In addition, all injectable drugs used to treat ESRD are included in the payment bundle as Part B renal dialysis services, regardless of whether they have an oral equivalent.

Comment: Many commenters indicated that they did not know which drugs were in the bundled base rate. Some commenters questioned whether non-dialysis-related drugs are included, such as those drugs used to treat diabetes, high blood pressure, cardiac drugs, or renal vitamins.

Response: We thank the commenters for their suggestions on which drugs should be included in the ESRD PPS. We also agree that in the proposed rule, we did not explicitly indicate which drugs would be in the proposed ESRD PPS base rate.

We proposed that payments for all drugs and biologicals furnished to ESRD patients and separately billable prior to January 1, 2011, would be included in the ESRD PPS payment bundle as renal dialysis services (74 FR 49929). Therefore, in the proposed rule, we included all drugs and biologicals on ESRD claims for 2007 for which separate payment was made in computing the proposed ESRD PPS base rate because the presumption was that all drugs and biologicals on ESRD claims were ESRD-related. We explained in the proposed rule (74 FR 49940 through 49941), our methodology of using CY 2007 claims data for determining the Medicare Allowable Amounts (MAPs) for the Part B and former Part D ESRD-related drugs and biologicals components of the ESRD PPS bundle, including the use of NDC codes for purposes of identifying by oral drugs covered under Part D by class.

With regard to the drugs and biologicals we proposed to bundle in the ESRD PPS, we identified in the proposed rule the top 11 Part B drugs and biologicals that accounted for 99.7 percent of total spending for Part B ESRD drugs and biologicals and identified the classes of oral ESRD-related drugs and biologicals currently covered under Part D that would be bundled. When listing the amount of spending for ESRD-related drugs and biologicals, we combined the products that accounted for the remaining 0.3 percent of total spending for Part B ESRD drugs and biologicals in a general category ("Other injectables" Part B drugs and biologicals) included in the proposed base rate (74 FR 49940 through 49941).

With regard to commenters' concerns about the inclusion of certain drugs, including non-ESRD related drugs, in the proposed bundle, in developing the proposed rule, we presumed that all separately billable items were drugs and biologicals on the ESRD claims were ESRD-related and therefore, all separately billable items on ESRD claims were included in the proposed ESRD PPS bundled base rate.

As a result of comments, for this final rule, we performed an extensive analysis of Medicare payments for

Part B drugs and biologicals billed on ESRD claims in 2007, 2008, and 2009 to identify drugs or biologicals that are ESRD-related and therefore meet the definition of renal dialysis services under section 1881(b)(14)(B) of the Act, and would be included in the ESRD bundled base rate. Drugs and biologicals that are generally not ESRD-related (for example drugs and biologicals used to treat diabetes, cardiac conditions and hypertension), would not be renal dialysis services and would be excluded from the ESRD bundled base rate.

We believe that categorizing drugs and biologicals on the basis of drug action would allow us to determine which categories (and therefore, the drugs and biologicals within the categories) would be ESRD-related. We evaluated each drug and biological to identify its category by indication or mode of action. We then analyzed the categories to determine those that would be expected to be utilized for ESRD-related conditions in a dialysis unit (and therefore would be a renal dialysis service).

We note that the current ESRD claims form does not differentiate between drugs and biologicals administered for an ESRD condition from drugs and biologicals administered during dialysis for non-ESRD related conditions. During this extensive analysis, we discovered that our presumption that all drugs and biologicals on the ESRD claims were ESRD-related was incorrect. In fact, there were categories of drugs and biologicals (and therefore specific drugs on ESRD claims for which separate payment had been made) that were not ESRD-related. These non-ESRD-related drugs and biologicals are discussed in detail below. Later in this section, we also discuss in detail the method used to identify ESRD-related drug and biological categories and drugs and biologicals included in the final ESRD PPS base rate below. Table C in the Appendix provides a listing of the specific drugs which were included in the proposed ESRD PPS base rate and how those drugs were treated in the final ESRD PPS base rate.

Specifically, we identified drugs and biologicals on the ESRD claims which are classified as chemotherapeutic drugs, immunosuppressant drugs, and vaccines. These drugs and biologicals, with the exception of hepatitis B and flu vaccines, had been included in the proposed ESRD PPS base rate. As these are not ESRD-related drugs and biologicals because they are not used for ESRD-related conditions and therefore, are not renal dialysis services, we excluded them from the final ESRD bundled base rate. As a result, we excluded the payments from the 2007 ESRD facility claims for these drugs and

biologicals in computing the final ESRD PPS base rate.

In performing our analysis of the ESRD claims for this final rule, we also identified drugs and biologicals that are included in the current composite payment rate but for which ESRD facilities received separate payment in addition to the composite rate payment. Because these composite rate drugs and biologicals were listed separately on the ESRD claims, separate payment was inadvertently made and we included these payments in the proposed ESRD PPS base rate. However, for this final rule, we excluded those inadvertently made payments from the final ESRD PPS base rate calculation.

We note that the Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1 lists the drugs and fluids included under the current composite payment system as heparin, antiarrythmics, protamine, local anesthetics, apresoline, dopamine, insulin, lidocaine, mannitol, saline, pressors, heparin antidotes, benadryl, hydralazine, lanoxin, solu-cortef, glucose, antihypertensives, antihistamines, dextrose, inderal, levophed, verapamil and antibiotics used at home by patients being treated for catheter site infection or peritonitis associated with peritoneal dialysis. The Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1 also explicitly states, "* * * drugs used in the dialysis procedure are covered under the facility's composite rate and may not be billed separately. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the composite rate." The manual further provides that "Administration of these items (both staff time and supplies) is covered under the current composite rate and may not be billed separately."

Also, in our analysis of drugs and biologicals for this final rule, we identified ESRD claims that included payments for drugs and biologicals, but did not include any dialysis treatments. Because ESRD facilities receive a payment under the current basic case-mix adjusted composite payment system which is treatment based (that is, based on the provision of a dialysis treatment) and separate payment is made for any items or services provided that are not considered part of the composite rate, payment for claims without treatments should not be paid. Therefore, for this final rule, payments for drugs and biologicals listed separately on the ESRD claim where there was no dialysis treatment included on the claim were excluded from the computation of the base rate.

In the analysis conducted for this final rule, we also identified drugs and biologicals on ESRD claims that were not identifiable because they were billed using unspecified or unclassified HCPCS codes. These codes are used when a HCPCS code has not yet been assigned. As a result, we were unable to determine the name of the drug or biological or if they were ESRD-related or administered for non-ESRD-related conditions. Because ESRD-related drugs and biologicals have HCPCS codes, we considered any drug or biological billed using an unclassified or unspecified HCPCS code as being non-ESRD-related. Therefore, any payments attributed to these unspecified codes were not included in computing the final ESRD base rate. We note that ESRD facilities should be using valid HCPCS codes for the drugs that they administer and should only use the unclassified codes for those drugs that do not have codes.

During our analysis for this final rule, we also identified drugs and biologicals as well as procedures which would not be considered renal dialysis services. For example, low molecular weight contrast administered for radiological purposes; pharmacy and administrative pharmacy code for administration of oral anti-emetics for cancer treatment; chemotherapy; and chest x-rays were reported on the ESRD claims. Because these procedures are not renal dialysis services (that is, they are not procedures that are used for the treatment of ESRD), we excluded the payments associated with these procedures from the final ESRD PPS base rate.

We also identified drugs, biologicals and procedures reported on ESRD claims which are unlikely to be performed or provided in an ESRD facility. For example, there were claims that included paralytic agents used to intubate patients. Because we do not believe that these drugs would be used to treat ESRD-related conditions, they would not be considered to be renal dialysis services. As a result, we excluded the payments made for these drugs in computing the final ESRD PPS bundled base rate.

We list the categories of drugs and biologicals that we would not consider ESRD-related and therefore would not be renal dialysis services included in the ESRD PPS base rate in Table 3 below. We note that the drugs, biologicals, and procedures that were excluded from the final ESRD PPS base rate represent a very small dollar amount accounting for less than one cent per dialysis treatment and represent less than 0.2 percent of payments made for separately billable drugs and biologicals. Table C in the Appendix identifies the Part B injectable drugs that were included in the proposed base rate and in the final base rate.

BILLING CODE P

Table 3 - ESRD Drug Category Excluded From the Final ESRD PPS Base Rate

Drug Category	Rationale for Exclusion
Anticoagulant	Drugs labeled for non renal dialysis conditions and not for vascular access
Antidiuretic	Used to prevent fluid loss
Antiepileptic	Used to prevent seizures
Anti-inflammatory	May be used to treat kidney disease (glomerulonephritis) and other inflammatory conditions
Antipsychotic	Used to treat psychosis
Antiviral	Used to treat viral conditions such as shingles
Cancer management	Includes oral, parenteral and infusions. Cancer drugs are covered under a separate benefit category
Cardiac management	Drugs that manage blood pressure and cardiac conditions
Cartilage	Used to replace synovial fluid in a joint space
Coagulants	Drugs that cause blood to clot after anti-coagulant overdose or factor VII deficiency
Cytoprotective agents	Used after chemotherapy treatment
Endocrine/metabolic management	Used for endocrine/metabolic disorders such as thyroid or endocrine deficiency, hypoglycemia and hyperglycemia
Erectile dysfunction management	Androgens were used prior to the development of ESAs for anemia management and currently are not recommended practice. Also used for hypogonadism and erectile dysfunction
Gastrointestinal management	Used to treat gastrointestinal conditions such as ulcers and gallbladder disease
Immune system management	Anti-rejection drugs covered under a separate benefit category.
Migraine management	Used to treat migraine headaches and symptoms
Musculoskeletal management	Used to treat muscular disorders such as prevent muscle spasms, relax muscles, improve muscle tone as in myasthenia gravis, relax muscles for intubation and induce uterine contractions
Pharmacy handling for oral anti-cancer, anti-emetics and immunosuppressant drugs	Not a function performed by an ESRD facility
Pulmonary system management	Used for respiratory/lung conditions such as opening airways and newborn apnea
Radiopharmaceutical procedures	Includes contrasts and procedure preparation
Unclassified drugs	Should only be used for drugs that do not have a HCPCs code and therefore cannot be identified
Vaccines	Covered under a separate benefit category

BILLING CODE C

Comment: Commenters noted that CMS needs to clearly delineate what is covered in the bundle. One commenter suggested differentiating between medications used for acute rather than chronic complications. One commenter recommended that a list of specific ESRD-only related drugs for inclusion in the bundle and that these be periodically updated to account for new technology and innovation. Some commenters suggested that we include only intravenous ESAs, iron, and vitamin D. One commenter stated that ESRD facilities separately bill and are reimbursed for ESAs, iron, vitamin D, alteplase and antibiotics for the treatment of access-related infections and peritonitis. Other commenters suggested that we include only intravenous ESAs, iron and vitamin D. One commenter believed that ESRD-related drugs used in the treatment of anemia, bone disease and iron deficiency should be included in the bundle. Some commenters suggested that only oral drugs that have "equivalent injectables" or other "equivalent non-oral forms" should be in the bundle. One commenter suggested that only ESRD intravenous drugs and their oral equivalents that are well known and most manageable be included.

Response: As we discussed in the previous response, we identified categories of drugs and biologicals which were not ESRD-related and

therefore, we excluded the payments for drugs in those categories from the final ESRD PPS base rate. We agree with the commenters that drug categories used for the treatment of anemia and iron deficiency (which includes ESAs and intravenous iron), access management (which includes alteplase), and bone and mineral metabolism (which includes vitamin D) would be renal dialysis services under the ESRD PPS. We also agree that antibiotics used for the treatment of venous access infections and peritonitis (specifically, vancomycin and daptomycin) and cellular management (specifically, levocarnitine) are renal dialysis services under the ESRD PPS. Therefore, payments for drugs in these categories in injectable forms (covered under Part B) and oral or other forms of administration (covered under Part D), were included in computing the final ESRD PPS base rate. We note one exception. We understand that the oral versions of vancomycin are not used for ESRD-related conditions and therefore, would not be a renal dialysis service. It is also our understanding that daptomycin does not have an oral equivalent. The categories and drugs which are renal dialysis services under the ESRD PPS are shown in Table 4 below.

Table 4 - Renal Dialysis Service ESRD Drug Categories Included in the Final ESRD PPS Base Rate

Drug Category	Rationale for Inclusion
Access management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Anti-infectives	Vancomycin and daptomycin used to treat access site infections. .
Bone and mineral metabolism	Drugs used to prevent/treat bone disease secondary to dialysis.
Cellular management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.

With regard to the suggestion that there be a differentiation between acute and chronic complications, we do not believe that such a differentiation is required as the definition of renal dialysis services does not distinguish between renal dialysis services provided for acute or for chronic conditions. For example, anemia management is a chronic condition and access management is more acute and the drugs and biologicals used for both are considered renal dialysis services.

With regard to the commenter's request to provide a list of specific ESRD-only drugs, we recognize that drugs and biologicals used for ESRD-related conditions may change over time based upon many factors including new developments, evidence-based medicine, and patient outcomes. By categorizing drugs and biologicals based on mechanism of action, we will account for other drugs and biologicals that may be used for those actions in the future under the ESRD PPS. In other words, while we have included drugs and biologicals used in 2007 in the final ESRD base rate, we recognize that these may change. Because there are many drugs and biologicals that have many uses and because new drugs and biologicals are being developed, we do not believe that a drug-specific list of drugs would be beneficial. We have provided a list of the specific drugs that were included in the ESRD PPS base rate in Table C in the Appendix. However, any drug or biological furnished for the purpose of access management, anemia management, vascular access or peritonitis, cellular management and bone and mineral metabolism will be considered renal dialysis services under the ESRD PPS.

We note that any ESRD drugs developed in the future that are administered by a route of administration other than injection or oral would be considered renal dialysis services and would be in the ESRD bundled base rate. Any drug or biological used as a substitute for a drug or biological that was included in the ESRD PPS bundled base rate would also be a renal dialysis service and would not be eligible for separate payment.

We believe that categories of drugs and biological used for access management, anemia management, bone and mineral metabolism, and cellular management would always be considered ESRD-related when furnished to an ESRD patient unless the ESRD facility indicates a drug or biological is non-ESRD-related through the use of a modifier. However, because anti-infectives are routinely furnished for ESRD-related reasons related to access infections and peritonitis, we included vancomycin and daptomycin and all other antibiotics on the 2007 ESRD claims in computing the final ESRD PPS base rate. Therefore, if any other anti-infective (including oral or other forms used as a substitute for an injectable anti-infective) is used for vascular access infections or peritonitis, the drug would be a renal dialysis service and separate payment would not be made.

Under this approach, we are presuming these drugs and biologicals are renal dialysis services because they were included on the ESRD facility claims and furnished in conjunction with a dialysis treatment. In addition, these drugs represent 99.8 percent of payments for separately billable drugs and biologicals furnished to ESRD patients.

In our analysis for this final rule of the drugs and biologicals on the ESRD facility claims, we analyzed the remain 0.2 percent of payments for separately billable drugs and identified drug categories that we believe could be ESRD-related, but are commonly used for non-ESRD-related conditions (for example, antiemetics and pain medications). These are shown in Table 5. Because these drug and biological categories could be ESRD-related, we included the payments made under Part B for these drugs and biologicals in 2007 in the final ESRD bundled base rate. In other words, for the purpose of the ESRD bundle, as of January 1, 2011, these drugs are presumed to be renal dialysis services unless the ESRD facility indicates on the claim (by using

a modifier) that a drug or biological in these categories is not ESRD-related and, separate payment would be made. (We discuss the use of the modifier in section II.K. of this final rule.)

Where these drugs are furnished and billed by ESRD facilities in conjunction with dialysis treatments, we presume these drugs and biologicals in whatever form they are furnished, to be renal dialysis services. As a result, we identified the drugs and biologicals for these categories and included the payments made under Part B for these drugs in computing the final ESRD PPS base rate. As ESRD facilities are required to report all drugs and biologicals they furnish and will be able to designate drugs and biologicals as being ESRD-related or non-ESRD-related through the use of a modifier, we will be able to monitor the drugs and biologicals to identify those that are being used for ESRD-related conditions and those that are not.

However, as the oral (or other form of administration) substitutes for the drugs and biological described above were not furnished or billed by ESRD facilities nor furnished in conjunction with dialysis treatments, we presume that these drugs and biologicals currently paid under Part D were prescribed for non-ESRD-related conditions and are not renal dialysis services. Therefore, we did not include payment for these oral drugs and biologicals with other forms of administration in the ESRD PPS base rate. However, if these drugs and biologicals currently paid under Part D are furnished by an ESRD facility for ESRD-related purposes, they would be considered renal dialysis services.

We will monitor the use of drugs and biologicals in these categories for the treatment of ESRD and may add categories of drugs and biologicals that constitute renal dialysis services (or if applicable, eliminate categories of drugs and biologicals that no longer constitute renal dialysis services) in the future.

Table 5 - ESRD Drug Categories Included in the ESRD Base Rate But May Be Used for Dialysis and Non-Dialysis Purposes.

Antiemetic	Used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple clinical indications but are included for their action to treat itching secondary to dialysis.
Anxiolytic	Drugs in this classification have multiple actions but are included for the treatment of restless leg syndrome secondary to dialysis.
Excess fluid management	Drugs/fluids used to treat fluid excess/overload
Fluid and electrolyte management including volume expanders	Intravenous Drugs/fluids used to treat fluid and electrolyte needs
Pain management	Drugs used to treat graft site pain and to treat pain medication overdose

Comment: One commenter questioned whether midodrine used to maintain blood pressure on dialysis was included in the bundle and would the bundle be expanded to include all blood pressure medications. Another commenter noted that the average patient is on 3 to 5 different anti-hypertensive drugs and suggested that if anti-hypertensive drugs were in the bundle, that more focus on optimal fluid management should occur.

Response: As we discussed above, the separately billable Part B payments made for cardiac drugs (including anti-hypertensive drugs) were not included in the final ESRD PPS base rate because cardiac drugs are included under the current basic case-mix adjusted composite payment rate. In addition, we note that we did not see midodrine reported in the 2007 ESRD claims data. However, to the extent that that any cardiac drug or biological (including anti-hypertensive drugs and biologicals) are furnished by an ESRD facility for ESRD-related conditions, the drug or biological would be considered a renal dialysis service and separate payment will not be made.

Comment: Some commenters indicated that in cooperation with other physicians and transplant centers and in the patients' interest, they administer medications that are not part of dialysis care, such as immunosuppressants and antibiotics. One commenter indicated that providers will have to undertake an expensive appeals process that could impair access if there is no recognition of non-ESRD-related drugs. The commenter further stated if the ESRD PPS does not consider that non-ESRD-related drugs and biologicals are furnished by ESRD facilities, nephrologists will only be permitted to order medications that are included in the final ESRD PPS base rate, and directly related to dialysis. This outcome would make it impossible for nephrologists to serve as primary care physicians and would force patients to see internists and family practice physicians incurring additional costs to insurers and patients. The commenter believed that this will result in repetition of unnecessary and expensive procedures resulting in higher costs, morbidity, and mortality.

Response: We are aware that drugs and biologicals may be administered for reasons unrelated to the treatment of ESRD or dialysis and would not be renal dialysis services covered under the ESRD PPS. As discussed above, because the 2007 ESRD claims do not distinguish between ESRD-related and non-ESRD-related drugs and biologicals, we were unable to exclude payments for those drugs and biologicals from the base rate with certainty. To the extent that we were able to presume a drug or biological was not ESRD-related, we excluded the payments. We identify the drugs and biologicals that were included in the base rate in Table C in the Appendix. We have developed a mechanism to be used by ESRD

facilities to identify and be paid separately for non-ESRD-related drugs and biological which is discussed in section II.K. of this final rule.

Comment: One commenter recommended that we develop a list of specific ESRD-only related drugs for inclusion in the bundle and that the list be periodically updated to account for new technology and innovation.

Response: As discussed above, rather than specifying the specific ESRD-related drugs and biologicals, we identified categories based on the mechanism of action of these drugs and biologicals. We did not specify all of the drugs and biologicals within these categories because, as we noted above, we did not want to inadvertently exclude drugs that may be substitutes for drugs we identified and we wanted the ability to reflect new drugs and biologicals developed or changes in standards of practice. Therefore, we are not restricting or limiting the tables to specific drugs or biologicals. However, the categories of drugs and biologicals which we identified as renal dialysis services were included in the final ESRD PPS base rate and are shown in Table 5. We will monitor the use of drugs and biologicals for the treatment of ESRD and may add categories of drugs and biologicals that constitute renal dialysis services (or if applicable, eliminate categories of drugs and biologicals that no longer constitute renal dialysis services) in the future.

Comment: Some commenters suggested that we include levocarnitine in the ESRD bundle.

Response: We agree that levocarnitine is used in the treatment of ESRD and meets the definition of a renal dialysis service. Levocarnitine is included in the drug categories shown in Table 4.

Comment: Some commenters indicated that the top 11 ESRD drugs and biologicals account for 99.7 percent of Part B payments for intravenous drugs and biologicals furnished to ESRD patients in 2007. The commenters believed that the Congress intended that only these drugs and their equivalents be included in the bundled rate, as these drugs normally are administered during the course of dialysis treatment.

Response: We do not agree with the commenters that only the top 11 drugs and biologicals should be included in the ESRD base rate. As we discussed above, the top 11 drugs, which in the analysis conducted for this final rule account for 99.8 percent of ESRD Part B separately billable drug payments, are included in the ESRD bundled base rate.

However, there are drugs and biologicals (and therefore, categories of drugs and biologicals) that were not among the top 11 ESRD drugs and biologicals, but were determined to be renal dialysis services. We discuss these categories of drugs and biologicals (for example, the pain management category), in the discussion above concerning categories of drugs that are ESRD-related but could be used for non-ESRD conditions.

Comment: A few pediatric dialysis facilities noted that drugs administered to children usually include antibiotics for peritonitis; peritoneal dialysis or hemodialysis central venous catheter infections; hemodialysis catheter related septicemia; alteplase for hemodialysis catheter de-clotting; anti-seizure medications; ESAs; and vitamin D analogs. The commenters indicated that antibiotic and alteplase use was more prevalent in younger children as well as higher ESA dosing per kilogram of body weight. Some of these commenters provided a list of the pediatric drugs and their costs.

Response: As we discussed above, we concur that drugs and biologicals that are used for anemia management (ESAs), bone and mineral management (vitamin D), access infections and peritonitis (vancomycin and daptomycin), and access management (alteplase) are renal dialysis services and payments for the drugs in these categories have been included in the ESRD PPS base rate. However, we did not include anti-seizure medications in the ESRD PPS base rate because we believed that anti-seizure drugs and biologicals were used for many conditions and were not likely to be renal dialysis services. We are not clear if the commenter was indicating that anti-seizure medications were administered to pediatric patients because of ESRD-related conditions or for other non-ESRD-related conditions.

However, we will monitor the use of anti-seizure drugs and biologicals for the treatment of ESRD and may add this category of drugs and biologicals that constitute renal dialysis services in the future. We expect that ESRD facilities that treat ESRD patients under the age of 18 will report the ESRD-related seizure medications on the ESRD claims. Where an anti-seizure drug or biological is furnished by the ESRD facility and reported without a modifier, separate payment would not be made. Further discussions on pediatric ESRD patients are in section II.G. of this final rule.

Comment: Many commenters opposed the inclusion of antibiotics in the bundled payment indicating that antibiotics are often administered during dialysis for non-renal reasons such as pneumonia or wound infection and, therefore, should remain separately billable. Others explained that antibiotics are administered when an infection is suspected in patients receiving dialysis treatment, noting that administration of antibiotics decreases hospitalizations, emergency room visits, shortens hospital days, and decreases mortality. These commenters believed that if antibiotics are included in the bundle, it would serve as a disincentive for early infection intervention. Others explained that antibiotics are often not prescribed by nephrologists and, therefore, would not be renal dialysis services. Still others noted that administering antibiotics during dialysis is less expensive to administer because there is vascular access readily available.

Another commenter indicated that antibiotics are administered to severely ill patients prior to transfer to the emergency department. Several commenters explained that dialysis "clears many antibiotics" and indicated that if patients do not receive antibiotics during or at the end of dialysis, there is a likelihood that their blood levels would be subtherapeutic, increasing the risk of recurrent infection and hospitalization. One commenter provided a case example. Some commenters predict that providers will decline to administer medications not directly related to kidney failure, such as antibiotics for infected foot ulcers, or will use less proven oral regimens to complete treatment.

Response: We acknowledge that antibiotics may be administered in an ESRD facility for purposes other than dialysis or ESRD-related conditions as well as for treatment of vascular access infections. Included in the top 11 drugs and biological are vancomycin and daptomycin. We believe that there are other antibiotics that may be administered for vascular access related infections and peritonitis. Therefore, we included all antibiotics, with the exception of antivirals, that were on the 2007 ESRD claims, into the ESRD bundled base rate. ESRD facilities will be able to identify on the ESRD claims any antibiotic administered for non-ESRD related reasons, and receive payment for those non-ESRD related antibiotics. We note, if an anti-infective (including anti-bacterials and anti-fungals) are administered for the purpose of a vascular access infection or peritonitis, the drug would be considered a renal dialysis service and not eligible for separate payment. This also applies to any drugs or biologicals that may be developed in the future.

Comment: In general, commenters supported the agency's reading of the

statute with regard to oral drugs with injectable equivalents (or some other form of administration). In particular, several commenters fully supported inclusion of oral drugs that are equivalent, full replacement products for injectable Part B drugs in the ESRD PPS.

Response: We appreciate these comments and agree that such oral drugs are required to be included in the ESRD PPS because such drugs meet the definition of "renal dialysis services" under section 1881(b)(14)(B) of the Act.

Comment: One commenter suggested that the bundle include oral drugs with intravenous equivalents, phosphate binders, and calcimimetics essential for bone health and mineral metabolism. A few commenters provided a list of drugs and cost amounts. One commenter believed bundling of intravenous drugs is straightforward with bundling of oral equivalents being less logical. Some commenters believed that oral drugs such as cinacalcet HCL, lanthanum carbonate, calcium acetate, sevelamar HCL, and sevelemar carbonate commonly taken by patients on dialysis and non-dialysis days, should not be in the bundle. One commenter acknowledged that zemplar and other vitamin D products belong in the bundle as they are oral equivalents of intravenous vitamin D. Another commenter believed that vitamin D and oral iron were the only currently available oral drugs with intravenous equivalents and therefore the only oral drugs in the bundle. One commenter stated that oral drugs with injectable equivalents are primarily prescribed for peritoneal dialysis and home hemodialysis patients. Other commenters supported the need to revisit the issue and ensure that the only drugs in the bundle are those that are separately billable by dialysis facilities and have an intravenous equivalent.

Response: As explained in section II.A.3. of this final rule, oral-only ESRD-related drugs and biologicals currently paid under Part D meet the definition of a renal dialysis service, but implementation of these drugs under the ESRD PPS is delayed until January 1, 2014. We do not agree with the comment that bundling of oral equivalents is less logical than bundling injectable drugs. As we have discussed above, section 1881(b)(14)(B)(iii) of the Act specifies that other drugs and biologicals that were furnished to individuals for the treatment of ESRD, and for which payment was made separately under this title, prior to the implementation of the ESRD PPS, and their oral equivalent forms, must be included in the ESRD PPS payment bundle.

Based upon our determination of the categories of drugs and biologicals that are renal dialysis services, at this time there are oral or other forms of injectable drugs only for the bone and mineral metabolism and cellular management categories. As discussed earlier in this section, we did not include the non-injectable form of vancomycin because we believe that the oral or other forms of these anti-infectives are not used for ESRD-related access infections. In addition, we were not able to identify any oral or other form of administration for iron prescriptions. Therefore, payments related to the oral or other forms of these injectable drugs were not included in the ESRD PPS base rate. As a result, for purposes of calculating the ESRD PPS base rate, we included the payments under Part D for oral vitamin D (calcitrol, doxercalcitrol and paracalcitrol) and oral levocarnitine. To the extent an ESRD facility furnishes an injectable, oral or other form of a drug or biological that is ESRD-related, the facility should report the drug or biological on the ESRD claim without a modifier and no separate payment would be made.

Therefore, we are finalizing the definition of renal dialysis services under § 413.171 as proposed.

4. Diagnostic Laboratory Tests and Other Items and Services

Section 1881(b)(14)(B)(iv) of the Act requires that diagnostic laboratory tests not included under the composite payment rate (that is, currently separately billable laboratory tests) must be included as part of the ESRD PPS payment bundle. We proposed to define such laboratory tests as laboratory tests that are separately billed by ESRD facilities as of December 31, 2010, and laboratory tests ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD patients that are separately billed by independent laboratories (74 FR 49929). We proposed that payments for these laboratory services would be included in the development of the proposed patient-specific case-mix adjusters and in the proposed ESRD base rate to which the adjusters would be applied.

Section 1881(b)(14)(B)(iv) of the Act also requires that the ESRD PPS payment bundle include "other items and services not described in clause (i)." In the proposed rule, we noted that this language can be reasonably interpreted to include other separately billable items and services used in the treatment of ESRD, such as supplies and other self-dialysis services (74 FR 49929). We noted that examples of such items and services would include, but would not be limited to, items such as syringes, specialized tubing, as well as blood and blood products, which facilities may furnish during the dialysis treatment. We also stated that we believe that the statutory language can be interpreted to include the cost of other self-dialysis training services in the ESRD PPS (for further detail on self-dialysis training (74 FR 49930)). We proposed that such items and services be included in the ESRD PPS bundle and that the inclusion of diagnostic laboratory tests and other items and services as renal dialysis services in the ESRD PPS payment bundle is set forth in proposed § 413.171.

The comments we received on this proposal and our responses are set forth below.

Comment: We received many comments addressing our methodology for the inclusion of diagnostic laboratory tests in the ESRD PPS payment bundle. Commenters noted that the inclusion of such tests in the bundled ESRD PPS will subject Medicare beneficiaries for the first time to a 20 percent coinsurance payment obligation. The commenters reasoned that our proposal that Medicare pay for 80 percent of diagnostic laboratory tests through their inclusion in the payment bundle violates the statutory requirement that the Secretary ensure that the estimated amount of total payments under title XVIII for renal dialysis services in 2011 equal 98 percent of the amount of payments that would have been made, but for the PPS. Some commenters stated that section 1833(a)(2)(D)(ii) of the Act specifies that for clinical laboratory tests paid under Medicare Part B on the basis of negotiated rates, the payment amount must equal 100 percent of the negotiated rate (incidentally, we note that a few commenters cited to section 1883(a)(2)(D)(ii) of the Act, but we presume those commenters intended to instead reference section 1833(a)(2)(D)(ii) of the Act). Accordingly, the commenters requested that we revise the payment amount for laboratory tests included in the bundle to reflect 100 percent of the allowable amount.

Response: Cost sharing with respect to laboratory services is addressed in section 1833(a)(2)(D) of the Act. We note that nothing changes in terms of the cost-sharing structure for non-ESRD-related laboratory tests. Under the definition of renal dialysis services under section 1881(b)(14)(B)(iv) of the Act, ESRD-related laboratory tests

would be considered to be renal dialysis services under the new ESRD PPS, subject to the usual coinsurance applied to such Part B services. A few commenters appeared to be under the impression that only 80 percent of payments for laboratory tests were included in the calculation of the base rate. This is incorrect. We included 100 percent of payments for laboratory services in the ESRD PPS base rate. As with all other renal dialysis services included in the payment bundle, these laboratory services will be part of the ESRD PPS payment rate and would be subject to the customary 20 percent Part B coinsurance amount.

Comment: Many commenters took issue with our proposal to include laboratory tests ordered by MCP physicians for treating ESRD beneficiaries, and that are billed separately by independent laboratories, and our proposal to include all these tests billed by independent laboratories for ESRD patients in the payment bundle. Numerous commenters pointed out that in many instances the MCP physician is the primary care physician for the ESRD patient and often has laboratory tests performed for conditions unrelated to ESRD. The commenters asserted that requiring ESRD facilities to pay for such tests would result in a potentially vast number of tests unrelated to the treatment of ESRD being inappropriately included in the ESRD payment bundle.

Response: Section 1881(b)(14)(B)(iv) of the Act specifies that the ESRD PPS must include "diagnostic laboratory tests * * * that are furnished to individuals for the treatment of end-stage renal disease." We interpreted this language to include laboratory tests ordered by MCP physicians for treating ESRD beneficiaries and that are currently billed separately by independent laboratories. We recognize that there is a small subset of laboratory tests that are typically performed in connection with a patient's ESRD, and that are appropriately considered renal dialysis services because they are furnished for the treatment of ESRD, but that can also be done for non-ESRD reasons. For example, a complete blood count (CBC) could be ordered for an ESRD patient in connection with routine testing for hemoglobin or hematocrit to ensure appropriate management of anemia, an ESRD-related purposes. However, a CBC could also be ordered for an ESRD beneficiary to measure the amount of blood loss in response to a suspected lower gastrointestinal bleed, or to measure infection (for example, white blood cell count for a suspected pneumonia), non-ESRD purposes.

The 2007 ESRD facility claims do not distinguish between ESRD-related and non-ESRD-related laboratory services. We included payments for all tests billed by independent laboratories for ESRD patients in calculating the final base rate in order to appropriately account for such tests as renal dialysis services. We presumed that MCP physicians, for the most part, order laboratory tests for ESRD beneficiaries for ESRD-related purposes. However, as we recognize that certain non-ESRD laboratory tests may be ordered in conjunction with ESRD-related laboratory tests, we have developed billing modifiers to provide for separate payment where the testing is not ESRD-related (section II.K.2. of this final rule).

Comment: Several commenters recommended that we include in the ESRD PPS payment bundle, only those laboratory tests that are generally furnished for the treatment of ESRD, and included lists of approximately 50 tests which they believe account for about 95 percent of the laboratory tests ordered by ESRD facilities for ESRD patients. The commenters pointed out that such specificity would leave no doubt as to whether a particular laboratory test would be included or excluded from the payment bundle, would not create billing rules other than the list of 50 to 60 current procedural technology (CPT) codes that would not be separately billable, and would not result in the attachment of testing frequencies to the included tests. The commenters also stated that there is precedent for their recommendation, pointing out that CMS excluded ESRD-related clinical laboratory tests from the skilled nursing facility consolidated payment, and published a list of those ESRD-related tests, which closely resemble the tests which the commenters submitted for consideration as ESRD-related for inclusion in the ESRD PPS. Other commenters submitted their recommended list of ESRD-related laboratory tests.

Response: We agree with the commenters that limiting the laboratory tests for payment under the ESRD PPS payment bundle to specific tests that are customarily performed in connection with the treatment of ESRD comports with section 1881(b)(14)(B)(iv) of the Act and would be a straight forward method of capturing only ESRD-related laboratory testing. In addition, we needed to develop a list of ESRD-related laboratory tests for consolidating billing edits to ensure that payment is not made to independent laboratories for ESRD-related laboratory tests. However, based on a review of the lists of ESRD-related laboratory tests in the Medicare Claims Processing Manual and received in public comments, it appears there is currently not consensus among the various stakeholders about the laboratory testing commonly furnished to ESRD patients.

Therefore, in order to develop a list of ESRD-related laboratory tests, we identified those laboratory tests that were most frequently identified on the lists we reviewed. Then, we received input from physicians working with UM–KECC. Lastly, CMS physicians and other clinical staff finalized the list which is contained in Table F of the Appendix. As discussed in more detail in section II.K.2. of this final rule, we will be implementing consolidated billing edits to prevent payment to independent laboratories for tests on the list of ESRD-related laboratory tests unless a modifier is reported indicating the test is not ESRD-related.

ESRD facilities should report on their claims all laboratory tests ordered by the MCP physician. We will establish a modifier so that ESRD facilities may continue to be paid separately for non-ESRD-related laboratory tests. We plan to review the ESRD-related laboratory tests reported by ESRD facilities to ensure that the laboratory list continues to reflect common ESRD-related laboratory testing.

Comment: Commenters noted that we proposed to include in the ESRD PPS blood and blood products to the extent these items were furnished by ESRD facilities and reported on the type ESRD claims. One commenter pointed out that patients are transfused infrequently in ESRD facilities, and that most transfusions occur in hospital outpatient settings. The commenter stated that if ESRD facilities are to be held responsible for blood transfusions administered to dialysis patients, then the costs from other outpatient settings need to be captured and added to the payments developed from dialysis facility claims to compute the ESRD PPS base rate.

Another commenter opposed the inclusion of blood and blood products in the payment bundle. This commenter stated that blood transfusions for outpatient dialysis patients do not represent the current first line standard-of-care intervention for the treatment of ESRD, having largely been replaced by anemia management drugs. Because their administration in dialysis facilities is relatively infrequent, the commenter requested that to the extent dialysis facilities furnish blood or blood products ordered by an MCP physician, these costs should be excluded from the

ESRD PPS payment bundle and remain separately billable.

Response: We agree with the commenter that the furnishing of blood and blood products by ESRD facilities to ESRD beneficiaries is a relatively infrequent and unusual occurrence, and we believe that it does not represent standard clinical practice for the management of anemia in connection with the treatment of ESRD. ESRD facilities may also furnish blood and blood products for non-ESRD reasons ordered by an MCP physician for the convenience of the patient undergoing dialysis. We also agree that the administration of blood and blood products is usually performed in a hospital outpatient setting, generally for non-ESRD reasons.

For these reasons, we do not consider the furnishing of blood and blood products to be renal dialysis services under the statute and, therefore, these services would be excluded from the ESRD PPS payment bundle. The furnishing of blood, blood products, and blood supplies in connection with transfusions will remain separately billable when they are administered in an ESRD facility. The total payments for blood and blood products to ESRD facilities as reported on available ESRD claims in CY 2007 was $1,504,831. We have excluded this amount from the computation of the final ESRD PPS base rate, consistent with our determination that blood and blood products are not renal dialysis services.

We note that the incentives under the ESRD PPS may lead to under treatment of anemia, a critical clinical indicator for ESRD patients, necessitating blood transfusions for patients whose hemoglobin levels drop too low. We plan to monitor the extent to which dialysis patients receive transfusions after implementation of the ESRD PPS. If practice patterns change such that the administration of transfusions and furnishing of blood and blood products substantially increase, we may subsequently reexamine whether these services should be considered renal dialysis services used for the treatment of ESRD and included in the ESRD PPS payment bundle.

With respect to the laboratory tests included in developing the ESRD PPS base rate, we are finalizing our proposal to include payments for outpatient laboratory tests billed on ESRD facility claims, as well as payments for laboratory tests ordered by physicians receiving MCP amounts and billed on carrier claims. We used the list of CY 2007 MCP physicians for this purpose. The ESRD related laboratory tests that will be subject to the ESRD PPS are identified in Appendix Table F of this final rule.

5. Physicians' Services

Section 1881(b)(14)(A)(i), as added by MIPPA, states as follows in pertinent part:

> * * * the Secretary shall implement a payment system under which a single payment is made under this title to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment * * * and for such services and items furnished pursuant to [section 1881(b)(4)].

As we indicated in the proposed rule, we believe this provision generally governs payment to ESRD facilities (74 FR 49931). With regard to physicians' services related to renal dialysis, such services are addressed separately in section 1881(b)(3) of the Act. In the ESRD PPS proposed rule, we indicated that we did not intend to significantly modify payment for physicians' services, and stated that any changes with regard to the payment for physicians' services related to renal dialysis would be addressed in future rulemaking (74 FR 49931).

Comment: Numerous commenters supported our decision in the proposed rule to exclude physician services from the ESRD PPS payment bundle. We received no comments endorsing the inclusion of these services in the bundle.

Response: We appreciate the views of the commenters. As we indicated in the proposed rule, we are limiting the scope of this rulemaking to payment for home dialysis and renal dialysis services furnished by ESRD facilities. Therefore, we do not, at this time, intend to modify payment for physicians' services. Any changes in payment for physicians' services related to renal dialysis would be addressed in future rulemaking.

6. Other Services

The comments and our responses are set forth below.

Comment: One commenter requested that we clarify that services that may be furnished to beneficiaries at the time of a dialysis session, but not furnished specifically for the treatment of ESRD, would be excluded from the proposed ESRD bundled payment system. The commenter cited apheresis treatment as an example. Because apheresis, like dialysis, filters a patient's blood, the commenter was concerned that this treatment regimen may be incorrectly viewed as a treatment for ESRD. The commenter further explained that although both dialysis and apheresis filter the patient's blood, the procedures accomplish different objectives. The commenter stated that in dialysis the purpose is to clear wastes from the blood, restore electrolyte balance, and eliminate excess bodily fluid, whereas the purpose of apheresis is to remove from the blood certain blood components such as abnormal proteins implicated in a disease.

The commenter recommended that Medicare policy take no steps that would financially incentivize fracturing dialysis and apheresis into separate patient visits, but encouraged service alignments.

Response: As described in greater detail in section II.A. of this final rule, items and services included within the ESRD PPS are home dialysis and those items and services that meet the definition of "renal dialysis services" and are furnished to individuals for the treatment of ESRD. Moreover, such services are considered essential for the delivery of outpatient maintenance dialysis. Therefore, the fact that an unrelated, non-ESRD item or service is furnished at the time of a maintenance dialysis treatment would not mean that the particular item or service would be bundled into the ESRD PPS.

Because at this time, we do not consider apheresis to be a renal dialyisis service that is furnished to individuals for the treatment of ESRD, or to be essential for the delivery of maintenance dialysis, we have not included apheresis services in the ESRD PPS. As a result, we would expect that the delivery of apheresis in the ESRD facility setting would occur infrequently. However, we note that to the extent that the coverage provisions for apheresis are met, as set forth in the National Coverage Determination (NCD) Manual, apheresis services may be payable outside the scope of ESRD facility payment, and in accordance with hospital or nonhospital setting payment policies (for example, hospital inpatient prospective payment system (IPPS), outpatient prospective payment system (OPPS), or the physicians' fee schedule).

Medicare coverage provisions for apheresis procedures for certain indications are set forth in the CMS Internet Only Manual (Pub. L. 100–03; Chapter 1, Part 2, section 110.14), available online at: *http://www.cms.hhs.gov/Manuals/IOM/list.asp?listpage=1*. Please note that indications not specifically addressed in section 110.14 of the NCD Manual are left to local contractor discretion.

Comment: One commenter pointed out that occasionally a hospital or ambulatory surgical center (ASC) may furnish services to an ESRD patient. The commenter expressed concern that the

"other items and services" language in section 1881(b)(14)(B)(iv) of the Act could be interpreted as including such services in the ESRD PPS payment bundle. The commenter requested that CMS clarify that the definition of "renal dialysis services" excludes inpatient services, emergency hospital services (including dialysis furnished to ESRD patients), and hospital or ASC services relating to the creation or maintenance of a patient's vascular access.

Response: None of the services which the commenter described were included in developing the ESRD PPS base rate, and none of them are considered renal dialysis services for inclusion in the PPS payment bundle. Moreover, these services are reimbursed under other Medicare payment systems. Hospital inpatient services, emergency services (including emergency dialysis) furnished to ESRD patients, and certain outpatient procedures necessary to maintain vascular access (that is, those which cannot be addressed by the ESRD facilities using procedures that are considered part of routine vascular access), are excluded from the definition of renal dialysis services and are not included in the ESRD PPS payment bundle. We note that currently ESRD facilities utilize medications to maintain vascular access. We would consider the administration of medications that are currently performed by ESRD facilities to fall within the definition of renal dialysis services and paid for under the ESRD PPS.

Comment: Several commenters requested confirmation that nutritional supplements such as intradialytic parenteral nutrition (IDPN) and intraperitoneal parenteral nutrition (IPN) are not included in the ESRD PPS payment bundle.

Response: We do not consider nutritional therapies, even though (as in the case of IDPN) they are often administered during a patient's dialysis treatment, to be related to the treatment of ESRD. Nutritional supplements have never been considered part of the ESRD benefit, because they have not been considered integral to the furnishing of outpatient maintenance dialysis, and are not included in the ESRD PPS as Part B renal dialysis services.

Comment: One commenter stated that when adding up the numbers in Table 8 of the proposed rule (74 FR 49940), the total expenditures for composite rate and separately billable services included in payment bundle was $9,876,466,063, more than $636 million higher than the total shown of $9,239,987,362. The commenter inquired as to the reason for the discrepancy.

Response: There is no discrepancy. The totals shown in Table 8 of the proposed rule for vitamin D ($402,447,416) and injectable iron ($234,031,283) are each subdivided to show the payment amounts for each of the drugs which comprise these categories. The commenter has inadvertently added the component amounts for each of these payment categories along with the totals for the two categories, resulting in an overstatement of ESRD expenditures of $636,478,699.

7. Home Dialysis Patients (Method I and II) and Self Dialysis Training

Section 1881(b)(4) of the Act authorizes the Secretary to make payment to providers of services and renal dialysis facilities, and to suppliers of home dialysis supplies and equipment, for the cost of home dialysis supplies and equipment and self-care home dialysis support services furnished to patients for self-care home dialysis under the supervision of such provider or facility. Currently, hemodialysis, continuous cycling peritoneal dialysis (CCPD), intermittent peritoneal dialysis (IPD) and continuous ambulatory peritoneal dialysis (CAPD) treatment modalities may be performed at home by appropriately trained patients. Medicare beneficiaries dialyzing at home must complete a Medicare Beneficiary Form (CMS–382) selecting between two methods of payment (Method I or Method II) as described in detail in the ESRD PPS proposed rule (74 FR 49929).

a. Payment for Home Dialysis (Method I and Method II)

As a result of the enactment of section 153(b) of MIPPA, we proposed that payment for home dialysis services (excluding physician services) furnished to both Method I and Method II home dialysis patients under the current basic case-mix adjusted composite payment system would be included in the bundled payment to the ESRD facility under the ESRD PPS (74 FR 49929 through 49930). We also proposed that the costs of home dialysis training be included in the composite rate portion of the two-equation regression model for determining payment adjustments under the ESRD PPS (74 FR 49930 through 49931).

Below we address the general comments we received on home dialysis, but in subsequent subsections we address more specific comments on the proposals on Method I and Method II and self-dialysis training.

Comment: A commenter noted that section 1881(b)(14)(D)(iv) of the Act gives the Secretary the discretionary authority to include payment adjustments to the ESRD PPS as the Secretary determines appropriate. The commenter requested that CMS provide a separate adjustment that would account for the unique cost associated with providing home dialysis that would include: (1) Training for home dialysis; (2) support services; and (3) emergency home dialysis supplies, so that dialysis facilities do not neglect their responsibility to the care of ESRD home dialysis patients for financial reasons. The commenter stated that in the proposed rule, the training reimbursement for home dialysis services was fashioned to apply to all patients regardless of whether training services were actually provided to them. The commenter stated that the current system fosters a financial disincentive for home dialysis by encouraging providers to minimize the number of home dialysis patients they accept. To eliminate this financial disincentive, the commenter recommended that CMS remove home dialysis costs from the bundled rate and include this reimbursement in a separate adjustment.

Response: Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made under this title to an ESRD facility for renal dialysis services for such services and items furnished pursuant to section 1881(b)(4) of the Act. Therefore, we are required to include payment for home dialysis training, equipment and supplies, and support services in computing the single bundled payment base rate.

As we explained in the ESRD PPS proposed rule (74 FR 59930), when ESRD facilities furnish home dialysis training, Medicare pays the ESRD facility its case-mix adjusted composite rate plus a training add-on of $12 for peritoneal dialysis and $20 for hemodialysis and CCPD to account for the staff time, supplies, and equipment associated with training treatments. We believe the ESRD PPS base rate adequately accounts for the costs associated with equipment and supplies. However, we agree with the commenter, that the base rate does not capture the unique staffing costs associated with home dialysis training. Section 494.100(a) of the ESRD Conditions for Coverage requires that training be conducted by a registered nurse. Thus, as training involves one-on-one training sessions with a nurse, we believe a separate adjustment to reflect those costs are warranted.

We discuss the training payment adjustment we are finalizing in

subsection (b) of this section of the final rule.

Comment: A commenter suggested that CMS evaluate the cost of care for nursing home hemodialysis patients and create an adjustment for these patients under the ESRD PPS. The commenter stated that nursing home hemodialysis patients incur unique costs that pertain to one-machine per patient, administrative burdens, co-morbidities, higher turn-over rates, and require nursing caregiver assistance for dialysis administration. The commenter asserted that despite certain co-morbidities not being included in the ESRD PPS for case-mix adjustments, a nursing caregiver staff assistant is still required for dialysis administration. The commenter further stated that CMS failed to explain how the inclusion of home dialysis costs in the ESRD PPS bundled payment system creates an incentive to provide home dialysis in cases where the costs to treat patients is greater than the reimbursement CMS proposed. The commenter suggested that a special adjustment be afforded to cover these unique costs.

Response: Nursing home patients are regarded as home dialysis patients because they are considered residents of the nursing home and receive dialysis treatments at the nursing homes and not at dialysis facilities. We disagree with this commenter's assertions because the unique costs they described are no different from any other home dialysis patient where there is one-machine per patient, co-morbidities, and patient turn-over occurs due to kidney transplantation. We, therefore, do not believe that a separate adjustment for nursing home ESRD patients is warranted.

The other unique costs identified by this commenter pertained to nursing-related caregiver services. The commenter stated that all nursing home dialysis patients must have a trained caregiver in order to dialyze at a nursing home and that these caregiver services are not covered under the ESRD benefit. The commenter is correct that caregiver services are not covered under the ESRD benefit, including caregiver services furnished to nursing home dialysis patients. Thus, caregiver services are not considered to be renal dialysis services and are not reflected in the ESRD PPS base rate nor in the payment adjustments.

Comment: Some commenters suggested that CMS allow for self-administration of injectable ESRD-related drugs at home by home dialysis patients. The commenters indicated that home dialysis patients would prefer to self-administer all injectable ESRD-related drugs at home to include EPO, rather than traveling to the dialysis facility to receive the injectable drugs. The commenters reasoned that since injectable drugs such as EPO, Vitamin D, and IV iron are included in the ESRD PPS bundle, patients should have the option to self-administer these drugs at home.

Response: Under section 1861(s)(2)(O) of the Act, self-administration of erythropoietin (EPO) is permitted for dialysis patients who are competent to use such drug without medical or other supervision with regard to the administration of such drug. If a dialysis patient meets this requirement, then he or she can self-administer erythropoietin at home. Payment for erythropoietin and supplies needed to self-administer the drug would be included in the ESRD PPS payment.

The ESRD PPS does not fundamentally alter how other injectable drugs are administered under Part B. Thus, under the ESRD PPS, home dialysis patients would continue to go to the dialysis facility for the administration of other injectable drugs.

Comment: Some commenters expressed concern that CMS did not fully account for supplies in estimating the cost of home dialysis programs. They indicated that there is a one-time cost associated with certain supplies and equipment (scales, thermometer, blood pressure equipment, etc.) and continuing costs for daily treatment including disposable supplies for peritoneal dialysis (dialysate, syringes, needles, masks, latex gloves, etc.).

The commenters were also concerned that since supplies are delivered monthly, the facility pays up front for those supplies. Commenters claimed that should a patient discontinue treatment, change modalities, or for other reasons stop using the delivered supplies, the dialysis facility cannot move supplies from one patient to another because of infection control issues. Commenters stated that the cost of these supplies is borne by the facility. The commenter stated that these cost are not recognized in the proposed ESRD PPS, and facilities will no longer be able to bill separately for supplies without a treatment.

Response: In accordance with § 410.52 and § 414.330, Medicare Part B pays for all medically necessary home equipment and supplies for the effective performance of a patient's dialysis in the ESRD patients home. Medicare currently pays for home dialysis equipment and supplies under the basic case-mix adjusted composite rate (Method I) and for claims submitted by the DME supplier of home dialysis equipment and supplies (Method II). We proposed that the costs of home dialysis services furnished under Method I and Method II, regardless of home treatment modality, would be included in the proposed ESRD PPS (74 FR 49929).

As explained in great detail in the data section of the proposed rule (74 FR 49934 through 49935), we obtained cost information from 4,573 CY 2006 cost reports, for both hospital-based and independent ESRD facilities. Cost data obtained from these cost reports included all costs necessary to furnish home dialysis treatments including staff, equipment and supplies. Even though a dialysis facility could incur some up-front costs for supplies for home dialysis patients, these costs are reported as supply costs on the provider's cost report and were included in the composite rate part of the model. Therefore, by including home dialysis costs in the composite rate portion of the two-equation ESRD PPS model (described in section II.D. of this final rule), we believe we have appropriately accounted for the cost of home dialysis services and supplies.

Comment: A number of commenters indicated that CMS should actively monitor home dialysis utilization after the ESRD PPS is implemented via a formal plan consistent with the GAO's recommendation, which CMS has publically supported.

Another commenter recommended that CMS monitor the effect of the new payment system on use of training services and home dialysis. Also, commenters suggested that more specific coding would facilitate such an effort by enabling CMS and researchers to better analyze trends in the use of these services. For example, commenters indicated that specific codes on facility claims could identify particular types of training services, home dialysis services, and in-facility dialysis services. Commenters also believe that a strengthened monitoring plan should help CMS assess the use of dialysis services, identify lapses in care, give providers an incentive to furnish all clinically necessary care, and lead to quality improvement.

Response: We agree with the commenters that increased monitoring will be needed to monitor the effects of the new ESRD PPS. We concurred with the GAO's recommendation in its May 2009 report and we intend to assess the effect of the expanded bundled payment on home dialysis utilization rates. We also agreed with GAO on the need to establish a monitoring plan under the new bundled ESRD PPS that includes an examination of home dialysis utilization. We expect to establish such

a plan after we promulgate this final ESRD PPS. With regard to establishing more specific code for home dialysis equipment, supplies, and services, we will take these comments into consideration as we make changes to the cost report to reflect the ESRD PPS. Changes in coding will be established through administrative issuances.

i. Method I—The Composite Rate

In accordance with § 414.330(a), under the basic case-mix adjusted composite payment system, the ESRD facility receives the same Medicare payment rate for a home dialysis treatment as it would receive for an in-facility treatment. Under Method I, the ESRD facility bills the fiscal intermediary Medicare administration contractor (FI/MAC) for needed supplies, equipment, and drugs, and the beneficiary is responsible for paying the Medicare Part B deductible and the 20 percent coinsurance on the total Medicare payment made to the facility. Although we proposed that the costs for home dialysis services furnished under Method I would be included in the single payment rate under the proposed ESRD PPS, we did not propose any changes to Method I as this approach could continue to be used under the ESRD PPS (74 FR 49930).

The comments we received on this proposal and our responses are set forth below.

Comment: Several commenters expressed support for continuing to provide the same payment for home dialysis and in-facility treatments, which commenters believe will support CMS's goal of increasing the number of patients that elect the various home dialysis therapies. The commenters applauded CMS's move to a bundled payment system and our interest in encouraging patient access to home dialysis services.

Response: We appreciate the commenters' support of our move to a bundled payment system that we believe will encourage patient access to home dialysis and recognize the importance of various home dialysis therapies.

Comment: Commenters from individual home dialysis patients thanked CMS for including all home dialysis options in the ESRD PPS and recognizing the importance of home dialysis. Many of the patients stated that they have access to more frequent dialysis that decrease hospitalizations and medications and increase their quality of life, which allows them to work or go to school and contribute to society.

Another commenter generally pointed out that there are no transportation costs incurred for home hemodialysis patients. Commenters stated that decreased hospitalizations are typical of home dialysis patients, which further reduced the costs within the system. Additionally, commenters pointed out that early discharge from acute and sub-acute care facilities to either the patient's home or a nursing home has allowed patients to receive care in less expensive and more appropriate settings.

Response: We appreciate the comments from individual home dialysis patients who support our recognition of the importance of home dialysis which we believe results in a better quality of life for the patient.

We did not receive any public comments objecting to our proposal for payment under the ESRD PPS of home dialysis services furnished under Method I payment. As we described above, numerous commenters supported payment under the bundle for Method I home dialysis patients stating it would increase beneficiary access to home dialysis services, which would increase their quality of life. Therefore, consistent with section 1881(b)(14)(A)(i) of the Act, we are finalizing our proposal to bundle home dialysis furnished under Method I and pay the bundled ESRD PPS rate for such home dialysis services, as set forth in § 413.210, § 413.217, and § 414.330, respectively.

ii. Method II—Dealing Directly With Suppliers

Currently, in accordance with regulations at § 414.330(a)(2), a Medicare ESRD beneficiary can elect to obtain home dialysis equipment and supplies from a supplier, that is not a Medicare approved dialysis facility (Method II). If a beneficiary elects Method II, the beneficiary deals directly with a single Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier to secure the necessary supplies and equipment to dialyze at home. The selected DMEPOS supplier must accept assignment and bills the Durable Medical Equipment Medicare Administrative Contractor (DME MAC). The beneficiary is financially responsible to the supplier for any unmet Medicare Part B deductible and for the 20 percent Medicare Part B coinsurance requirement. Currently, the amount of Medicare payment under Method II for home dialysis equipment and supplies may not exceed $1,974.25 per month for CCPD and $1,490.85 per month for all other modalities of home dialysis (*see* 57 FR 54186, published on November 17, 1992).

For each beneficiary it serves, the supplier is required to maintain a written agreement with an approved ESRD facility to provide backup and support services. An ESRD facility that has a written agreement to supply backup and support services bills the FI/MAC for services provided under the agreement. Under Method II, an ESRD facility may be paid up to $121.15 per month for home dialysis support services, such as arranging for the provision of all ESRD-related laboratory tests and billing for the laboratory tests that are included in the composite payment rate (*see* 57 FR 54186, published on November 17, 1992). An ESRD facility may not be paid for home dialysis equipment or supplies under Method II.

As we indicated previously, section 1881(b)(14)(A)(i) of the Act requires that a single payment for renal dialysis services and items and services under section 1881(b)(4) be made to an ESRD facility. As a result, we proposed: (1) That payment for all home dialysis services excluding physicians' services would be included in the bundled payment to the ESRD facility; (2) that all payments made for home dialysis services furnished under Method I and Method II, regardless of home treatment modality, would be included in computing the proposed ESRD PPS base rate; and (3) that the Method II home dialysis approach in its present form would no longer exist when the ESRD PPS is implemented January 1, 2011. We proposed to revise § 414.330 to reflect that the ESRD PPS payment as established in section 1881(b)(14) of the Act will be the basis of payment for home dialysis supplies, equipment, and home support services and that payment limits applicable for such services would no longer apply (74 FR 49930). We noted that effective January 1, 2011, a supplier could only furnish, home dialysis equipment and supplies to a Medicare home dialysis beneficiary under an arrangement with the ESRD facility, and that the supplier would need to look to the ESRD facility for payment.

We received several comments from various ESRD organizations and individuals who rely on the Method II home dialysis payment approach who oppose our proposed elimination of Method II. These and other comments we received on our proposals, including our responses, are set forth below.

Comment: One commenter stated that working with Method II supply companies is vital to their home dialysis program because the supply companies

take on the costs and responsibility of furnishing home dialysis supplies and equipment.

Response: Under the ESRD PPS, the supplier could still furnish, under arrangement with the dialysis facility, home dialysis equipment and supplies to a Medicare home dialysis beneficiary. However, effective January 1, 2011, the supplier would be required to look to the ESRD facility for payment since the ESRD PPS payment would be made to the facility. As such, under the ESRD PPS, DME MACs would no longer make payment to suppliers of home dialysis equipment and supplies. All payments previously paid to DME MACs for home dialysis supplies and equipment has been built into the ESRD PPS base rate so that ESRD facilities can pay for the supply and equipment costs for their home dialysis patients.

Comment: A commenter stated that the elimination of Method II is a complete contradiction of the CMS goals for promoting better outcomes and increased utilization of more cost effective home dialysis treatment modalities.

Response: We do not agree that the elimination of Method II will undermine our goals for increased use of home modalities and better outcomes. We will continue to support home dialysis as indicated in our decision to pay the same under the ESRD PPS for home and in-center treatments even though home dialysis is less costly for ESRD facilities and our decisions regarding payment for home dialysis training discussed later in this section.

Comment: Some commenters stated that the loss of the Method II payment system will result in higher administrative costs and logistical burdens that will greatly increase the cost of providing treatment to home dialysis patients and create a disincentive for ESRD facilities to provide home modalities.

Response: We do not believe that the elimination of Method II will result in significant increased burdens to ESRD facilities such that it would create disincentives for ESRD facilities to provide home treatment modalities. Most ESRD facilities currently have arrangements with DME suppliers to furnish dialysis equipment and supplies for their in-facility dialysis patients and home dialysis patients. Under the ESRD PPS, in order to minimize the impact on patients of the requirement that DME suppliers now must look to the ESRD facility for payment, home patients could continue with these same arrangements. We believe that ESRD facilities will have a financial incentive to provide home treatment modalities since we will pay the same base rate for less expensive home modalities than we pay for in-facility treatments.

Comment: Commenters from pediatric facilities that use Method II suppliers expressed concern that the specialty products they use are not available through the major manufacturers of dialysis products and that pediatric products are more expensive to purchase due to the limited demand and negotiating power of pediatric facilities.

Response: We do not believe that the elimination of Method II option under the ESRD PPS will have a negative effect on pediatric dialysis facilities. The pediatric facilities have indicated that their home dialysis patients are mostly peritoneal dialysis (PD) patients. As discussed in the proposed rule, we described a comparison of composite rate costs by modality for CYs 2004 through 2006 which showed that PD is a substantially less costly mode of dialysis compared to in-facility hemodialysis (74 FR 49967 through 49968). Data from the Medicare cost report and Medicare claims data showed a significant difference in resource utilization, with PD patients incurring significantly lower composite rate and separately billable expenses. Since payment under the ESRD PPS for home dialysis patients will be based on Method I, we believe that paying the same amount for all types of dialysis modalities will not disadvantage pediatric facilities. We believe that pediatric facilities will still be able to make arrangements with their current DME suppliers to furnish the special supplies and equipment that are needed for small children and infants. The only difference is that the DME supplier must look to the pediatric ESRD facility for payment. Also, we note that pediatric facilities could form a group purchasing arrangement to enhance their negotiating power when purchasing supplies and equipment for their home patients.

Comment: Commenters claim that the elimination of Method II under the ESRD PPS would require children's hospitals to become a "flow-through" for supplies and equipment that previously would have been obtained by patients directly from Method II suppliers.

Response: We agree with this "flow-through" description made by the commenter because under the ESRD PPS, the payments for the equipment and for supplies will be made to the ESRD facility which then buys the equipment and supplies from a DME supplier.

Comment: Commenters from pediatric facilities requested that CMS perform further analysis to determine whether the elimination of Method II billing under the ESRD PPS will have a negative effect on pediatric dialysis facilities.

Response: Since publication of the proposed rule, we have continued to examine the ESRD data in order to refine the model. The cumulative effect of the changes we have made to the ESRD PPS is projected to beneficially impact pediatric facilities. *See* section IV. of this final rule for specific impacts.

Comment: Some commenters had concerns with the elimination of Method II and the resulting change in incentives for dialysis facilities. The commenters suggested that CMS needs to understand the adverse effects that eliminating Method II would have on the dialysis facilities' ability to furnish home treatment modalities.

Response: Effective January 1, 2011, Medicare will pay the ESRD PPS base rate to ESRD facilities for home dialysis services furnished to home dialysis patients under Method I . Under Method I, the incentives will be different because we will only pay the ESRD facility the ESRD PPS base rate which includes the costs of all dialysis services such as staff time, equipment, and supplies. Despite the elimination of Method II under the ESRD PPS on January 1, 2011, the Method I payment includes the following provisions were supported by many other commenters.

First, Medicare will continue to pay on a per treatment unit of payment. Second, Medicare will pay the same base rate for both in-facility and home dialysis. Third, the same base rate will also be paid for all dialysis treatment modalities furnished by a dialysis facility (hemodialysis and the various forms of peritoneal dialysis). Since home dialysis treatment modalities cost less than in-facility dialysis (especially home PD, which is the primary home dialysis treatment modality for pediatric home patients) ESRD facilities that have home dialysis programs should continue to benefit by providing home dialysis under ESRD PPS Method I payments.

We believe there are also some administrative benefits for dialysis facilities with the elimination of the Method II home dialysis. Dialysis facilities and home patients will have less burden because they will no longer need to complete or file the CMS Form-382 which is the form currently used to determine whether the dialysis patient has selected Method I or Method II home dialysis. Under the ESRD PPS, dialysis facilities will no longer be required to submit separate bills for home support services and suppliers no longer need to bill Medicare for home

dialysis equipment and supplies furnished to Method II home dialysis patients. The costs of home dialysis services for all home dialysis treatment modalities have been included in the composite rate part of the bundled ESRD PPS payment.

Comment: Commenters expressed concerns that the elimination of Method II payment system will affect the ability of ESRD facilities to establish and grow their home dialysis program. Commenters stated that using the Method II approach allows the dialysis facility to remove the supply and equipment costs associated with a home program from their total costs, making the utilization of home modalities more economically feasible and available to their patient population. Another commenter stated that CMS created financial disincentives for the provision of home hemodialysis because the cost of treating hemodialysis patients is generally higher than the cost of treating facility-based patients.

Response: We disagree with this commenter. We do not believe that financial disincentives have been created because, based on our cost report data, the cost for home hemodialysis is less costly than in-facility. As we noted in the proposed rule, the reliance on separately billable services as a source of revenue growth for ESRD facilities has potentially impeded the greater use of less costly PD (which typically uses fewer separately billable drugs and less provider and facility overhead expense) (74 FR 49931). We also noted that others have argued that constraining payment based on number of treatments may reduce the use of alternative treatment regimens such as increased frequency nocturnal dialysis, home HD using compact portable dialysis machines, and shorter but more frequent dialysis sessions (for example, 1.5 to 2 hours, five or six days per week).

We do not agree that a financial disincentive has been created for the provision of home hemodialysis. Under the ESRD PPS, payment for all home dialysis services (excluding physician services) would be included in the bundled payment to the ESRD facility and would not be subject to the current composite payment limits on what Medicare would pay for home dialysis supplies, equipment, and home support services as described in § 413.330(c). We disagree with the commenter that the elimination of the Method II payment system will affect the ability of ESRD facilities to establish and grow their home dialysis program, because the ESRD PPS takes into account the supplies and equipments costs associated with a home program. The intent is to continue to preserve the utilization of home modalities under Method I of the ESRD PPS, and to make home dialysis economically feasible and available to the ESRD patient population.

Comment: A commenter expressed concern that the elimination of Method II would deprive beneficiaries of access to specialty products, recent technologies, and cost effective home modalities.

Response: Although Method II would be eliminated under the ESRD PPS, we note that the suppliers would still be able to play a role under the new ESRD PPS. The supplier could still furnish, under arrangement with the support dialysis facility, home dialysis equipment and supplies to a Medicare home dialysis beneficiary under the ESRD PPS. However, the supplier would have to look to the ESRD facility for payment since the ESRD PPS payment would be made to the ESRD facility and DME MACs would no longer make payment for ESRD-related supplies to suppliers. As such, we disagree that because of the ESRD PPS, beneficiaries would be deprived of enjoying specialty products, recent technologies and cost effective home modalities. Dialysis facilities are encouraged to ensure that ESRD patients continue to receive all necessary supplies and equipment under the ESRD PPS. Additionally, under the ESRD PPS, lower cost patients offset the higher cost for patients who utilize specialty products and new technology.

Comment: A commenter stated that the current Method II payment system allowed a "level-playing field" in which small and medium-sized dialysis organizations have the financial flexibility to offer their patients home modality options. With the elimination of Method II under the ESRD PPS, the commenter claimed that he is now at a disadvantage because the risks are now borne by the facilities.

Response: We believe that the final base rate which is addressed in section II.E. of this final rule and the revised payment for home dialysis training add-on adjustment which is addressed later in this section, are sufficient. The goals of creating a bundled prospective payment system were to create a single comprehensive payment for all renal dialysis services. The elimination of Method II under the ESRD PPS serves to further this goal by eliminating separate payments to suppliers so that a single payment is made to ESRD facilities for all renal dialysis services. We disagree that the elimination of Method II creates a disadvantage as the commenter states as all payments for renal dialysis services, including those paid to Method II suppliers, have been included in the ESRD PPS base rate. It is our belief that such a payment system serves to allow a "level-playing field" in which all dialysis organizations regardless of size, have a single payment method.

Comment: A few commenters currently using Method II claimed that the ESRD PPS does not provide for the unique equipment and supply services costs for providing dialysis to home patients. The commenters claimed that supply companies install and maintain dialysis equipment and deliver both equipment and supplies to one patient at a time, and further noted that reimbursement is based upon a one machine per patient model. As a result, suppliers cannot achieve the economies of scale enjoyed by ESRD facilities.

Response: We note that having to install and maintain dialysis equipment and deliver both equipment and supplies to individual patients is not unique to Method II home dialysis patients. Currently all home dialysis patients, whether under Method I or Method II are impacted by "economies of scale" described by the commenter in a one patient-one machine application. Under the ESRD PPS, while home dialysis suppliers may not achieve the same economies of scale as dialysis facilities, suppliers remain able to provide equipment and supplies to multiple dialysis facilities and can negotiate competitive prices with the ESRD equipment and supply manufacturers. We note that all payments related to Method II suppliers and amounts paid by ESRD facilities to Method I suppliers have been included in the ESRD PPS base rate which we believe is sufficient to account for the equipment and supply costs of home dialysis patients.

Comment: Several commenters expressed concern that the ESRD PPS payment and elimination of Method II will make them less able to offer nursing caregiver staff-assisted dialysis to patients in nursing homes. The commenters indicated that Method II enables beneficiaries with secondary private insurance that includes nursing caregiver dialysis staff-assistance coverage, the opportunity to dialyze in their homes or in a nursing home and have the cost of a nurse caregiver dialysis assistant covered under their secondary insurance. Some of the commenters suggested that CMS create an adjustment or exception to the bundled payment rate for home hemodialysis patients receiving nursing caregiver staff-assisted care in their homes or in a nursing home setting.

Other commenters suggested that CMS offer an alternative that meets the equivalent of the current Method II mechanism that would serve to deny coverage of nursing home caregiver dialysis assistance or offer an additional Method I option at a reduced PPS rate. Because Medicare does not cover payment for nursing caregiver staff-assistance to dialysis patients, an Explanation of Benefits (EOB) denial is automatically generated by the FI/MAC. The EOB denial would allow suppliers to continue to bill for nurse caregiver staff-assistance to home hemodialysis patients paid by private insurers secondary to Medicare.

Response: Once the ESRD PPS takes effect January 1, 2011, DME suppliers will no longer be able to bill Medicare for ESRD equipment, supplies, and nurse caregiver staff-assistance. We will consider the commenter's suggestion to create a Medicare denial of these services as we develop billing instructions later this year.

Comment: One commenter urged that we retain Method II and indicated that the costs to Medicare are lower for nursing staff-assisted dialysis for home dialysis patients than in-facility dialysis patients. The commenter believed that Method II supply companies dedicated to dialysis supplies and services have saved the Medicare Program significant amounts of money because the DME supplier is paid 80 percent of the amount paid for supplies, which is less than $1,200 each month. The remainder is paid by the secondary insurance, as a secondary for the supplies and, in some cases, as a primary for the nursing services.

Response: Section 1881(b)(14)(A)(i) of the Act specifies that the Secretary must implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment, and for such services and items furnished for home dialysis and self-care home dialysis support services. The Method II home dialysis option where the supplier of dialysis equipment and supplies bills the DME MAC is no longer authorized under the Act after January 1, 2011.

Comment: A few commenters encouraged CMS to clarify that only DME supplies and equipment related to the provision of renal dialysis services are included in the ESRD PPS payment. The commenters further stated that there are many DME supplies and equipment utilized by ESRD beneficiaries that are unrelated to their dialysis and should not be included in the ESRD PPS such as wheelchairs, diabetic testing supplies, oxygen, wound care, ostomy and urological supplies and equipment.

Response: We agree with the commenters and have clarified in section II.A.4. of this final rule that renal dialysis services include only DME supplies and equipment, necessary for the delivery of home dialysis services under the ESRD PPS. Although we did not provide a specific listing of the supplies and equipment, they were in fact considered and included. The Medicare Claims Processing Manual Chapter 8, Section 90.3.2, identifies the home dialysis supplies and equipment that are (currently) separately billable by DME suppliers.

Comment: Some commenters were concerned that under the ESRD PPS, the ESRD facility would become responsible for the billing of a variety of items and services that patients now receive directly from other suppliers. The commenter stated that the new ESRD PPS may create confusion for ESRD facilities, Method II suppliers, and patients. For example, DME suppliers submit their claims to DME MACs for reimbursement and the DME MACs are guided by their local coverage determinations and other aspects of DME billing and payment. The commenter questioned what would apply under the new ESRD PPS during the transition period.

Response: Under the current Method II home dialysis payment system, for each beneficiary it serves, the supplier is required to accept assignment by the beneficiary, and bill the DME MAC. Suppliers are also required to maintain a written agreement with a support dialysis facility to provide backup and support services. A dialysis facility, in turn, is required to maintain a written agreement to supply backup and support services and bill the FI/MAC for services it provides under the agreement.

As explained in the proposal (74 FR 49929), section 153(b) of MIPPA, section 1881 (b)(14)(A)(1) of the Act requires the Secretary to implement a payment system under which a single payment is made to an ESRD facility under this title for renal dialysis services and items furnished pursuant to section 1881 (b)(4) of the Act.

All costs associated with home dialysis services (both Method I and Method II) are included in the composite portion of the two equation model. Effective January 1, 2011, all home ESRD patients will be considered Method I home patients and all Medicare payments for home dialysis services will be made to the ESRD facility. Medicare payment for home dialysis services will be made to the ESRD facility whether the facility elects to participate in the transition period or elects to be paid under the ESRD PPS. DME suppliers will no longer submit claims to DME/MACs for home dialysis supplies and equipment effective January 1, 2011. Since FI/MACs will be processing ESRD facility claims for Method I home dialysis patients, the reasonable charge DME payment rules are no longer applicable. After January 1, 2011, a supplier could only furnish, under an arrangement with the ESRD facility, home dialysis equipment and supplies to a Medicare home dialysis beneficiary, and then the supplier would need to look to the ESRD facility for payment. Payment to the DME supplier from the ESRD facility will be based upon the payment arrangements agreed to between the two parties for furnishing home dialysis equipment and supplies to the home dialysis patient.

Comment: Commenters expressed concern that Method II suppliers would no longer be permitted to bill Medicare directly for ESRD-related supplies furnished to ESRD beneficiaries. The commenters believed that suppliers, ESRD facilities, and patients would be confused about the changes made under the ESRD PPS and urged CMS to ensure that all interested parties receive adequate provider education regarding the changes it implements under the ESRD PPS.

Response: We agree that interested parties should receive adequate provider education and once the final rule is published, we intend to provide multiple opportunities for training and education to patients and ESRD facilities. We also intend to provide information at our sponsored open-door forums for other groups such as DME suppliers and laboratory providers.

Comment: Two commenters affiliated with US Military Services commented that they serve many ESRD patients who are retirees or dependents of active duty military personnel. In order to maintain war-time readiness, the commenters stated that they keep their physician and nursing staff trained by performing dialysis on a small population of ESRD dialysis patients. The commenter explained that Method II has been the means of providing seamless home care for their patients while allowing them to follow these patients and provide their ancillary care. Absent a Method II reimbursement equivalent, they would not be able to maintain a nephrology fellowship program which would impact the training of military physicians. However, another commenter affiliated with another branch of the military stated that utilization of Method II reimbursement

for home PD should have no direct effect on the quality of their nephrology fellowship training program as these patients are still required to be evaluated monthly.

Response: While both commenters raise points that relate to the ESRD PPS, the impacts they describe (military readiness training and ongoing education needs) are not germane to the intent of the legislation and not within the scope of this rulemaking.

Comment: One commenter described a study in a recent clinical journal which claimed that CMS could save more than a billion dollars in five years if the utilization of PD increased from its current 8 percent to 15 percent. The commenter questioned why Method II was to be eliminated under the ESRD PPS. He described that this was tantamount to "eliminating one of the very tools that help dialysis providers establish and expand home PD programs."

Response: Although the statute no longer provides discretion to retain Method II, we believe there remain very good reasons to develop and expand home PD programs. For example, PD treatment costs considerably less than comparable in-facility treatments.

Comment: The commenters claimed that as the new ESRD PPS will require billing changes and create other challenges, CMS should consider deferring the application of the consolidated billing edits regarding DME services until the full implementation of the ESRD PPS.

Response: Although we acknowledge that the ESRD PPS will require some billing changes, we do not have the authority to continue to pay DME suppliers directly for ESRD-related items furnished to ESRD patients.

b. Self-Dialysis Training

Currently, Medicare makes a separate payment per treatment for home hemodialysis training and two forms of PD training programs. Home dialysis and self-dialysis can only be performed after an ESRD patient has completed an appropriate course of training. The scope of training services that a certified facility provides to ESRD patients is described in § 494.100(a).

We proposed that ESRD facilities would no longer receive an add-on of $12 for CAPD and $20 for hemodialysis and CCPD to the otherwise applicable payment amount per treatment for the costs of training. We also proposed that the ESRD facility training expenses would be included in the ESRD PPS base rate to which the payment multipliers in the proposed payment model are applied (74 FR 49930).

Also, we proposed that training costs be included in the regression analysis to compute the composite rate payment adjusters. We noted that total composite rate costs included in the per treatment calculation included costs incurred for training expenses, as well as all home dialysis costs (74 FR 49947). We proposed to use the ESRD facility's cost reports to identify provider costs for training and include these costs in the composite rate portion of the two-equation ESRD PPS model described in the proposed ESRD PPS (74 FR 49947.) We proposed to include training and home dialysis costs, as set forth in § 413.217. We specifically invited public comments on our proposal to include home dialysis training services in the proposed ESRD PPS base rate.

The comments we received on these proposals and our responses are set forth below.

Comment: Numerous commenters expressed strong opposition to our proposal to include payments for the training of patients for home dialysis in the ESRD PPS base rate. The commenters pointed out that treatment of training payments as any other overhead expense would have the effect of giving every dialysis facility a small payment for home dialysis training regardless of whether it offered a home training program. These commenters indicated that our proposal fails to target training payments to facilities actually furnishing training treatments, and reduces the magnitude of the training payment by averaging the amount over all hemodialysis equivalent treatments. The commenters believe that the training proposal would have a devastating impact on training programs and discourage the growth of home dialysis.

Commenters also disagreed with our statements that most training treatments were likely to occur within the first four months after the onset of dialysis and that the proposed 47.3 percent adjustment (new onset adjustment) to the otherwise applicable case-mix adjusted payment for treatments occurring within this period would cover the costs of furnishing home dialysis training programs. These commenters pointed out that a high proportion of training treatments do not occur within the first four months after the start of dialysis.

Several commenters pointed out that the ESRD Conditions for Coverage result in higher training expenses, costs which commenters believe should be reimbursed through a separate training adjustment. Other commenters reasoned that failure to provide a separate training adjustment will result in disparities in care, as facilities would find it too expensive to train the elderly, patients with language difficulties, or patients with complex medical conditions.

Most of the commenters recommended that we develop a separate payment for training treatments outside of the payment bundle. However, one commenter opposed the implementation of a separate payment for training services. The commenter maintained that the proposed ESRD PPS provides an adequate incentive for PD training, while acknowledging the higher expenses for home HD training.

Response: Although we are continuing to include training payments in computing the ESRD PPS base rate, we agree with the commenters that we should treat training as an adjustment under the ESRD PPS. We believe the ESRD PPS base rate alone does not account for the staffing costs associated with one-on-one focused home dialysis training treatments furnished by a registered nurse. Because the patient-focused training requires greater nursing resources than provided for non-training treatments, we feel that a separate training add-on adjustment is warranted.

We explored whether we could develop a regression-based adjustments as we have conducted for the rest of the ESRD PPS payment adjustments. However, in analyzing training information in ESRD facility cost reports and comparing those costs to training claims submitted by ESRD facilities, we found that some training costs were under-reported by some facilities and over-reported by others. Therefore, we were unable to develop a regression-based adjustment due to a lack of cost report data for many ESRD facilities.

For purposes of developing a training adjustment under the ESRD PPS, we have decided to use a dollar add-on adjustment similar to the existing training add-on payments under the current basic case-mix adjustment payment system. We also explored various options for updating the training current add-on payment amounts under the current basic case-mix adjusted composite payment system because the training add-on amounts have not been updated since they were established in the 1970s and do not believe such amounts reflect the cost of the training nurse. We believe the training add-on amounts when first implemented, represented staff time, supplies and equipment. Thus, under the ESRD PPS, we considered various options to update the training add-on adjustment to reflect 1-hour of nursing time because home and self-dialysis training must be

conducted by a registered nurse in accordance with the ESRD Conditions for Coverage requirements at § 494.100(a).

The updated training add-on adjustment will be computed by using the national average hourly wage for nurses from Bureau of Labor Statistics data updated to 2011. The amount for the training add-on adjustment we are finalizing under the ESRD PPS will be $33.44 per treatment. This amount would be added to the ESRD PPS payment amount or ESRD PPS portion of the blended payment amount for those ESRD facilities in the ESRD PPS transition. Specifically, this amount will be added to the ESRD PPS payment rate or ESRD PPS portion of the blended payment amount for those ESRD facilities in the ESRD PPS transition, each time a training treatment is provided by the Medicare certified training ESRD facility.

As the training add-on adjustment is directly related to nursing salaries and nursing salaries differ greatly based on geographic location, we will adjust the $33.44 training add-on by the geographic area wage index applicable to the ESRD facility so that the training add-on adjustment reflects local nursing wages. Using the proposed wage index values issued in the CY 2011 PFS proposed rule, the training add-on amounts after application of the wage index would range from $20.03 to $45.84. The wage index is further described in section II.G.3.a. of this final rule.

The training add-on adjustment will only apply to training treatments furnished to dialysis patients by Medicare-certified dialysis training facilities. This amount represents one hour of nursing time to conduct one-on-one training with a patient for either hemodialysis or PD for training treatments furnished by a Medicare-certified training facility. We believe that this approach would eliminate the differential paid for hemodialysis training that accounts for supplies and equipment.

Given that payments for equipment and supplies, as required under the statute, have been captured in the base rate and training facilities would also receive the ESRD PPS base rate and all applicable adjustments, we no longer need to pay these costs as part of a training adjustment. We believe this provides for an adequate increase in the current training adjustment, and that it is appropriate to eliminate the differential paid for HD training.

For those ESRD training facilities that opt to go through the ESRD PPS transition, Medicare will continue to pay $20.00 per training treatment for hemodialysis and CCPD and $12.00 for PD for the basic case-mix adjusted composite rate portion of the ESRD PPS blended payment. These training rates will not be wage adjusted and will continue to be paid based on the maximum number of training treatments explained below.

The payment adjustments for the onset of dialysis adjustment, as well as all other adjusters we are finalizing under the ESRD PPS, are the result of the regression models for composite rate and separately billable services. The regression analysis for this final rule which used cost reports and Medicare claims for 2006–2008, indicated higher composite rate costs associated with the first four months of dialysis. As home dialysis training costs represents one-on-one staff time to train a patient for home dialysis, we believe we have captured staffing costs for training in the 4-month onset of dialysis adjustment. Since we have already accounted for training salary costs in the 4-month onset of dialysis adjustment, we believe that applying the training add-on adjustment in addition to the 4-month onset of dialysis adjustment would have the effect of compounding the composite rate costs and result in an overpayment of nursing staffing costs associated with training dialysis patients for home dialysis. Therefore, ESRD facilities will not receive the training add-on adjustment for patients who are receiving the first 4-month onset of dialysis adjustment (section II.F.3. of this final rule for more detailed explanation of the 4-month onset of dialysis adjustment).

The training add-on adjustment is not a multiplicative adjustment like the other final adjustments under the ESRD PPS. Rather, the training adjustment is added to the product of the ESRD PPS base rate or blended base rate and applicable adjustments. For further explanation, please refer to the Comprehensive Payment Model examples provided in section II.I. of this final rule.

Comment: Some commenters requested that CMS continue to make payment for retraining treatments furnished to home dialysis patients. The commenters pointed out that under some circumstances a home patient may change from one mode of dialysis to another (for example, from home hemodialysis to CAPD) or there are changes to the hemodialysis equipment which requires the home patient to be retained to continue as a self-dialysis patient.

Response: Under the ESRD PPS, we will continue to pay for self-dialysis training after a patient has completed the initial training course. The conditions under which we make payment for retraining treatments follow the same coverage rules for training under the ESRD PPS. Criteria for retraining are unchanged and explained in greater detail in the Medicare Claims Processing Manual, Chapter 8, Section 50.8 Training and Retraining. In addition, the patient must continue to be an appropriate patient for self-dialysis.

Comment: Commenters varied in their suggestions for how the training payments should be applied. For example, one commenter recommended a "hold back" in which a portion of the training payments would be withheld from the ESRD facility pending demonstration of the patient's successful transition to home dialysis. Other commenters recommended that we establish a monitoring system to determine the degree to which any separate adjustment for the provision of home training treatments results in more patients successfully transitioning to home dialysis.

Response: We will continue to require that ESRD facilities are a Medicare certified training facility in order to receive the training add-on adjustment each time a training treatment is provided. In an effort to promote more training for home dialysis, we are not limiting payment for training through a hold-back mechanism. We fully intend to monitor how the updated training add-on adjustment relates to changes in the proportion of ESRD patients on home dialysis modalities and may propose limits in the future.

Comment: We received numerous comments requesting that CMS retain the existing policy that limits coverage of the total number of training treatments at the current level of 15 for peritoneal dialysis (CAPD and CCPD) and 25 for hemodialysis.

Response: We agree with the commenters. Under the ESRD PPS, we will continue the current cap on training treatments at 15 for peritoneal dialysis (CAPD and CCPD) and 25 for hemodialysis training because most commenters indicated that they can complete training within these training treatment parameters.

In summary, we are finalizing a training add-on adjustment under the ESRD PPS in the amount of $33.38 per training treatment, adjusted based on the geographic wage index for nursing salaries to account for the hourly nursing time for dialysis training treatments. This adjustment would apply to HD and PD modalities. This training add-on adjustment is applied

after all other adjustments under the ESRD PPS have been made. We have added paragraph (c) to § 413.235 and revised the description of the per treatment payment amount in § 413.230 to reflect the training add-on adjustment.

B. Unit of Payment

Under section 1881(b)(14)(C) of the Act, as added by section 153(b) of MIPPA, the ESRD PPS may provide for payment on the basis of renal dialysis services furnished during a week, or month, or such other appropriate unit of payment as the Secretary specifies. We proposed to establish an ESRD PPS which relies on a per treatment unit of payment (74 FR 49931). We proposed to continue the present per treatment basis of payment in which ESRD facilities would be paid for up to three treatments per week, unless there is medical justification for more than three weekly treatments (74 FR 49931). ESRD facilities treating patients on PD or home HD would also receive payments for up to three treatments for each week of dialysis, unless there is medical justification for the furnishing of additional treatments. In the proposed rule, we discussed in detail the factors and data we considered in developing our proposal (74 FR 49931 through 49934). The comments we received with regard to our proposals for the unit of payment and our responses are discussed below:

Comment: Numerous commenters supported our selection of a per treatment unit of payment for the bundled payment system. The commenters noted that a per treatment unit of payment preserved access for patients who travel, and would minimize operational difficulties and administrative complexity for the approximately 19 percent of patients who incur an interruption of service or receive treatment at more than one dialysis facility. Generally, commenters noted that a larger unit of payment, such as a monthly payment, would complicate the phase-in of the payment system. MedPAC noted that a larger unit of payment would be consistent with several aspects of dialysis care, pointing out that a weekly unit of payment corresponds to the typical weekly interval for PD. MedPAC also noted that Medicare pays nephrologists a monthly capitated payment for caring for dialysis beneficiaries. MedPAC recommended that we reconsider the unit of payment, once a strengthened dialysis quality monitoring system is implemented, to assure that quality of care does not decline.

Response: We agree with the commenters that maintaining a per treatment unit of payment is the best method to achieve the effect of the bundled payment system without adversely impacting beneficiary access to home dialysis services. As we explained in the proposed rule (74 FR 49931), we considered other units of payment such as a monthly ESRD PPS, which would provide ESRD facilities more flexibility in alternative treatment requirements, such as increased frequency nocturnal dialysis, home HD using compact portable dialysis machines and shorter but more frequent dialysis services. However, given the difficulties of implementing a monthly ESRD PPS during the transition period in which a per treatment methodology applies, we proposed to continue the current per treatment payment methodology in connection with the proposed ESRD PPS as set forth in § 413.215.

In this final rule, we are adopting the per treatment unit of payment for the ESRD PPS for the reasons set forth above. As we indicated in the proposed rule, we may reconsider this decision after the transition period has ended (74 FR 49934). At that time, we may evaluate whether the ESRD PPS has resulted in improved clinical outcomes, the degree to which home dialysis has increased, and whether interested stakeholders would favor an alternative to the per treatment approach we are finalizing in this final rule.

Comment: Several commenters recommended that we change the definition for reporting the volume of treatments to eliminate the use of hemodialysis equivalents. The commenters stated that the use of HD equivalents for the home dialysis modalities distorts the real costs associated with that modality, pointing out that home HD patients may be receiving 5–7 treatments per week, with some commercial payers paying for more than three treatments per week.

Response: The practice of converting PD treatments to HD equivalent treatments arose in the context of developing an appropriate unit of analysis for the PD modalities in which multiple exchanges of dialysate occur during the course of a day. These exchanges are not discrete treatments in the same sense that an HD session represents a treatment. In order to encourage home dialysis, the policy decision not to develop separate bundled payment rates for the in-facility and home dialysis modalities required that the base rate also be applied to home dialysis. Therefore, we believed that conversion of each week of home dialysis to three equivalent HD treatments was the most feasible approach. The alternative would have been to develop a separate bundled payment rate for each week of home dialysis. We rejected this approach in order to use a per treatment payment for all ESRD treatments, including home treatments.

To the extent that patients on home HD receive more than three treatments per week, we point out that use of the additional treatments to develop the base rate would have decreased that rate. Particularly for PD, we believe that use of three HD equivalent treatments for each week of PD represents a reasonable basis for establishing payment rates per treatment that can be applied to both in center and home dialysis modalities.

In summary, we are finalizing § 413.215(a) which established the dialysis treatment as the unit of payment under the ESRD PPS.

C. Data Sources

Section 1881(b)(14)(B) of the Act, as added by section 153(b) of MIPPA, defines the renal dialysis services that must be included in the ESRD PPS. In the proposed rule, we identified the components used to construct the payment bundle (74 FR 49934) based on the following Medicare cost and payment information:

- Composite rate services as measured using composite rate costs calculated from the Medicare cost reports;
- Drugs and biologicals (for example, injectables) that are separately billed by ESRD facilities on Medicare outpatient institutional claims;
- Drugs and biologicals (for example, oral) used to treat ESRD patients obtained from claims submitted by Part D stand alone prescription drug plans;
- Laboratory tests that are separately billed by ESRD facilities on Medicare outpatient institutional claims;
- Laboratory tests ordered by a physician who receives MCPs for treating ESRD patients, which are separately billed by independent laboratories;
- Other items and services separately billed by ESRD facilities that are used in conjunction with injectable medications or laboratory tests, such as blood products, syringes, and other dialysis supplies that are billed on Medicare outpatient institutional claims.

The cost report and claims data sources used to construct the bundled payment system, as set forth in this final rule, remain the same as described in the proposed rule, with the exception that CY 2006, 2007, and 2008 records

have been used for this final rule instead of CY 2004 through 2006 data that were used in the proposed rule. This is consistent with our statement in the proposed rule that we planned to use the latest available cost report and claims information to develop the final rule, given the lead time necessary to prepare the final rule (*see* 74 FR 49934 through 49935).

Section 1881(b)(14)(A)(ii) of the Act requires that the estimated total amount of payments for 2011 be equal to 98 percent of the estimated total amount of payments for renal dialysis services that would have been made in 2011 if the ESRD PPS had not been implemented. That section requires that we use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization. To comply with this provision, we evaluated payment data from 2007, 2008, and the first 9 months of 2009, the latest available given the lead time required to prepare this final rule, as described later in this section.

In the proposed rule, we cited the application of a statistical methodology referenced in UM–KECC's February 2008 report for removing composite rate costs with extreme values from the cost report database used to develop the composite rate portion of the ESRD PPS payment model (74 FR 49947). That methodology employed a standard outer fence definition. The outer fence is a threshold for identifying extreme outliers. The upper outer fence, which is the threshold that was used to identify outliers with extremely high costs, is defined as the 75th percentile plus three times the interquartile range (IQR). This is the 75th percentile minus the 25th percentile. The lower outer fence, which is the threshold that was used to identify outliers with extremely low costs, is the 25th percentile minus three times the IQR.

The outer fence values for average cost per treatment were calculated on the log scale, since a log transformation was used to estimate the models. When retransformed to dollars, the lower outer fence for composite rate costs was $68.81 per treatment, and the upper outer fence was $470.70 per treatment. However, a test model that applied these exclusion criteria yielded especially large prediction errors for facilities with reported composite rate costs below $100.00 per treatment. Accordingly, we applied a separate methodology to identify additional outliers that could affect the analysis and reduce the accuracy of the case-mix adjusters resulting from the model estimates.

This method was also used to develop the set of composite rate cost per treatment values analyzed in connection with the proposed rule (74 FR 49947). The method involved an analysis of studentized residuals, which are residuals divided by an estimate of their standard deviation. Approximately 95 percent of the facilities with average costs between $68.81 and $100.00 per treatment had studentized residuals less than −2, and approximately 32 percent had studentized residuals less than −4. Based on this analysis of studentized residuals, a slightly more restrictive lower limit of $100.00 was applied.

Together, these methodologies for identifying outlier values for composite rate costs resulted in the exclusion of 460 facility year records (approximately 3 percent) from the analysis of 2006–2008 data that was used to develop the composite rate portion of the ESRD PPS payment model described in this final rule.

While cost information for composite rate services is available from the Medicare cost reports, the cost report does not contain information on the costs of the separately billable categories of services noted above. The ESRD PPS described in this final rule incorporates payment for separately billable services based on separately billable payment information from Medicare claims.

The descriptive statistics, case-mix model, and other analyses presented in this final rule were based on CMS claims files for Medicare ESRD patients, and the Medicare cost reports for hospital-based ESRD outpatient dialysis providers and independent ESRD facilities. Resource utilization for separately billable services was based on patient-level Medicare outpatient claims for CYs 2006 through 2008 (the latest available claims), in order to be able to prepare this final rule. Since composite rate cost information is available only at the facility level, resource utilization for composite rate services was measured using the Medicare cost reports for CYs 2006 through 2008 for each outpatient dialysis provider and facility (that is, hospital-based and independent facilities). These years represented the latest and most complete data available for the preparation of this final rule.

As we did in the proposed rule (74 FR 49935), we also used several data sources for evaluating the patient and facility characteristics that were used with the case-mix analyses. Patient demographic information was obtained from the Renal Management Information System (REMIS)/Consolidated Renal Operations in a Web-Enabled Network (CROWN), and the ESRD Standard Information Management System (SIMS). These data sources include the Medical Evidence Report Form (Form 2728), which is completed at the onset of renal replacement therapy (RRT), which is either dialysis or transplantation to sustain life at the onset of kidney failure. Patient body size measures were developed from the height and weight values reported on the Form 2728. Beginning April 1, 2005, these values were obtained from the patient claims for outpatient dialysis. Although we have revised the proposed set of patient co-morbidities used as case-mix adjusters in the development of this final rule for reasons explained in section II.F.3. of this final rule, the cost report and paid claims data used to develop the case-mix adjusters based on co-morbidities described in the proposed rule (74 FR 49935) remain the same.

We measured dialysis facility characteristics using a combination of SIMS (ownership type and geographic location), the Medicare cost reports (facility size), the Online State Certification and Reporting System (OSCAR) (hospital affiliation for satellite units), and other available information (for example, identifying facilities with composite payment rate exceptions).

1. Patient Claims Data

The outpatient facility paid claims file is the primary source of information for payments that ESRD facilities receive for the treatment of ESRD patients. The "type 72X" claims (ESRD claims) provided the detailed data for dialysis payments. As we did in the proposed rule, the claims files used for the analyses in this final rule were based on patients with at least one claims record for dialysis. We used carrier claims and durable medical equipment (DME) claims to track dialysis-related payments to other providers such as independent laboratories.

The case-mix models were based on claims from CYs 2006, 2007, and 2008. These were the most complete CY records available for use with the Medicare cost reports from the same periods to develop the payment methodology, given the time necessary for the preparation of this final rule. As with the composite rate costs obtained from the Medicare cost reports and patient claims used to develop the proposed ESRD PPS (74 FR 49936), we similarly used the statistical outer fence methodology described previously to exclude unusually high separately billed values (statistical outliers) obtained from the claims used to develop the system as set forth in this final rule. Based on the statistical outer fence methodology, claims with total

separately billed amounts greater than $2,545.65 were excluded from the analysis of 2006 through 2008 data used to develop the separately billed portion of the ESRD PPS payment model. Application of this methodology for the analysis that was used to develop the separately billed portion of the ESRD PPS payment model for pediatric patients resulted in no exclusions. The number of Medicare claims, patients, dialysis sessions, and ESRD facilities represented in the source claims data are shown in Table 6. We have also provided the same information for CY 2005 for comparison purposes.

Table 6
Medicare Dialysis Patients, Treatments, ESRD Facilities, and Claims by Year, 2005-2008

	2005	2006	2007	2008
Medicare Dialysis Patients[1]	318,590	324,943	329,012	332,713
Hemodialysis Equivalent Dialysis Treatments[2]	35,141,558	36,004,086	36,747,662	37,550,676
ESRD Facilities	4,699	4,812	4,957	5,184
Patient Month Claims	3,038,498	3,096,880	3,156,914	3,216,416

[1]Includes home dialysis patients for whom payments were made under Method II.
[2]Hemodialysis-equivalent treatments were capped at the equivalent number of days per month. Includes PD in which one week of PD is considered equivalent to 3 HD treatments. For Method II patients, an estimate of 12.5 HD-equivalent treatments per month was used, based on the average number of treatments per month reported for Method I peritoneal dialysis patients.

We did not receive any public comments objecting to our intention to use the latest available Medicare cost report and claims data to develop the final rule. Therefore, we are finalizing § 413.220(a)(1) and (2) as proposed.

2. Medicare Cost Reports

We obtained facility-level cost and treatment data from the CMS Medicare Hospital Cost Report (Form CMS 2552–96) and the CMS Medicare Independent Renal Dialysis Facility Cost Report (Form CMS 265–94). The number of available cost reports for CYs 2006 through 2008, which contained necessary cost and treatment data for purposes of the composite rate cost analyses, are shown in Table 7. For most ESRD facilities, a single cost report encompassed the entire calendar year. For FY cost reports that spanned two CYs, we used a weighted average based on the proportion falling in each CY.

Table 7
Available Cost Reports by ESRD Facility Type, 2006-2008[1]

Facility Type	2006	2007	2008
Freestanding	4,188	4,356	4,431
Hospital Based	436	435	421
Total	4,624	4,791	4,852

[1]Based on the December 2009 quarterly update of HCRIS. Includes Cost Reports with composite rate cost and treatment fields greater than 0.

3. Patient Claim and Cost Report Summary Data 2006–2008

The case-mix models were based on data sets that linked claims and cost report records for each year from CY 2006 through CY 2008. The claims data for patients treated in hospital satellite facilities were matched to the parent hospital using OSCAR, since cost reports are only submitted by the parent facility. Table 8 shows the resulting analysis files that included both claims and cost report data for measuring separately billable and composite rate resource utilization.

Table 8
Medicare Dialysis Patients, Treatments, ESRD Facilities, and Claims for Patients and Facilities with Measured Costs per Treatment, by Year, 2006-2008[1]

	2006	2007	2008[2]
Medicare Dialysis Patients	320,652	324,063	320,380
Hemodialysis Equivalent Dialysis Treatments	35,356,748	36,008,729	35,745,487
ESRD facilities	4,529	4,683	4,744
Patient Month Claims	2,926,590	2,975,474	2,942,265

[1]Includes patient months and ESRD facilities with Medicare hemodialysis-equivalent treatments >0 from the outpatient dialysis facility claims and measured composite rate costs and treatments from the Medicare Cost Reports.
[2]Using the latest update of HCRIS that was available in time to complete these analyses, the number of patients with cost report data available for analysis of facility composite rate costs was somewhat lower in 2008 than in 2007.

In the proposed rule, we explained that we trimmed claims data to exclude statistically aberrant or clinically implausible values (74 FR 49947 through 49948). We received the following comments regarding excluded claims data.

Comment: Several commenters expressed concern that we inappropriately excluded claims from the computation of the 2007 base rate using arbitrary exclusion criteria. For example, one commenter noted that the use of 30,000 units of epoetin alfa (EPO) per treatment as a clinically implausible threshold did not comport with CMS's own EPO Claims Monitoring Policy in which 400,000 units per month is the established threshold. Another commenter stated that the capping of patient months in which more than 20 treatments were furnished at 20 treatments was an inappropriate exclusion. The commenter stated that their attempted replication of the 2007 base rate computation resulted in 1.3 and 1.45 percent more paid treatments than were included in the MAP calculation. Other commenters stated that nowhere in the proposed rule did CMS state exactly how many facilities and payments were excluded from its calculations. These commenters stated that all paid Medicare claims should be included in the computation of the MAP so as not to yield an understatement of the base rate.

Response: In response to the concerns raised by the commenters, we have reevaluated our basis for excluding certain claims from the calculation of the CY 2007 base year amount. All payments made on behalf of Medicare ESRD beneficiaries as reported on type 72X claims have now been included, but with the following modifications and exclusions:

- Payments for EPO in excess of 500,000 units per month in 2007, and 400,000 units per month in 2008 and 2009 (that is, the medically unbelievable thresholds), were capped at 500,000 units and 400,000 units, respectively, consistent with CMS's ESA monitoring policy. A similar cap was applied to claims for ARANESP®, in which the caps based on the medically unbelievable thresholds were 1500 mcg. per month in 2007, and 1200 mcg. per month in 2008 and 2009. We believe that the portion of the base rate that reflects ESA utilization should comport with the ESA dosing guidelines under CMS's ESA Claims Monitoring Policy in effect at the time.
- Claims in which the number of dialysis treatments exceeded the number of days in the month were capped so that the number of dialysis treatments equaled the number of days in the month. No adjustments were made to the paid amounts associated with these claims. Payments to dialysis facilities in connection with claims with no dialysis treatments reported were excluded. On these claims, the payments to facilities were for services other than dialysis. Accordingly, they would not be considered renal dialysis services.
- Payments for blood and blood products. ESRD facilities rarely furnish blood as part of a patient's ESRD-related anemia management. As we discuss in section II.a.4. of this final rule, we have determined that blood and blood products do not meet the definition of renal dialysis services. Therefore, payments for blood and blood products were excluded. Blood and blood products are not included in the ESRD PPS payment bundle.
- Payments for vaccines and vaccine administration were excluded. Section 1881(b)(14)(B) of the Act specifically excludes vaccines from the ESRD PPS payment bundle.
- Immunosuppressive drug payments were excluded because immunosuppressive drugs are paid under a separate Medicare benefit.
- Payments for unclassified drugs (HCPCS J3490) and unknown drugs

were excluded because we do not know whether these drugs are ESRD-related. As their status is unknown, we did not consider them renal dialysis services.

- Payments for non-ESRD-related drugs, as identified in Table C in the Appendix were excluded because such drugs would not constitute renal dialysis services.
- Payments for pharmacy supplies, procedures not considered ESRD-related, and other non-ESRD miscellaneous services were also excluded.

We believe that these revised exclusion criteria permit the inclusion of statistically aberrant but plausible payments in the calculation of the base year amounts, while ensuring that amounts paid incorrectly are excluded.

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Table 9

Medicare Allowable Payments (MAP) for composite rate and separately billable services, 2007-09*

	2007	2008	January to Sept 2009
Dialysis patients	328,787	332,509	314,056
Hemodialysis (HD)-equivalent dialysis treatments	36,747,662	37,550,676	28,377,271
Total MAP for services in the expanded ESRD PPS			
Total for Part B and Part D services	$8,809,732,068	$8,982,276,591	$6,935,728,601
Total for Part B services	$8,799,031,984	$8,967,237,697	$6,922,162,833
Composite rate services	$5,719,657,831	$5,927,753,351	$4,505,292,198
Separately billable services (Part B)			
EPO^	$1,876,926,573	$1,787,217,266	$1,438,439,497
Darbepoetin^	$167,935,970	$152,927,193	$118,173,449
Calcitriol	$3,125,613	$1,551,993	$1,587,991
Doxercalciferol	$76,901,723	$70,664,928	$61,615,143
Paricalcitol	$322,849,348	$376,986,283	$286,428,841
Iron sucrose	$166,219,339	$174,019,193	$158,134,159
Sodium ferric gluconate	$68,086,707	$69,101,908	$42,830,961
Levocarnitine	$5,026,446	$3,593,143	$2,471,497
Alteplase	$26,697,321	$27,676,417	$21,903,525
Vancomycin	$3,583,504	$2,543,805	$2,140,261
Daptomycin	$1,234,405	$2,229,550	$2,241,182
Other injectables	$4,943,934	$3,442,832	$2,047,144
Laboratory tests	$295,508,409	$320,871,175	$243,481,931
Ultrafiltration	$2,563,656	$3,268,772	$2,581,117
Dialysis facility supplies and IV fluids	$38,263,239	$35,441,489	$27,920,874
Durable medical equipment and supplies (method II)	$18,060,483	$7,374,631	$4,541,261
Dialysis support services (method II)	$1,447,484	$573,767	$331,801
Total MAP per treatment for Part B services	$239.445	$238.804	$243.933
Dialysis patients with Part D spending	221,154	229,009	212,180
HD-equivalent dialysis treatments for patients with Part D spending	24,737,326	25,916,896	19,625,085
Total MAP for Part D services	$10,700,084	$15,038,895	$13,565,768
Calcitriol (oral)	$2,678,711	$3,059,551	$2,393,787
Doxercalciferol (oral)	$4,965,189	$7,392,035	$6,744,117

Paricalcitol (oral)	$3,008,544	$4,537,404	$4,388,569
Levocarnitine (oral)	$47,639	$49,905	$39,295
Total MAP per treatment for Part D services	$0.433	$0.580	$0.691
Total MAP per treatment for services in the expanded ESRD PPS	$239.88	$239.38	$244.62
Total MAP per treatment for services in the expanded ESRD PPS, adjusted for price inflation to 2009#	$243.65	$243.08	$244.62
Total MAP for composite rate drugs that were billed separately (excluded from base rate calculation)	$17,771	$6,980	$6,546
Total MAP from type '72X' claims excluded from ESRD PPS	$40,584,378	$44,318,791	$36,860,703
Separately billed services on claims with no dialysis treatments	$2,660,008	$2,392,576	$1,984,623
EPO exceeding the medically unbelievable threshold under the CMS ESA Monitoring Policy	$993,511	$1,912,588	$1,075,260
Darbepoetin exceeding the medically unbelievable threshold under the CMS ESA Monitoring Policy	$283,569	$119,922	$50,184
Blood and blood products	$1,504,831	$1,505,337	$1,538,284
Hepatitis B vaccine	$24,388,150	$26,533,803	$23,386,921
Flu vaccine	$1,922,271	$2,047,204	$1,171,542
Pneumonia vaccine	$709,726	$1,190,564	$1,037,558
Other vaccine	$41,803	$50,374	$32,394
Vaccine administration	$4,917,878	$6,339,116	$5,058,122
Immunosuppressive drugs	$148,740	$168,140	$76,712
HCPCS J3490 (unclassified drug)	$618,745	$459,160	$566,291
Non-ESRD drugs	$143,355	$173,624	$107,410
Pharmacy supply	$784	$1,280	$912
Excluded procedures	$188,465	$132,080	$46,152
Unknown drug (drug revenue center and no HCPCS)	$1,436,055	$1,039,131	$524,298
Other dialysis facility services	$626,486	$253,891	$204,040

*The estimates above exclude patient facility months with no hemodialysis-equivalent treatments. The monthly hemodialysis-equivalent treatments were capped at the number of days in the month (e.g., 31 for January).

^Payments for EPO and darbepoetin were capped to reflect the medically unbelievable thresholds that applied at the time under the CMS ESA Monitoring Policy (500,000 and 400,000 units of EPO per month in 2007 and 2008-09, respectively, and 1,500 and 1,200 mcg of darbepoetin per month in 2007 and 2008-09, respectively).

#The price inflation adjustments to 2009 are described below for services in the ESRD PPS.

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Table 9 shows the total MAP amounts for CY 2007, 2008, and the first 9 months of 2009. The MAP amount for the first nine months of 2009 is shown because of the requirement in section 1881(b)(14)(A)(ii) of the Act that the budget neutrality per patient utilization comparison include data from 2009.

Table 9 shows the MAP amounts for each period on a per treatment basis, after adjustment for price inflation to 2009, in accordance with the inflation factors described below.

Table 9 reveals that the MAP for CY 2007, the year with the lowest per patient utilization of renal dialysis services as described in section II.C.5. of this final rule, was $243.65 per treatment.

Comment: One commenter noted that we eliminated claims from our analysis

with a missing date of birth which is necessary in order to assign patients accurately to the correct age group category for purposes of determining the impact of age on composite rate costs and separately billable payments under the two-equation model. The commenter stated that in the Standard Analytical Files (SAF), an age range is assigned to patients, and the SAF denominator file similarly assigns an age to patients. The commenter said that because their data includes an age designation for all patients, no patients were eliminated from the commenter's calculations of treatments or payments.

Response: Our elimination of patients with no valid date of birth is only relevant in connection with the development of the payment adjusters for the age variable in the two-equation model and not for purposes of the computation of the base rate. This was done in order to prevent any distortion in the age adjusters. We point out that the number of claims eliminated was extremely small. No claims were eliminated due to the lack of a valid date of birth in the calculation of the base rate because age is not a classification variable in computing that rate. We are unaware of the assignment of an age range in the SAF claims files. Rather than relying on a methodology which assigns an age to patients, which may be incorrect, we believe that the exclusion of claims where a correct determination of age is necessary for the development of payment adjusters is appropriate.

4. Data for the Case-Mix Analyses, 2006–2008

The case-mix analyses required data for several patient and facility characteristics, such as age, co-morbidities, facility size, etc. After the exclusion of statistical outliers or otherwise unusable records (such as patients with no valid date of birth), the data shown in Table 8 was refined to yield the data set used in the primary analyses for both composite rate and separately billable services.

Table 10 summarizes these records.

Table 10

Medicare Dialysis Patients, Treatments, ESRD Facilities, and Claims
Final Analysis Sample by Year, 2006-2008[1]

	2006	2007	2008	Pooled, 2006-2008
Medicare Dialysis Patients	313,151	317,322	315,412	475,491
Hemodialysis Equivalent Dialysis Treatments	34,254,928	34,997,174	35,018,357	104,270,459
ESRD Facilities	4,214	4,389	4,559	4,809
Patient Month Claims	2,839,554	2,896,020	2,885,352	8,620,926

[1]Based on the sample of dialysis patients and ESRD facilities included in the case-mix analyses for both composite rate and separately billable services.

The primary case-mix analyses relied on pooled data from CY 2006 through CY 2008, which included a total of 8,620,926 Medicare ESRD patient months. The case-mix analyses included 97.4 percent of patients with Medicare outpatient dialysis claims during CYs 2006 through 2008. Over the 3-year period, the case-mix analyses included data for 475,491 Medicare ESRD patients treated in ESRD facilities.

5. Prescription Drug Event Data, CY 2007, CY 2008, Jan–Sept 2009

We obtained the total payments for Medicare Part D drugs from Part D claims submitted by prescription drug plans (drugs formerly covered under Part D prior to the ESRD PPS). The claims were restricted to Part D claims for oral drugs with an injectable form used to treat ESRD submitted on behalf of Medicare ESRD beneficiaries with valid ESRD claims in CY 2007, CY 2008, and for the first 9 months of 2009 (the latest available in time for the preparation of this final rule). As discussed in section II.A.3. of this final rule, payment of oral-only drugs under the ESRD PPS is being delayed until 2014. Therefore, payments for such drugs were excluded from the calculations. As a result, we are finalizing § 413.220, but revising paragraph (b) to reflect the exclusion of oral-only drugs from the computation of the final base rate.

The drugs included in the ESRD bundle are the three vitamin D analogues (calcitriol, doxercalciferol, and paricalcitol), and levocarnitine. The National Drug Coes (NDCs) used to identify these drugs in the Part D claims are shown in Table D of the Appendix.

Table 11 below shows the number of Medicare ESRD beneficiaries for which valid ESRD claims were filed in CY 2007, CY 2008, and the first nine months of 2009; number of ESRD beneficiaries with Part D drug coverage from the stand alone Part D plans; and number of beneficiaries with Part D claims for the above oral drugs.

Table 11

Medicare Dialysis Patients with Payments for Part D Drugs, 2007, 2008, and January-September 2009

	2007		2008		January to September 2009	
	Patients	%	Patients	%	Patients	%
ESRD patients with Medicare payments on outpatient dialysis facility claims[1]	328,787	100.0%	332,509	100.0%	314,056	100.0%
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs	221,154	67.3%	229,009	68.9%	212,180	67.6%
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs included in the ESRD PPS[2]	20,874	6.3%	23,422	7.0%	19,647	6.3%

[1]Includes 'type 72X' outpatient institutional claims with treatments > 0.
[2]Includes Vitamin D analogs (Calcitriol, Paracalcitol, and Doxercalciferol), and levocarnitine.

D. Analytical Approach

In the proposed rule, we presented a case-mix model that UM–KECC developed, using standard techniques of multivariate regression. In the proposed rule, we described in detail two approaches for developing the case-mix models using multivariate regression (74 FR 49938). The case mix model we proposed in the development of the proposed ESRD PPS rule was the two-equation model.

We noted that, for those interested, a more extensive and detailed mathematical explanation of the two-equation model used to develop the case-mix adjusters is contained in UM–KECC's February 2008 report, *End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle* (*see* pp. 38–44 and Technical Appendix).

We did not receive any public comments in connection with our use of the two-equation model to develop the case-mix adjusters.

E. Development of ESRD PPS Base Rate

The patient-specific case-mix adjustments developed from the two-equation model for composite rate and separately billable services are applied to a base payment rate per treatment ("base rate"). We proposed that the ESRD base rate would be adjusted to reflect ESRD facility differences in area wage levels using a proposed wage index (74 FR 49947).

In this section, we describe the calculation of the ESRD base rate, as set forth in § 413.220, and the computation of the reduction factors used to adjust the ESRD base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act. We define the ESRD base rate at § 413.171. The proposed ESRD base rate, which represents the average Medicare allowable payment (MAP) for composite rate and separately billable services, was developed from CY 2007 claims data.

We used claims data from CY 2007 in connection with the preparation of the proposed rule because such data were the latest available. In the proposed rule, we stated that we expected to have claims data for CY 2008 and partial claims information for CY 2009 in connection with our preparation of the final rule (74 FR 49939). We also stated that in order to comply with the statute's requirement to use per patient utilization data from 2007, 2008, or 2009 (whichever year had the lowest per patient utilization), we planned to use available claims for Medicare ESRD beneficiaries from those years, to determine which year resulted in the lowest average payment amount per treatment (74 FR 49934).

We received several comments in connection with our proposed methodology for determining the year with the lowest per patient utilization of renal dialysis services, as required under section 1881(b)(14)(A)(ii) of the

Act. The comments received, and our responses to them, are set forth below.

Comment: Several commenters pointed out that section 1881(b)(14)(A)(ii) of the Act directs the Secretary to use "per patient utilization data from 2007, 2008, or 2009" in estimating the total amount of payments that would have been made under title XVIII in 2011 for renal dialysis services. The year selected in making that estimation must be the year which has the lowest per patient utilization. The commenters explained that CMS's proposed methodology for determining the unadjusted base rate per treatment, in which the total expenditures for the specified renal dialysis services included in the payment bundle is divided by the total annual number of hemodialysis (HD)-equivalent treatments (74 FR 49940 through 49942), represents an inaccurate approach for complying with the law. The commenters maintained that the effect on the Part D drugs component of the payment bundle was to inflate the denominator (that is, total HD-equivalent treatments) to include all eligible Medicare ESRD beneficiaries, regardless of Part D participation, while the numerator with respect to Part D drugs only included ESRD drug payments for Medicare Part D enrollees. The commenters stated that this resulted in a gross understatement of the Part D drugs component of the payment bundle. The commenters asserted that in order to calculate per patient utilization accurately, the pool of patients in the numerator and denominator of the base rate per treatment computation must be congruent.

Response: We believe that the commenters are correct in concluding that our proposed methodology for calculating the base rate yielded an inappropriately low payment amount for the Part D component of the ESRD PPS payment bundle. This occurred because the total payments for the Part D drugs we proposed to include in the bundle reflected payments for those drugs for those Medicare ESRD beneficiaries enrolled in Part D, while the denominator reflected the total number of HD-equivalent treatments for all Medicare ESRD beneficiaries, regardless of their enrollment in Part D. For this final rule, we have revised the denominator in the calculation described above to reflect the total number of treatments for those ESRD beneficiaries enrolled in Part D.

In addition, given the commenters' concerns regarding our proposal for determining the lowest per patient utilization year and the calculation of the per treatment base year amount, we reevaluated our proposed methodology and adopted a revised approach. We believe our revised methodology more closely comports with the language set forth in section 1881(b)(14)(A)(ii) of the Act, requiring the determination of the year with the lowest per patient utilization of renal dialysis services by Medicare ESRD beneficiaries. The methodology is similar to the calculation used for the composite rate drug add-on, in that the effects of price and enrollment are removed from total expenditures to obtain per patient utilization. The method used is described in detail below. We have also revised our computation of the base rate with respect to the Part D drug component to yield an amount which we believe is no longer understated.

Section 1881(b)(14)(A)(ii) of the Act requires that we compare data from 2007, 2008, and 2009 to select the year with the lowest per patient utilization of renal dialysis services. Although we have complete data for 2007 and 2008, we only have partial year data for 2009. To control for the effects of potential seasonal variation in the utilization of dialysis services, we first compared renal dialysis expenditures for the first nine months of each year. We felt this approach was preferable to completing the 2009 data, in order for it to represent a full year's value, as this could introduce bias in the estimation.

We eliminated the effects of price inflation by adjusting expenditures for 2007 and 2008 to reflect 2009 price levels using the actual annual rates of inflation for the various components of the bundle. Payments for composite rate services were inflated to the 2009 base rate of $133.81 per treatment and drug add-on percentage of 15.2 percent. The inflators for Part B drugs and biologicals were based on actual ASP+6 percent prices, because that is what they were paid (see Table 12 below for the full year prices).

Payments for laboratory tests were inflated 4.5 percent from 2007 to 2009 and from 2008 to 2009. The inflators for laboratory services are based on updates to the laboratory fee schedule. The laboratory fee schedule is required to be updated using the CPI–U and any statutory adjustments to the CPI–U update factor. As the price update for laboratory services from 2007 to 2008 was statutorily set to be 0 percent, no inflator was applied for that year.

Because DME supplies and equipment, and self dialysis support services for Method II patients are subject to a monthly capitation payment that has not increased, we did not use an inflation adjustment. In addition, because supplies and other services are primarily composed of the $0.50 administration fee for separately billable Part B drugs, and this has not increased, we did not inflate this category.

Part D drugs were inflated 6.0 percent from 2007 to 2009, and 3.4 percent from 2008 to 2009, using the growth rates for overall prescription drug prices that were used in the National Health Expenditure Projections.

Table 13 shows payments per Medicare ESRD beneficiary for the first nine months of each year, for the renal dialysis services which comprise the payment bundle, excluding former Part D oral drugs, with prices inflated to 2009 levels. Table 14 shows payments for Medicare ESRD beneficiaries enrolled in Part D, for the oral drugs with an injectable equivalent based on Medicare Part D claims, similarly adjusted for price inflation to 2009.

By looking at these components separately, we are able to calculate the per capita spending based on the number of beneficiaries that are eligible for the service. By calculating the spending on a per capita basis, we are eliminating the effects of enrollment. The sum of the two values yielded the average expenditures per Medicare ESRD beneficiary for the renal dialysis services included in the payment bundle. These values are shown in Table 15. The indicated per capita spending amounts represent the per patient price and utilization of renal dialysis services. Because we are controlling for the effects of price inflation for the comparable 9 month periods in 2007, 2008, and 2009, the variability in per capita amounts is due to utilization. We believe that this methodology is responsive to the commenters' concerns in that the Part D spending amount is divided by the number of beneficiaries enrolled in Part D, and there is no understatement of this component.

Table 15 reveals that for the 9-month periods, 2007 was the year with the lowest per patient utilization, with per capita expenditures of $21,568. We performed the same computations using the full year of data for 2007 and 2008, as a check for the results obtained. (Tables 16, 17, and 18). We did not use the 2009 data in this comparison, as it is incomplete. The results revealed that per capita spending for Medicare ESRD beneficiaries was again lower in 2007, with total expenditures per beneficiary of $27,232.

Accordingly, we have determined that 2007 is the year representing the lowest per patient utilization of the renal dialysis services which comprise the ESRD payment bundle, and have used

that year to develop the base rate set forth in this final rule. For the reasons described above, we are finalizing 413.220(b)(1). However, we have revised the title to reflect per patient utilization in CY 2007, 2008 or 2009 and revised the content to clarify that we remove the effects of enrollment and price growth from total expenditures for 2007, 2008 or 2009 to determine the year with the lowest per patient utilization. In addition, we have revised § 413.220(a)(3) to clarify that 2007 is the year with the lowest per patient utilization.

Table 12: ASP+6 Percent Price Updates

Drugs and biologicals	2007 to 2009	2008 to 2009
EPO	3.2%	4.5%
Paricalcitol	-3.1%	-2.6%
Sodium_ferric_glut	-0.8%	-1.8%
Iron_sucrose	3.9%	7.3%
Levocarnitine	-20.0%	2.3%
Doxercalciferol	16.8%	14.1%
Calcitriol	-15.4%	13.7%
Iron_dextran	6.4%	6.4%
Vancomycin	-11.4%	-4.6%
Alteplase	4.7%	5.2%
ARANESP®	-10.1%	3.3%
Daptomycin	15.8%	6.9%
Other injectables	1.7%	-3.7%

Table 13: Renal dialysis services, excluding former Part D drugs

9 months	Total Payments	Enrollment	Per Capita Spending
2007	6,668,151,925	309,724	21,529
2008	6,792,065,430	313,714	21,651
2009	6,922,162,833	314,056	22,041

Table 14: Oral drugs with an injectable equivalent

9 months	Total Payments	Enrollment	Per Capita Spending
2007	8,047,968	208.444	39
2008	11,341,027	216,088	52
2009	13,565,768	212,180	64

Table 15 Total Renal dialysis services

9 months	Per Capita Spending
2007	21,568
2008	21,703
2009	22,105

Table 16: Renal dialysis services, excluding former Part D drugs

Full Year	Total Payments	Enrollment	Per Capita Spending
2007	8,936,542,191	328,787	27,180
2008	9,105,145,441	332,509	27,383

Table 17: Oral drugs with an injectable equivalent

Full Year	Total Payments	Enrollment	Per Capita Spending
2007	11,340,484	221,154	51
2008	15,550,217	229,009	68

Table 18 Total Renal dialysis services

Full Year	Per Capita Spending
2007	27,232
2008	27,451

1. Calculation of the CY 2007 Unadjusted Rate Per Treatment

Sections 1881(b)(14)(A)(i) and 1881(b)(14)(B) of the Act, as added by MIPPA, specify the renal dialysis services, and other items and services, which must be included in the payment bundle of the ESRD PPS. We proposed to include payments for the various components (*see* Table 8 at 74 FR 49940), which comprise the renal dialysis services in the development of the proposed base rate. A detailed description of each of the components of the ESRD PPS payment bundle included in the CY 2007 unadjusted rate per treatment was discussed in the ESRD PPS proposed rule (74 FR 49941). We also described the adjustments used to calculate the ESRD PPS base rate from the CY 2007 unadjusted rate per treatment (74 FR 49942). Table 19 shows the various components of the ESRD PPS payment bundle based on CY 2007 claims, after adjustment for price inflation to 2009.

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Table 19

Average Medicare Allowable Payments (MAP) for composite rate and separately billable services, 2007, with adjustment for price inflation to 2009[1]

	Total	Average MAP per treatment
Dialysis patients	328,787	--
Hemodialysis (HD)-equivalent dialysis treatments	36,747,662	--
MAP for services in the expanded ESRD PPS		
Total for Part B and Part D services	$8,947,882,675	$243.65
Total for Part B services	$8,936,542,191	$243.19
Composite rate services	$5,792,196,328	$157.62
Separately billable services (Part B)		
EPO	$1,937,063,301	$52.71
Darbepoetin	$150,925,735	$4.11
Calcitriol	$2,645,644	$0.07
Doxercalciferol	$89,814,291	$2.44
Paricalcitol	$313,002,443	$8.52
Iron sucrose	$172,625,432	$4.70
Sodium ferric gluconate	$67,575,376	$1.84
Levocarnitine	$4,021,810	$0.11
Alteplase	$27,960,906	$0.76
Vancomycin	$3,176,525	$0.09
Daptomycin	$1,429,021	$0.04
Other injectables	$5,038,108	$0.14
Laboratory tests	$308,732,410	$8.40
Ultrafiltration	$2,563,656	$0.07
Dialysis facility supplies and IV fluids	$38,263,239	$1.04
Durable medical equipment and supplies (method II)	$18,060,483	$0.49
Dialysis support services (method II)	$1,447,484	$0.04
Dialysis patients with Part D spending	221,154	--
HD-equivalent dialysis treatments for patients with Part D spending	24,737,326	--
MAP for Part D services	$11,340,484	$0.46
Calcitriol (oral)	$2,839,032	$0.11
Doxercalciferol (oral)	$5,262,356	$0.21

Paricalcitol (oral)	$3,188,606	$0.13
Levocarnitine (oral)	$50,490	<$0.01

[1]The estimates above exclude patient facility months with no hemodialysis-equivalent treatments. The monthly hemodialysis-equivalent treatments were capped at the number of days in the month (e.g., 31 for January). Payments for EPO and darbepoetin were capped to reflect the medically unbelievable edit threshold that applied at the time (500,000 and 400,000 units of EPO per month in 2007 and 2008-09, respectively, and 1,500 and 1,200 mcg of darbepoetin per month in 2007 and 2008-09, respectively).

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As we explained above, we determined that CY 2007 was the year with the lowest per patient utilization of renal dialysis services. The categories which comprise the ESRD PPS payment bundle remain the same as set forth in the proposed rule (Table 8 at 74 FR 49940). The payment amounts associated with each component are presented in Table 19, and reflect the modifications and exclusions previously described (for example, the Part D drug component excludes oral-only drugs and biologiclas, payments for blood and blood products are excluded, payments for separately billed drugs which should be considered composite rate drugs were excluded, etc.).

a. Composite Rate Services

The first MAP component of the ESRD PPS payment bundle shown in Table 19 is "Composite rate services". This line item refers to total CY 2007 payments for composite rate services as obtained from ESRD facility claims (bill type 72X claims), inflated to 2009. This total includes all composite rate payments to ESRD facilities, including exception payments made in accordance with § 413.182 through § 413.186.

b. Part B Drugs and Biologicals

The next 11 line items in Table 19 reflect the categories of injectable drugs. In the proposed rule, we noted that the top 11 Part B drugs and biologicals accounted for 99.7 percent of total separately billable Part B drug payments (74 FR 49943). For this final rule, we found that total payments in 2007 for the top 11 Part B drugs and biologicals reported on ESRD claims, and used to calculate the base rate, accounted for 99.8 percent of total spending for Part B drugs. Monthly payments for EPO and ARANESP® were capped in accordance with the applicable medically unbelievable edits, described previously in this section. For all other injectable Part B drugs, we have provided a separate line item. In section II.A.3. of this final rule, we discuss Part B drugs and biologicals in detail.

c. Laboratory Tests

Another component of the ESRD PPS bundle shown in Table 19 is laboratory tests. Payments for laboratory tests represent the total amount paid to dialysis facilities for outpatient laboratory tests billed on ESRD claims, as well as payments for laboratory tests ordered by physicians receiving MCP amounts and billed on carrier claims. We identified laboratory tests ordered by physicians receiving MCP using the list of physicians for CY 2007, which was the latest list available in connection with the publication of the final rule. We discuss laboratory tests under the ESRD PPS in detail in section II.K.2. of this final rule.

d. Durable Medical Equipment (DME) and Supplies

DME and supplies is another component of the ESRD PPS payment bundle. Payments for these items and services were obtained from the form CMS 1500 claims for Method II home patients.

e. Dialysis Support Services

We computed a total amount for the next component of the ESRD PPS payment bundle shown in Table 19, "Dialysis support services." This total represents total payments for support services furnished to Method II home dialysis patients, and reported under subcategory 5 of revenue codes 082X through 085X on ESRD claims.

f. Supplies and Other Services Billed by Dialysis Facilities

This category of the ESRD PPS payment bundle primarily includes payments for syringes used in the administration of intravenous drugs during the provision of outpatient dialysis. These supplies and services were billed by the dialysis facilities on ESRD claims.

g. Former Part D Drugs

This amount represents total payments made on behalf of the ESRD beneficiaries with Part D coverage in CY 2007 (inflated to 2009), for the oral equivalents of injectable drugs and biologicals which were furnished for the treatment of ESRD. These drugs and biologicals (three vitamin D analogues and levocarnitine) were obtained from Part D claims submitted on behalf of the Medicare ESRD beneficiaries with valid type 72X claims in CY 2007 with Part D coverage. We received several comments concerning payment for Part D drugs.

Comment: One commenter suggested that the payment amount for oral drugs included in the base rate use the Part D data for beneficiaries with the low income subsidy. The commenter stated that this amount would then be applied to all Medicare ESRD beneficiaries, regardless of their particular insurance arrangement (Part D coverage, retiree coverage, or out-of-pocket). The commenter believed that such an approach would likely produce a more robust estimate of the costs of the drugs for inclusion in the payment bundle.

Response: In calculating the component of the base rate which reflects payments for former Part D drugs (excluding oral-only drugs), we used Part D claims for 2007 for all Medicare ESRD beneficiaries who were enrolled in Part D. This included payments not only made by the Part D drug plan, but also payments made by or on behalf of the beneficiary, for which the Part D beneficiary was responsible. Total Part D drug expenditures for the oral equivalents of ESRD injectables were divided by the number of treatments for Medicare ESRD Part D enrollees. This amount per treatment was added to the per treatment amount reflecting total 2007 ESRD expenditures for all Medicare ESRD beneficiaries, divided by the number of treatments for those beneficiaries. Because total payments for Part D drugs were divided by the number of HD-equivalent treatments furnished to Part D enrollees, we believe that this methodology does not result in an understatement of the oral drug component of the payment bundle. Comparison of the price adjusted amounts for 2007, 2008, and available data for 2009 revealed that 2007 was the year with the lowest per patient utilization of renal dialysis services (see paragraph E. above). The NDC codes

used to identify these drugs are shown in Table D of the Appendix.

Comment: Several commenters asserted that even if CMS has the statutory authority to include oral-only Part D drugs in the calculation of the base rate, the proposed computed amount of $12.48 per treatment is inordinately low. The commenters believed the amount was too low because it reflected the amount of payments made for two-thirds of all beneficiaries divided by the number of Medicare HD-equivalent treatments provided to the entire universe of Medicare ESRD beneficiaries, including those not enrolled in Part D. One commenter stated that this represents the imposition of an unfunded mandate. After consideration of inflation, prescription rates, and patient compliance, the commenter presented an analysis suggesting that the proper per treatment amount in 2011 for oral Part D drugs should be about $45.00.

Response: We have revised the base rate component of the bundled ESRD PPS for Part D drugs so that it excludes oral-only ESRD drugs (*see* section II.A.2. of this final rule for a discussion of our decision to delay payment of oral-only ESRD drugs under the ESRD PPS until January 1, 2014). We have also revised the methodology for computing the portion of the base rate attributable to Part D drugs so that it represents the average Part D payment per treatment for each Part D enrollee. This revision responds to the commenter's concern that the payment amount included in the proposed rule was understated because it represented Part D payments for only two-thirds of all Medicare ESRD beneficiaries, divided by the number of HD-equivalent treatments for all Medicare ESRD beneficiaries. With respect to the suggestion that the Part D payment amount included in the base rate should also be adjusted to reflect increased inflation, prescription rates, and patient compliance, we decline to include these factors for the following reasons.

The commenter asserted that the actual rate of price inflation in Part D drugs would be about 16 percent annually from 2007 through 2011 based on historical data, but calculated a projection using a more conservative figure of 12.2 percent. We reject the magnitude of this projection as it differs significantly from forecasted rates of drug price inflation using the producer price index. Moreover, we believe that using projected increases in patient prescription rates and anticipated increases in patient compliance as a basis for calculating the Part D drug component of the base rate is highly speculative.

We believe the data we used for the Part D drugs that we are including in the base rate at this time are appropriate and reflect an adequate payment amount for this component of the base rate. Accordingly, we decline to incorporate the commenter's suggested variables. We note that we will address data issues pertaining to oral-only drugs and the base rate payment amount for such drugs in the future when we bundle oral-only drugs beginning January 1, 2014.

With respect to the commenter's concern that the per treatment amount for the Part D drugs component of the bundle is inordinately low because the number of treatments used reflected all Medicare ESRD beneficiaries, not just those enrolled in Part D, we point out in a response to a previous comment that we have addressed this concern by revising the computation of the base rate, so that the Part D drugs component reflects Part D payments divided by HD-equivalent treatments for Part D enrollees. With respect to the adequacy of Part D drug payments, we have delayed the inclusion of oral-only drugs until January 1, 2014. We will address data issues pertaining to oral-only drugs, and the per treatment payment amount for these drugs, in the future when these drugs are included in the payment bundle. For the Part D drugs which we are including in the ESRD PPS beginning January 1, 2011, the source data are the actual payments from the 2007 Part D claims for the oral drugs with an injectable version. We believe that these data are appropriate and adequate.

Comment: Several commenters pointed out that our proposed methodology for calculating the base rate resulted in an understatement of the Part D drug component of the payment bundle (74 FR 49940). This occurred because, while total payments for renal dialysis services (excluding Part D drugs) were properly divided by the total number of HD-equivalent treatments for Medicare ESRD beneficiaries, the total payments for Part D drugs for Medicare ESRD beneficiaries enrolled in Part D, was similarly divided by the same number of HD-equivalent treatments. This yielded an understatement in the amount of the payments per treatment for Part D drugs included in the payment bundle, because the number of treatments for Part D enrollees was overstated, reflecting total treatments for all ESRD beneficiaries instead of treatments for Part D enrollees only.

Response: The commenters are correct. In this final rule, for all components of the base rate excluding the portion for Part D drugs, we used the total number of CY 2007 Medicare HD-equivalent dialysis sessions (36,747,662) to calculate the portion of the base rate attributable to all composite rate and separately billable services. For the portion of the MAP attributable to oral Part D drugs with an injectable version, the number of CY 2007 HD-equivalent treatments used to compute the Part D drugs component was 24,737,326. This represents the number of treatments for Medicare ESRD beneficiaries enrolled in Part D.

Comment: Several commenters stated that based on a plain reading of the statute, the Congress intended CMS to take into account all of the costs for Part D drugs, regardless of Medicare beneficiaries' source of prescription drug coverage. Therefore, some commenters asserted that an accurate estimate of total Part D drug costs should include a determination of the cost of oral drugs for Medicare ESRD beneficiaries who obtain their drug coverage from Medicare Part D or through another source. One commenter included a specially commissioned study which purported to quantify the utilization of oral ESRD drugs (using pill counts) among three payer groups: Medicare Part D, private coverage (including employer coverage), and other/unclassified coverage. Because the average pill counts for specific oral ESRD drugs varied among the payer groups, the commenter suggested that this difference in utilization would need to be considered to adjust the Part D component of the base rate. In addition, the commenter recommended that CMS adjust this component to reflect anticipated changes in oral drug use, expected improvements in beneficiary adherence to oral drug regimens, and an appropriate inflation adjustment.

Response: For reasons expressed in the response to the preceding comment, we decline to adjust the Part D component of the base rate using expected increases in oral drug use, and increases in patient compliance. We also believe that we have appropriately inflated the base rate to 2011 to reflect price changes. Under the methodology for calculating the per treatment amount for the specified renal dialysis services included in the base rate, the sum of the composite rate and separately billable components is divided by the number of treatments for ESRD beneficiaries. Total payments for the oral equivalents of injectable drugs were divided by the number of treatments for Medicare ESRD Part D enrollees. These two

amounts were summed to obtain the unadjusted MAP per treatment. Therefore, the Part D component of the unadjusted base rate amount was calculated only using beneficiaries with Part D coverage.

The commenter's cited study suggests that differences in oral drug utilization occur depending on the source of the payment. Although the commenter's study was limited to a sample using 12,706 Medicare ESRD beneficiaries and did not control for differences in dosage (utilization was based on pill counts regardless of the dosage amount), we believe that a finding that the utilization of Part D drugs among Medicare ESRD beneficiaries differs depending on payer source would have no impact on our calculation of the base rate. Section 1881(b)(14)(A)(ii) of the Act refers to the total amount of payments "under this title," which we have interpreted as meaning under Title XVIII of the Social Security Act.

Therefore, even if differences in the utilization of Part D drugs among Medicare ESRD patients were confirmed based on non-Medicare sources of payment for these drugs, we believe this information could not be used to develop weighting factors to adjust the Part D component of the base rate based on differences in utilization across payer groups. Non-Medicare sources of payment for these drugs, such as employer groups, unions, private insurance, etc., could not be considered because we interpret section 1881(b)(14)(A) of the Act as requiring that the ESRD PPS reflect payments under Title XVIII for renal dialysis services.

h. Total Medicare Hemodialysis (HD)-Equivalent Sessions

In order to calculate the proposed ESRD PPS base rate per treatment, it was necessary to divide the total payments for each MAP amount described above by the number of corresponding Medicare HD-equivalent sessions. The number of Medicare HD-equivalent sessions represents the total Medicare treatments for outpatient dialysis as reported on ESRD claims submitted by dialysis facilities. For PD patients, patient weeks were converted to HD-equivalent sessions. For this purpose, one week of PD was considered equivalent to three HD treatments. Accordingly, a patient on PD for 21 days would have $(21/7) \times 3$ or 9 HD-equivalent sessions. In determining the total number of Medicare treatments, the number of HD-equivalent sessions was capped so as not to exceed the number of days in the month in which treatments were furnished.

i. Average MAP per Treatment

We summed the total payments for the composite rate and separately billable portions of the bundle. The total of $8,936,542,191 (which excludes all Part D drugs) was divided by the number of HD-equivalent treatments (36,747,662), to yield an average MAP per treatment of $243.19. The MAP per treatment for Part D drugs (excluding oral-only drugs) was similarly computed by dividing the total payment for those drugs ($11,340,484) by the number of HD-equivalent treatments for Medicare ESRD Part D enrollees (24,737,326), to obtain a MAP per treatment of $0.46. The sum of the MAP amount for all renal dialysis services excluding Part D drugs ($243.19), plus the MAP amount for the Part D drugs component, which excludes oral-only drugs, ($0.46), yielded the total average MAP per treatment for the renal dialysis services included in the ESRD PPS payment bundle. This amount, $243.65, is the unadjusted base rate amount and reflects price inflation to 2009. The renal dialysis services which comprise the base rate, both in terms of total payments for each component and the average payment per treatment, inflated to 2009, are shown in Table 19.

2. Determining the Update Factors for the Budget-Neutrality Calculation

In order to estimate payments under the current payment system for each facility in CY 2011, the first year of the ESRD PPS, the components of the CY 2007 unadjusted per treatment rate were updated to reflect estimated 2011 prices, using the methodology as described in the proposed ESRD PPS rule (74 FR 49942). It is necessary to estimate 2011 payments under the current ESRD payment system (including all separately billable items) for each facility in order to meet the statutory budget-neutrality requirement for the ESRD PPS.

Section 1881(b)(14)(A)(ii) of the Act requires that the ESRD PPS payment system be 98 percent budget neutral in 2011. In other words, the estimated total amount of payments under the ESRD PPS in 2011, including any payment adjustments, must equal 98 percent of the estimated total amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS system had not been implemented. In the proposed ESRD PPS, we described the update factors used to estimate CY 2011 payments for each component (74 FR 49939).

a. Composite Rate Services

In order to update the basic case-mix adjusted composite payments to 2011, we began with the CY 2009 base composite rate ($133.81) and the CY 2009 drug add-on percentage of 15.2 percent. At the time of the proposed rule (74 FR 49942), in accordance with section 1881(b)(12)(G) of the Act, as amended by section 153(a)(1) of MIPPA and in accordance with section 1881(b)(14) of the Act, we updated the composite rate by 1.0 percent for CY 2010 and by the estimated ESRD bundled market basket percentage increase minus 1 percentage point (1.5 percent) for CY 2011, respectively, resulting in a proposed 2011 composite rate of $137.18.

We proposed (74 FR 49942 through 49943) to use this base composite rate for CY 2011, which included the ESRD bundled market basket update minus 1 percentage point to update the CY 2010 composite rate, for purposes of establishing the ESRD PPS base rate, given that we interpreted section 1881(b)(14)(F)(ii) of the Act to require us to update the composite rate portion of the blend by the market basket update minus 1.0 percentage point in all years of the transition (which included CY 2011). We stated that using the market basket in this way would be a consistent approach (74 FR 49943). At the time of the proposed rule, we proposed an ESRD bundled market basket update of 2.5 percent for CY 2011. Therefore, we proposed (74 FR 49942 through 49943) a 1.5 percent update to the composite rate for CY 2011, resulting in a proposed CY 2011 composite rate of $137.18 ($135.15 * 1.015).

We noted that the drug add-on percentage was reduced from 15.2 percent to 14.8 percent as a result of the increases to the composite rate in CYs 2010 and 2011. Since the drug add-on is calculated as a percentage of the base composite rate, the drug add-on percentage decreases with increases in the composite rate. The CY 2009 PFS final rule (73 FR 69755) explains why increases to the base composite rate require decreases to the drug add-on percentage to ensure that the total drug add-on dollar amount remains the same. We stated our intent to update the drug add-on, if necessary, for the ESRD PPS final rule (73 FR 69755).

In the proposed rule, we used the applicable facility-level and patient-level basic case-mix adjustments from the CY 2007 claims to re-compute payment using the applicable basic case-mix adjustments applied to a 100 percent CBSA wage-adjusted composite rate using the most recently available

ESRD wage index, which is the CY 2009 final rule ESRD wage index with a 0.60 floor. We stated that we did this to use the most recent wage indexes available in estimating 2011 payments (74 FR 49943). We also noted that the other components of the bundle discussed in the proposed rule do not have payments which are computed with wage indexes (74 FR 49943). In addition, we noted in the proposed rule that payment rates to facilities that have chosen to retain their exceptions under the basic case-mix composite payment system are not updated because, once approved, the exception amounts were fixed payment amounts, and hence the 2007 amounts represent the 2011 amounts (74 FR 49943).

We did not receive any public comments regarding our proposal with regard to composite rate services. However, following the release of the ESRD PPS proposed rule, section 3401(h) of the Affordable Care Act of 2010 amended section 1881(b)(14)(F) of the Act, by revising the ESRDB market basket update for CY 2011 from a market basket update minus one percent to a full market basket update. Thus, a 2.5 percent update to the composite rate for CY 2011, results in a final CY 2011 composite rate of $138.53 ($135.15 * 1.025). We note that $135.15 is the final CY 2010 composite rate, which was derived from the CY 2009 composite rate of $133.81 increased by one percent as required by section 153(a)(1) of MIPPA ($133.81 * 1.01). We also note that, as discussed in the CY 2011 PFS proposed rule issued on June 25, 2010, we have used the proposed CY 2011 drug add-on percentage of 14.7 percent, and the CY 2011 proposed ESRD wage index values with a 0.60 floor for computing the ESRD PPS budget neutral base rate. In this way, we are using the most current data available for computing the final CY 2011 ESRD PPS base rate. The final CY 2011 ESRD PPS base rate will not be adjusted to reflect final decisions regarding the drug add-on percentage and the wage index floor for CY 2011. However we note that we will use the final drug add-on and wage index floor values in computing the composite rate portion of the blended payments during the transition.

b. Self-Dialysis support services for Method II patients

Currently, the allowance per month under Method II for home dialysis support services may not exceed $121.15 per month for all forms of dialysis. Since home dialysis support services for Method II patients are subject to a monthly capitation payment that is not increased, we proposed (74 FR 49943)that the CY 2007 amounts represent the CY 2011 amounts.

We did not receive any public comments regarding our proposal. Since the monthly capitation payment has not increased, we are finalizing the approach that the CY 2007 amounts represent the CY 2011 amounts.

c. Part B Drugs and Biologicals

Under the current system, payments for ESRD drugs and biologicals under Part B are paid on average sales price plus 6 percent (ASP+6 percent) methodology. For the proposed rule, we reviewed ASP prices for four quarters of 2006, 2007, 2008, and two quarters of 2009 for the top eleven separately billable drugs. We proposed to use the 2009 prices as a proxy for 2011 values (74 FR 49943). We indicated that we would revaluate our decision with updated quarterly ASP pricing data.

For other ESRD-related Part B drugs, we used a proposed weighted average of the top eleven Part B drugs to update those drug prices to 2011. As the top eleven drugs represented 99.7 percent of total separately billable Part B drug payments at the time of the proposed rule, we indicated that the overall weighted average was representative of the remaining 0.3 percent of drugs. (*See* Table 10 in the ESRD PPS proposed rule (74 FR 49943) for the price updates used.) We have refined our data and the top eleven drugs that now represent 99.8 percent of total separately billable Part B drug payments.

The comments we received on this proposal and our responses are set forth below.

Comment: Commenters expressed concern about the lack of an update for ASP-priced drugs and biologicals and suggested that we use the Producer Price Index for Drugs (PPI) to inflate Part B drug prices.

Response: We agree with the commenters about the need for an update in ASP prices for Part B drugs and to use the PPI for the update. For that reason, we took the latest available ASP pricing data, which represented the second quarter of 2010, and updated these prices using the PPI for drugs. This update resulted in a 3.9 percent increase to the top eleven separately billable Part B Drugs from 2010 to 2011. Similar to the proposed rule, since the top eleven drugs account for over 99 percent of total spending, for the final rule we used a weighted average growth of the top eleven drugs (4.6 percent) for the remaining Part B drugs. Table 20 below shows the price increases, from 2007 to 2011, of the separately billable Part B drugs.

Table 20: Price Increases from 2007 to 2011 of Separately Billable Part B Drugs

Drugs and biologicals	Price Updates
EPO	7.0%
Paricalcitol	-3.2%
Sodium_ferric_glut	-0.2%
Iron_sucrose	2.6%
Levocarnitine	-22.5%
Doxercalciferol	16.6%
Calcitriol	-26.3%
Vancomycin	-3.1%
Alteplase	16.9%
Aranesp	-9.0%
Daptomycin	30.1%
Other injectables	4.6%

d. Laboratory Tests

We proposed to update payments for laboratory tests paid through the laboratory fee schedule to 2011 using projected CPI–U increases and any legislative adjustments that would be applied to this fee schedule (74 FR 49943). Using this approach, we proposed (74 FR 49943) a growth update of 5.1 percent from 2007 to 2011.

We did not receive any public comments regarding our proposal. Since the CPI–U increase, with any legislative adjustments, is the statutory updated required for laboratory testing, we are finalizing this approach. However, we have updated the growth percentage using more recent forecasts of the CPI–U data. For this final rule, the growth from 2007 to 2011 is 3.9 percent.

e. DME Supplies and Equipment

Since payments for supplies and equipments for Method II patients are subject to a monthly capitation payment that has not increased, we proposed that the CY 2007 amount represents the 2011 amounts (74 FR 49943).

We did not receive any public comments regarding our proposal. Therefore, for the reasons above, we are finalizing the proposed approach for updating the amount for DME supplies and equipment.

f. Supplies and Other Services

This category primarily includes the $0.50 administration fee for separately billable Part B drugs. Since this fee has not increased, as there is no update for such fees, we proposed no price update (74 FR 49943).

We did not receive any public comments regarding our proposal. Given that the administration fee has not increased, we are finalizing the proposed approach for supplies and other services.

g. Former Part D Drugs

We proposed that former Part D drugs would be updated by the growth rates for overall prescription drug prices that were used in the National Health Expenditure Projections and referred to the following link for further information on the National Health Expenditure Projections: *http://www.cms.hhs.gov/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp#TopOfPage.* Using the National Health Expenditure Projections, we proposed a growth of 12.2 percent from 2007 to 2011 (74 FR 49943). We proposed this approach because we did not have enough data to establish a trend for Part D prices and we use this price growth in the overall Part D projections. Therefore, we believed it was an adequate proxy for updating prices for former Part D drugs.

The comments we received on this proposal and our responses are set forth below.

Comments: A few commenters suggested the use of the PPI to update the Part D drugs.

Response: We continue to feel that the growth rates for overall prescription drug prices that are used in the National Health Expenditure Projections are the best proxy, as they are consistent with the price growth proxy used in Part D spending projections. However, due to new National Health Expenditure Projections, the final growth for Part D drugs is 12.9 percent. This growth factor would be applied to those Part D drugs that are to be included in the ESRD PPS bundle as of January 1, 2011. We note that oral-only Part D drugs will not be included until after the transition, as discussed in section II.A.3. of this final rule.

Once we determined updated CY 2011 payments for each component of the items and services discussed above, we proposed to add the components together to determine each ESRD facility's total payments under the current payment system in CY 2011. These estimated total 2011 MAPs divided by the total 2007 Medicare HD-equivalent sessions yielded the proposed unadjusted per treatment base rate for renal dialysis services in CY 2011 of $261.58 (74 FR 49944).

The comments we received on this proposal and our responses are set forth below.

Comments: We received comments that we should account for increases in enrollment and utilization in determining the base rate.

Response: We do not typically make utilization increase assumptions in setting budget neutrality for PPS payment systems. In addition, the statute requires us to use the utilization for the lowest of 2007, 2008 and 2009. Enrollment growth assumptions would not affect a per treatment rate calculation, as it would increase total spending and total treatments.

However, due to changes in the components of the final ESRD PPS bundle described in section II.A. of this final rule, the final updated unadjusted per treatment base rate for renal dialysis services in CY 2011 is $251.60. We note that the reduction is primarily due to the delay in implementing oral-only Part D drugs under the ESRD PPS, as we have removed these MAPs from the unadjusted base rate computation. Other changes related to the composition of

the final ESRD bundle and hence the reduction in the unadjusted per treatment base rate are discussed in section II.A. of this final rule.

We are finalizing $251.60 as the starting point for further adjustments in determining the final ESRD PPS per treatment base rate. The 2011 unadjusted average payment per treatment of $251.60 was then used in the payment model to estimate final total payments under the ESRD PPS in CY 2011. These final CY 2011 ESRD PPS estimated payments are based on treatment data from the CY 2007 claims file.

3. Standardization Adjustment

CY 2011 payments under the proposed ESRD PPS were initially estimated without a budget-neutrality adjustment, using the unadjusted CY 2011 average payment per treatment amount of $261.58 (74 FR 49944). We calculated the proposed PPS payments using treatment counts from the 2007 claims file. The wage index and all applicable proposed patient-level and facility-level adjustments were applied to the unadjusted CY 2011 average payment per treatment to determine the estimated payment amount under the proposed ESRD PPS for each treatment and ESRD facility. We noted that to simulate payments, we used the latest available final CY 2009 ESRD wage indexes, with no floor (74 FR 49944) because it was the latest available wage index data at the time, and we had proposed to apply no floor to the PPS payments beginning January 1, 2011. In the proposed rule, we discussed how we standardized payments (74 FR 49942) and calculated the standardization factor (74 FR 49944) for the ESRD PPS.

Payments were standardized to account for the overall effects of the proposed ESRD PPS case-mix patient and facility adjustment factors and wage indexes. We must standardize payments in order to ensure that total projected PPS payments are equal to the payments under the current basic case-mix adjusted composite payment system. The proposed standardization factor was calculated to be 21.73 percent. As a result, the proposed CY 2011 unadjusted per treatment base rate of $261.58 was reduced by 21.73 percent to $204.74 (74 FR 49944).

The comments we received on this proposal and our responses are set forth below.

Comment: We received numerous comments disagreeing with the significant reduction in the per treatment base rate caused by standardization. The commenters indicated that the per treatment base rate is too low to account for their high staffing and medical costs. The commenters suggested fewer adjustments yielding a smaller standardization adjustment and a high per treatment base rate.

Response: In an effort to respond to the concerns expressed about the amount of the base rate, as discussed in section II.F.3. of this final rule, we have removed a number of patient adjustments and co-morbidity categories. Following the methodology from the proposed rule, we have recomputed the standardization adjustment using the final ESRD PPS adjustments. The final standardization factor was calculated by dividing total estimated payments in 2011 under the current payments system by estimated payments under the final ESRD PPS in 2011. We have used the same method as in the proposed rule and since we received no comments on the standardization calculation, we are finalizing this approach and § 413.220(b)(3) as proposed. The final standardization adjustment is .9407 or a reduction of 5.93 percent from the unadjusted per treatment base rate. As a result, the CY 2011 standardized per treatment base rate is $236.68.

Based upon our review of the public comments and for the reasons described above, we are finalizing § 413.220(b)(3). However, we have corrected the cross reference to reflect the patient-level and facility-level adjustment sections (§ 413.231 through § 413.235).

4. Calculation of the Budget-Neutrality Adjustments

a. Outlier Adjustment

Section 1881(b)(14)(D)(ii) of the Act provides that the ESRD PPS shall include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of ESAs necessary for anemia management. We proposed that outlier payments be applied in a budget neutral manner, as doing so would ensure that estimated total payments under the proposed ESRD PPS equals 98 percent of the estimated total amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS system had not been implemented (74 FR 49944).

To ensure that the proposed outlier policy (74 FR 49944) under the ESRD PPS is budget neutral, we proposed to reduce the base rate by the proposed outlier percentage, or 1.0 percent. Specifically, we proposed to reduce the base rate from $204.74 to $202.69. We did this to account for the 1.0 percent of aggregate ESRD PPS payments estimated to be made as outlier payments. We then re-estimated the prospective payment amounts with the new reduced base rate of $202.69, allowing 1.0 percent of payments to be outliers. The outlier amount was computed for all treatments and the total outlier payment amount across all treatments was added to the prospective payment amount for all treatments.

We did not receive any public comments regarding our proposal to reduce the base rate to account for the outlier percentage and, therefore, we are finalizing 413.220(b)(4) as proposed. Specific comments about the outlier policy are discussed in section II.H. of this final rule. However, using the final standardized base rate of $236.68, we reduced this amount by 1.0 percent to account for outlier payments. This reduction resulted in a revised base rate of $234.31.

b. 98 Percent Budget-Neutrality Adjustment

Section 1881(b)(14)(A)(ii) of the Act requires that the ESRD PPS payment system be 98 percent budget neutral. In other words, the estimated total amount of payments under the ESRD PPS in 2011, including any payment adjustments, must equal 98 percent of the estimated total amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS had not been implemented. Therefore, we proposed to reduce the 2011 standardized base rate, which was already adjusted for 1.0 percent outlier payments, by an additional 2.0 percent, from $202.69, to yield a proposed base rate of $198.64 (74 FR 49944).

The comments we received on this proposal and our responses are set forth below.

Comment: We received numerous comments indicating that the proposed per treatment base rate of $198.64 is too low to account for the costs of dialysis.

Response: As we indicated in the previous section, due to changes made to the final ESRD PPS payment model (specifically, the patient-level and facility-level adjustment factors described in sections II.F.3. and II.F.4, respectively, of this final rule), the final standardization adjustment is considerably lower that the proposed adjustment. For this reason, the final standardized base rate used as the starting point for the budget-neutrality adjustments is over $31 higher than the proposed amount.

Comment: Several commenters requested that the outlier percentage be

withheld after the 98 percent budget-neutrality adjustment.

Response: The budget-neutrality adjustments are multiplicative, and as a result, the order of the reductions has no effect on the final adjusted base rate. The adjustments for the outlier payments and the 98 percent budget-neutrality requirement are needed to ensure that total payments under the PPS are equal to 98 percent of payments under the current basic case-mix adjusted composite payment system.

In consideration of the comments received and for the reasons discussed above, we are finalizing § 413.220(b)(5). However, we have deleted the cross-references to the ESRD PPS regulatory citations. Instead, we have revised the language to clarify that CMS adjusts the per treatment base rate so that the aggregate payments in 2011 are estimated to be 98 percent of the amount that would have been made under Title XVIII of the Act if the ESRD PPS described in section 1881(b)(14) of the Act were not implemented. We made this change because we believe the revised language is more straightforward and clear.

To summarize, the final base rate per treatment with an outlier adjustment and budget-neutrality is calculated to be $229.63. This amount includes a 5.93-percent reduction from $251.60 to account for standardization to the projected CY 2011 current system payment per treatment, a 1.0 percent reduction to account for outlier payments, and a 2.0 percent reduction for the required 98 percent budget-neutrality. We note that if the reader were to multiply the outlier adjusted base rate of $234.31 by .98 for the budget-neutrality requirement, they would calculate $229.62. However we did not round the figures in the calculation of each step and arrived at $229.63.

5. Calculation of the Transition Budget-Neutrality Adjustment

Section 1881 (b)(14)(E)(i) of the Act requires the Secretary to provide "a four-year phase-in" of the payments under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011, with payments under the ESRD PPS "fully implemented for renal dialysis services furnished on or after January 1, 2014." Although the statute uses the term "phase-in", we are using the term "transition" to be consistent with other Medicare payment systems.

Section 1881(b)(14)(E)(ii) of the Act permits ESRD facilities to make a one-time election to be excluded from the transition. An ESRD facility that elects to be excluded from the transition receives payments for renal dialysis services provided on or after January 1, 2011 based on 100 percent of the payment rate under the ESRD PPS, rather than a blended payment based in part on the payment rate with regard to the current basic case-mix adjusted composite payment system and in part on the payment rate under the ESRD PPS. The proposed implementation of the transition is discussed in detail in the proposed rule (74 FR 50003). Section 1881(b)(14)(E)(iii) of the Act also requires that we make an adjustment to payments for renal dialysis services provided by ESRD facilities during the transition so that the estimated total amount of payments under the ESRD PPS, including payments under the transition, equals the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition.

In the proposed rule (74 FR 49944 through 49947), we discussed that the transition budget-neutrality adjustment would be comprised of two parts. First, we proposed to make a payment adjustment under the basic case-mix adjusted composite payment system portion of the blended rate during the transition to account for the per treatment costs of drugs that are currently paid under Part D. Second, we proposed to compute a factor that would make the estimated total amount of payments under the ESRD PPS, including payments under the transition equal the estimated total amount of payments that would otherwise occur without such a transition (3.0 percent reduction).

In the proposed rule, we described in detail our rationale for the transition budget-neutrality adjustment and alternatives considered (74 FR 49944). We invited comments on the calculation and application of the proposed two-part transition budget-neutrality adjustment factor. The comments we received on this proposal and our responses are set forth below.

Comment: We received numerous comments about the proposed transition budget-neutrality adjustment. Many commenters focused on the transition budget-neutrality adjustment related to payment for Part D oral drugs. The commenters indicated that the proposed $14 adjustment is too low and does not reflect all of the ESRD patients covered under the ESRD PPS.

Response: As discussed in section II.A.3. of this final rule, although oral-only Part D drugs meet the definition of renal dialysis services and are included in the ESRD PPS bundle, we are not implementing these drugs under the PPS until after the transition. That section also addresses our rationale for the Part D component of the base rate and the data used for that analysis. As a result, we removed the amounts for those drugs from the base rate. However, oral drugs or other forms of ESRD-related Part B injectable drugs are in the ESRD PPS bundle and will be implemented January 1, 2011.

In addition, as discussed in section II.E. of this final rule, based on the comments, we reviewed our methodology to determine if there were ways to compute the Part D per treatment amount that would more accurately reflect payments for Part D ESRD-related drugs by ESRD beneficiaries. As a result of this review, for this final rule we revised the method of computing the Part D per treatment amount to divide by the number of Part D enrolled ESRD beneficiaries rather than total ESRD beneficiaries. As a result of these changes, the final transition budget-neutrality adjustment related to Part D drugs has been recomputed to be $.49. If we had not changed our methodology to divide by the number of Part D enrolled ESRD beneficiaries and had instead divided by the number of Part B enrolled ESRD beneficiaries, we would have calculated the Part D per treatment amount to be $.33. While we recognize the $.49 does not cover all the ESRD patients under the PPS, the statue limits us to payments made under Title XVIII of the Act.

Comment: Numerous commenters questioned CMS's legal authority to impose a transition budget-neutrality adjustment. They expressed concern about the proposed 3.0 percent reduction going beyond the 98 percent budget neutrality requirement in 2011. Commenters also expressed concern about the size of the transition budget-neutrality adjustment related to the cost of the transition. The commenters indicated that the adjustment was too high and may not reflect ESRD facility decisions regarding the transition, and expressed concern about our proposed method of determining which facilities would choose to opt out of the transition. Several commenters believed that the 3.0 percent reduction during the years 2012 and 2013 will go beyond the 98 percent budget-neutrality requirement. Commenters expressed concern that we should consider 2012 and 2013 payments in calculating this part of the transition budget-neutrality adjustment.

Response: We believe section 1881(b)(14)E)(iii) of the Act requires us to implement the transition budget-neutrality adjustment. We do not believe the proposed 3.0 reduction goes

beyond the 98 percent budget neutrality requirement; as it is necessary to ensure that total payments under the PPS do not exceed the 98 percent requirement. Since we assume that facilities will act in their best financial interest and opt to transition if it is beneficial, it is likely that total payments would exceed what is allowed. As we discussed in the proposed rule (74 FR 49946), we proposed to apply this adjustment to both the ESRD PPS and the blended payment so as not to affect provider decisions in opting out of the transition.

We recognize that the transition budget-neutrality adjustment may not reflect actual choices made by ESRD facilities regarding opting out of the ESRD PPS transition. We are requiring that ESRD facilities notify their FI/MACs by November 1, 2010 of their decision to opt out of the ESRD PPS transition. We are unable to wait until then to establish the transition budget-neutrality adjustment which is necessary to meet statutory budget-neutrality requirement.

As a result, we based the final transition budget-neutrality adjustment on our best projections of how ESRD facilities will fare under the ESRD PPS compared to the basic case-mix adjusted composite payment system. With regard to conducting the analysis using 2012 and 2013 projections, we note that the transition budget-neutrality adjustment will be updated each year of the transition to reflect the appropriate blend of PPS and composite rate payments. We agree that it is not possible for us to predict accurately which facilities will opt out of the ESRD PPS transition. Given that the transition budget neutrality adjustment applies in each year of the transition, we are considering whether to prospectively correct for over or understatement of the number of facilities that choose to opt out of the transition when we update the adjustment for 2012. We would address this issue in rulemaking for the CY 2012 ESRD PPS.

We conducted a preliminary analysis for the final rule, to simulate payments for 2012 and 2013 in order to assess whether considering these years in the calculation of the transition budget-neutrality adjustment is warranted due to the change in the blend of payments for those years. We determined that it makes very little difference in the adjustment calculation.

In consideration of the public comments and for the reasons described above, we are finalizing § 413.220(b)(6).

In § 413.239(d), we proposed to apply the transition budget neutrality adjustment during the first three years of the transition. As this characterization of the period during which the transition budget neutrality adjustment applies, we are revising proposed § 413.239(d) to clarify that there is a 4-year transition period.

In summary, for the final rule, due to revised estimates of simulated payments under the current basic case-mix adjusted payment system and under the ESRD PPS payment system by facility, we estimate that 43 percent of ESRD facilities will choose to be excluded from the transition and that 57 percent of ESRD facilities will choose to be paid the blended rate during the transition. Consequently, we estimate that during the first year of the transition, total payments to all ESRD facilities would exceed the estimated payments under the ESRD PPS in the absence of the transition.

Thus, in order to maintain the 98 percent budget-neutrality required by section 1881(b(14)(E)(iii) of the Act during the initial year of the transition period, we are finalizing the reduction of all payments to ESRD facilities in CY 2011 by a factor that is equal to 1 minus the ratio of the estimated payments under the ESRD PPS were there no transition (that is, 98 percent of total estimated payments that would have been made under the current basic case-mix adjusted payment system) to the total estimated payments under the transition, or 3.1 percent.

For 2011, application of this factor would result in a 3.1 percent reduction in all payments to ESRD facilities, that is, we intend to apply this adjustment to both the blended payments made under the transition and payments made under the 100 percent ESRD PPS. We are finalizing this approach because, as we stated in the proposed rule (74 FR 49946), we believe that it would evenly distribute the effect of the transition budget-neutrality adjustment and it would not affect ESRD facilities' incentives with respect to whether to opt out of the transition.

F. Regression Model Used To Develop Final Payment Adjustment Factors

1. Regression Analysis

In the proposed rule, we described the two-equation methodology used to develop the proposed adjustment factors that would be applied to the base rate to calculate each patient's case-mix adjusted payment per treatment (74 FR 49947 through 49949). The two-equation approach used to develop the proposed ESRD PPS included a facility–based regression model for composite rate service, and a patient-level regression model for separately billable services. The composite rate and separately billable components of the model described in the proposed rule, used CY 2004–2006 Medicare cost report and claims data to develop the specific adjusters associated with the variables included in the payment model (74 FR 49947).

For purposes of developing the payment adjusters included in this final rule, we have updated the proposed two-equation methodology using CY 2006–2008 Medicare cost report and claims data. These are the latest available cost reports and claims given the time necessary for the preparation of this final rule. We have also reduced the number of co-morbidities and revised the definitions of co-morbidities for which payment adjusters apply; modified the separately billable regression model so that it reflects information for a patient-month rather than patient-year; added facility training status as a control variable; and eliminated sex and race as payment variables.

The addition of facility training status as a control variable and modification to the separately billable regression so that it reflects information for a patient-month rather than patient-year are described below. The basis for the reduction in the number of co-morbidities used to develop the case-mix adjusters and elimination of sex and race as payment variables are discussed in section II.F.3. of this final rule. For this final rule, the measures of resource use, specified as the dependent variables for developing the payment model in each of the two equations, are also explained below.

a. Dependent Variables

i. Average Cost per Treatment for Composite Rate Services

As described in the proposed rule (74 FR 49947) and for purposes of this final rule, we measured resource use for the maintenance dialysis services included in the current bundle of composite rate services, using ESRD facility data obtained from the Medicare cost reports for hospital-based ESRD providers and independent ESRD facilities. The average composite rate cost per treatment for each ESRD facility was calculated by dividing the total reported allowable costs for composite rate services for CYs 2006, 2007, and 2008 (Worksheet B, column 11, rows 7–16 on CMS 265–94; Worksheet I–2, column 11, rows 2–11 on CMS 2552–96) by the total number of dialysis treatments and Worksheet C, column 1, rows 1–10 on CMS 265–94; Worksheet I–4, column 1, rows 1–10 on CMS 2552–96). CAPD and CCPD patient weeks were multiplied by

3 to obtain the number of HD-equivalent treatments. We point out that our computation of the total composite rate costs included in this per treatment calculation includes costs incurred for training expenses, as well as all costs incurred by ESRD facilities for home dialysis patients.

The resulting composite rate cost per treatment was adjusted to eliminate the effects of varying wage levels among the areas in which ESRD facilities are located using the proposed ESRD PPS CY 2011 wage index published July 13, 2010, in connection with the proposed CY 2011 physician fee schedule (PFS)(75 FR 40673), and the estimated labor-related share of costs from the composite rate market basket. This was done so that the relationship of the studied variables on dialysis facility costs would not be confounded by differences in wage levels. The description of that labor-related share was contained in the Secretary's 2008 Report to Congress, *A Design for a Bundled End Stage Renal Disease Prospective Payment System.*

The proportion of composite rate costs determined to be labor-related (53.711 percent of each ESRD facility's composite rate cost per treatment) was divided by the ESRD wage index to control for area wage differences. No floor or ceiling was imposed on the wage index values used to deflate the composite rate costs per treatment in order to give the full effect to the removal of actual differences in area wage levels from the data. We applied a natural log transformation to the wage-deflated composite rate costs per treatment to better satisfy the statistical assumptions of the regression model, and to be consistent with existing methods of adjusting for case-mix, in which a multiplicative payment adjuster is applied for each case-mix variable.

As with other health care cost data, there was skewness in the cost distribution for composite rate services in which a relatively small fraction of observations account for a disproportionate fraction of costs. Cost per treatment values which were determined to be unusually high or low in accordance with predetermined statistical criteria, were excluded from further analysis. (For an explanation of the statistical outer fence methodology used to identify unusually high and low composite rate costs per treatment, see pages 45 through 48 of UM–KECC's February 2008 report.)

ii. Average Medicare Allowable Payment (MAP) for Separately Billable Services

For purposes of the final rule, resource use for separately billable ESRD-related services was measured at the patient level using the payment data on the Medicare claims for CYs 2006–2008. This time period corresponded to the most recent three years of Medicare cost report data that were available to measure resource use for composite rate services. Measures of resource use included the following separately billable services: injectable drugs billed by ESRD facilities, including ESAs; laboratory services provided to ESRD patients, billed by freestanding laboratory suppliers and ordered by physicians who receive monthly capitation payments for treating ESRD patients, or billed by ESRD facilities; other services billed by ESRD facilities, including support services for Method II home patients; medical equipment and supplies for Method II home patients billed by durable medical equipment suppliers.

In the proposed rule, we stated that complete data for CYs 2006–2008 for Part D claims were not available in sufficient time for the development of the proposed case-mix adjusters (74 FR 49947). Our decision not to implement oral-only drugs in the ESRD PPS until after the transition period ends January 1, 2014, as explained in section II.A.3. in this final rule, means that only oral drugs with an injectable version (that is, drugs other than oral-only drugs) would be relevant for inclusion in the separately billable regression model. Total payments for these drugs in 2007 and 2008 averaged about $12.8 million each year, an amount which on a per treatment basis would have a minimal impact on the magnitude of the case-mix adjustments.

In addition, there is a technical issue of how payments for prescription drugs taken at home over a period of time should be linked to specific patient HD-equivalent treatments, so that the regression results for patient utilization of separately billable services would not be distorted. Because of the time necessary to prepare for this final rule, we deferred resolution of this issue. Given that oral drugs and biologicals included in the payment bundle represent a very small proportion of the total annual total expenditures for the renal dialysis services included in the ESRD PPS ($8.8 billion in 2007), we believe that not including these drugs in the regression model used to develop the case-mix adjusters at this time is of little consequence.

We will need to revisit this issue prior to the expansion of the ESRD PPS to include all oral ESRD-related drugs and biologicals beginning in January 2014, because expenditures for oral-only ESRD-related drugs are significantly higher ($445 million in 2007), compared to those for the oral and other forms of injectable drugs. Including drug expenditures of this magnitude in the regressions used to develop the case-mix adjusters could impact the size of the adjustment factors in the ESRD PPS and will need to be evaluated. Accordingly, the regression model set forth in this final rule does not reflect the inclusion of oral or other forms of injectable ESRD-related drugs. Although these drugs have been excluded from the regression model, we point out that payments for these drugs have been included in the calculation of the ESRD base rate to which the case-mix adjusters will be applied.

We obtained Medicare claims data for separately billable services for CYs 2006–2008 for patient-months in which outpatient dialysis was provided and Medicare was the primary payer. Measures of resource use were based on MAPs, which were calculated using the payment data on the claims.

Medicare payments were inflated by a factor of 1.25 for services that have a 20 percent patient co-insurance (for example, ESRD-related injectable drugs), to yield the MAP. For laboratory tests that have no patient co-insurance obligation, the Medicare payment is identical to the MAP. The MAP amounts do not include the annual Part B payment deductible which may apply to separately billable services because we were unable to determine whether the deductible amount was incurred in connection with another Part B service. We point out that the Part B payment deductible can apply in connection with any Part B service, not just outpatient dialysis. As required under section 1881(b)(14)(B) of the Act, vaccines are excluded from the ESRD PPS and, therefore, were excluded from the computation of separately billable drugs.

Comment: One commenter questioned why CMS repriced injectable drugs, but not other payments included in the analysis. The commenter noted that the repricing was done to the first quarter of 2008 and pointed out that the ASP value for EPO for this period was the lowest value for the drug in four years. The commenter stated that the effect of selecting this quarter was to reprice several injectable drugs downward, dampen variations in payments, and lower the value of the case-mix adjustments.

Response: In the proposed rule, we repriced the payments for injectable drugs for CYs 2004–2006 to the first quarter of 2008. This was accomplished by using a ratio which was obtained by dividing the Medicare payment rate in the first quarter of 2008 by the Medicare rate in 2004, 2005, and 2006. The ratios used to adjust the MAPs for the 11 specified injectable drugs were shown in Table 11 in the proposed rule (74 FR 49948). The basis for the repricing of the top 11 injectable drugs in the proposed rule was due to the shift in the drug pricing methodology in 2006, from Average Wholesale Price to ASP+6 percent. The first quarter of 2008 was selected as the end quarter for the repricing because it represented the latest available quarter for which we had pricing information, consistent with the lead time necessary for the preparation of the proposed rule.

There was no attempt to select a quarter which would lead to reduced prices and reduced case-mix adjustments. For this final rule, we believe there is no need to reprice injectable drugs due to a change in the pricing methodology, because CY 2006, 2007, and 2008 drug prices consistently reflect the ASP+6 percent method.

The adjusted MAP values were standardized to reflect the number of Medicare outpatient dialysis treatments reported on the claims. This approach is consistent with the unit of payment under the current composite payment system. For patients who received PD during the month, the number of PD days reported on the claims was multiplied by 3/7 to obtain the number of HD-equivalent treatments. For example, 7 PD days were converted to 3 treatments since hemodialysis is typically performed 3 times per week. Monthly treatments reported on the claims were capped so as not to exceed the number of days in the month treatments were furnished, as treatments in excess of this number were considered clinically implausible.

Comment: Several commenters pointed out that our exclusion of claims in which the average utilization of EPO per treatment exceeded 30,000 units based on clinical implausibility was inconsistent with CMS's ESA Claims Monitoring Policy.

Response: We agree with the commenters and have revised the thresholds to conform with the medically unbelievable edit thresholds (MUE) for EPO and ARANESP® applicable to each year. Payments for EPO and ARANESP® in excess of the MUE thresholds of 500,000 units for EPO in 2006 and 2007, and 400,000 units in 2008 were excluded from the claims. Similarly, payments for ARANESP® in excess of the MUE thresholds of 1500 mcg in 2006 and 2007, and 1200 mcg in 2008 were also excluded from the claims. The ratio of the adjusted MAP values for separately billable services divided by the total number of treatments was used to calculate the average adjusted MAP per treatment.

As with the analysis of composite rate services described in section II.D. of this final rule, we similarly used the statistical outer fence methodology to exclude unusually high separately billed values. Claims with total separately billed amounts greater than $2,545.65 were excluded from the analysis of 2006 through 2008 data, used to develop the separately billed portion of the ESRD PPS payment model for patients age 18 and older. For the analysis used to develop the separately billed portion of the ESRD PPS payment model for pediatric patients for purposes of the pediatric payment adjustment, the application of this methodology resulted in no exclusions.

b. Independent Variables

In the proposed rule, we explained that two major types of independent or predictor variables were included in the composite rate and separately billable regression equations—case-mix payment variables and control variables (74 FR 49948 through 49949). Case-mix payment variables were included as factors that may be used to adjust payments in either the composite rate or in the separately billable equation. Control variables, which generally represent characteristics of ESRD facilities such as size, type of ownership, facility type (whether hospital-based or independent), etc., were specifically included to obtain more accurate estimates of the payment impact of the potential payment variables in each equation. Control variables were excluded from consideration as actual payment adjusters because they represent facility characteristics rather than patient characteristics. In the absence of using control variables in each regression equation, the relationship between the payment variables and measures of resource use may be biased.

i. Control Variables

In the proposed rule, we described seven control variables that were included in the regression analysis (74 FR 49948). They were: (1) Renal dialysis facility type (hospital-based versus independent facility); (2) facility size (<3,000 for less than three years, 3,000–5,000, 5,000–10,000, and > 10,000 dialysis treatments); (3) type of ownership (independent, large dialysis organization, regional chain, unknown); (4) whether the ESRD facility received a composite rate payment exception between November 1993 and July 2001; (5) adequacy of dialysis, based on the percentage of patients having a urea reduction ratio (URR) < 65 percent; (6) rural versus urban location; and (7) calendar year. For the proposed rule, calendar years 2004, 2005, and 2006 were included as a control variable in analyses that pooled three years of data. In order to avoid excluding dialysis facilities that treated PD patients from the analysis with control variables, for these facilities, if no URR was available for any patients in the facility, we used the average percentage of patients with a URR greater than 65 percent.

For this final rule, we have added an eighth control variable, training treatments, in which the proportion of training treatments furnished by each dialysis facility is specified. This was done in order to remove any confounding cost effects of training on other independent variables included in the payment model, particularly the onset of dialysis within 4-months variable. In addition, for the calendar year control variable, we have used CYs 2006, 2007, and 2008 in analyses that pooled 3 years of data.

ii. Case-Mix Adjustment Variables

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix, but gives the Secretary broad discretion with regard to the selection of patient-specific measures which would comprise the case-mix adjusters. In the proposed rule, we stated that as part of our case-mix analysis, we identified the same patient demographic variables used in connection with the basic case-mix adjusters under the current composite payment system: age (five groups, excluding patients less than age 18), BSA, and low BMI (values less than 18.5 kg/m^2) (74 FR 49949)). BSA was calculated as a function of height (H, in centimeters) and weight (W, in kilograms) using the following formula:

$$BSA = 0.007184 \times H^{(0.725)} \times W^{(0.425)}$$

BMI values below 18.5 kg/m^2 were used to identify patients who were underweight. BSA and low BMI are currently used as part of the basic case-mix adjustment for the composite payment system.

The same set of independent variables was included in both the composite rate and separately billable regression equations. To define the independent

variables for each equation, however, it was necessary to link patient and facility-level data. For example, measures for patient characteristics (for example, female gender) were included as potential payment variables in the facility-level composite rate equation, while measures for facility characteristics (for example, hospital-based or independent facility) were included as control variables in the patient level separately billable equation. For the composite rate equation, we defined case-mix measures using data for all Medicare dialysis patients treated in each facility. Specifically, we determined the percentage of a facility's patients having each patient characteristic. For example, patient sex was measured as the percentage of patients that were female. For the equation of the separately billable MAPs, we defined measures for facility characteristics using data for all facilities that treated each Medicare dialysis patient.

These patient and facility control variables were weighted to give greater emphasis to patient and facility observations that accounted for more of the care that was delivered, based on the number of dialysis treatments. For example, in defining facility-level case-mix measures, the characteristics of patients who were treated at the dialysis facility for twelve full months (for example, with 13 treatments each month), were given twelve times as much weight as the characteristics of patients who were treated at the facility for only 1 month (that is, with 13 treatments). Similarly, to define patient-level measures for the control variables, the characteristics of the facility that treated the patient for nine full months were given three times as much weight as the characteristics of the facility that treated the patient for the remaining three full months.

The resulting case-mix variables were examined as potential payment variables in the composite rate equation (for example, percent female and average BSA among patients in each facility). This was the same approach used to define the basic case-mix measures under the composite payment system. The resulting facility variables were included as control variables in the separately billable equation (for example, percent of a patient's treatment furnished in a hospital-based facility).

We have not departed from the use of facility control and patient-specific variables as described above in developing the case-mix adjusters set forth in this final rule. In the sections that follow, in response to public comments and for the reasons outlined below, we describe how we reevaluated and revised the proposed independent variables for use as potential case-mix adjusters in the ESRD PPS to determine their relationship to composite rate costs and separately billable payments.

Before we explain how the final set of case-mix adjustment variables was determined, we must first explain the difference between an annual model and a monthly model in connection with the separately billable regression equation component of the two equation model used to develop the case-mix adjustments. There are subtle but important differences in the interpretation of what variation in costs is being captured by the case-mix multipliers depending upon whether an annual model or monthly model is used. This has particular relevance in connection with the multipliers for co-morbidities.

2. Choosing Between a Separately Billable Model Based on Patient-Year or Patient-Month Data

The composite rate cost component of the two-equation model is based on Medicare cost reports that are submitted annually. The separately billable payment portion of the two-equation model is based on claims submitted monthly by ESRD facilities. Accordingly, the composite rate model is based on data that are observed annually, while the separately billable model is based on data that are observed monthly. In order to create consistency between the two models, the various versions of the separately billed models which we have analyzed have been based on annualized data.

For a chronic condition, the measurement of the co-morbidity at the annual or monthly level does not vary, because the patient either always has the condition or never has it. Aside from first time diagnoses, there is no distinction in how the co-morbidity is coded on an annual or monthly level, that is, patients will either have a zero or one for the variable. However, most patients with acute conditions (as will be shown later), are measured as present in the current month of treatment or previous 3 months, only have the condition for part of the year. Therefore, the coding of the co-morbidity variable for an acute condition will differ substantially on the annual versus monthly basis. On an annual basis, the value often lies between zero and one, representing the fraction of treatments in the year which occurred in months with the co-morbidity present (currently or within the three prior months). On a monthly basis, the value for the co-morbidity variable will be either zero or one, depending on whether the diagnosis is present in that month or the three preceding months.

We believe this distinction is important. The values of the case-mix adjustments for the acute co-morbidity variables in an annual model compared to a monthly model, create subtle but significant differences in the interpretation of what variation in costs the multipliers capture. Statistically, an omitted variable bias occurs when variables that predict the outcome (cost) are not included in the model, but are correlated with some of the variables that are included. As more variables predictive of costs are dropped from the model, the magnitude of the bias tends to increase. In this context, the proper interpretation of the multipliers is that they capture the costs directly associated with the co-morbidity being measured, plus part of the costs related to the omitted factors correlated with the condition.

In a payment model, this could be seen as either a positive or a negative characteristic. On the positive side, the omitted variables bias allows the model to partially adjust for unmeasured factors that influence costs, but are not reflected in the payment system. However, this bias undercuts the face validity of the case-mix multipliers because part of what they are capturing is unknown. Further, the larger multipliers would increase the incentive to report relatively minor cases of the co-morbidity that may not even be associated with whatever unmeasured conditions the multiplier reflects.

With respect to using an annual versus monthly unit of analysis in the separately billable model, the case-mix multipliers for acute co-morbidities in the annual model are likely to be subject to a greater degree of omitted variables bias because of the longer time span. In the annual specification, the question being answered is "Is a patient with this acute co-morbidity more costly to treat throughout the year?" Those higher costs could be directly attributable to the co-morbidity and occur in those months in which the co-morbidity was present. However, they could also represent costs directly attributable to the co-morbidity that occur outside the three month time interval in which the co-morbidity was coded as present (for example, if there is some impact on costs beyond three months), or costs attributable to any other correlated omitted conditions that occur at any time of the year.

Therefore, for those patients with the acute conditions coded for only part of the year, the case-mix adjuster in an

annual model can reflect costs occurring outside the time frame during which the co-morbidity was actually present. In other words, having the acute condition present for part of the year might be a marker for having other costly conditions at any time of the year.

In a monthly model, the case-mix multiplier can still reflect costs associated with correlated, omitted variables, but only if those costs occur in the same months the co-morbidity is coded as present. Any costs occurring outside the months in which the co-morbidity is coded as present, regardless of whether those costs are directly related to the co-morbidity, or arise from correlated, omitted conditions, will not be reflected in the multiplier because the co-morbidity is coded as zero in those months.

We want to focus on specific conditions that are associated with more costly resource intensive dialysis, not other unspecified conditions that may be an indicator for more costly care at any time of the year. We also want to minimize omitted variables bias as much as possible, but particularly for omitted conditions that can occur at any time of the year. Accordingly, in connection with this final rule, we have adopted the patient-month separately billable model. The case-mix adjusters reflected in the proposed rule were based on the annual unit of analysis for separately billable services (Table 14 at 74 FR 49954).

As shown in Table A of the Appendix in this final rule, the case-mix adjusters for acute conditions are substantially smaller in the patient-month model in comparison to the annual model. This indicates that the multipliers in the annual model are capturing costs that occur outside the time window during which the condition was coded as present. As will be explained later in section II.F.3. of this final rule, on co-morbidities, we have dropped certain co-morbidities after considering comments received and for the reasons highlighted below, with more of an emphasis on acute as opposed to chronic conditions, and modified the definitions of others. As conditions are dropped from the model, the tendency is for omitted variables bias to become more pronounced in the patient-year model. In the patient-month model, the case-mix adjustments are less affected by the elimination of co-morbidities as independent variables.

In selecting a patient-month separately billable model, we believe that the case-mix adjustments more closely reflect costs associated with the specific co-morbidity being measured, and occurring in the specific months in which the co-morbidity was present. We believe that this approach will more closely align the costs of furnishing dialysis with patient-specific conditions requiring more resource intensive care in a timely manner. Because composite rate cost data are only available on an annual basis through the Medicare cost reports, the option of switching to a monthly model for the composite rate component of the two equation regression model used to develop the case-mix adjusters is not possible. Therefore, the case-mix adjustments set forth in this final rule were developed using an annual model for the composite rate portion of the regression model and a patient-month model for the separately billable portion.

3. Patient-Level Adjustments

We proposed to include patient age, patient sex, body surface area (BSA), body mass index (BMI), onset of dialysis and certain co-morbidities as patient-level adjusters (74 FR 49949). Over one hundred commenters representing patients, health care professions and their professional organizations, ESRD facilities and ESRD organizations, renal organizations, and pharmaceutical companies commented on the patient-level adjusters.

The comments we received relating to the specific adjusters and our responses to those specific comments are discussed in their respective sections below.

Comment: Some commenters indicated that weight, size and age have little impact on overall costs of providing dialysis. One commenter did not believe that our analysis of the proposed adjustments reflected actual payments that facilities would receive. Another commenter suggested that the proposed adjustments would increase patients' co-payment obligations. Several commenters were concerned that the patient-level adjustments would lead to facilities "cherry picking" patients with better defined case-mix adjustments and turn away others whose reimbursement would not cover costs.

Response: As discussed in the proposed rule, multiple regression analysis was used to develop the proposed payment adjustment factors. The results of the proposed two-equation model (composite rate and separately billable items) using the latest data that was available at that time, demonstrated that age, sex, BSA, BMI, co-morbidities and onset of dialysis were indicators of higher cost patients (74 FR 49947). The discussion on the current analysis and findings is in section II.F.3. of this final rule. We appreciate the concerns raised about ESRD facilities "cherry picking" patients. We plan to monitor the effects of the payment system, which are discussed in section II.K. of this final rule and will be discussed in the future, and could make adjustments to the ESRD PPS in the future. We expect that ESRD facilities will not "cherry pick" patients under the ESRD PPS.

We believe that the same incentives and concerns could exist under the current composite rate payment system, as well. In other words, if ESRD facilities will select more lucrative patients under the ESRD PPS, they could also do so currently under the basic case-mix adjusted composite payment system. We also believe that in the absence of such adjustments, high cost patients could be turned away, thereby "cherry picking" only the least costly patients. Providing patient-level adjustments to the ESRD PPS base rate should result in adequate payment for the higher resource utilization and therefore higher cost patients.

Comment: Some commenters suggested that we decrease the number of case-mix adjustments to include only those affecting cost. Others stated that multiple adjustments will decrease the overall base payment rate taking funding away from the cost of providing care to the majority of patients. Some commenters suggested that money from the case-mix adjustments should be added to the base rate to provide the same reimbursement for all patients.

Response: As discussed in the proposed rule (74 FR 49938), our analysis demonstrated that the proposed patient-level adjustments did affect cost and those that did not were rejected. However, we did consider the concerns and comments about the adjustments and have eliminated some of them. These adjustments are discussed in the respective sections below. We discuss the methodology for computing the ESRD base rate in section II.E. of this final rule.

Comment: One commenter suggested that we provide all facilities with an electronic calculator to ensure consistency among providers. Several commenters believed that CROWNWeb would be used for documentation to be eligible for the patient-level adjustments. One commenter disputed our belief that nephrologists complete the Medical Evidence Form 2728 (Form 2728) indicating that the form is more likely completed by someone not medically trained. Therefore, this commenter believed the data on the form could be inaccurate, missing or incompletely filled out.

This observation was reiterated by another commenter who suggested that a study be conducted prior to the ESRD PPS 2011 implementation to determine who should complete the Form 2728. The commenter suggested that the study also include the experience and training of personnel completing the Form 2728 as well as a random selection of Form 2728. The commenter further suggested that the Form 2728 be compared with patient/family interviews, physician interviews, and medical record review. One commenter suggested that we continue to study and research additional variables that demonstrate a good correlation between resource consumption and patient characteristics.

Response: We appreciate the commenter's concerns regarding consistency among providers and agree that it is important. However, we do not believe that providing a tool such as an electronic calculator will ensure consistency as ESRD providers will be required to identify the appropriate patient-level adjustments for their individual patients. In addition, it is the responsibility of each ESRD facility to ensure that all information on patient claims submitted is accurate under any Medicare payment system. Contrary to the commenter's belief, CROWN is not the source for documenting eligibility for the patient-level adjustments. For the purposes of payment, the requisite information would be obtained from the claim or from sources that are discussed in the specific patient-level adjustments below.

We are concerned about the assertion made by the commenters about the completion of the Form 2728. We maintain that it is the ESRD facilities' responsibility to ensure that the information provided to Medicare is accurate. While there is no requirement that the nephrologist complete the form, instructions on the Form 2728 specify that the form "[b]e signed by the physician supervising the patient's kidney treatment [sic]." The instructions also specify that stamp signatures are not acceptable. In other words, the nephrologist may not complete the entire form but his or her signature serves to attest that the information is accurate. Therefore, we do not believe that performing a study to determine the qualifications of the person completing the form is warranted. However, we do believe that ESRD facilities are responsible for ensuring that appropriate staff who provide care, include documentation as appropriate. We agree with the commenter that we should continue to study and research the correlation between resource consumption and patient characteristics and we plan to do so.

After considering these comments and other comments below, we are finalizing age, BSA, BMI, certain co-morbidities and onset of dialysis as the patient-level case-mix adjustments in this final rule. Our rationale for including these factors, as well as the reasons for excluding patient factors for patient sex and race or ethnicity, are discussed below. We are revising § 413.235 to reflect the patient-level, case-mix adjustments to be implemented effective January 1, 2011.

a. Patient Age

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's age. In the proposed rule we pointed out that the basic case-mix adjusted composite payment system currently in effect includes payment adjustments for age based on five age groups (74 FR 49949), based on analyses that showed a strong relationship between composite rate costs and patient age. Table 12 from the proposed rule (74 FR 49950) contained the payment multipliers for each of these groups, along with a special multiplier that applies to pediatric dialysis patients. The proposed ESRD PPS adjustment factors for age reflected the U-shaped relationship of age with the CY 2007 MAP per treatment, a relationship similar to that observed in developing the current basic case-mix adjusted composite payment system.

The regression analyses performed in connection with the development of the ESRD PPS payment adjustments for this final rule indicate that age continues to be a strong predictor of variation in composite rate costs and separately billed payments, although the magnitude of the adjusters for the two oldest age categories has been attenuated as a result of other changes in the payment model (for example, elimination of sex and race/ethnicity as payment variables, revisions in the co-morbidities used for payment, modification of the low-volume threshold, etc.). Therefore, we are implementing payment adjustment factors for the same five age groups as proposed, calculated in accordance with the two equation regression methodology described elsewhere in this final rule. The final payment adjustment factors for age are shown in Table 21.

Table 21 – Patient Age

Variable	Multiplier
Ages 18-44	1.171
Ages 45-59	1.013
Ages 60-69	1.000
Ages 70-79	1.011
Ages 80+	1.016

We received several comments on our proposed use of age as a payment variable in the proposed ESRD PPS.

Comment: Several commenters stated that age is an objective and easily collected variable, demonstrably related to cost, and that continuing to collect age data would not be burdensome or require systems changes.

Response: We agree with the commenters. The use of a payment variable that is objective, easily collected, and related to patient-specific differences in the cost of dialysis strongly support its use as a case-mix adjuster in the ESRD PPS.

Comment: Several commenters suggested that we combine age with gender and ethnicity. Another commenter recommended that we match age with an adjuster for home dialysis training.

Response: The reason that age is included in the ESRD PPS is because analyses demonstrate that age is a significant independent predictor of variation in composite rate costs and separately billable payments. For reasons explained elsewhere later in this section, we have not adopted patient sex and race/ethnicity as payment adjusters in connection with the ESRD PPS set forth in this final. For information on our development of a special add-on to the otherwise applicable prospective payment rate for the costs of home dialysis training, *see* section II.A.7. of this final rule.

Comment: Several commenters suggested that we use an age adjuster for patients of "advanced age and/or frailty". One commenter recommended age specification of pediatric patients, claiming that both groups require specialized care resulting in higher costs for ESRD facilities.

Response: Both the proposed rule (74 FR 4995) and this final rule incorporate an age group for patients age 80+. Further disaggregation of the proposed age groups did not result in more statistically homogeneous age groups for the application of case-mix adjustments based on age. Therefore, we have not modified the proposed age classification categories. Nor have we identified a separate variable for patient frailty, as this would be very difficult to quantify objectively and measure with currently available sources of claims data. With respect to age classification groups for pediatric patients, we point out that we have adopted pediatric payment adjustments for two age groups (<13, and 13–17), and explain the basis for the selection of these two age categories in section II.G. of this final rule.

Comment: Two commenters representing ESRD facilities opposed the use of age as a basis for case-mix adjustment, claiming that they did not see any merit in its use.

Response: We strongly disagree with the commenters. The analyses in support of the payment adjustments for age used in connection with the basic case-mix adjusted composite payment system, the proposed ESRD PPS (74 FR 49949 through 49950), and the ESRD PPS described in this final rule, show that age is an important predictor of facility differences in ESRD composite rate costs, and patient-specific differences in separately billed payments. Therefore, we are incorporating age as a case-mix payment variable in the final ESRD PPS, and have specified the use of age as a patient-level adjustment in § 413.235(a).

b. Patient Sex

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a number of variables and may include "other appropriate factors." Consequently, for the proposed rule (74 FR 49950), we analyzed patient sex as part of the regression analysis and found that patient sex was a strong predictor of variation in payments for ESRD patients. In addition, we indicated that we believed patient sex is an objective measure and that data on patient sex are readily available.

Based on our analysis, we found that females were 13.2 percent more costly on a per treatment basis than males, primarily due to differences in use of ESAs. Therefore, we proposed an adjustment of 13.2 percent for female patients (74 FR 49951). We solicited public comments on this proposed adjustment, in addition to raising the possibility of unintended consequences of providing a payment adjustment for female patients that may lead to admission practices favoring female patients.

The comments we received on this proposal and our responses are set forth below.

Comment: Most commenters supported adding patient sex as a case-mix adjustment. One commenter recommended that CMS monitor ESRD facility admission practices with regard to female patients. Two commenters indicated that they did not believe patient sex affects the cost of dialysis.

Response: As discussed in the proposed rule, the regression analysis showed that patient sex (female) was a strong predictor of variation in ESRD payments and the cost of dialysis. However, we are not convinced that a patient sex adjustment is necessary to ensure beneficiary access to ESRD services. That is, we believe that there may be sex-neutral factors that have not been identified in the ESRD PPS modeling that would explain the increased cost associated with providing renal dialysis services to members of a certain sex.

We intend to work to identify underlying patient-specific conditions that may result in increased treatment costs and also how a patient sex adjustment might be applied. To the extent that these factors are identified, they could be incorporated into the ESRD PPS model as patient-level adjustments. We will also continue to monitor and evaluate the impact of patient sex on cost to determine consistency in findings and identify other variables that may be responsible for producing cost variations.

Comment: Many commenters were opposed to or expressed concerns about the inclusion of patient sex as a case-mix adjuster. Some commenters opposed patient sex as a variable outright, while others indicated that the addition of patient sex adjustment could result in limited access to care for male patients, if providers engaged in "cherry-picking" behavior. Other commenters felt the impact would be debatable in view of a study that had been done 5 years ago indicating that men rather than women were the most costly beneficiaries in the dialysis setting and, therefore, would we see another shift in costs during the next 5 years.

Response: Beneficiary access to ESRD services and medications was an important factor we considered with regard to using a patient sex adjustment. At this point, we are not convinced that a patient sex or gender adjustment is necessary to ensure beneficiary access to appropriate ESRD services and medications. As we discussed above, the issue of patient sex influencing the cost of ESRD drugs and services will continue to be monitored with the possibility of including an adjustment for patient sex at some future date.

Therefore, in this final rule, we are not finalizing our proposal to include patient sex as a patient-level case-mix adjustment. We have revised § 413.235(a) to reflect the exclusion of patient sex (female) as a patient-level adjustment.

c. Body Surface Area and Body Mass Index

Section 1881(b)(14)(D)(i) of the Act requires that the bundled ESRD PPS must include a payment adjustment based on case-mix that may take into account patient weight, BMI, and other appropriate factors. Consequently, we evaluated height and weight because the combination of these two characteristics allows us to analyze two measures of body size: BSA and BMI. In the proposed rule, we analyzed both BSA and low BMI (< 18.5 kg/m^2) as independent variables in the regression

analysis and found that both body size measures are strong predictors of variation in payments for ESRD patients. In addition, both BSA and BMI are objective measures and the necessary data, that is, height and weight, to compute them are readily available from patient claims. In the proposed rule, we discussed our rationale for developing the adjustment factors for BSA and BMI in detail (74 FR 49951).

The comments we received on this proposal and our responses are set forth below.

Comment: Some commenters agreed that CMS should continue to use only the existing case-mix adjustments which include age, BSA and BMI, because these adjustments are familiar to facilities and eligible patients can be identified using information that is currently available to ESRD facilities.

Response: We disagree with the commenters that we should only use the existing case-mix adjustments. As we discussed in the proposed rule (74 FR 49947), the results of our analysis demonstrated that in addition to the existing case-mix adjustments, other variables such as co-morbidities, were predictive of patient differences in cost. In this final rule, our analysis continues to show that BMI and BSA are strong predictors of variation in costs and payments for ESRD patients. Their use as payment variables ensure that ESRD facilities receive appropriate compensation for the costs associated with their specific patient population.

Comment: Two commenters believed that it was untrue that small-sized patients require less medication and fewer laboratory tests than larger-sized patients. The commenters believed that the "one size fits all" approach for drugs and laboratory tests based on the size of the dialysis patient may lead to discrimination against smaller patients and those patients with fewer applicable case-mix adjustments may find it difficult to gain admission to a dialysis center or possibly be undertreated with medications. One commenter suggested that the proposed rule created the false impression that dialysis is prescribed in a dosing format like drugs with well known pharmacokinetics that must be prescribed on patients parameters of BSA and BMI.

Response: As we discussed in the proposed rule, we individually analyzed both BSA and BMI (as two measures of body size) as part of the regression analysis, and found that both body size measures were significant predictors of variation in composite rate costs and separately billed payments for ESRD patients. Our analysis for this final rule demonstrates the same relationship. We do not believe that our analysis and findings imply a "one size fits all" approach. Because we recognized that there are other variables that explain the variation in costs for ESRD patients, we included other factors such as age, co-morbidity and onset of dialysis. We explain these variables in great detail in the proposed rule and later in this section. Because of these findings, we have included these variables as patient-level adjustments, as well as BSA and BMI.

Comment: One commenter questioned the methodology used to address the BMI fluctuation between a post dialysis weight on the last treatment and the post dialysis weight on the prior treatment. The commenter wanted to know if there would be an adjusted payment reflecting the two differing post dialyses weights or would the physician prescribed dry weight (weight without the excess fluid that builds up between dialysis treatments) be applied as the qualifier for the case-mix adjustment, because the post dialysis weight may drift enough to trigger a cost-adjustment. The commenter expressed concern that by using the physician prescribed dry weight, the treatment facilities and physicians would be rewarded for adjusting dry weights to reflect more profitable case-mix adjustments.

Response: As described in the Medicare Claims Processing Manual, Chapter 8, Section 50.3, facilities are required to report the weight of the patient after the last dialysis session of the month. However, the commenter raises an interesting point. We will need to consider the use of dry versus wet weight in future rulemaking.

In this final rule, the case-mix patient-level adjustment for BSA (per $0.1m^2$) is 1.020 and for low BMI (BMI <18.5) is 1.025 effective for renal dialysis services provided on or after January 1, 2011. We are also finalizing the inclusion of the factors for BSA and BMI in § 413.235(a).

d. Onset of Dialysis (New Patient Adjustment)

Section 1881(b)(14)(D)(i) of the Act, as added by MIPPA, requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's length of time on dialysis. Consequently, we analyzed the length of time beneficiaries have been receiving dialysis. We noted in the proposed rule (74 FR 49952), that the regression analysis demonstrated that patients who are in their first 4 months of dialysis have higher costs. We also looked at the amount of separately billable payments relative to the number of months the patients had been on dialysis. After reviewing the separately billable payment amounts for patients ranging from one month to twelve months since the onset of dialysis, we found that there was a drop in the separately billable payment amounts after the first 4 months of dialysis. Therefore, we proposed to define the onset of dialysis beginning with the starting date reported on Form 2728 through the first 4 months a patient is receiving dialysis (74 FR 49952).

We also proposed that the onset of dialysis adjustment be applied to both in-facility and home dialysis patients. We acknowledged that there may be patients whose first 4 months of dialysis occur when they are not yet eligible for the Medicare ESRD benefit. In these circumstances, we proposed that no onset of dialysis adjustment would be made. In other words, the onset of dialysis adjustment would be made only in the first 4 months of dialysis where the individual is also eligible for the ESRD benefit (74 FR 49952).

We received over 70 comments from nephrologists, ESRD facilities, nurses, ESRD organizations, health care professionals, patients, professional organizations, and hospitals. Most commenters supported the inclusion of an onset of dialysis patient-level adjustment factor. Some commenters were, however, opposed to the inclusion of home dialysis training as part of the onset of dialysis adjustment factor and recommended that the training be removed from the onset of dialysis adjustment. The commenters suggested that CMS create a separate training adjustment instead. Home training is discussed in detail in section II.A.7. of this final rule.

Comment: A few commenters recommended that the onset of dialysis adjustment not be implemented because the commenters believed it would be duplicative of other adjusters such as hospitalization and race that the commenters believed more accurately predicted treatment costs. Another commenter recommended that CMS eliminate the onset of dialysis adjustment in favor of other adjustments which focused on the root causes of higher costs during the first 4 months of dialysis.

Response: We do not agree with the commenters who stated that the onset of dialysis adjustment is duplicative of other adjustments in predicting treatment costs. The adjustment for the onset of dialysis reflects higher costs seen during the first 4 months a patient receives dialysis and is independent of the effects of other adjustment factors

(such as hospitalization), included in the regression analysis. There is however a risk that a hospitalization adjustment would create an inappropriate financial incentive for ESRD patients to be hospitalized for the purpose of receiving a payment adjustment. We discuss the issue of using race as an adjustment factor in section II.F.3. of this final rule.

We agree with the commenters who noted that patients in the first 4 months of receiving dialysis may be frail and unstable. We believe that the onset of dialysis case-mix adjustment recognizes the higher costs associated with newly diagnosed patients and reflects the care required to stabilize their conditions. As discussed above, in the proposed rule our analysis showed that patients who are in their first 4 months of receiving dialysis have higher costs. Subsequent to the proposed rule, we performed additional analyses.

In our analysis for this final rule, our findings confirmed that higher costs were attributed to the first 4 months of dialysis in both the composite rate model and in the separately billable model. We believe that at the current time, the onset of dialysis adjustment is a good predictor of higher costs during the first 4 months of receiving dialysis and, therefore, in this final rule we are retaining the onset of dialysis payment adjustment.

Comment: Several commenters strongly urged adoption of the onset of dialysis adjuster because of the effort required to obtain consents, waivers, and complete forms and all other compliance documents required under the Conditions for Coverage for new ESRD patients from nursing homes.

Response: As discussed in the proposed rule, we believe that the higher costs associated with patients during the first 4 months of receiving dialysis may be due to: the need to stabilize patients' conditions; administrative and labor costs associated with patients new to dialysis; or initial costs to train patients (74 FR 49952). The analysis conducted for this final rule continues to indicate higher composite rate costs and separately billable payments associated with patients new to dialysis. As the commenter indicates, some of the increased administrative costs associated with providing dialysis in the first 4 months that a beneficiary begins dialysis treatment may be attributed to the costs associated with obtaining medical or other records from other providers and suppliers of services.

Therefore, we are retaining the onset of dialysis adjustment under the final ESRD PPS. We note that the onset of dialysis adjustment is applicable only for those patients 18 years or older, during the first 4 months of the onset of dialysis and would not apply to any patient who might receive renal dialysis services by an ESRD facility for subsequent treatments.

Comment: One commenter claimed that there are higher costs due to the need to increase hemoglobin levels; hospitalizations in the first months of diagnosis for cardiovascular disease and catheter-induced infections; and staff time needed for patient assessment and care planning required by the new conditions for coverage. Other commenters also supported this assertion stating that it was "well documented that staff and drug costs with new patients and the conditions of participation outline the intense responsibilities during this period."

Response: We thank the commenters for their support of the onset of dialysis adjustment. We acknowledge that our analysis in the proposed rule and this final rule showed higher composite costs and payment for separately billable items during the first 4 months of dialysis. As we noted in the proposed rule, the higher costs for new patients in the first 4 months of receiving dialysis, may be due to stabilization of a patient's condition; administrative and labor costs associated with the patient being new to dialysis; or initial costs of training patients and their caregivers to perform home dialysis (74 FR 49952). Therefore, the intent of the onset of dialysis adjustment was to account for the higher costs through the first 4 months a patient is receiving dialysis in response to the need for separately billable items such as ESAs.

Due to our further analysis of onset of dialysis for this final rule, our findings confirm an increase in costs for the composite rate portion of the two-equation model for patients in their first 4 months of dialysis. The analysis also demonstrates an increase in measured costs based on the separately billable portion of the model, particularly for ESA utilization. Because of the absence of patient-level data on resource use for composite rate services, and the relatively small number of individuals who historically received home dialysis training during the first 4 months of dialysis (which limits the potential of facility-level analysis to examine resource utilization for home training), we are unable at this time to determine the extent of overstatement of composite rate costs if we apply both the onset of dialysis adjustment and the training adjustment discussed in section II.A.7. of this final rule. In order to avoid potentially overstating payments to ESRD facilities under the ESRD PPS for costs related to new dialysis patients and training during the first 4 months of dialysis, the training add-on adjustment will not apply for patients receiving the onset of dialysis adjustment. We note that home dialysis training is not included in the onset of dialysis adjustment and is a separate payment adjustment which we discuss in section II.A.7. of this final rule.

Comment: One commenter disagreed with the onset of dialysis adjuster indicating that there was little data proving that higher labor costs was associated with the onset of dialysis. The commenter stated that costs associated with the initial months of dialysis do not prevent access to dialysis care and, therefore, if the intent of case-mix adjustments is to erase disincentives to treat costly patients, the adjustment is not necessary.

Response: Contrary to the commenters' views, our analysis demonstrates that the first 4 months of receiving dialysis was a predictor of higher resource utilization. As discussed in previous responses, our subsequent analysis for this final rule confirmed our findings as discussed in the proposed rule (74 FR 49952). Our updated analysis for this final rule shows a drop in the amount of separately billable payments after 4 months on dialysis, which was the basis for our establishing a 4-month time period for the onset of dialysis adjustment.

The intent of a case-mix adjustment is to provide payment that reflects the resources associated with patients, whose needs are greater than patients without certain characteristics or conditions. The onset of dialysis adjustment is intended to provide payment that reflects the higher composite rate costs and higher separately billable payments associated with patients during the first 4 months of dialysis.

Comment: One commenter alleged that dialysis services are provided at great expense to the taxpayer with "very little benefit to the individual" and questioned if this adjustment was "good policy."

Response: We do not agree with this commenter. We believe that the onset of dialysis adjustment reflects the average higher costs associated with patients during the first 4 months of dialysis. We believe that the ESRD PPS will support the care needed by Medicare beneficiaries receiving dialysis treatment while controlling costs.

Comment: One commenter questioned whether the onset of dialysis adjuster was underestimated because of the 90-

day delay in Medicare entitlement for the ESRD benefit under Medicare and suggested that the period be 180 days. Other commenters suggested that the eligibility requirement be reduced to allow ESRD facilities to receive the adjustment for more than one month. One commenter suggested that the 90-day waiting period be reduced and the payment be increased. The commenter acknowledged that statutory change would be required to make these changes.

Response: We do not agree that the onset of dialysis adjustment is underestimated. We analyzed ESRD facility claims beginning with the dialysis onset date on the Form 2728 and found an increase in separately billable payments in the first 4 months. We also found increased composite rate costs. We believe that our analysis adequately and accurately reflects the higher costs associated with the first 4 months of dialysis among patients eligible for Medicare.

We believe the commenters are referring to the need for legislative changes to reduce the 90-day waiting period for entitlement to benefits under Part A and eligibility to enroll under Part B required by section 226A of the Act and an increase in payment to ESRD facilities. We agree that a legislative change would be required to change the 90-day waiting period, however, such changes are beyond the scope of this final rule.

Comment: One commenter noted that new patients are costly to care for, but indicated that many of the patient "problems" are not ESRD-related. The same commenter believed that the onset of dialysis adjustment will give ESRD facilities an incentive to care for new patients.

Response: Our analysis demonstrated that patients in the first 4 months of dialysis have higher composite rate costs and separately billable payments. To the extent that ESRD patients may have other non-ESRD–related issues or conditions, we do not believe that our analysis would have captured this. Therefore, in this final rule, we do not believe that we captured non-ESRD-related costs.

We agree with the commenter that the onset of dialysis adjustment will have a positive effect in access to care for patients during the first 4 months of receiving dialysis.

Comment: Several commenters indicated that the proposed onset of dialysis adjustment was too high and that the duration for the eligibility requirement for ESRD facilities to receive payment was too long. A few commenters noted that the high onset of dialysis adjustment would result in beneficiaries assuming responsibility for large co-payments. Some of these commenters provided recommendations on changing the time frame for the onset of dialysis, as well as the amount of the adjustment.

Some commenters suggested the adjustment should be a 90-day initial adjustment with the difference re-allocated for a home dialysis adjustment. Another commenter noted that if the onset of dialysis adjuster is intended to protect small dialysis providers who cannot easily spread risk, than the weighting should be recalculated to ensure accuracy as the proposed weight of 1.47 appears quite high. Others believed the adjustment should be reduced to 15 or 30 percent using the remaining percentage for a home dialysis adjustment.

Response: The multiplier amounts for the onset of dialysis adjustment, as well as all other adjustments, are the result of the regression models for composite rate and separately billable services. In the proposed rule, we analyzed Medicare claims for 2004–2006, which indicated greater resource utilization for separately billable items among patients treated during the first 4 months of dialysis. An analysis of cost reports for the same period indicated higher costs for composite rate services associated with the first 4 months of dialysis. Based on our subsequent analysis for this final rule, (which used cost reports and Medicare claims for the years 2006–2008), the onset of dialysis adjustment under the ESRD PPS for ESRD items and services provided on or after January 1, 2011 is 1.510.

We note that our analyses also suggest there are effects of co-morbidities on resource utilization for separately billable items that are independent of the onset of dialysis. We performed further analysis of the co-morbidity diagnostic categories for this final rule, in combination with the onset of dialysis. We found that while costs were higher on average for dialysis patients with co-morbidities during the first 4 months of dialysis, the effect of compounding a co-morbidity adjustment along with the onset of dialysis adjustment would, on average, result in overstatement for separately billable services. Therefore, ESRD facilities will not receive a co-morbidity adjustment for dialysis patients during the first 4 months of dialysis.

We plan to continue to study the onset of dialysis adjustment because we believe that it is important for us to be cognizant of the impacts of additional adjustments made to ESRD facilities, the ESRD base rate, as well as effects on patient co-insurance liabilities.

Comment: One commenter strongly opposed the onset of dialysis adjustment citing a number of reasons such as: (1) Most of the higher costs occurring in the first 4 months of dialysis are explained by hospitalization, race, and age; (2) most beneficiaries in the first 120 days do not receive home training; (3) those under 65 are not covered by Medicare for the first 90 days unless they begin training for home dialysis.

The commenter asserted that this would then have the effect of increasing the number of patients who become entitled to Medicare earlier. The commenter further stated that the characterization of the onset of dialysis adjustment as independent of the other ESRD patient-level adjustments will overestimate the onset of dialysis adjustment's value. The commenter suggested that the onset of dialysis adjustment be examined in tandem with other parts of the proposed rule to formulate a fair and accurate facility payment. The commenter further suggested that if reliable data such as labor costs are elevated (as asserted by CMS) at the beginning of dialysis, are found to not exist, the onset of dialysis adjuster should not be included in the ESRD PPS. The commenter further noted that CMS's reliance on cost reports is misplaced because the cost reports are not limited to Medicare, thereby skewing the sample with non-Medicare patients. The commenter asserted that patients with commercial primary insurance are over-represented among new dialysis patients. Other commenters believed the onset of dialysis adjustment would lead to patients under 65 years of age, to begin home dialysis therapy in the first 90 days in order to trigger early Medicare entitlement for the purpose of higher payment.

Response: In our analysis we found that there was an association of higher composite rate costs and separately billable costs even when controlling for race and age. The onset of dialysis adjustment reflects higher costs for patients eligible for Medicare during the first 4 months of dialysis.

With regard to concerns about the inclusion of patients not covered under the Medicare ESRD benefit, patients who were not entitled to the ESRD benefit under Medicare during this period were not used in our analysis for determining the onset of dialysis adjustment because they would not be eligible for the adjustment. As we discussed in a previous response, the onset of dialysis adjustment we are

finalizing under the ESRD PPS will not be applied in combination with either the co-morbidity adjustment or the home training payment add-on adjustment.

We do not agree with the commenter who expressed concern that the onset of dialysis adjustment would trigger an earlier Medicare entitlement. We will be monitoring the onset of dialysis adjustment, specifically, to determine if there is an increase in the number of individuals who become entitled to Medicare prior to the 90-day waiting period as a result of receiving home dialysis training.

We are aware of the prevalence of patients who receive home dialysis during the first 4 months of dialysis. As many commenters have noted, few patients receive home or self dialysis training during the first 4 months of dialysis. We would not expect to see more patients receiving home or self dialysis training in the first 4 months of dialysis in order for ESRD facilities to receive the onset of dialysis payment adjustment. We expect that ESRD facilities, nephrologists and other health care providers will provide care in accordance with the established plan of care and would not require home or self dialysis for the purpose of a payment adjustment.

With regard to the comment concerning our misplaced reliance of cost reports, cost reports capture ESRD data and provide the only comprehensive national data source to measure ESRD resource use of composite rate services, and reflect costs for Medicare patients. Therefore, we believe cost reports provide the best available data.

Comment: One commenter expressed concern that many facilities will no longer accept patients for no fees (free) for the first 90 days since overall payments will be decreased.

Response: We do not understand the association between the onset of dialysis adjustment and the facility's decision to not accept patients for free. However, we believe the decision of an ESRD facility to accept or not accept patients without payment is beyond the scope of this final rule.

Comment: One large dialysis organization noted that an adjuster "of this magnitude invites gaming or cherry picking." The commenter expressed concern that ESRD providers could or do routinely provide dialysis services for the first 4 months of dialysis, and then transferred the patient to another ESRD facility.

Response: We are concerned about ESRD facilities "cherry picking" patients for the purpose of receiving the onset of dialysis adjustment. We believe that in the absence of any case-mix adjustments which provide for additional payments for patients with higher resource utilization and associated higher costs, ESRD facilities may refuse to provide dialysis services to higher cost patients over less costly patients.

We are also concerned that ESRD patients may be inappropriately placed on home dialysis who either do not want home treatments or who require more frequent monitoring for medical, social and other reasons, in order to decrease the eligibility period for the purpose of receiving the onset of dialysis adjustment.

The ESRD patient's plan of care must reflect the patient's needs. If a patient is unwilling or unable to self-dialyze at home, insisting that the patient go on home dialysis would be a violation of the patient plan of care as described in § 494.90. An ESRD patient who cannot/would not comply with a home dialysis plan of care is likely to have poor clinical outcomes and may require additional care, both of which negate any cost benefits for ESRD facilities of home dialysis. The ESRD Conditions for Coverage can be found at 42 CFR Part 494. We expect that ESRD facilities will provide an appropriate plan of care and continued monitoring will identify ESRD facilities that do not.

Comment: Several commenters believed the onset of dialysis adjuster should apply to all patients and not solely Medicare beneficiaries, as all dialysis patients receive more care at the beginning of dialysis. A few commenters complained that patients under 65 only have 30 days of increased payment as facilities would need to wait for these patients to be covered by Medicare before they can receive payment.

Response: The onset of dialysis adjustment will only apply to ESRD patients who are entitled to receive the ESRD benefit under Medicare. As explained in a previous response, data for patients who were not eligible for Medicare during this period were not used in the analysis for determining the onset of dialysis adjustment. ESRD facilities would only receive the onset of dialysis adjustment for patients that are covered under the ESRD Medicare benefit. Therefore, the onset of dialysis adjustment would not apply to individuals receiving dialysis care paid for by other third party payers during the first 90 days. We note that ESRD facilities would receive the onset of dialysis adjustment for the 4-month adjustment period for its new patients who are already entitled to Medicare at the time of the onset of dialysis.

Comment: A few commenters noted that the onset of dialysis adjuster had "limited administrative complexity or burden" and therefore, approved the onset of dialysis adjuster.

Response: Information on the Form 2728 and stored in our systems will be used to determine if a patient is within the first 4 months of dialysis. Therefore, ESRD facilities will not have any additional reporting requirements or burden associated with the onset of dialysis adjustment.

Comment: While one commenter was in favor of including home training in the onset of dialysis adjuster because the commenter believed it could help increase the number of patients on home dialysis, most commenters opposed inclusion of home dialysis training costs in the onset of dialysis adjustment. Many of the commenters were opposed to the inclusion of home dialysis training indicated that training ESRD patients for home dialysis does not occur in the first 4 months of dialysis because individuals are more likely to receive the initial treatments in a facility. Other commenters believed that expecting newly diagnosed ESRD patients to assume responsibility for home dialysis while they are adjusting to an overwhelming diagnosis would be inappropriate. Commenters also stated that new patients are often medically unstable, psychologically compromised by anxiety and depression, and unable to make home dialysis decisions.

Several commenters noted that training or retraining for home dialysis may be needed for modality changes after the initial 4 months of dialysis and therefore, the training portion of the onset adjustment should be removed. These commenters all recommended that training be adjusted separately regardless of when training begins.

One commenter noted that ESRD facilities that do not provide home dialysis training would receive the same enhanced reimbursement as the facilities that do provide the home training. The same commenter further believed that inclusion of home training in the onset of dialysis adjustment would penalize facilities with active growing ESRD programs. One commenter noted that the increased payment from this adjustment "defrayed some increased expenses with indigent patients and as most patients elect home dialysis after 120 days there is little incentive to initiate training." One commenter believed that even a significant increase in payment will not encourage home treatments.

Response: The data analysis conducted for this final rule supports the commenters' views that most ESRD

patients are not trained for home dialysis in their first 4 months of dialysis. In our analysis, there were too few training patients in their first 4 months of dialysis to assess the composite rate costs associated with patients training for home dialysis compared to those related to the onset of dialysis.

With regard to payment for both training and the onset of dialysis adjustments, as we discussed in a previous response, we believe that the costs associated with the onset of dialysis adjustment and the training add-on adjustment overlap (that is, costs for services could be accounted for in both adjustments). Therefore, to avoid duplicative payment, ESRD facilities will not receive the home dialysis training adjustment while they are receiving the onset of dialysis adjustment for a patient. We will continue to study the relationship between costs related to the onset of dialysis and home training for future refinement of the ESRD PPS.

The payment multipliers are based on the regression analysis that compared costs and payments among Medicare ESRD patients. It would not be appropriate for Medicare to make duplicative payments to fund care for indigent or other patients.

Therefore, after considering the public comments and for the reasons stated above, we are finalizing the onset of dialysis adjustment. ESRD facilities will receive the onset of dialysis adjustment for renal dialysis services provided on or after January 1, 2011. We are finalizing an adjustment of 1.510 for in-facility and home dialysis patients eligible for the Medicare ESRD benefit for the first 4 months of the initial onset of dialysis. We are finalizing the definition of the onset of dialysis as the date reported on the Form 2728 that dialysis begins through the first 4 months a patient is receiving dialysis. The onset of dialysis adjustment will only apply for the period of time in the first 4 months of dialysis that occurs while the patient is covered under the ESRD benefit. In other words, the onset of dialysis adjustment will not apply after the initial 4 months of dialysis. We are finalizing that ESRD facilities that are eligible for and receive the onset of dialysis adjustment for a patient may not receive a co-morbidity adjustment, nor will they receive the home training add-on adjustment for that patient during the first 4 months of dialysis. We are finalizing § 413.225(a) to include onset of dialysis (new patient) as a patient-level adjustment.

e. Co-morbidities

Section 1881(b)(14)(D)(i) of the Act requires that the bundled ESRD PPS include a payment adjustment based on case-mix that may take into account patient co-morbidities. In the proposed rule, we analyzed co-morbidities as part of the regression analysis and found that certain co-morbidities are predictors of variation in costs for ESRD patients (74 FR 49952). We noted that the potential co-morbidity adjustments are intended to recognize the increased costs by providing additional payments for certain conditions that occur concurrently with the need for dialysis. We explained that we used stepwise regression analysis for the current basic case-mix adjusted composite payment system to identify case-mix factors that explained statistically significant variation in ESRD facility costs. We summarized our findings as a result of our analysis (74 FR 49952).

As discussed in the proposed rule, we retained UM–KECC to assist us in developing a case-mix adjustment for the ESRD PPS (74 FR 49947). One of the tasks was the identification of specific diagnoses within co-morbidity categories. We explained the methodology we used to capture changes in patient conditions and patient co-morbidities. We explained that we began with a long list of patient characteristics based on diagnostic categories developed for the Medicare Advantage Program and categories developed for the co-morbidities on the Form 2728.

We also explained that we used co-morbidity diagnoses reported in multiple types of Medicare claims (inpatient dialysis and other outpatient, skilled nursing facility, physician/supplier, hospice, and home health). We acknowledged that because some diagnoses reported on laboratory claims may represent a condition being excluded by the test, diagnoses reported on laboratory claims were not used. We solicited recommendations on the type of claims that reflect the co-morbidities for beneficiaries receiving renal dialysis services that could be used in future analyses (74 FR 49953).

Comment: We received a few comments questioning our use of claims rather than relying on Form 2728 to identify co-morbidities of ESRD patients. Some commenters questioned the use of other sources such as emergency room claims to determine co-morbid conditions for ESRD patients.

Response: We believe that the predominant use of hospital and physician claims, as well as other types of claims (such as skilled nursing facilities, home health and hospice claims) to identify co-morbidities, provided for a more comprehensive picture of co-morbidities that ESRD patients may have during the course of their dialysis. The Form 2728 accurately provides the co-morbid conditions at the time the ESRD diagnosis was made and, therefore, does not reflect any other medical condition(s) that may have come about subsequent to that time. We note that the level of co-morbidity reporting on the Form 2728 is quite low. The ICD–9–CM diagnostic codes for patients' co-morbid medical conditions should be reported in compliance with coding requirements on the ESRD 72x claim, as well as the official ICD–9–CM Coding guidelines, which can be found at: *http://www.cdc.gov/nchs/icd.htm,* regardless of whether a payment adjustment could be associated with the diagnosis. Entering complete and accurate codes enables CMS to better evaluate our payment systems and provide updates as necessary.

In the proposed rule, we discussed how we would ensure that each proposed case-mix adjuster would have a statistically significant relationship to cost in order to ensure that the magnitude of the relationship is economically meaningful. We also explained that we evaluated a refined list of case-mix co-morbidities comprised of 1,022 ICD–9–CM diagnosis codes for persistence of effect and cost. The co-morbidity categories we proposed were: Cardiac arrest; pericarditis; substance abuse; positive HIV status and AIDS; gastrointestinal tract bleeding; cancer since 1999 (excludes non-melanoma skin cancer); septicemia/shock; opportunistic infections (pneumonias); aspiration and specified bacterial pneumonias; pneumococcal pneumonia, empyema, lung abscess; monoclonial gammopathy; myelodysplastic syndrome; leukemia; hereditary hemolytic anemias and sickle cell anemia; lymphoma; Hepatitis B; and multiple myeloma (74 FR 49953).

We also discussed the use of the stepwise regression model in analyzing co-morbidity data for case-mix adjustments (74 FR 49953). We explained that the eleven proposed co-morbidity variables had statistically significant relationships to cost. However the magnitude of the co-morbidity effects varied substantially. We found that short-term acute conditions (for example, infections, gastrointestinal bleeds, and pericarditis) would result in a temporary ESRD payment adjustment. We found that long-term chronic conditions would result in a permanent increase of an ESRD payment adjustment. We believe

the long-term chronic conditions may tend to have a more persistent effect on cost (74 FR 49953).

We explained how we applied the composite rate and separately billable services using the modeling approach (74 FR 49952). We discussed the rationale for proposing to include cancer, for example, as a co-morbidity eligible for a patient-level adjustment if the cancer has a direct effect on the cost of ESRD treatment. We also explained why HIV/AIDS was included as our proposed co-morbidity case-mix adjustment although it has since been eliminated from the current basic case-mix adjusted composite payment system. We acknowledged that including HIV/AIDS as a co-morbid adjuster would have benefits that would need to be balanced with stringent confidentiality concerns (74 FR 49954). In our proposed rule, we also solicited public comments on suggested conditions or diseases that CMS should consider for future refinements.

We received comments from approximately one hundred commenters on the proposed inclusion of co-morbidities as a patient-level case-mix adjustment. In general, most commenters were opposed to the inclusion of co-morbidities, or specified co-morbidities that they would like to see included. Many commenters offered suggestions on certain diagnoses to include as an adjustment, as well as those that should be eliminated. A few commenters expressed support for the proposed co-morbidities, stating that these adjusters would provide a more accurate payment for complex patients. Specific comments and responses are discussed below.

Comment: A few commenters offered to work with CMS to identify co-morbidities that: Influence the cost of dialysis care; are based on verifiable data; and can be implemented and administered in a practical manner. They also urged CMS to develop methods to enhance access to information for conditions that predict hospitalization.

Response: We reviewed public comments on co-morbidities and considered each for this final rule. In general, we believe that the commenters were suggesting future collaborative efforts to identify co-morbidities that influence the cost of dialysis care. We thank these commenters and we anticipate continuing to work with ESRD facilities, patients, physicians, organizations, and other stakeholders to refine the ESRD PPS.

Comment: One commenter suggested that we use facility size as a co-morbidity adjustment.

Response: As we discussed in the proposed rule, a co-morbidity is a specific patient condition that is secondary to the patient's principal diagnosis that necessitates dialysis, yet has a direct effect on dialysis (74 FR 49952). Therefore, contrary to the commenter's suggestion, a facility's size does not meet the definition of a co-morbidity.

Comment: Some commenters asserted that CMS excluded the co-morbidities that affect dialysis treatment, such as: Hyperglycemia; hypoglycemia; peripheral vascular disease (PVD) manifested as gangrene requiring wound care or special therapy; amputations and peripheral artery disease (which they believed were the major cause of morbidity, hospitalization, antibiotic expense and poor outcomes); recent re-entry of transplant patients with re-introduction, continuation, and tapering of transplant medication; hypertension; hypotension; angina with chest pain; post-operative affecting heparin dose; sepsis with antibiotics; routine Coumadin with diagnosis unrelated to ESRD; recurrent transfusions for hematologic problems and site access issues. A few commenters indicated that patients returning after hospitalizations incur extra cost and changes in outcome. One commenter alleged that ESRD facilities need to address nutritional and volume issues after hospitalizations that require extra time and attention.

Response: We thank the commenters for their many suggestions. The inclusion or exclusion of a diagnostic category was based on the regression model. As we explained in the proposed rule, we found that certain co-morbidities are predictors of variation in costs for ESRD patients. We also explained that these co-morbidities have a direct effect on dialysis. We discussed the process used in identifying the universe of ICD–9–CM codes that were initially used in the analysis and how we derived the proposed eleven diagnostic categories.

We do not agree with the commenters' conclusion that we had excluded co-morbidities that affect treatment because, in fact, we did analyze co-morbidities that affect ESRD patients and contribute to increased payments. In our proposed rule, we explained that to ensure that each potential case-mix adjuster had a relationship to cost that was statistically significant and to ensure that the magnitude of the relationship was economically meaningful, low magnitude association with cost, as well as co-morbidities with ambiguous definitions were excluded. Several patient co-morbidities were analyzed having statistical significance and low magnitude association with cost in the preliminary models. Also, co-morbidities with high prevalence such as diabetes and vascular disease were excluded from the proposed diagnostic categories (74 FR 49952).

Based on various issues and concerns raised in public comments regarding the proposed co-morbidity categories recognized for a payment adjustment, we further evaluated the co-morbidity categories with regard to: (1) Inability to create accurate clinical definitions; (2) potential for adverse incentives regarding care; and (3) potential for ESRD facilities to directly influence the prevalence of the co-morbidity either by altering dialysis care, diagnostic testing patterns, or liberalizing the diagnostic criteria. We utilize these criteria (referred to "criteria") in subsequent discussions below.

We reiterate that it is important for ESRD facilities to report all patient co-morbidities accurately, regardless of whether or not these codes are or are not eligible for an ESRD PPS adjustment. The ICD–9–CM diagnosis codes should be reported in compliance with coding requirements on the ESRD 72x claim as well as the official ICD–9–CM Coding Guidelines.

Comment: Several commenters cited the higher cost of treating patients with Hepatitis B because of facility costs associated with complying with the isolation requirements under the ESRD Conditions for Coverage. Commenters stated that facility costs include providing isolation rooms, protective garments such as gowns and gloves, and special cleaning protocols. Another commenter did not believe the Hepatitis B adjustment amount covered the actual costs for full isolation, special gowning, and the limitations on staff while also caring for additional patients. The same commenter recommended either eliminating the Hepatitis B adjuster or substantially increasing the amount.

Response: Our model demonstrated that Hepatitis B is a stable predictor of separately billable costs. We also recognize that there are costs associated with the ESRD Conditions for Coverage requirements. We utilized the criteria as described above in evaluating the inclusion of Hepatitis B for a payment adjustment. We believe that while there are accurate definitions of Hepatitis B, in our analysis for the proposed and the final rule, we did not access whether a shorter term (acute) or a longer term (chronic) payment adjustment would be most appropriate. This information may depend on the conditions reported on the claims in our determination of whether Hepatitis B is classified as an

acute or chronic co-morbidity adjustment. Further research could also be helpful to determine if the cost of providing care to ESRD beneficiaries with Hepatitis B approximates or exceeds the costs associated with the coefficient. Because we recognize that we need additional research on Hepatitis B, we did not proceed with the remainder of the evaluation. Therefore, in this final rule, we are eliminating Hepatitis B as a co-morbidity diagnostic category adjustment to the ESRD PPS base rate.

Comment: Some commenters opposed the inclusion of cardiac arrest as a patient-level adjustment. One questioned if someone with end-stage cardiac disease would be less complicated to care for in the absence of cardiac arrest. Another commenter asked how long a history of cardiac arrest could be valid in order to receive the cardiac arrest adjustment. Some commenters objected to the cardiac arrest adjustment, citing reasons such as: The nephrologist would need to know about the cardiac arrest and communicate this to staff; HIPPA (patient privacy) may restrict sharing of such information; cardiac arrest is more costly to hospitals but not to ESRD facilities; and difficulty in obtaining cardiac arrest information by the ESRD facility. One commenter recommended eliminating this adjustment because they believed a cardiac event did not significantly affect the amount of time required to provide care for an ESRD patient unless the cardiac arrest was very recent and the patient was unstable. Another commenter tentatively supported inclusion of cardiac arrest as a patient-level adjuster, pending clarification of the testing and documentation required to substantiate the initial and ongoing diagnosis.

Response: We believe the commenters have expressed valid concerns. We applied the criteria as discussed above to cardiac arrest. We believe the first criterium is met because there is a potential for misclassifying a medical episode as a cardiac arrest (for example, considering a patient with transient unresponsiveness during dialysis to have had a cardiac arrest). Other medical episodes and situations can be mistakenly classified as a cardiac arrest, when in fact they are not an actual cardiac arrest. As a result, there is the potential for ESRD facilities to influence the prevalence of cardiac arrest as a co-morbidity recognized for a payment adjustment (criteria number 3). Because we believe there is a lack of consistency in what constitutes a cardiac arrest diagnosis and because commenters generally did not support the inclusion of cardiac arrest as a co-morbidity adjustment, we are not finalizing cardiac arrest as a co-morbidity diagnostic category recognized for a co-morbidity payment adjustment under the ESRD PPS in this final rule.

Comment: Several commenters were in favor of the payment adjustment for infections because commenters believed that treating infections adds cost and intensity of care. A few commenters suggested that an additional outlier payment should be given for each patient month in which a patient is treated for either infections or symptoms of infection to reflect the additional costs of laboratory work, greater use of antibiotics and higher ESA needs. The commenters believed that this met the legislative intent for outliers.

Response: We assume the commenters believed that Congress intended outlier payments to address infections and therefore suggested that an outlier payment be made for each patient month in which symptoms of infection existed or an infection was treated. We do not agree with the commenters because we do not believe that Congress intended for any particular co-morbidity to be eligible for outlier payments. Rather, under the outlier policy described in section II.H. of this final rule, an outlier payment will be made to share the cost of renal dialysis services beyond a fixed dollar loss amount. To the extent that the use of outlier services (that is, drugs and laboratory tests) as a result of an infection exceeds the fixed dollar loss amount, Medicare will make an outlier payment.

As we discussed in the proposed rule, we used a stepwise regression analysis model in analyzing co-morbidity data for case-mix adjustments. The relationship between patient characteristics was related to the reported facility costs. A patient-level model was used to identify potential payment adjusters for separately billable services. We identified co-morbidities that had statistically significant relationships to cost. Based on our analyses, we proposed adjustments for eleven co-morbidity categories. In other words, because our analyses found a correlation between the diagnostic categories (including infections) and higher costs, we proposed to provide a payment adjustment to be applied to the proposed ESRD PPS base rate. For co-morbidities found to be short term, we proposed that the condition must have existed within the past 3 months and affected treatment. In the proposed rule, infections were classified as a short-term co-morbidity eligible for a payment adjustment to the ESRD proposed base rate (74 FR 49953 and 49954). However, we are not including all infections as co-morbidities recognized for separate payment in the final ESRD PPS as we discuss in greater detail below.

Comment: Other commenters opposed the inclusion of infections citing the facilities' success in decreasing infections. Several commenters expressed concern that higher payment (such as the infection adjustment) may be provided for conditions such as bacteremia (related to dialysis catheter) or pneumonia (related to lower vaccination rate) that could be attributed to poor care.

MedPAC expressed concern that paying more for septicemia, for example, could give ESRD facilities an incentive not to provide the necessary care to minimize infections, and could reverse the effectiveness of Medicare's quality improvement efforts for promoting arterio-venous fistulas. (Septicemia was included in the proposed infections co-morbidity category recognized for a proposed payment adjustment.) MedPAC further opined that suboptimal care should not be rewarded.

A few commenters suggested that an adjuster for sepsis/septicemia should be excluded because the commenters believe that it is not a consistent factor in the cost of dialysis care and that paying for infections and hospitalizations serves as a disincentive for reducing catheter use. One commenter believed that if infections remain as an adjustment, peritonitis for patients on PD should be added.

One commenter noted that in addition to the vague meaning of septicemia, the adjustment largely reflects high use of Epoetin® from the acute illness and inflammation. The commenter further stated that variation in Epoetin® dose accounted for almost all cost variation among dialysis patients, thereby driving the associations in the statistical models.

Response: Our analysis for the proposed rule demonstrated that certain diagnostic categories showed effects on cost either long-term or short-term (74 FR 49953). Infections showed higher cost effects for 3 months after the date of diagnosis. Our analysis for this final rule indicated the same findings. We are, however, convinced by the concerns expressed by commenters who opposed the inclusion of infections as a co-morbidity diagnostic category recognized for a payment adjustment to the ESRD PPS base rate.

The intent of a case-mix adjustment is not to award higher payments to ESRD facilities for medical conditions that could be avoided through ESRD facility

practices. To do so, would have the effect of inadvertently rewarding poor quality care. We acknowledge that there may be a greater risk for certain types of infections that we proposed for payment adjustment, including septicemia known to result from vascular access infections.

We evaluated pneumonia, septicemia, and other pneumonia/opportunistic infections using the three criteria described earlier in this section. It is our understanding that vascular access infections are often the result of organisms that cause bacteremia/septicemia conditions in ESRD patients. Prevention of these infectious conditions is a fundamental tenet of dialysis care. Septicemia is a clinical syndrome consisting of a number of non-specific symptoms and signs. In the context of a suspected or known infection, the diagnosis of sepsis is considered when some or all of the defining signs and symptoms are present depending on the severity of those signs and symptoms. The inherent ambiguity of this definition makes the diagnosis subjective. Lack of an objective standard in the diagnosis of septicemia creates the opportunity for providers to increase their payments by changing the sensitivity of the diagnostic criteria for this condition.

Furthermore, we are concerned the inclusion of septicemia as part of the infection co-morbidity category could create perverse financial incentives not to follow this fundamental tenet. This is an area where further research may inform us that subsequent modification of the case-mix adjustment is needed. As additional information becomes available for further analysis, it may be possible to develop an adjustment for septicemia while not negating facility efforts to minimize vascular access infections. Therefore, in this final rule, we are not finalizing septicemia as part of the infection co-morbidity diagnostic category.

We also are not finalizing other pneumonias/opportunistic infections as part of the infection co-morbidity category. We believe that other pneumonias/opportunistic infections meet all of the criteria. Therefore, their inclusion as a co-morbidity payment adjustment category could, as commenters have noted, negate the positive gains made in controlling infections. In the analysis conducted for this final rule, we analyzed the pneumonias/opportunistic infections separately from other infections and did not find the same degree of association with higher costs associated with higher separately billable items and services, as was seen with bacterial pneumonia. For this reason, we do not believe these infection diagnoses warrant a co-morbidity adjustment.

We note that the elimination of "other pneumonias" has a limited effect on the magnitude of the adjustment for patients with bacterial pneumonia and only slightly reduces the number of pneumonias that would be used to determine eligibility for the adjustment. Therefore, for this final rule, we excluded the diagnoses for primary plague pneumonia, unspecified pneumonia, primary coccidiodomycosis unspecified, and rare non-bacterial opportunistic infections.

We believe that bacterial pneumonia does not meet the 3 criteria and, therefore, should be included as a co-morbidity adjustment. Once the other infections were removed, we reran the regression analysis. The regression analysis showed that bacterial pneumonia have a strong validity as a cause of ESA resistance and, therefore, increased ESA requirement for 4 months. Therefore, we are finalizing bacterial pneumonia as the infection co-morbidity diagnostic category eligible for a payment adjustment under the ESRD PPS. The list of bacterial pneumonia ICD–9–CM codes that will be recognized for a payment adjustment to the ESRD PPS base rate appears in Table E of the Appendix. We note that as discussed earlier in this section, an ESRD facility will not receive co-morbidity adjustments during the 4-month onset of dialysis time period.

We will require a documented radiographic diagnosis in the patient's clinical or medical record, in order for an ESRD facility to be eligible for the co-morbidity payment adjustment for the bacterial pneumonia infection category. We will discuss the documentation requirements in future administrative issuances. After the implementation of the ESRD PPS, we will monitor the reporting of bacterial pneumonia on ESRD claims and compare the prevalence of bacterial pneumonia with their prevalence over the past several years.

Comment: A few commenters believed that patients with gastrointestinal bleeding should be eligible for a fixed outlier payment due to ESA and transfusion expense, because this meets the legislative intent of high cost outliers.

Response: We do not agree with the commenters who believed that there should be an additional outlier payment for patients with gastrointestinal bleeding due to ESA and transfusion expense because we believe that the co-morbidity adjustment is more appropriate than applying the outlier policy. We discuss the outlier policy in detail in section II.E.4. of this final rule.

The regression analysis for this final rule demonstrated that certain diagnostic categories showed higher costs over either the long term or the short term. Gastrointestinal bleeding showed higher cost effects for three months after the date of diagnosis (that is, the month of the diagnosis and three months after). As we indicated above, based on various issues raised in public comments regarding the proposed co-morbidity payment adjustment categories, we further evaluated the proposed categories, including the gastrointestinal tract bleeding diagnostic category, based on three criteria. The gastrointestinal tract bleeding co-morbidity category met all of the three criteria, however, as we discussed above, we believe that by limiting gastrointestinal bleeding to gastrointestinal bleeding with hemorrhage, we have satisfied the established criteria by creating accurate clinical definitions and mitigating the potential for adverse incentives regarding care for ESRD facilities to influence the prevalence we are finalizing it as a co-morbidity diagnostic category because our analysis for this final rule also indicated significant validity of gastrointestinal tract bleeding as a cause for increased ESA utilization and, therefore, higher separately billable costs.

However, because we are concerned that the gastrointestinal tract bleeding diagnostic category we proposed is overly broad (as determined by criteria number 1) and could be "gamed" (as noted by the commenter), we have limited in this final rule the diagnoses to gastrointestinal tract bleeding with hemorrhage and have limited the ICD–9–CM codes for luminal ulcers with associated hemorrhage which would be eligible for the payment adjustment. In addition, in order to receive a co-morbidity payment adjustment for this co-morbidity category there must be documentation of an associated hemorrhage with a gastrointestinal tract bleed. We will monitor ESRD claims after the implementation of the ESRD PPS is implemented to see if the prevalence has changed over the past several years.

Comment: Most commenters opposed the inclusion of HIV/AIDS and alcohol or substance dependence as patient-level adjustments. Many cited State confidentiality laws protecting patients' privacy against discrimination, as well as difficulty in obtaining this information for the purposes of documenting the presence of HIV/AIDS and substance abuse.

One commenter questioned how a substance abuse diagnosis would be made if not disclosed by the patient. The same commenter indicated that the inclusion of these codes would be inappropriate, as it would stigmatize patients and require facilities to violate State law in order to meet the requirements to be eligible for the payment adjustment. The commenters therefore believed that if they did not comply with the requirements, they would be inappropriately forced to forego payment. Several commenters stated that substance abuse is highly subjective diagnoses and prone to "gaming" and, therefore, should be eliminated as payment adjustments.

A few commenters believed that a diagnosis of HIV should be a patient level adjuster due to the increased cost of care. However, the commenter questioned how the information would be obtained in order to qualify as an adjustment. Other commenters indicated that HIV/AIDS and substance abuse diagnoses could not be reported without the patient's permission. Other commenters stated that often the ESRD facilities would not be aware of the diagnoses. One commenter opined that providers do not alter their overall treatment practices because of HIV/AIDS suggesting that HIV/AIDS actually may be a surrogate for other costly patient characteristics such as being hypo-responsive to ESA, increased hospitalization, or race. The same commenter suggested that if HIV/AIDS remains a payment adjustment, it should be as a facility-level adjuster.

Response: We concur with the commenters that requiring ESRD facilities to place a diagnosis of HIV/AIDS or a diagnosis of alcohol/drug dependence on the claim may be contradictory to State and other privacy requirements. We acknowledged in the proposed rule that we recognized the difficulties encountered by ESRD facilities that must comply with State privacy requirements (74 FR 49953 and 49954). As a result, the diagnostic categories may be misreported. We do not understand the commenter's suggestion that HIV/AIDS should be a facility adjustment rather than a patient-level adjustment.

Because of the concerns expressed by commenters about State privacy requirements, we are not finalizing HIV/AIDS and Alcohol/Drug Dependence as co-morbidity diagnostic groups and, therefore, HIV/AIDS and Alcohol/Drug Dependence will not be recognized as co-morbidity diagnostic groups for purposes of the co-morbidity payment adjustment under the ESRD PPS.

Comment: Several commenters expressed concerns about patients in nursing homes or long term care (LTC) facilities. One commenter believed the adjustment for alcohol and drug dependency was adequate to compensate for the effort required to determine dependency needs and that alcohol and drug dependency were frequent problems in nursing homes. One commenter indicated that many of the new admissions in nursing homes were for infection. The commenter did not indicate whether to include or exclude the infection adjustment as a payment adjustment until further clarification was provided by CMS regarding testing and documentation requirements. Another commenter claimed that the cost for treating nursing home dialysis patients is higher than community-dwelling patients, because nursing home dialysis patients had higher acuity due to the extent of their co-morbidities; the need for one-on-one caregiver assistance; and higher staffing costs.

Some commenters complained that many of the co-morbidities seen in nursing homes, such as hypertension, diabetes, coronary artery disease, peripheral vascular disease, Alzheimer's, senile dementia, and other mental impairments and ventilator dependence were not considered as being eligible for a payment adjustment. One commenter indicated that the administrative burden for a provider with a disproportionate number of nursing home dialysis patients, because of the limited time they were under the care of the ESRD provider, as well as high turnover. The commenter also suggested that the request for medical records to obtain nursing home patient information should be added to the co-morbidity condition information being tracked on the Form 2728 to help determine patient acuity and cost to treat. Other commenters believed that functional limitations such as inability to walk should be factors included in determining payment adjustments.

Response: The purpose of the co-morbidity adjustments is to provide added payment for those co-morbid diseases that result in higher dialysis costs. Therefore, to the extent that a patient residing in a nursing facility has one of the designated co-morbidity diagnostic categories, the ESRD facility would receive an adjustment to the ESRD PPS base rate.

The only information on functional limitations available to us is from Form 2728 (inability to ambulate or transfer). Our analyses used in developing the proposed rule did explore functional variables, when they were reported, and found no statistically significant relationship to cost for such functional variables. We believe, however, that functional limitations are important measures and will consider these in the future if more complete data become available and show a significant relationship to costs.

We disagree with the commenter requesting changes on Form 2728 to allow it to be used to determine changes in patients' acuity and the resulting cost to treat them. We do not believe that adjustments on a form which is used for the purpose of establishing the ESRD diagnosis should be the basis for determining on-going case-mix adjustments because the Form 2728 would not reflect changes in patient's conditions. In other words, the Form 2728 is a snapshot at the time of the onset of ESRD (capturing, for example, any co-morbidity that exists at the onset of dialysis) and not an ongoing reflection of that individual (capturing, for example, any co-morbidity that might occur during the span of dialysis).

Comment: Some commenters stated that they often do not know about patient's temporary conditions, such as pneumonia, gastrointestinal (GI) bleeding, and pericarditis and, therefore, would not be able to indicate their presence on ESRD claims for the purpose of a payment adjustment.

Response: We believe it is important for ESRD facilities to be aware of patients' conditions. For example, § 494.80(a)(1) indicates that a patient's comprehensive assessment must include evaluation of current health status and medical condition, including co-morbid conditions. For the purpose of receiving a payment adjustment, the appropriate ICD–9–CM codes are required to be present on the claim, and documentation in the patients' medical record supporting the diagnosis is also required.

We discussed in previous responses that bacterial pneumonias and gastrointestinal tract bleeding with hemorrhage as short-term, acute co-morbidity diagnostic categories that would be recognized for the co-morbidity payment adjustment under the ESRD PPS. In addition, our analysis for this final rule supports the inclusion of pericarditis as a co-morbidity diagnostic category because ESRD patients with pericarditis have increased ESA utilization. Therefore, we believe pericarditis would be a predictor of higher costs in ESRD patients with this condition.

We evaluated the pericarditis co-morbidity diagnostic category using the criteria discussed earlier. Because there are distinct clinical definitions for

pericarditis (and diagnostic criteria) and we do not believe that pericarditis has the potential for adverse incentives or the potential to be directly influenced by ESRD facilities (in that an ESRD facility could not influence the development or prevalence of pericarditis), we are finalizing pericarditis as a co-morbidity diagnostic category recognized for the co-morbidity payment adjustment under the ESRD PPS.

We will require ESRD facilities to provide documentation in the patient's medical/clinical record to support any diagnosis recognized for a payment adjustment, utilizing specific criteria. We will address these documentation requirements in sub-regulatory guidance. As we have responded to previous comments, we will be monitoring the prevalence of any co-morbidity diagnoses recognized for the co-morbidity payment adjustment under the ESRD PPS as compared to the prevalence of these categories over the past several years. In this manner, we will be able to identify any changes in the prevalence of any of the co-morbidity diagnoses recognized for purposes of the co-morbidity payment adjustment as compared to previous trends.

Comment: We received a wide variety of comments suggesting an array of co-morbidities that commenters believed should or should not be included as being eligible for the co-morbidity payment adjustment. Most commenters opposed the inclusion of the proposed co-morbidity categories, either in totality or in part.

Of the commenters who supported the inclusion of the proposed co-morbidity categories, most supported the chronic co-morbidity categories such as cancers,

Hepatitis B, hereditary hemolytic anemias/sickle cell anemia, monoclonal gammopathy, and myelodysplastic syndrome. Some commenters offered suggestions regarding co-morbidities they believed should have been included in the ESRD PPS such as senility and Alzheimers; methylcyline resistance staphlococcus aureus (MRSA); staphylococcus septicemias; and diabetes. Other commenters opposed the inclusion of cardiac arrest, pericarditis, septicemia, bacterial pneumonia, gastrointestinal bleeding, sickle cell anemia, cancer, myelodysplastic syndrome and monoclonal gammopathy. Some commenters indicated that they were unaware of patients' prior medical histories, such as a history of cancer.

Response: As we explained in the proposed rule, we found that certain co-morbidities are predictors of variation in resources for ESRD patients. We discussed the process we used to identify the ICD–9–CM codes that we initially used in the analysis and how we derived the proposed eleven diagnostic categories. We also explained why certain conditions such as diabetes and vascular disease were excluded from the proposed diagnostic categories (74 FR 49952).

With regard to the cancer co-morbidity diagnostic category, we recognize that a co-morbidity payment adjustment would be applied for patients that may differ greatly in the clinical severity of their cancer diagnosis.

For example, we believe that for patients successfully treated in the past for their cancer, there may be few or no implications for the dialysis care currently being received in an ESRD facility. In contrast, we believe patients undergoing treatment for cancer may require a higher intensity of care (that is, higher use of separately billable services) and, therefore, have higher costs.

We believe that the proposed payment adjustment for the cancer co-morbidity category may have overstated costs for some patients whose dialysis treatment is no longer affected by their history of cancer and may have understated the costs of patients whose current cancer diagnosis and treatment affect their dialysis treatment because, at the current time, we are unable to differentiate the cost impact between the two groups. Therefore, we are not finalizing cancer as a co-morbidity diagnostic category recognized for the co-morbidity payment adjustment under the ESRD PPS.

Future research may identify the cost of providing dialysis care to patients receiving active cancer treatment and potentially could be used to determine a co-morbidity payment adjustment that would more accurately reflect the ESRD resources being used. We believe that differentiating a history of a cancer diagnosis from an active cancer diagnosis, could provide information on how the type of cancer or whether the cancer is being treated affects the cost of dialysis care.

Using the three criteria referenced above, we evaluated the proposed co-morbidity diagnostic categories for chronic, long-term conditions of hereditary hemolytic anemia, myelodysplastic syndromes, and monoclonal gammopathy. Due to the consistent effect (that is, not limited to a short period of time) of the hereditary hemolytic anemias (including sickle cell anemia) on higher EPO useage and therefore, higher separately billable costs, we are finalizing this as a co-morbidity diagnostic category eligible for a payment adjustment to the ESRD PPS. We also believe that myelodysplastic anemia and monoclonal gammopathy should be finalized as co-morbidity diagnostic categories because both of these co-morbidity diagnostic categories have shown an association with higher ESA usage and, therefore, higher separately billable costs. However, we have excluded multiple myeloma, a form of cancer included in the monoclonal gammopathy diagnostic co-morbidity category, because multiple myeloma is a form of cancer and, as we noted above, additional research is needed on the effect of cancer on dialysis costs.

Accordingly, we are finalizing six co-morbidity diagnostic categories and the associated payment adjustment multipliers, which are as shown in Table 22, recognized for the co-morbidity payment adjustment under the ESRD PPS for renal dialysis services provided on or after January 1, 2011. We also are finalizing the diagnostic codes for each of the six diagnostic categories found in Table E in the Appendix. For the co-morbidity payment adjustment to apply, an ESRD facility must document in the patient's medical or clinical records the presence of one of the diagnosis codes eligible for the co-morbidity payment adjustment under the ESRD PPS. We will provide specific instructions for such documentation in the future.

Table 22. Co-Morbidity Diagnostic Categories Recognized for a Payment Adjustment Under the ESRD PPS

Diagnostic Category	Multiplier
Pericarditis (acute)	1.114
Bacterial Pneumonia (acute)	1.135
Gastrointestinal Tract Bleeding with Hemorrhage (acute)	1.183
Hemolytic Anemia with Sickle Cell Anemia (chronic)	1.072
Myelodysplastic Syndrome (chronic)	1.099
Monoclonal Gammopathy (chronic)	1.024

The ICD–9–CM diagnostic codes should be reported in compliance with coding requirements on the ESRD 72x claim, as well as the official ICD–9–CM Coding guidelines. Accurate reporting of co-morbid diagnoses will enable CMS to evaluate the need to update the co-morbidities that would be recognized for the co-morbidity payment adjustment under the ESRD PPS.

Comment: One commenter believed that facilities should receive higher payments for certain "problematic" patients to balance losses on average patients with few adjustments.

Response: We believe that the commenter is referring to financial losses that ESRD facilities may experience under the ESRD PPS treating patients with few characteristics that would be recognized for a payment adjustment. We do not agree with the commenter that ESRD facilities will experience losses on the average patient to whom few payment adjustments would apply and that this would be balanced by higher payments for certain "problematic" (that is, patients for whom the facility receives multiple payment adjustments) patients. The ESRD PPS base rate reflects the cost of the average patient.

Our analysis has identified certain co-morbidity diagnostic categories that have shown higher use of separately billable renal dialysis items and services, which are recognized for a payment adjustment under the ESRD PPS. The co-morbidity payment adjustments are based on evidence from the regression model that the presence or absence of certain co-morbid conditions are related to costs. Therefore, the payment model should neither favor nor disfavor patients with co-morbidity adjustments relative to those who do not qualify for such adjustments; rather the payment adjustment should reflect the higher costs associated with providing renal dialysis services.

As we discussed above, we will need to conduct further research to identify additional co-morbidity categories and diagnoses that could be recognized for the co-morbidity payment adjustment. For these reasons, for this final rule, we have reduced the number of co-morbidity diagnostic categories from eleven to six and among these categories, we are finalizing three acute, short-term diagnostic categories (pericarditis, pneumonia, and gastrointestinal bleeding) and three chronic diagnostic categories (hereditary hemolytic anemia, myelodysplastic syndrome, and monoclonal gammopathy).

Under the final ESRD PPS, the three acute co-morbidity adjustments will be paid for the month the diagnosis is reported on ESRD facility claims and for the next three months. The chronic co-morbidity adjustments will continue to apply to all claims submitted.

Comment: One commenter questioned how the Form 2728 would be updated once it has been completed. Another commenter expressed concern about the time period for applying the co-morbidity adjuster, particularly for gastrointestinal bleeding.

Response: The purpose of the Form 2728 is to attest to the initial ESRD diagnosis. Included in that attestation are additional demographic and clinical information that are present at the time of the initial ESRD diagnosis. As we indicated earlier, the Form 2728 is a snapshot of the ESRD patient's status at the onset of dialysis. Therefore, we would not use information on the Form 2728 to determine the presence of a co-morbid condition for payment adjustment under the ESRD PPS. Instead, co-morbidity payment adjustments under the ESRD PPS will be based upon the diagnosis codes reported by ESRD facilities on their Medicare claims. We plan to use those reported diagnoses for future refinements to the co-morbidity categories and diagnoses.

Comment: Several commenters indicated that they were unable to replicate the proposed co-morbidity adjustments. One commenter claimed that we had overestimated the number of co-morbidities, resulting in an overestimation of reimbursement. Several commenters provided their own analyses (using data resources available to them, such as their own medical records, electronic medical records, hospital discharge summaries, paper charts, health care professional notes, and discussions with professional staff) and were unable to replicate our findings. The commenters indicated that in each of their analyses, their calculated adjustment was lower than the adjustments in the proposed rule. The commenters acknowledged that they do not have access to the vast data resources regarding patient conditions and, therefore, CMS can more accurately determine the adjustments. The commenters questioned CMS' projections of the financial consequences on ESRD facilities due to the proposed "overstated" adjustment factors.

Response: We regret the inability of commenters to replicate our findings. As the commenters acknowledged, claims data are not available due to confidentiality requirements and, therefore, commenters are unable to replicate our findings. We believe that the inability of the commenters to replicate CMS' findings may contribute to the commenters' belief that we have over- or under estimated reimbursement amounts. Historically, there has not been a financial incentive for ESRD facilities to document the presence of co-morbidities. We believe that by including co-morbidity adjustments under the ESRD PPS, ESRD facilities

will implement more active processes for gathering diagnostic information, which will facilitate care planning. We appreciate that commenters were able to identify co-morbidities for their patients for their analyses as it confirms our belief that co-morbidity information is available to ESRD facilities.

Comment: One commenter claimed that six of the proposed co-morbidities were unstable. The commenter indicated that when comparing the co-morbidity adjusters in the proposed rule with the adjusters published by UM–KECC in 2008, six of the adjusters (HIV/AIDS, Hepatitis B, bacterial/other pneumonias/opportunistic infections, hereditary hemolytic/sickle cell anemias, cancer and monoclonal gammopathy) were highly "unstable" and not reliable predictors of cost and, therefore, they should be eliminated as payment adjustments.

Response: Three of the six co-morbidities referred to by the commenter as unstable are not being used to adjust payments in this final rule (HIV/AIDS, Hepatitis B, and cancer). Their exclusion as co-morbidity adjusters was based on other factors which are described above in the response to other comments.

For the three remaining co-morbidities mentioned by the commenter (bacterial/other pneumonias/opportunistic infections, hereditary hemolytic/sickle cell anemias, and monoclonal gammopathy), similar measures are included as payment adjusters for the final rule. These measures, which have undergone several refinements since the proposed rule, are bacterial pneumonia, hereditary hemolytic/sickle cell anemias, and monoclonal gammopathy. In conjunction with the exclusion of cancer as a co-morbidity adjuster, the monoclonal gammopathy category has been narrowed by the exclusion of multiple myeloma (a malignancy). As with the bacterial pneumonia category being used for the final rule that excludes other pneumonias and opportunistic infections, making this category more homogeneous may also serve to enhance its stability. Similarly, sickle cell trait is no longer sufficient for the patient to be classified into the heredity hemolytic anemia/sickle cell anemia category, which should also serve to focus this classification on relatively severe cases most likely to impact dialysis facilities.

For each of these co-morbidity measures, the adjustments in the final rule are for separately billable services only, where the estimated payment multipliers were found to be relatively stable both in the analyses for the final rule and in previous analyses of similar measures that were used for the proposed rule and for the 2008 UM–KECC report. It should be noted that for some co-morbidities, there has been less stability in the estimated payment multipliers based on facility level models for composite rate services. Partly for this reason, the co-morbidity adjusters in this final rule are based on separately billable services only, and are not based on composite rate services. Generally, the payment adjusters are those deemed to best satisfy multiple criteria for inclusion (for example, objective measurability, limited variability in severity, not likely to result from poor quality care, consistent relationship to costs in multiple years of data, and non-trivial impact on costs).

Comment: One commenter asserted that the co-morbidities were not predictive of dialysis costs because they involved medical conditions that are not relevant to dialysis treatment, especially when significant time has elapsed between the condition and the onset of dialysis. Another commenter believed the purpose of case-mix adjusters was valid, but questioned how well the adjustments reflect resource consumption. Another commenter complained that the co-morbidity adjustments do not identify differences in patient utilization of drugs and other resources. One commenter believed the proposed co-morbidity categories did not align with actual resource utilization for dialysis treatment. The commenter believed that CMS was inconsistent in assigning co-morbidity adjustments used for the regression analysis which casts doubt on the predictive value of adjusters produced.

Response: We do not agree with the commenter who believed the co-morbidities were not predictive of dialysis costs because they involved medical conditions not relevant to dialysis treatment. We believe that the co-morbidity adjustments reflect resource consumption and utilization because they reflect higher separately billable payments made for ESRD-related drugs and biological and laboratory tests for patients with certain co-morbid diagnoses. Our analysis has demonstrated that the co-morbidity adjustments have predictive value as evidenced by the overall predictive power of the model. We articulated in the proposed rule how we determined co-morbidities. We began by discussing the process initiated in the CY 2005 PPS proposed rule, whereby we proposed a limited number of patient characteristics including a large number of specific co-morbidities. We explained the methodology we used in selecting the co-morbidities as well as why certain ones were excluded (74 FR 49952). We then explained the rationale used for the CY 2005 final rule (including why we did not include co-morbidities), which implemented the current case-mix adjusted composite payment system (74 FR 49953).

In the proposed rule (74 FR 49953), we explained that the relationship between patient characteristics and cost for composite rate services was estimated using a facility level regression model. We stated that the average patient characteristics were related to the reported facility costs. We further stated that a patient level model was used to identify potential payment adjusters for separately billable services. While the modeling approach used separate equations for the composite rate and separately billable services to select patient characteristics as payment variables, we combined the estimated payment multipliers for composite rate and separately billable services. The payment multipliers were calculated as the weighted average of the composite rate and separately billable multipliers (74 FR 49953), where the weights are the shares of total costs attributable to composite rate and separately billable services. As the cost reports are not patient specific, we believe that we addressed costs using the best methodology with the data available.

The range used in the analysis in the proposed rule was based on the years during which our contractor began and continued analyzing ESRD data. For some categories, which we identified as acute, there was a clear break in the data at the 4-month interval, with the presence of the co-morbidity more than 3 months prior to the current month resulting in a substantially weaker relationship to current costs. For others, which we identified as chronic conditions, we could not identify a clear break. For this final rule, the analysis of the co-morbidity diagnostic categories looked at 2006, 2007, and 2008 claims for acute conditions and claims since 2000 for a 6-year span for the chronic conditions. We used 2006, 2007, and 2008 claims for the separately billable analyses.

While the proposed rule used a patient year separately billable model to create consistency between the composite rate and the separately billable models, for this final rule, we used a patient-month level separately billable model for the acute short-term diagnostic category, as the coding of the variable will differ substantially on the annual versus monthly basis because patients only have the condition for part of the year. Measurement for a chronic

condition at the annual or monthly level generally does not vary because the patient either has the condition or does not. The change to the monthly observation tended to reduce the multipliers, especially the short-term acute co-morbidity diagnostic categories. Statistically, this reduction in multipliers for acute conditions is likely to have occurred because patients coded as having the acute condition for part of the year may also have had higher costs at other times of the year. Therefore, the multiplier in an annual model can reflect not just the costs during the months in which an acute condition was present. Because we wanted the short-term multipliers to reflect short-term increases in costs, we believe that changing to a monthly model is appropriate. The net effect in the changes to the separately billable model is smaller adjustments for the acute, short-term diagnostic categories. By using the patient-month separately billable model, the multipliers would more closely reflect costs associated with the specific co-morbidity being measured and occurring in the specific months in which the co-morbidity was present.

The composite rate model continues to be based on data only observed annually. In the proposed rule, the only short-term co-morbidity adjustment in the composite rate model was for bacterial pneumonias/other pneumonias and opportunistic infections. For the final rule, we dropped a measure of bacterial pneumonia from the composite rate model. The exclusion of this co-morbidity adjustment from the composite rate model involves the same reasoning that was used in changing the unit of analysis for the separately billable model from the patient year to the patient-month. We found, for example, that the bacterial pneumonia multiplier in the composite rate model was relatively sensitive to the presence of other co-morbidities in the model, including those that were used in the composite rate model for the proposed rule. As a result, a relatively large portion of this adjustment is likely to capture the effects of other unmeasured factors that increase facility costs. Unlike the separately billable model, however, the same option is not available to change the unit of analysis for modeling composite rate costs, because the cost data are only available at the facility level.

Another concern with applying the bacterial pneumonia adjustment from the composite rate model was that the magnitude of the effect was relatively unstable from year to year in the analysis for the final rule. Therefore, in this final rule, the composite rate model was not applied.

Comment: One commenter suggested that we calculate co-morbidity adjustments not from data from other settings, but on data readily available to ESRD facilities. Other commenters claimed that use of hospital and emergency department records to determine co-morbidities overstated adjusters because these claims include acute illnesses. Commenters suggested that CMS delineate chronic outpatient co-morbidities, resulting in higher reimbursement, and discount the unadjusted mean bundled payment.

Response: We presume that the commenter is referring to sources, such as hospital and physician claims, that were used in conjunction with the ESRD claims. In the proposed rule, we explained our rationale for using the Form 2728, the ESRD cost reports, and claims from various health care providers (74 FR 49952 through 49954). We indicated that we had encouraged ESRD facilities in the past to report co-morbidities on the ESRD claims (74 FR 49953) for purposes of establishing future payment refinements. However, as sufficient co-morbidity diagnoses were not reported on ESRD facility claims, we used other sources of data for the regression analyses.

We believe that given the co-morbidity adjustments under the ESRD PPS, ESRD facilities will take a more active role in gathering information in order to receive a payment adjustment. If so, it may be possible to use diagnostic information reported on claims for future refinements to the ESRD PPS.

With regard to the comment concerning chronic co-morbidities, we believe that the commenter is alleging that chronic co-morbidities rather than acute co-morbidities should be considered for payment adjustment. We do not share this view. As we explained in detail above, we believe the methodology used in determining acute and chronic co-morbidities recognized for the co-morbidity payment adjustment captures those conditions that require more composite rate and separately billable services.

Comment: One commenter expressed concern that many of the proposed co-morbidity adjusters were neither reliable nor robust and, therefore, the commenter recommended the exclusion of the proposed 11 co-morbidity categories. The commenter claimed that the regression methodology that CMS proposed results in overestimation of the adjuster values. The commenter further stated that unless clinical evidence exists to support the independence of the variables in the model, as they pertain to ESRD services furnished and such services' cost distribution, the co-morbidities should be excluded.

One commenter stated that it was not clear how the co-morbidities were identified in the regression analysis or in assigning patients. The commenter also stated there was no reference, analysis, or statistical evaluation of the period of time in the past, for which the co-morbidity condition is relevant. The commenter concluded that flagging patients for each adjuster could be different if co-morbidity codes were searched on claims at different time periods. The same commenter stated that in the proposed rule, we did not provide an explanation about how we determined that an "old" diagnosis no longer affected treatment and, therefore, did not qualify as an adjuster, nor did we discuss how we had historically evaluated which co-morbidity condition was relevant.

Response: As we discussed in the proposed rule (74 FR 49952), we proposed case-mix adjusters in the CY 2005 PFS proposed rule. We explained in the proposed rule that for some diagnoses, such as cancer, we looked at any occurrence since 1999. We also explained that in the proposed rule we used 2007 claims (74 FR 49954). For this final rule, co-morbidities referred to as "acute" were identified in the current month of the analysis or previous 3 months of claims. Co-morbidities referred to as "chronic" were identified in claims since 2000.

For some categories, which we identified as acute, there was a clear break in the data at the four-month interval, with presence of the co-morbidity more than three-months prior to the current month resulting in a substantially weaker relationship to current costs. For others, which we identified as chronic conditions, we could not identify a clear break.

For this final rule, the analysis of the co-morbidity diagnostic categories involved 2006, 2007, and 2008 claims for acute conditions and claims since 2000 for a six-year span for the chronic conditions, although the actual Medicare history will vary based on when a patient became entitled under Medicare. Because some patients have shorter Medicare histories, the claims may miss some diagnoses that were actually present, resulting in an underestimate of their clinical prevalence.

We used 2006, 2007, and 2008 claims for the separately billable analyses. Estimating the regression models year by year (rather than for the full 3-year

period) showed that the same co-morbidities tended to predict costs in each year, which suggested the adjusters were reliable and robust. In our analysis for this final rule, we once again identified a clear break in the higher utilization of separately billable items and services after 4 months for the acute conditions and no break for the chronic conditions.

In the proposed rule, we used a patient year separately billable model to create consistency between the composite rate and the separately billable models. For this final rule, we used a patient-month level separately billable model for the acute short-term diagnostic category. The coding of the variable will differ substantially on the annual versus monthly basis because patients only have the condition for part of the year. Measurement for a chronic condition at the annual or monthly level generally does not vary, because the patient either has the condition or does not. The change to the monthly observation tended to reduce the multipliers, especially the short-term acute co-morbidity diagnostic categories.

Statistically, this reduction in multipliers for acute conditions is likely to have occurred because patients coded as having the acute condition for part of the year, may also have had higher costs at other times of the year. Therefore, the multiplier in an annual model can reflect not just costs during the months in which an acute condition was present. Because we wanted the short-term multipliers to reflect short-term increases in costs, we believe that changing to a monthly model is appropriate. The net effect in the changes to the separately billable model is smaller adjustments for the acute, short-term diagnostic categories. The composite rate model remains as data only observed annually because the cost reports which are used are completed on an annual basis. By using the patient-month separately billable model, we believe that the multipliers would more closely reflect costs associated with the specific co-morbidity being measured and occur in the specific months in which the co-morbidity was present.

As for the assertion by commenters that there was a lack of independence of predictors, we found that there were no strong correlations between the presence of different co-morbidities. Regression analysis identifies the independent contribution of different variables on the outcome of interest. If multiple variables were highly correlated, the regression analysis would be unlikely to show that each of the variables had a statistically significant, independent effect on the outcome.

Comment: One commenter opposed the inclusion of the proposed co-morbidities out of the belief that ESRD facilities' lack access to reliable data, which would prevent facilities from tracking and reporting co-morbidities in a manner that is adequate to support reimbursement. The commenter argued that the disparity in the findings using data available to ESRD facilities was not surprising and referenced an article published in the Journal of the American Society of Nephrology. The commenter alleged that in the article, the CMS contractor, UM–KECC, had conceded that additional data not currently available to CMS is required to improve the predictive power of its case-mix model. The commenter further alleged that what data exists is incomplete or inaccurate with respect to occurrence, frequency, and severity. The commenter also stated that in the article, UM–KECC acknowledged that some co-morbidities were difficult to collect and the prevalence varies with the "look-back" period. The commenter further noted that in the article, UM–KECC stated that reporting on the claims would create a new administrative burden and that adjusting payments for co-morbidities could create inappropriate incentives.

Response: Although UM–KECC acknowledged that the article does refer to limitations that exist in the available data, they believe that the available data are sufficient to estimate some of the important predictors of costs. UM–KECC has indicated that it does not doubt that additional data would improve the predictive power of the models, but acknowledges that such data are not available. UM–KECC noted the prevalence varied most with look-back period for those co-morbidities that were used as acute conditions. For those conditions, older diagnoses had substantially weaker relationships to costs and therefore, were not proposed as case mix adjusters.

Given the low level of reporting of co-morbid conditions on current ESRD claims, UM–KECC agrees that obtaining and reporting the information could create some new burden, but hopes that encouraging facilities to increase awareness of co-morbid conditions will facilitate improvements in the care planning process. Given that in-center dialysis patients typically are in the facility three times weekly and see a nephrologist about four times per month, we believe the additional burden will be relatively minor.

Comment: Some commenters claimed that we overstated the prevalence of the co-morbidity diagnoses because their findings did not demonstrate the same prevalence for the adjusters we identified. One commenter noted their findings about prevalence were lower than the prevalence that we reported in the proposed rule, with the magnitude of the difference very large for hepatitis B, septicemia, cancer HIV/AIDS, hemolytic or sickle cell anemia, monoclonal gammopathy, myelodysplastic syndrome, and pericarditis. One commenter reported a higher prevalence for cardiac arrest, pneumonia/other opportunistic infections, alcohol-drug dependence, and gastrointestinal bleeding, but noted that in each case the difference was less than 2 percent.

One commenter stated they were only able to replicate the prevalence rate for cardiac conditions. The commenters acknowledged that they used their own data sources, which they recognize are not as comprehensive as the data available to CMS.

Response: We appreciate that commenters were able to identify co-morbidities for their patients for their analyses, as it confirms our belief that co-morbidity information is available to ESRD facilities.

As we discussed above in response to commenters' inability to replicate our findings, historically there has not been a financial incentive for ESRD facilities to document the presence of co-morbidities because there was no payment associated with a co-morbidity. We believe that given the co-morbidity adjustments under the ESRD PPS, ESRD facilities will take a more active role in gathering and reporting co-morbid diagnostic information.

However, frequencies of co-morbidities found in the Medicare claims files may still differ from those found in the historical records of ESRD facilities, because each ESRD facility may not have the same number or percentage of patients with the same co-morbidities as other ESRD facilities or they may differ from the national average. The reported diagnosis information provided by ESRD facilities will serve as the basis for subsequent revisions to and improvements in the case-mix adjustments.

Comment: One commenter believed that without access to all the claims data that was used to ascertain the adjusters, ESRD facilities will under-report them, resulting in systematic underpayment.

Response: We believe that the commenter means that if ESRD facilities do not have access to other claim sources (such as hospital claims), they may under-report co-morbidities. We acknowledge that ESRD facilities will

need to be proactive in obtaining co-morbidity information from other health care providers.

We will require ESRD facilities to report the appropriate ICD–9–CM code for the co-morbid condition recognized for purposes of the co-morbidity payment adjustment under the ESRD PPS, if the ESRD facility wishes to receive the adjustment. However, as we discussed and explained above, we are finalizing a smaller number of co-morbidity diagnostic categories in this final rule. The number of co-morbidity diagnostic categories we are finalizing for purposes of the co-morbidity payment adjustment has been reduced from eleven to six.

We also are providing in Table E in the Appendix, the list of ICD–9–CM codes that would be recognized for purposes of the co-morbidity payment adjustment. The number of specific diagnostic ICD–9–CM codes eligible for the co-morbidity payment adjustment has been reduced from hundreds to eighty-eight. We believe these reductions will mitigate many of the concerns expressed by commenters.

As we discussed in a previous response, § 494.80 in the ESRD Conditions for Coverage, specifies that a patient's comprehensive assessment must include an evaluation of current health status and medical condition, including co-morbidities. We acknowledge that the Conditions for Coverage do not require that co-morbidities be documented on the ESRD claim using ICD–9–CM codes. However, for the purpose of receiving a co-morbidity payment adjustment for an eligible co-morbidity, ESRD facilities will be required to document the ICD–9–CM code on the ESRD claim with documentation to support the ICD–9–CM code maintained in the patient's medical or clinical chart. We will discuss the documentation requirements further in the future in administrative issuances.

Comment: One commenter expressed concern that our reliance on cost reports is misplaced and claimed that there is nothing to support a presumption that facility cost report data can be linked with patient-level variance in the cost of care. The same commenter claimed that company practices, such as staffing practices, volume discounting, and group purchasing, may have a greater impact on facility costs than a transitory combination of patient characteristics and conditions that may not be tied to the cost reporting period.

Response: We do not share the commenter's view that the use of cost reports is misplaced. We acknowledge that ESRD facility cost reports cannot be linked with individual patient level variance in the cost of care. In the proposed rule, we indicated that the relationship between patient characteristics and cost for composite rate services was estimated using a facility-level regression model to relate the average patient characteristics to the reported facility costs. We further stated that a patient level model was used to identify potential payment adjusters for separately billable services. While the modeling approach used separate equations for the composite rate and separately billable services to select patient characteristics as payment variables, we combined the estimated payment multipliers for composite rate and separately billable services. The payment multipliers were calculated as the weighted average of the composite rate and separately billable multipliers (74 FR 49953).

To assess the relationship between patient characteristics and costs for composite rate services, we are currently limited by the absence of patient-level cost data. Instead, this analysis must be done by relating differences in patient characteristics across facilities with differences in average facility costs for composite rate services, using cost report data. For example, if each 10 percent increase in the prevalence of a co-morbidity within an ESRD facility's population is associated with one percent higher cost per treatment (across all treatments the ESRD facility provides), that characteristic would have a multiplier of 1.10. This is the same approach that was used to develop the basic case-mix adjustment for the composite rate.

We recognize there are limitations to this approach for co-morbidities that are relatively uncommon, where estimates of the increment in cost for a particular condition are generally based on very small differences in the prevalence of the condition across facilities. Therefore, unlike the payment model in the proposed rule, the current payment model does not reflect co-morbidity adjustments for composite rate costs.

Most cost reports cover a calendar year. In cases where the cost report does not coincide with the calendar year, weighted averages of success cost reports were calculated to link the cost reporting period more closely to the period over which patient characteristics were measured. For example, if a facility's reporting period is October 1 through September 30, its 2006 costs would be a weighted average of its report covering October 1, 2005 through September 30, 2006 and its report covering October 2006 through September 30, 2007, with three quarters of the weight placed on the earliest report (which included three quarters of the 2006 calendar year).

Comment: One commenter indicated that we did not take into account certain diseases that require more care and costs. The commenter believed we failed to take into account the variations in caring for individual patients, and were penalizing facilities that provide more comprehensive care (thus eliminating patients' need to spend non-dialysis days in other health care settings). Examples that the commenter cited were diabetes management, hypertension management, anti-coagulant monitoring, and pre-transplant testing.

Response: We do not believe that we are penalizing ESRD facilities that provide comprehensive care to patients. For example, as discussed in section II.E.1. of this final rule, commenters indicated that ESRD facilities administer drugs and biological for purposes other than for renal dialysis-related conditions. Consequently, we provided for these services to continue to be paid as separately billable items. In section II.K. of this final rule, we discuss how we will provide for laboratory tests that are performed for non-ESRD-related conditions, to be paid as separately billable items.

With regard to the comment that we have not accounted for other conditions that require more care or costs, in the proposed and in this final rule, we have addressed the methodology of how we identified payment adjustments that capture higher resource utilization and, therefore, higher costs. We believe that the patient-level adjustments, the home training add-on adjustment and the outlier payment all address patients who require higher resource utilization. We will continue to analyze ESRD claims and costs after the implementation of the ESRD PPS and will discuss any refinements that may be needed in future rulemaking.

Comment: Most commenters cited administrative reasons for wanting to exclude the co-morbidity categories as patient-level adjusters, such as difficulties in obtaining hospital data; difficulties in determining beginning and end dates of co-morbidities such as gastrointestinal bleeding; the financial burden on the facilities due to the cost of training and hiring coders to document conditions properly with cost possibly exceeding payment increases; changes in systems to collect and update data continuously to capture adjusters and codify them on claims requiring additional staff; limited number of diagnoses that facilities use to justify dialysis treatment; complexity

overwhelming facilities; risk of reducing staff time from patient care to allow them to code diagnoses; incurring fees from other providers for copying medical records; difficulty in tracking co-morbidities; the need to create new documentation processes to capture necessary medical information and accurately code, entailing efforts by medical records personnel, clinical personnel, nurses, and physicians; and the need to add complex administrative resource intensive systems.

Several commenters claimed the co-morbidity adjustments would cause administrative burdens to small dialysis organizations. The same commenters indicated that the information would be hard to collect and assure accuracy except for hepatitis B. Others cited lack of reporting of co-morbidities due to patients' and caregivers with poor memories or cognitive abilities; multiple hospitalizations in multiple hospitals; and the need to obtain information from nephrologists.

One commenter believed the adjustments were too high and that there would be a financial risk to providers who will require increased resources to code correctly. One commenter claimed that the facilities facing severe financial losses would reduce costs and shift from the goal of seeking the best or highest standards of patient care towards those that are merely acceptable or adequate. Some commenters claimed that the co-morbidities have not historically been collected and should be eliminated because it is difficult, unreasonable, unrealistic and almost impossible to obtain the information that may affect the ability to provide care. Another commenter stated that the administrative and information technology burden for tracking co-morbidities outweighed the benefit.

A few commenters opined that the new payment system should revert back to the system prior to 2005, whereby all facilities received a lump sum payment for every dialysis treatment provided to all patients. Several commenters believed the system is too complex for patients and families to follow the calculations to determine their responsibility. Several commenters indicated that most providers accurately code all chronic ESRD problems and rely on hospital certified coders to code problems in the discharge summary. The same commenters were concerned that they will need to capture all new co-morbidities in the month that they occur with incomplete data thereby delaying claims processing resulting in lost reimbursement. A few commenters suggested that the adjusters be limited to those at the time of initiation of dialysis, because they claim there is no mechanism to update information when co-morbidities change. Others cited the lack of access to hospital and other records.

Response: We thank the commenters for sharing their concerns. We understand that the implementation of the ESRD PPS, including the requirement to document co-morbidity diagnostic categories to be eligible for adjustment to the ESRD PPS, will be new to some ESRD facilities. However, since the ESRD Conditions for Coverage were issued in 2008, ESRD facilities have been aware of their responsibility to assess and record co-morbid medical conditions in the medical records.

We believe that ESRD facilities will obtain diagnostic information through increased communication with their patients, their patients' nephrologists and their patients' families. When an ESRD patient misses a treatment, the ESRD facility should determine whether the patient has been hospitalized and, if so, what was the condition treated. To the extent the patient is unable to provide the information the ESRD facility would consult with the patient's nephrologists or family to seek additional information.

The reduction of the number of co-morbidity diagnostic categories should reduce the burden on ESRD facilities to identify co-morbidity diagnostic categories that would need to be entered on ESRD claims to be recognized for a payment adjustment. Given that we have reduced the number of co-morbidity adjustments and that in-center dialysis patients typically are in the ESRD facility three times per week, and that ESRD patients typically see a nephrologist about four times per month, we believe the burden of tracking co-morbidities will not be as onerous as the commenters fear.

Comment: Some commenters suggested that co-morbidity adjusters should only be those that are chronic in nature and do not change each month, and that we should consider operating costs in deciding which adjusters to use.

Response: The determination of which co-morbidity diagnostic category would be recognized for purposes of the co-morbidity payment adjustment is based on results of the analyses we described above. We identified and are finalizing three chronic and three acute co-morbidity diagnostic categories that would be recognized for the co-morbidity payment adjustment under the ESRD PPS.

Comment: Several commenters suggested that CMS be responsible for assessing when adjusters are necessary. The commenters noted that because CMS has access to all claims, CMS should incorporate the co-morbidities that it identifies into payment determinations without burdening providers. The commenters further suggested that if CMS assumed responsibility for determining which diagnosis were eligible for a payment adjustment, adjustments would not be subject to fraud and abuse.

Response: We believe that ESRD facilities should be aware of patients' co-morbidities and we assume are in the best position to determine such information and, therefore, should be responsible for identifying all co-morbidities on the ESRD claim whether or not they are eligible for a payment adjustment. Accordingly, we do not believe that we should be assuming responsibility for identifying patient co-morbidities for ESRD facilities. We do not believe that our assuming responsibility for identifying payment adjustments would, in itself, serve to eliminate fraud and abuse, because other health care providers would be documenting co-morbidities on their respective claims and we would be obtaining the co-morbidities from those claims. It is incumbent on all providers to put correct information on claims, whether or not there are payments associated with the information.

As we noted above, in order to receive a payment adjustment to the ESRD PPS base rate, ESRD facilities will be required to document on ESRD claims the co-morbidity using the appropriate ICD–9–CM code in accordance with ICD–9–CM coding guidelines.

Comment: One commenter expressed concern that ESRD organizations will determine which combination of co-morbidities would generate large payments. One commenter suggested that we consider the compound effect of multiple adjusters that may have a singular association, but may not warrant compounding when used for a single patient and treatment. Other commenters believe that the adjusters will result in facilities only treating the sickest patients with the most co-morbidities in order to increase revenue. Some commenters expressed their concerns about adjusters being manipulated resulting in up-coding in order to seek higher payment. Another commenter indicated that facilities would be motivated to have patients with as many adjustments as possible regardless of whether there were appropriate numbers and quality of trained staff or the ability to care for more complex patients.

Several commenters predicted that the fallout of including co-morbidities

as adjusters would result in "cherry picking" leading to a crisis in dialysis care. One commenter expressed concern that extra care may be the same for a patient with a single co-morbidity, as a patient with multiple ones. Another commenter indicated adjusters are based on past history and subject to interpretation and abuse. The commenter questioned whether ESRD facilities will try to maximize revenues by qualifying patients for greater reimbursement due to previous medical histories that have no impact on patients and do not add costs to their current treatment regimen.

Some commenters expressed concern that sicker patients with multiple co-morbidities may not find an ESRD facility to provide care. A few commenters believed patients with few or no co-morbid conditions may be unable to transfer to another facility because facilities will fill open slots with patients who have enough co-morbid conditions to cover the cost of providing dialysis to them. Other commenters acknowledged the potential of errors and manipulation with the co-morbidities, citing alcohol dependency as an example. One commenter suggested eliminating the adjusters, if ESRD facilities would be responsible for tracking them.

Response: We appreciate the concerns raised by commenters. We do not agree that the inclusion of co-morbidities as payment adjustments will lead to "cherry picking" of patients, because in the absence of case-mix adjustments reflecting patient cost, "cherry picking" the healthiest patients may well be a more serious problem. We believe that ESRD facilities will provide appropriate care under the ESRD PPS and we believe that our continued monitoring will identify the few ESRD facilities that do not.

We acknowledge that the number of co-morbidities that an individual has does not necessarily determine the need for additional care. As commenters have noted, there may be other factors, such as functional limitations, that result in the need for additional care. However, at this time, with the data available to us, we have identified six co-morbidity diagnostic categories which have shown higher costs due to higher separately billable costs. These co-morbidity diagnostic categories will be recognized for the co-morbidity payment adjustment under the ESRD PPS base. We will continue to look at other factors and other co-morbidities as ESRD facilities begin to enter co-morbidities on ESRD claims.

With regard to the commenters expressing concerns about dialysis organizations determining which combination of co-morbidities would generate large payments and "cherry picking" these patients, we performed further analysis of the co-morbidity diagnostic categories for this final rule. We found that although costs were somewhat higher for patients with multiple co-morbidities, the effect of compounding two or more co-morbidity adjustments would on average result in a higher payment adjustment than is warranted. However, because we are unable to determine the extent of this higher cost, we do not believe that providing an adjustment for more than one co-morbidity, is warranted at this time. In addition, the costs the co-morbidity adjustments are capturing are mostly related to separately billable services, primarily the use of EPO. We believe that providing multiple co-morbidity adjustments would overstate EPO utilization, especially in light of the medically unbelievable edits applied under the EPO Claims Monitoring Policy.

In order to avoid overly-high payments for co-morbidities, under the final ESRD PPS an ESRD facility may receive only one co-morbidity case-mix adjustment per co-morbidity category per claim, regardless of whether the patient has co-morbid conditions from different co-morbidity diagnostic categories. In the event that there is more than one co-morbidity diagnosis category that is applicable, we will apply the highest payment adjustment in order to reflect the slightly higher costs associated with patients with multiple co-morbidities.

In addition, our analysis has shown that it is very rare for an ESRD patient to have more than one of the final diagnostic categories recognized for a payment adjustment. Using the same comprehensive data sources we used to identify co-morbidity categories (including claims from hospital inpatient stays, outpatient encounters, physician, skilled nursing facilities, etc.), we determined that approximately 92 percent of patient-months have no co-morbidities reported; approximately 7.4 percent of patient-months had only one reported co-morbidity. Less than 0.45 percent of patient-months had two co-morbidities reported.

Therefore, in the rare event that a patient has more than one co-morbidity diagnostic category, the adjustment for the category with the highest adjustment factor would be applied. Where there are two chronic categories reported, a payment adjustment would be applied using only the chronic co-morbidity category with the highest adjustment. Since the acute co-morbidity categories all have higher values than the highest chronic co-morbidity category, in the event a patient with a chronic condition that is eligible for a payment adjustment acquires an acute condition that is also eligible for a payment adjustment, the payment adjustment would only apply for the acute condition. In the event that a patient has 2 or more acute co-morbidities eligible for a payment adjustment, the adjustment would only apply to the acute co-morbidity with the highest adjustment.

We wish to ensure that patients continue to have access to high quality dialysis care. It will be an important focus of our monitoring efforts to review multiple data sources on co-morbidities and determine if these trends change as a result of the ESRD PPS and the co-morbidity adjustments so that we can ensure continued access for patients. We will track data on co-morbidities to detect changes in prevalence or type of conditions coded. To the extent that an ESRD patient has higher resource needs, as a result of multiple co-morbid conditions, or some other complication, we expect that the outlier adjustment and blended transition payments, as set forth in this rule, would provide sufficient protection against extraordinarily high costs, particularly in the first year of the transition. We will consider future refinement of our co-morbidity adjustment policy based on data from ESRD claims and other sources from the period after implementation of the new payment system to ensure that patients continue to have access to high quality care.

As we noted in the onset of dialysis discussion earlier in this section of this final rule, our analysis for this final rule indicates an increase in costs for the composite rate portion of the two-equation model, which may reflect an increase in the level of resource utilization required to stabilize individuals who are new to dialysis. The analysis also demonstrates an increase in measured costs for the separately billable portion of the model, particularly for ESA utilization. While we found that costs were higher, on average, for dialysis patients with a co-morbidity during the first 4 months following the onset of dialysis, the effect of compounding a co-morbidity adjustment with the onset of dialysis adjustment would, on average, result in higher payment adjustment than is warranted for separately billable services. Therefore, the co-morbidity payment adjusters will not apply for facilities receiving the onset of dialysis payment adjustment.

With regard to the comment that adjusters are based on past history, we

are finalizing three chronic co-morbidity categories which are based on the patient's medical history and, which would be recognized for a continuous payment adjustment (except when there is an acute co-morbidity as described above); and, three acute co-morbidities that are based on the co-morbidity's presence in the current claim month and for three subsequent months.

With regard to commenters' concern about errors and manipulation of the reporting of co-morbidities, specific documentation of co-morbid conditions in patient medical/clinical records using specific guidelines will be required for this payment adjustment and we will address such details in future administrative issuances. We anticipate monitoring the use of co-morbidities. We will continue to assess the current as well as future co-morbidity diagnostic categories to ensure that all Medicare beneficiaries with ESRD have access to appropriate renal dialysis services.

Comment: One commenter cautioned that the number of co-morbidities would go up, stating the analogy of increased Epogen® use by the LDOs due to financial gains. The same commenter suggested that providers will encourage physicians to admit high-cost patients to other facilities and order expensive medications and tests at these facilities. One commenter expressed concern that the current claims processing system does not accommodate the potential number of adjustments needed.

Response: The current claims are able to accommodate the reporting of nine co-morbidities as secondary diagnoses. We will explain billing issues relating to co-morbidity adjustments in sub-regulatory guidance in the future.

As we indicated above, we expect ESRD facilities to furnish appropriate care to their patients under the ESRD PPS, but we will monitor the ESRD PPS to identify the ESRD facilities that may not. We believe the concerns raised by the commenters could also exist under the current basic case-mix adjusted composite payment system.

Comment: Some commenters explained that many adjustments do not have significant impact on the delivery of care. One commenter believed that the case-mix adjusters are for the purpose of protecting small providers against financial consequences of high-risk patients.

Response: We recognize that the presence of a co-morbidity does not always result in high costs. As explained in the discussion of the regression model in this final rule, adjustments to the ESRD PPS base rate are based on average costs. In other words, on average, patients with diagnoses in the co-morbidity diagnostic categories will have higher separately billable costs. The payment adjustment reflects this average. There may be patients with the co-morbidity who have less-than-average separately billable costs and others with higher costs. Because of this variability, some patient costs will be lower than the adjusted payment rate while others will be higher. In the absence of co-morbidity payment adjustments, differences between patient costs and payment are greater. The purpose of adjusting for co-morbidities and other patient characteristics is to reduce the average difference between actual patient cost and payment.

Comment: Several commenters expressed concern that the adjustments decrease the base rate. These commenters recommended a higher base rate with fewer adjustments. Some commenters stated that in order to recapture the payment lost to the base rate, ESRD facilities would have to ensure that some of their patients have the co-morbidities recognized for a payment adjustment to the ESRD PPS base rate. Several commenters suggested eliminating all adjustments and providing the same payment for all.

Response: The commenters are correct that the base rate has been reduced as a result of the co-morbidity diagnostic categories in order to maintain budget neutrality as discussed in section II.E.3. of this final rule. Failure to adjust for patient characteristics related to cost could result in reduced access to care for patients with characteristics generally known to be associated with cost.

Eliminating all adjusters and providing the same payment for all facilities is not an option, as section 1881(b)(14)(D)(i) of the Act specifies that the Secretary shall include a payment adjustment based on case-mix that may take into account patient weight, body mass index, co-morbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors. We believe that providing for the case-mix and other adjustments we are including in this final rule to account for the higher costs for certain patients meets the intent of the statute.

Comment: One commenter believed that bundling oral drugs would impact management of common co-morbidities such as anemia, secondary hyperparathyroidism and metabolic bone disease.

Response: We discuss the oral drugs in section II.A.3. of this final rule. With regard to the co-morbidities that the commenter identified (anemia, secondary hyperparathyroidism, and metabolic bone disease), we are not finalizing these three diagnoses for purposes of the co-morbidity payment adjustment under the ESRD PPS. We explained in detail in the proposed rule and in this final the methodology that was utilized in identifying co-morbidities that would be recognized for a payment adjustment. Furthermore, anemia, secondary parathyroidism and metabolic disease are complications that occur in ESRD patients (that is, they are ESRD-related). If we apply the criteria that we discussed above, these conditions would meet two of the three criteria. That is, because these conditions are ESRD-related, there is a potential for adverse incentives regarding care (criteria number 2) and there is a potential for ESRD facilities to directly influence the prevalence of the co-morbidity either by altering dialysis care, diagnostic patterns, or liberalizing the diagnostic criteria. Therefore, they would not be considered as co-morbidities recognized for a payment adjustment.

Comment: One commenter expressed concern that facilities obtaining multiple co-morbid adjustments would result in patients paying more co-insurance and those lacking supplemental coverage facing financial hardship or even involuntary discharge for non-payment. One commenter suggested adding money for units that provide care to higher-acuity patients.

Response: As discussed in section II.K.l. of this final rule, beneficiary co-insurance liability is based upon the total payments made to an ESRD facility on behalf of the beneficiary. As we discussed earlier, ESRD facilities will only receive a payment adjustment for one co-morbidity and, therefore, beneficiaries will not be held financially accountable for a co-insurance based upon multiple co-morbidities.

With regard to the commenter who suggested adding money for units that provide care to higher acuity patients, we note that the patient-level adjustments are intended to provide additional payment for higher cost patients.

f. ICD–9–CM Coding

We proposed that in order to receive a co-morbidity payment adjustment, the appropriate ICD–9–CM code, using the official ICD–9–CM Coding Guidelines, would need to be entered on the claims (74 FR 49954). This includes codes from both the individual body system chapters (codes 001.0–999.2), as well as appropriate codes from the supplementary classification of factors

influencing health status and contact with health services chapter (VO1.0–V89.09). We acknowledge that many of these codes, such as those for a history of a disease would not be eligible for a co-morbidity adjustment. We noted that we would issue through sub-regulatory guidance, any changes in codes eligible for a co-morbidity payment adjustment in the event of any changes in coding in the future (74 FR 49954). For example, ICD–10–CM will be implemented for services occurring on or after October 1, 2013. (See 74 FR 3328–2238–3362 for information on the Implementation of ICD–10–CM). We are finalizing our determination that in order to receive a co-morbidity payment adjustment, the appropriate ICD–9–CM code, using the official ICD–9–CM Coding Guidelines, would need to be entered on the claims.

In the proposed rule (74 FR 50027), we explained the analyses that we performed to determine the extent that specific diagnoses within the eleven co-morbidity categories are on ESRD claims. We also explained our analysis of the ICD–9–CM diagnosis codes, as identified by UM–KECC, and we provided a complete list of the codes identified by UM–KECC. We also provided a list of codes associated with diseases/conditions that we proposed would be recognized for the purposes of an ESRD co-morbidity payment adjustment (74 FR 50069).

We also explained that we eliminated specific ICD–9–CM codes associated with specific diseases/conditions that we proposed would not be recognized for purposes of a co-morbidity payment adjustment, and we provided a listing of these ineligible codes (74 FR 49955).

Comment: Some commenters expressed concern that facilities will face a huge administrative burden to ensure accuracy of data in order to be eligible for the patient-level adjusters, which "could and likely will result in cutting corners in care delivery." Others expressed concern about the need to change systems or lack of data to support eligibility for adjusters. A few commenters suggested including only adjustments that do not require administrative time, have a real impact on care, and do not need to be changed or documented. Other commenters stated that they have access neither to ICD–9–CM codes nor to claims from other health care providers who do document ICD–9–CM codes. Some commenters lamented that the co-morbidity adjustments did not offset the cost to change systems, obtain staff, and document codes correctly. One commenter believes that the difficulty of documenting ICD–9–CM codes would indicate that the co-morbidities should be eliminated.

Response: We do not believe that changes in a payment structure that represent appropriately case-mix adjusted payments should be eliminated because of administrative changes that result. We also do not agree that patient-level adjusters should be comprised of only those that do not require staff to ensure accuracy or are easier to manage administratively. We agree with the comment that adjustments with "real impact on patient care and care planning should be principle factors for which information should be reported," as we believe that our analysis on correlating payment with the adjustments does support patient care and planning principles.

Comment: We received two comments indicating that the elimination of the heading for myelodysplastic syndrome resulted in no codes for this condition that would be eligible for the co-morbid payment adjustment.

Response: We thank the commenter for bringing this to our attention and for providing a list of codes that can be used. We acknowledge that we inadvertently omitted the specific ICD–9–CM codes for myelodysplastic syndrome in the proposed rule. We have indicated the specific ICD–9–CM codes for myelopdysplastic syndromes in Table E of the Appendix.

In the proposed rule (74 FR 49955 through 49962), we proposed a number of tables identifying specific ICD–9–CM codes which would not be recognized for purposes of the co-morbidity payment adjustment. We solicited comments on the ICD–9–CM codes which we proposed to not recognize. We did not receive any comments pertaining to the ICD–9–CM codes we proposed not to recognize for purposes of the co-morbidity adjustments. Therefore, in this final rule, we are eliminating the tables with ICD–9–CM codes for co-morbidities not affecting costs in outpatient ESRD facilities; NEC/NOS/Unspecified codes; benign tumors; and category headings.

In this final rule, we are finalizing in Table E of the Appendix, the ICD–9–CM codes for the six co-morbidity diagnostic categories which would be recognized for an adjustment to the ESRD PPS base rate. As we have reduced the final co-morbidity diagnostic categories to six and made changes to the diagnoses we are finalizing in this final rule, we have updated Table E to contain only the ICD–9–CM codes which will be recognized purpose of the co-morbidity payment adjustment under the ESRD PPS. We note that we have included the list of ICD–9–CM codes that were used by UM–KECC in the analysis of the co-morbidity diagnostic categories for this final rule. This list is in Table E in the Appendix of this final rule. We are also finalizing the inclusion of co-morbidities as patient-level adjustments in § 413.235(a).

As we discussed earlier, documentation supporting the eligible co-morbidity diagnosis on the ESRD claim will be required in the patient's medical record. We will be providing specific instructions about such documentation requirements in the future.

g. Race/Ethnicity

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's race and ethnicity (as well as other patient characteristics such as patient weight, body mass index, etc.). In the proposed rule, we presented analyses of potential case-mix adjustments based on race and ethnicity (74 FR 49962). We indicated that while the inclusion of race and ethnicity factors may improve the predictive value of the proposed ESRD PPS, we had concerns about whether the data were of sufficient quality upon which to base payment adjustments (74 FR 49966). The regression analysis we conducted for purposes of the proposed rule relied on two separate data sources for race and ethnicity status to assess the extent to which race and ethnicity would account for cost factors that are otherwise unexplained in the model. The first analysis was based on race and ethnicity data retrieved from the Renal Management Information System (REMIS) and the second analysis was based on data retrieved from the Medicare Enrollment Database (EDB). We note that in the proposed rule we inadvertently indicated that race and ethnicity data that were collected on the Form 2728 were retrieved from REMIS for purposes of conducting the analysis. We wish to clarify that these data were retrieved from the Standard Information Management System (SIMS). From this point forward we refer to data that were collected from the Form 2728 as SIMS data.

In the proposed rule, we presented a comparison between SIMS and EDB data of the potential for race and ethnicity to predict differences in composite rate costs among ESRD facilities, as well as differences in MAP for separately billable services at the patient level (74 FR 49962 through 499650). We identified several concerns with the quality of the SIMS and the

EDB data (74 FR 49966). With respect to the SIMS data, we noted that for data analysis purposes, it was necessary to default beneficiaries into the category of "Other" making it more difficult to assess the effect of race and ethnicity on costs and payments (74 FR 49966). With respect to the EDB data, we noted that race and ethnicity data was either unavailable or defaulted into the "Unknown" category (74 FR 49966). We also indicated that in accordance with MIPPA, we planned to explore opportunities for improving Medicare program data on race and ethnicity for purposes of addressing health care disparities (74 FR 49966).

Although we did not propose case-mix adjustments for race and ethnicity, we requested comments on the data issues presented, other potential data sources for race and ethnicity that we could consider, and specifically, the need for adjustments for race and ethnicity in the final ESRD PPS. The comments that we received on whether race or ethnicity adjustments may be warranted under the ESRD PPS and our responses are set forth below.

Comment: We received three types of comments-–some in support, some in opposition and some that requested that CMS delay the inclusion of race and ethnicity as payment adjusters until the accuracy of Medicare race and ethnicity data could be improved. Commenters presented a variety of views. Some commenters believed that we should implement race and ethnicity adjustments in the final rule as a mechanism of preserving access to care for patients in the high cost racial categories. Many commenters believed that an adjustment for race has the potential to improve payment accuracy and to meet clinical needs of African Americans and other minority dialysis patients. Some commenters asserted that the exclusion of an adjustment for race would produce significant social and racial inequalities. Commenters cited fundamental concerns with the implementation of race or ethnicity adjustments indicating that such policy would not be appropriate. The commenters expressed concerns pertaining to individual rights, equality, and stereotyping. Commenters also opposed the implementation of adjustment factors that were not clinically or biologically based. Several commenters expressed concern about basing payment on racial or ethnic status indicating that race or ethnicity adjustments may infringe on individual rights. Some commenters believed that we should not implement race or ethnicity payment adjustments, suggesting that such a policy could be viewed as discriminatory. One commenter believed that implementation of race or ethnicity adjustments would open CMS up to risk of claims of racial bias and legal challenge.

Finally, other commenters believed that we should continue to work to improve the accuracy of the data, study the extent to which race or ethnicity discrimination was occurring, and consider implementing race or ethnicity adjustments at a future date.

Response: To maximize Medicare payment accuracy, we considered targeting higher payments to facilities on behalf of patients of certain racial or ethnic groups that, as demonstrated in the regression analysis, have been shown to have higher resource needs. We note the regression analysis is discussed further in section II.F. of this final rule. However, given the concerns we noted in the proposed rule, we do not believe it is appropriate to provide a patient-level payment adjustment based on race or ethnicity at this time.

In particular, we are not convinced that race or ethnicity adjustments are necessary to ensure beneficiary access to ESRD services. That is, we believe that there may be race-neutral biological factors that have not yet been identified in the ESRD PPS modeling that could explain the increased cost associated with providing renal dialysis services to members of certain racial or ethnic groups. We intend to work to identify underlying patient-specific conditions that may result in increased treatment costs and also how a race/ethnicity adjuster might be applied. To the extent that these factors are identified, they could be incorporated into the ESRD PPS model as patient-level adjustments. We anticipate presenting our further analyses in future rulemaking.

Comment: Several commenters believed that a race adjustment may shift payment for a large portion of the population on behalf of one racial group, African Americans. Another commenter noted that some groups, such as African Americans, would "gain" with the adjuster, while other groups such as Asians and Hispanics would "lose".

Response: We believe the commenter is referring to the financial implications of a race adjuster. While a case-mix adjustment may result in higher payments to ESRD facilities that treat patients with the specified characteristic, the adjustment is intended to offset a demonstrated increased cost associated with treating patients with that characteristic. As described further in section II.E.3. of this final rule, all adjustment factors are accounted for in reductions to the base rate. As a result, all facilities will be impacted by the reduced base rate whereas only those facilities that treat patients who qualify for the adjustment factors would receive the higher payments associated with those factors. We intend to continue to study this issue and will present our findings in future rulemaking.

Comment: Some commenters opposed adjustments based on race or ethnicity, including patients who would be included as part of the class/group to which the adjustment would apply. One commenter who opposed implementation of race or ethnicity adjustments, raised concerns about being labeled or stereotyped based on race, especially when the label may adversely affect that individual's care. Other commenters argued that it would be wrong to reimburse dialysis based on a patient's identification with a particular ethnic group. The commenters believed that all dialysis patients, without regard to racial or ethnic status, deserve the best care that is provided equally to all.

One commenter who supported the inclusion of an ethnicity adjustment suggested that in clinical practice certain patient ethnic groups are more or less compliant as patients. The commenter further indicated that non-compliant patients require greater effort in counseling, monitoring and communication with physicians.

Response: ESRD facilities are required to provide care that is based on individual patient need without regard to race or ethnicity. It is not our intent for ESRD facilities to rely on collective identity whereby the characteristics of a group are attributed to every member of that group, rather than basing treatment decisions on individual patient characteristics. We believe that patients should be assessed and treated according to their individual need, not according to the stereotypical traits ascribed to or manifested by (many or most but not all members of) their group.

Comment: Several commenters opposed the implementation of race and ethnicity adjustments stating that these factors would not be clinically verifiable. Commenters expressed concern about whether race has been shown to be a clinically-driven, independent variable that predicts the cost of providing ESRD services. One commenter stated that race is not a biological concept, but rather, it is a social concept. The commenter asserted that basing public policy on the social concepts of race or ethnicity has been judged by the Supreme Court to deserve

condemnation. The commenter further asserted that there would need to be a biological basis for racial and ethnic classifications upon which payment adjustments would be made. The commenter stated that there is no biological basis for racial categories noting that a person's classification is commonly based on self-reported information.

Other commenters who supported race or ethnicity adjustments asserted that scientific literature supports the validity of self-reported data. In addition, a commenter stated that major epidemiological entities in the U.S. government such as the U.S. Census, CDC, NIH and OMB use self-reported race and self-reported race is used to make national policy decisions.

Response: We agree with the commenter that race and ethnicity are not biological factors. According to the OMB, racial and ethnic categories should not be interpreted as being biological or genetic in reference. Rather, the race and ethnicity variables are based purely on categorization. By definition, race and ethnicity are based on social and cultural characteristics and ancestry.

OMB considers self-reported race and ethnicity classification to be the most appropriate mechanism for establishing an individual's race or ethnicity. As OMB further indicated in its Provisional Guidance on the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity, self-identification means that the race and ethnicity responses are based on self-perception and therefore, are subjective, but by definition, the responses are accurate (December 15, 2000, *http://www.whitehouse.gov/omb/assets/information_and_regulatory_affairs/re_guidance2000update.pdf*).

While race and ethnicity are not biologically based, as described above, we intend to perform additional studies to determine whether there are underlying clinical or biological factors contributing to the increased cost of providing renal dialysis services to certain racial or ethnic groups. For this reason, we are not implementing a case-mix adjustment for race or ethnicity in this final rule. We intend to continue analyses that may identify the race-neutral factors that explain the higher costs concentrated in certain racial or ethnic groups. If associations between race or ethnicity and cost are present after addressing race-neutral factors that may be associated with increased treatment cost, we will consider development and implementation of race or ethnicity adjustments in future rulemaking. In the interim, we will continue to monitor for evidence of decreased access to renal dialysis services by racial or ethnic groups, following implementation of the ESRD PPS.

Comment: Several commenters expressed concern over decreasing the base rate and adjustment amounts for case-mix variables that are objective and clinically verifiable, to account for the factors of race and ethnicity, which are not objective and clinically verifiable. The commenters indicated that it would be better to provide a sufficient base rate to support better treatment delivery.

Response: As described above, we are not implementing in this final rule, case-mix adjustments under the ESRD PPS for race or ethnicity. As a result, there will be a lower standardization factor resulting in a higher base rate as described further in section II.E.3. of this final rule.

Comment: A patient asserted that if CMS were to consider a patient's perception of their racial or ethnic status as a basis for an adjustment, then CMS should also consider accounting for the patient's perception of their dialysis provider's performance based on how they feel, whether they are informed about the dialysis process, etc.

Response: We appreciate the commenter's suggestion to consider an adjustment based on patient's satisfaction with care received at the ESRD facility. We intend to take this suggestion under consideration in future rulemaking, as we develop QIP measures.

Comment: Many commenters cited studies demonstrating differences in cost and utilization of renal dialysis services, primarily medications, among racial and ethnic groups. These commenters asserted that research demonstrates that race is a predictor of health care cost and believe that race may explain cost variability in patients more effectively than other adjusters. These commenters stated that African American patients require more ESAs, vitamin D therapies, and calcimimetics for bone and mineral metabolism disorders than other racial and ethnic groups. Commenters also stated that African Americans have higher rates of venous catheter use than other groups. Several commenters cited studies illustrating differences in disease severity and clinical management for secondary hyperparathyroidism between African Americans and other races.

Several commenters provided alternative suggestions for race adjustments including a patient-level "black vs. non-black" adjustment or a facility-level race adjustment.

Response: We thank the commenters for their analysis of studies on race and we will take them into consideration.

Comment: Several commenters noted that case-mix adjusters help ensure equal access to care, especially for those with higher costs of care. Several not-for-profit small dialysis organizations (SDOs) did not believe that facilities would discriminate against African American patients in the absence of race or ethnicity adjustments by withholding adequate doses of ESAs.

Response: We agree with the commenters and intend to monitor access to care under the ESRD PPS and stand poised to take necessary measures to ensure equal access to care for all ESRD patients regardless of cost.

Comment: Commenters believed that the payment policy should not hinder access to care for minority populations. Many commenters provided their analyses of regional impacts, and compared them to CMS' impact analysis in the proposed rule.

Commenters were concerned that in instances where higher costs are associated with a racial group, such as costs for ESAs associated with hypo-responsive patients, and given that these costs would be bundled into the ESRD PPS and no longer separately paid, facilities with patients who are mostly in the high cost racial group will be negatively impacted.

Many commenters referred to CMS' impact files showing that facilities serving the African American population have the most significant reduction in payments. We received divergent comments with respect to where the most severe impact of not implementing race or ethnicity adjustments would be realized including those facilities in various regions of the country according to facility-type, urban and rural status.

Response: We expect facilities to treat ESRD patient regardless of their race or ethnicity. To a certain extent, variations in resource intensity and the associated cost of providing renal dialysis services to individual patients, are reflected in the patient-level adjustments within the ESRD PPS model. However, to protect ESRD facilities from unusually high costs attributed to individuals, we have finalized an outlier policy described in section II.H. of this final rule. In instances where costs of providing ESRD services exceed the projected amount plus a fixed dollar loss amount, we will pay a percentage of the difference.

Comment: One commenter asserted that scientific studies provide evidence that for-profit ESRD facilities engaged in gaming behavior that resulted in higher

cost to the Medicare ESRD program and compromised patient safety. Commenters claim that these studies illustrated that "* * * patients in for-profit facilities were EPO "sensitive" during the period of time that payments were being made per administration and they became EPO "resistent" when the reimbursement system changed." These commenters believed that a large portion of increased pharmaceutical costs related to African Americans are based on past over-utilization of anti-anemia drugs and that factoring out the overuse identified in scientific studies may result in a smaller cost difference among racial or ethnic groups.

One commenter asserted that for-profit providers will rely on race and ethnicity adjustments to circumvent the elimination of incentives currently in place related to drugs such as Epogen®.

Response: We thank the commenter for identifying these scientific studies. We plan to consider such information for further analysis of race or ethnicity adjustments in the future.

Comment: Several commenters questioned whether other factors in the model may be correlated with the increased cost associated with treating African American patients. One commenter stated that race and weight or BMI, may be correlated and points to a study that found a correlation between African Americans and higher than average weight and BMI. A commenter also noted that the manufacturer of EPO includes dosing instructions calling for an increase in dose as the patient's BMI increases. The commenter believes that one may infer that treating African American patients may be more costly simply based on their higher than average BMI and associated greater use of EPO.

Another commenter questioned whether adjusting for co-morbidities would address the variability between patients of different races. The commenter stated that there is not enough scientific evidence for CMS to account for every underlying cause of utilization differences among races. A commenter who conducted an independent analysis of the proposed rule asserted that based on their analysis, race is a better predictor of cost than the co-morbidities and onset of dialysis that were specified in the proposed rule.

Many commenters supported the concept of patient level adjustments that are based on a demonstrated variation in resource utilization. MedPAC reiterated this point in referring to our analysis in the proposed rule that demonstrated associations between race and ethnicity and composite rate costs and separately billable payments (74 FR 49966). MedPAC stated that if race and ethnicity predict providers' resource needs, then these factors should be included as adjusters. Alternatively, MedPAC suggested that we include clinical factors that are correlated with race and ethnicity that would make moot the effect of race and ethnicity on predictors' resource needs.

Response: We believe that a portion, but not all, of the incrementally higher dialysis costs among African American patients are accounted for by other patient characteristics in the model, such as body size and co-morbidities. Despite the remaining effect that race has on the model, we have decided not to implement race or ethnicity as case-mix adjustments in this final rule. As described above, we believe that there are specific underlying factors that contribute to higher costs among certain racial groups and intend to study this further. We will continue to assess payments made on behalf of patients under the ESRD PPS during the transition. The results of this additional study potentially could be incorporated into future refinements of the ESRD PPS.

Comment: Several commenters indicated that according to their own analyses, when the basic case-mix adjusters were implemented under the basic case-mix adjusted composite payment system, reimbursement for Chinese, Japanese and other Asians with smaller body size dropped. These commenters were concerned that a case-mix adjuster for race or ethnicity would extend this reimbursement inequality to laboratory tests and medications under the expanded bundle of services in the ESRD PPS, resulting in lower reimbursement for laboratory tests and medications on behalf of average Asian patients, than average White or African American patients. Commenters believed that the basic case-mix variables have little impact on providers' overall cost of care.

One commenter indicated that Asian patients do not have shorter dialysis times nor the associated decrease in the ESRD facility's staffing and salaries. This commenter asserted that Asian patients have the same needs regarding assessment, dietary education and monitoring, psychosocial issues, medications and laboratory tests. The commenter asserted that race and ethnicity adjustments would create a bias against patients of Asian descent and further decrease reimbursement for dialysis care that is already below the national average and create inequalities in reimbursement.

Response: Many of the services described by the commenter have been taken into account in developing the base rate amount. As described above, we are not implementing a case-mix adjustment for race or ethnicity under the ESRD PPS in this final rule. We intend to continue studying the underlying clinical conditions behind the increased cost that is linked to certain racial groups. We note that, as described in section II.F.3. of this final rule, we are finalizing our proposal to retain the adjusters for body size, BSA and low BMI, that are currently in place under the basic case-mix adjusted composite payment system in the final ESRD PPS.

Comment: One commenter was concerned about a decrease in reimbursement for medications noting that beneficiaries of certain races may be perceived as potentially costly, which could result in these patients being denied access to care. Another commenter believed that individuals who require the most resources may be at increased risk of not receiving adequate care for conditions such as anemia and bone and mineral disorders under the ESRD PPS.

Response: We are also concerned about beneficiaries being denied access to care based on racial or ethnic status and are concerned about any potential for a provider to make choices to provide treatment solely based on that provider's perception of an individual's racial or ethnic status. For this reason, and as discussed previously, we have decided to continue to study this issue and therefore, we will not implement race or ethnicity case-mix adjustments under the ESRD PPS at this time. We have been and will continue to monitor inappropriate care based upon race and ethnicity.

Comment: Several commenters believe that the inclusion of calcimimetics and phosphate binders in the ESRD PPS is likely to result in negative consequences disproportionately for African Americans.

Response: As discussed previously in section II.A.3. of this final rule, the implementation of the oral-only medications, including calcimimetics and phosphate binders, into the ESRD PPS will be delayed until January 1, 2014. Potential impacts of including these drugs under the ESRD PPS, including those on racial and ethnic groups, will be addressed through future rulemaking.

Comment: Several commenters asserted that considering each patient's differing makeup, there may be a built-in disparity in patient co-insurance

amounts for relatively the same care plan. Another commenter indicated that a race case-mix adjuster would increase individuals' co-insurance obligations regardless of whether the individual required increased amounts of medications such as ESAs.

Similarly, MedPAC indicated that including payment adjusters for beneficiaries' demographic and clinical characteristics would result in some beneficiaries having higher copayments than others. MedPAC intends to study this issue in the future.

Response: For the various reasons we have discussed above, we have decided to exclude the race and ethnicity case-mix adjustments from the ESRD PPS. Similarly, as described in section II.F.3. of this final rule, we have narrowed the list of patient co-morbidity case-mix adjusters which will decrease beneficiary co-insurance obligations. In doing so, we believe that co-insurance payment obligations will be more uniform among beneficiaries. We are targeting higher payments and the associated higher beneficiary co-insurance obligations to facilities that treat patients with verifiable conditions known to be associated with an increased treatment cost.

Comment: Several commenters indicated that they were unable to replicate UM–KECC's regression analysis that supported the proposed case-mix adjustments in the proposed rule. Commenters further noted that higher costs are not distributed evenly or randomly across the population but are concentrated in areas where demographics are dominated by one group. These commenters also found increased payment by racial group, primarily for medications for African Americans. In addition the commenters' analyses revealed that whites have higher costs compared to Native American, Hispanic and Asian patients.

Another commenter indicated that its analysis differed from the regression analysis set forth in the proposed rule. The commenter's findings suggested that the case-mix adjustment for African Americans would be approximately 11 percent and 3 percent for Whites.

Response: The results of the regression based case-mix adjustments for the race and ethnicity categories are summarized in the proposed rule (74 FR 49965). We believe that the reason for the differing results between our proposed rule analysis and that of the commenter relates to the data that was used. Specifically, we believe that the commenter's data was more limited in scope to the facility or chain with which the commenter was associated. As indicated above, we have decided to study this further and are not implementing race and ethnicity case-mix adjustments in this final rule.

Comment: One commenter indicated that minorities are disproportionately affected by chronic kidney disease (CKD) and believes that the solution lies in addressing the root cause of this problem by providing stage 4 CKD education, pre-dialysis anemia and access care and other means rather than race and ethnicity case-mix adjusters within the ESRD PPS.

Response: We appreciate the commenter's view on this matter and note that kidney disease patient education provisions authorized under section 152(b) of the MIPPA were implemented in the CY 2010 Medicare PFS final rule (74 FR 61894). We intend to evaluate the extent to which patient participation in the new kidney disease patient education benefit impacts the cost of dialysis and whether these patient outcomes would be relevant to the adoption of race or ethnicity adjustments.

Comment: Several commenters believed that the data sources identified in the proposed rule provided a significant amount of data to inform decisions regarding race and CMS currently has the means to implement a case-mix adjuster based on race. Commenters referred to CMS' efforts that have improved the quality of race data including beneficiary surveys, annual file updates from NUMIDENT, and work with the Indian Health Service that helps to identify American Indians and Alaska Natives. Other commenters were skeptical about the implementation of race or ethnicity adjustments and suggested that we conduct further analysis.

Response: As described in the proposed rule, we considered two distinct sources of race and ethnicity data upon which the race or ethnicity adjustments could be modeled. We believe this commenter is referring to the EDB data source. We agree that the accuracy of the EDB data has improved as a result of our supplementary data file matching procedures over the last 15 years such as the annual updates, surveys and coordination with the Indian Health Service (74 FR 49963). Despite these efforts, the core race and ethnicity data for the Medicare population that are sent to us by the Social Security Administration (SSA) on a daily basis from the master beneficiary record (MBR) are not currently collected in a format that is compliant with OMB standards for the collection of this data.

To summarize, OMB requires race and ethnicity data to be collected using a two-question format, with the ethnicity question preceding the race question. In addition, OMB also requires the following minimum set of race categories: (1) White, (2) Black or African American, (3) American Indian or Alaska Native, (4) Asian, and (5) Native Hawaiian or Other Pacific Islander. However, as described in the proposed rule, the SSA's collection instrument includes the following categories: (1) Asian, Asian-American or Pacific Islander; (2) Hispanic; (3) Black (Not Hispanic); (4) North American Indian or Alaska Native; or (5) White (Not Hispanic). Conversely, the SSA's collection instrument groups race and ethnicity into one question with instructions to "check one only." We are obligated to follow OMB standards.

We note that OMB's standards were last updated in the October 30, 1997 **Federal Register** Notice: Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (62 FR 58782). OMB also released Provisional Guidance on the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity on December 15, 2000. That guidance is available at: *http://www.whitehouse.gov/omb/assets/information_and_regulatory_affairs/re_guidance2000update.pdf.*

As a result, these data with EDB are known to be inaccurate. Only an improvement of the MBR's race and ethnicity data collection will provide a long-range solution to the problem. We do not believe that it would be appropriate to establish race or ethnicity adjustments that would be based on EDB data until additional improvements are made to ensure that EDB race and ethnicity data are collected in a manner that is consistent with OMB standards.

Comment: Several commenters suggested that CMS continue to improve the data. One commenter suggested methods set forth in various reports generated from public, private and academic entities. One commenter suggested that HHS issue guidelines for the uniform collection of data on race by health care organizations. Another commenter specified that CMS should consider conducting a mailing to persons with race coded as "other" or "unknown" and evaluate the effectiveness of using surnames to identify the race of enrollees.

One commenter believed that we may be able to develop coding modifiers to further verify the accuracy of the data provided. A commenter also believed that Medicare Advantage plans should be required to collect and report to CMS the race of all Medicare members. The commenter further suggests that the SSA should collect race information on

the SS–5 Form and through the enumeration at birth process using 1997 OMB standards for race.

Response: We appreciate the commenters' suggestions for improving race and ethnicity data. Improving the accuracy of race and ethnicity data by establishing consistent mechanisms by which race and ethnicity data are collected are essential for identifying and addressing health disparities. We are in the process of carrying out provisions of MIPPA and the Affordable Care Act (ACA) of 2010 that require the Secretary of Health and Human Services to evaluate race and ethnicity data and provide recommendations for improving the quality of the data.

We appreciate the commenter's suggestion that Medicare Advantage plans should collect and report the race of their enrollees. We will take this suggestion under consideration, but note that Medicare Advantage plan requirements are beyond the scope of this rule. Similarly, we clarify that it would be beyond our authority to impose requirements on the SSA.

Comment: Several commenters believed that race and ethnicity should not be case-mix adjusted asserting that the current data does not provide a rigorous statistical basis for reaching a reliable conclusion on the relevance of this characteristic.

Other commenters believed that the reliability of CMS' existing data sets (REMIS and EDB) is sufficient for purposes of implementing race and ethnicity case-mix adjusters. Several commenters referred to a presentation at the 2009 American Society of Nephrology meeting that revealed near perfect agreement between the Medicare EDB and REMIS for three major U.S. race groups (Caucasian, African American and Asian) suggesting that race could be used as a case-mix adjuster for these three race groups.

Another commenter believed that ESRD facilities may face operational difficulties in collecting race and ethnicity data, but believed that the 4-year phase-in period would allow providers to operationalize data collection. Other commenters stated that if deemed appropriate upon reconsideration, CMS should implement race and ethnicity adjustments. Several commenters stated that race and ethnicity adjustments would be more administratively manageable to report and would not require ongoing documentation especially for facilities that do not have sophisticated systems capabilities to track multiple patient-level adjusters.

Response: Based on subsequent analyses, we agree with the commenter that the agreement between data collected on the Form 2728, located in SIMS, as compared to data in EDB is very high for Blacks and Whites. However we continue to have concerns that about the level of accuracy for the remaining racial and ethnic groups. Specifically, analyses reveal that the agreement for Asians is considered substantial and low moderate for American Indians or Alaska Natives and Hispanics. As indicated previously, we intend to continue to evaluate race and ethnicity data and provide recommendations for improving the quality of the data and re-evaluate the extent to which it would be appropriate to adopt race or ethnicity adjustments. As described above, we intend to set forth our additional analyses and proposal for handling race or ethnicity adjustments in future rulemaking.

Comment: In comparing the two data analyses conducted by CMS, REMIS and EDB, one commenter believes that payment amounts would vary by as much as $21,000 on behalf of individuals whose race is defaulted to "Other." The commenter believes that this difference is unacceptable considering the volume of Medicare ESRD beneficiaries. Another commenter stated that the category "Other" produced wildly different results for adjusters in REMIS as compared to other databases.

Response: To the extent that we were to implement race or ethnicity payment adjustments in the future, we do not believe that it would be appropriate to provide an adjustment for "Other" as this category may fail to reflect the characteristics of the individual. Rather, we would rely on OMB's established list of racial categories including: (1) White, (2) Black or African American, (3) American Indian or Alaska Native, (4) Asian, and (5) Native Hawaiian or Other Pacific Islander. As mentioned previously we intend to consider the extent to which OMB's guidance for allocating individuals who select more than one racial category into a single category would be appropriate for payment adjustment purposes.

Comment: One commenter believed that we would need to further refine the race and ethnicity categories to avoid distortions that might result from lumping Native Hawaiians (the largest race/ethnic group) with Asians (one of the smallest race/ethnic groups).

Response: As indicated in the proposed rule (74 FR 49963) the EDB is populated with race and ethnicity data that come from the SSA. The SSA's race and ethnicity data are collected on the SS–5 form which groups Asian, Asian-American or Pacific Islander into a single category. We agree with the commenter that to the extent we were to rely on data obtained from the EDB, there would be an increased risk of distortion. We further believe that it would be essential to base any proposed race or ethnicity adjustments on data collected from a source that is supplied by data that is collected in a manner that is consistent with OMB standards.

Comment: One commenter asserted that Native Hawaiians have the highest average BMI and increased rates of obesity and diabetes. As such, the commenter believes that CMS should include a payment adjuster for ESRD patients in the state of Hawaii to reflect the higher costs involved in treating patients in that state.

Response: As described in section II.F.3. of this final rule, we are finalizing the BMI case-mix adjustment under the ESRD PPS. To the extent Native Hawaiians have higher than average BMI, the ESRD facilities that provide treatment to these individuals will be compensated for this factor. In addition, our impact analysis reveals that the ESRD PPS would adequately reimburse ESRD facilities located in Hawaii. Specifically, facilities located in Hawaii are expected to see a 4.2 percent increase in payment. Therefore, consistent with our decision to not implement race or ethnicity adjustments, we decline to adopt the commenter's suggestion.

Comment: One commenter suggested that we collect patient-level data for purposes of determining the extent to which race and ethnicity are independent predictors of cost associated with the treatment of ESRD. The commenter believed that implementation should only occur after CMS has an appropriate mechanism by which to collect the data. Another commenter questioned the extent to which the race and ethnicity variables used in the proposed rule were independent in relation to the other factors being used in the model. The commenter emphasized the importance of independence of the variables to assure accurate payments that are reflective of the differences in cost in treating certain patients. The commenter asserted that the discussion in the proposed rule pertaining to the findings from the different regression models suggests that the variables may not be independent. Thus, the model may result in overpayment to certain patients and underpayment to others.

Response: As we indicated in the proposed rule, the race and ethnicity case-mix adjustments were based on a regression analysis that used patient-level separately billable payments and

facility-level costs (74 FR 49962). Each of the proposed payment variables, including race and ethnicity were independent variables. However, we believe that the race and ethnicity adjustment factors may reflect factors that are not otherwise reflected in the model. We intend to study this further and include our findings in future rulemaking.

Comment: One commenter stated that many minority populations are of lower socioeconomic status and lack sufficient insurance coverage outside of Medicare. As such, the commenter indicated that race and ethnicity adjustments are even more important. Another commenter requested that we consider an adjustment for socioeconomic status to encourage dialysis providers to establish facilities in disadvantaged communities. The commenter suggested that a socioeconomic status adjustment may be a less problematic patient-level adjustment, as compared to other adjustments in the proposed ESRD PPS. For example, the commenter asserted that socioeconomic status cannot be gamed and would not raise privacy issues.

Response: We do not have access to socioeconomic status data within our Medicare databases. However, because Medicaid eligibility is based on an individual's income and resources, we consider it to be one measure of socioeconomic status and one for which we have data. We have started to explore the extent to which Medicaid status is associated with increased cost. To date, we have not found that Medicaid status is associated with increased cost but we intend to study this potential variable in future proposed rulemaking.

Comment: Several commenters believed that we should delay implementation of race and ethnicity case-mix adjusters and continue to investigate the degree to which such adjusters would be appropriate. Commenters asserted that the goal should be to close health disparity gaps first and then create an adjuster for any differences that remain. The commenters stated that to provide an adjustment without fully understanding the cause of the health disparity would create inappropriate incentives.

The commenters suggested that we work to improve the adequacy of data that could be used as the basis of future race or ethnicity adjustments. For example, commenters asserted that specifying the race adjuster eligibility criteria would improve data accuracy and decrease the risk of provider gaming. Commenters requested that we specify the timeframe for completing refinements that would allow for adjustment. In the meantime, commenters stated that we should continue to collect data based on the categories included on the Form 2728 that was implemented on June 1, 2005 and develop a placeholder that recognizes the impact of race on the cost of dialysis. Other commenters believed that we should implement an adjustment for race while working with the community to develop further appropriate case-mix adjusters in the future. Another commenter stated that the initial adjusters could be periodically revised as additional, proven sources of data become available.

Response: As described in the most recent IOM report in December 2009 (Standardization for Health Care Quality Improvement, Institute of Medicine, 2009), Kilbourne and colleagues identify three key phases in addressing disparities: Detecting, understanding and reducing. We are currently in the detecting phase of accurately identifying vulnerable racial and ethnic groups and developing valid measures. Part of this phase involves implementation of a reliable tool for collecting racial and ethnic data that will ensure the linking of data to quality measures. Once we have a more complete understanding of the determinants of health disparities, we will be positioned to consider the extent to which a payment intervention is appropriate. We do not believe that it would be appropriate to implement payment intervention until the earlier phases of detecting and understanding racial and ethnic health disparities have been completed.

As indicated previously, section 185 of MIPPA requires further study to identifying and addressing healthcare disparities in the Medicare program including those related to race or ethnicity. In addition, section 4302 of ACA requires ongoing analysis of race and ethnicity data to detect and monitor for trends in health disparities. In addition to these analyses, we intend to issue a Report to Congress recommending improvements to identifying health care disparities.

Comment: Several commenters believed that we should continue to explore race and ethnicity case-mix adjustments and develop a methodology to collect racial and ethnic data that is reliable for reimbursement purposes. MedPAC suggested that CMS use current OMB categories to collect race and ethnicity data. This data could be collected via Form 2728. Other commenters believed that Form 2728 has sufficiently provided the race and ethnicity data for USRDS utilization analyses for several years.

Other commenters were concerned about the potential for providers to misidentify racial and ethnic status to qualify for greater payments. The commenter suggested that we consider expanding racial and ethnic categories to minimize gaming and account for patients who associate with more than one racial category. Another commenter believed that instructions to patients to identify themselves with only one supplied race and ethnicity category on the form would mitigate data quality issues. Another commenter suggested that patients who elect to not select race or ethnicity categories should default to other or unknown and thus, become ineligible for the race or ethnicity adjustments.

Other commenters indicated that many facilities rely on clerical personnel to complete the Form 2728. The commenter was concerned that this practice may result in incorrect or missing data which would have an impact on reimbursement.

Response: To the extent we were to implement race or ethnicity adjustments in the future, we would rely on a collection instrument that is consistent with OMB standards. However, as discussed previously, we are not including a race or ethnicity adjustment in the ESRD PPS at this time. With the exception of the self-identification criteria, race and ethnicity data collected on the Form 2728 after May 31, 2005 is consistent with the OMB collection standards. As mentioned previously in section II.C. of this final rule, the final ESRD PPS model is based on 2006–2008 data. Therefore, race and ethnicity data collected on the Form 2728 during the timeframe and reflected in SIMS is consistent with OMB's race categorizations. We note that ESRD facility costs and payments on behalf of patients during 2006–2008 that have been incorporated into the ESRD PPS model would not have been limited to incident patients. That is to say, costs and payments on behalf of patients between 2006–2008 included patients for whom the Form 2728 was completed prior to June 1, 2005. As indicated in the proposed rule, the Form 2728 that was in use prior to June 1, 2005 did not reflect the current OMB standards for collecting racial and ethnic information (74 FR 49963).

With respect to addressing individuals who identify with more than one racial category, we note that OMB standards do not permit guiding an individual to select only one race. However, to account for individuals who select more than one racial

category, we believe that it may be possible to allocate these individuals into one race category. OMB has issued guidance to agencies for the allocation of multiple race responses for use in civil rights monitoring and enforcement. The March 9, 2000 OMB bulletin No. 00–02 is available on OMB's Web site at: *http://www.whitehouse.gov/omb/BULLETINS_b00–02/?print=1.*

While we believe that this guidance may also be appropriate for purposes of establishing individuals' most appropriate payment adjustment factor related to racial designation, we intend to consider this issue further and present our analyses in subsequent rulemaking and solicitation of public comments.

In response to the commenters concern that data on the Form 2728 may be incorrect or missing, we believe that for the majority of patients the information is correct. We note that block 49 includes a physician attestation that the information on the form is correct. For this reason, we expect that information collected on the form to be correct and reliable.

In summary, we believe that the use of data collected from the Form 2728 may be appropriate both for purposes of establishing race or ethnicity adjustments and making payment adjustments under the ESRD PPS in the future. However, to ensure consistency with OMB's standards for the collection of race and ethnicity data, we intend to modify the administration instructions for completing the Form 2728 to specify that the information on race and ethnicity must be self reported. We believe that this modification will further improve the accuracy of the race and ethnicity data collected on the Form 2728. In addition, we believe that the physician attestation would verify that the patient had self-reported the racial and ethnic status. At that time we could also consider the extent to which it would be appropriate to expand the race categories.

For the various reasons we discussed above, and after considering the public comments, we are not finalizing race or ethnicity case-mix adjustments in this final rule. We intend to continue efforts in improving Medicare program data on race and ethnicity. As described above, we intend to modify the Form 2728 to ensure consistency with OMB's standards for data collection. We also intend to complete the studies required under MIPPA and ACA that will assist us in identifying and monitoring health disparities on the basis of race or ethnicity. Upon completion of these studies, further analysis of studies referenced by commenters, and using updated data, we intend to re-evaluate the extent to which it would be appropriate to include patient-level case-mix adjustments for race or ethnicity under the ESRD PPS. We will set forth a description of our further analysis and the basis of any proposed race or ethnicity adjustments in rulemaking to the extent that it is warranted.

h. Modality

Section 1881(b)(14)(D)(iv) of the Act, as added by section 153(b) of MIPPA, gives the Secretary the authority to establish an ESRD PPS, which may include payment adjustments as the Secretary determines appropriate. Therefore, the Act gives the Secretary the authority to develop an ESRD PPS under which payment rates are based on dialysis modality.

In the proposed rule, we presented data showing that per treatment composite rate PD costs were approximately 11 percent less than HD costs ($151.15 vs. $168.99) (74 FR 49967). Separately billable PD per treatment payments were about 60 percent less than those for HD payments. (See tables at 74 FR 49967.) We also cited data from the United States Renal Data System (USRDS) (74 FR 49967) showing that the average annual cost for PD patients ($53,327) was substantially less than that for HD patients ($71,889) (74 FR 49967).

Despite these differences in cost between HD and PD, we did not propose to develop an ESRD PPS which uses type of dialysis modality as a payment variable. Using modality as a payment variable would result in increased predictive power in the resulting regression equations. Because composite rate costs and separately billable payments are lower for PD, the use of a modality payment variable would result in substantially lower payments for PD patients. The payment rates for HD patients would be slightly higher, because of the greater volume of HD patients, and the exclusion of the smaller proportion of PD patients from the average payment amount that would apply to HD patients. We stated that we believed the substantially lower payments for PD patients that would result if modality were used as a payment adjuster in the ESRD PPS would discourage the increased use of PD for patients able to use that modality (74 FR 49967). Because we want to encourage home dialysis, in which PD is currently the prevailing mode of treatment, we proposed an ESRD PPS which did not rely on separate payment rates based on modality (74 FR 49967). We stated that by establishing prospective payment rates that are higher for PD patients than they otherwise would be if separate payments were established based on modality, we believed home dialysis would be encouraged for patients able to use PD. We invited comments on this approach.

The comments we received and our responses are as follows:

Comment: Several commenters expressed gratitude that CMS had not proposed an ESRD PPS in which differential payments were made based on modality. By using the same base rate for HD and PD, the commenters maintained that this would encourage PD. A few commenters cited their own personal experiences on both HD and PD, pointing out the benefits of home PD, and how their quality of life, certain clinical outcome measures, and sense of well being improved after switching to PD. These commenters stated that more should be done to encourage PD.

Response: We agree with the commenters, and we are finalizing the application of the same base rate payment amount for both HD and PD patients. We are hopeful that this will encourage the use of home PD for those patients able to benefit from that modality.

Comment: One commenter stated that in countries such as Canada and Australia, payers incentivize PD when patients can benefit from dialysis at home. The commenter noted that currently there is no incentive to make PD more available in the U.S., but supported one bundled payment system for both HD and PD.

Response: We believe that by providing one basic payment rate under the ESRD PPS for both PD and HD, facilities will have a powerful financial incentive to encourage the use of home PD among dialysis patients where feasible. Accordingly, we are finalizing the application of the same base rate payment amount under the ESRD PP for both HD and PD patients in this final rule. We will be monitoring the degree to which home dialysis increases in the future under the ESRD PPS.

In the proposed rule, we pointed out that the case-mix adjustments proposed for pediatric patients (74 FR 49981), distinguished between HD and PD as a payment variable. The small number of pediatric dialysis patients, the limited ability of the two-equation regression model to accurately predict the separately billable MAP for pediatric patients, and the far greater prevalence of PD among pediatric patients, led us to examine alternative approaches in devising case-mix adjustments for those patients. The pediatric payment

adjustments described in the proposed rule, used modality, in part, to determine the case-mix adjusters for pediatric dialysis patients.

For responses to the comments on the use of modality as a payment variable in connection with the proposed pediatric payment model, see section II.G. of this final rule.

4. Proposed Facility-Level Adjustments

a. Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act, as added by section 153(b) of MIPPA, specifies that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment by a geographic index, such as the index referred to under the existing basic case-mix adjusted composite payment system.

In the current basic case-mix adjusted composite payment system, we use an index based on hospital wage and employment data from Medicare cost reports. In the CY 2006 PFS final rule with comment period (70 FR 70167), we announced our adoption of the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to develop revised urban/rural definitions and corresponding wage index values for purposes of calculating ESRD composite rates under the basic case-mix adjusted composite payment system. OMB's CBSA-based geographic area designations are described in OMB Bulletin 03–04, originally issued June 6, 2003, and is available online at: *http://www.whitehouse.gov/omb/bulletins/b03-04.html.* In addition, OMB has published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. We stated that this and all subsequent ESRD rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage index (73 FR 69758). The OMB bulletins may be accessed online at: *http://www.whitehouse.gov/omb/bulletins/index.html.*

We also stated in the proposed rule that we intended to update the current ESRD wage index values annually (70 FR 70167). The ESRD wage index values used in the basic case-mix adjusted composite payment system are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix (71 FR 69685 and 73 FR 69758). Also as stated in proposed rule, we applied the current ESRD wage index to a 53.711 labor-related share of the composite rate. As we indicated, this labor-related share was developed from the labor-related components of the ESRD composite rate market basket (70 FR 70168). The ESRD wage index in the current basic case-mix adjusted composite payment system applies a wage index budget neutrality factor to ensure that the ESRD wage index is made in a budget neutral manner (70 FR 70170). As we previously noted, in our current basic case-mix adjusted composite payment system, we incorporate the wage index budget neutrality factor into the wage index. We compute a wage index factor and adjust it so that wage index budget neutrality can be achieved by the labor share component only.

In the ESRD PPS proposed rule (74 FR 49968), we proposed to use the same method and source of wage index values as we have been using for the basic case-mix adjusted composite payment system. Specifically, we proposed that the ESRD wage index values to be used in the proposed ESRD PPS, would be calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act, and would utilize pre-floor hospital data that are unadjusted for occupational mix (74 FR 49968). We also proposed to use the OMB's CBSA-based geographic area designations to define urban/rural areas and corresponding wage index values. Consistent with those definitions, we proposed to define urban and rural areas at § 413.231(b) (74 FR 50024).

Under the current basic case-mix adjusted composite payment system, we apply a floor as a substitute wage index for areas with very low wage index values. However, we have gradually reduced the ESRD wage index floor from 0.90 in CY 2005, to 0.85 in CY 2006, 0.80 in CY 2007, 0.75 in CY 2008, 0.70 in CY 2009, and 0.65 in CY 2010 (74 FR 33637 and 33638). We also stated that a gradual reduction was needed to ensure patient access in areas that have low wage index values, and that we would continue to reassess the need for a wage index floor in future years.

In the ESRD PPS proposed rule, we proposed not to adopt a wage index floor (74 FR 49968). We noted that ESRD facilities affected by the floor may opt to go through the transition to the ESRD PPS, where the portion of their payment that is based on the ESRD PPS would be gradually increased from 25 percent of their payments in 2011 to 100 percent of their payments in 2014. We intended to continue to gradually reduce the ESRD wage index floor for the portion of the payment that is based on the current basic case-mix adjusted composite payment system during the transition. Applying a gradual reduction only to the floor that applies to the existing basic case-mix adjusted composite payment system ESRD wage index was intended to accelerate the decline in the floor so that ESRD facilities would be less dependent on the floor. At the end of the transition, we indicated that we would apply their actual wage index values (74 FR 49968).

In CY 2006, while adopting the CBSA designations for the basic case-mix adjusted payment system, we identified a small number of ESRD facilities in both urban and rural areas where there are no hospital data from which to calculate ESRD wage index values. Since there are ESRD facilities in these areas, we developed policies for each of these areas. The areas with ESRD facilities that have no hospital data are rural Massachusetts, rural Puerto Rico, and Hinesville, GA (CBSA 25980). In the ESRD PPS proposed rule (74 FR 49969), we proposed to continue with our current policies for rural Massachusetts and Hinesville, Georgia (74 FR 49969). For rural Massachusetts, we proposed to adopt the methodology originally adopted, for CY 2008 PFS final rule, in which we compute the entire rural area consists of Dukes and Nantucket Counties. We determined that the borders of Dukes and Nantucket Counties are contiguous with CBSA 12700, Barnstable Town, MA, and CBSA 39300, Providence-New Bedford-Fall River, RI for establishing a wage index value. For Hinesville, GA (CBSA 25980), we proposed to continue to use the methodology, that is, we computed the average wage index value of all urban areas within the State of Georgia, that was adopted in the CY 2007 PFS final rule.

Since the publication of the ESRD PPS proposed rule, we have determined that there is an additional urban area, Anderson, South Carolina (SC) (CBSA 11340), with no hospital data. For this urban area, Anderson, SC, we are using the same methodology we have used for the other urban area with no hospital data, that is, Hinesville-Fort Stewart, GA (CBSA 25980). Under the methodology used for that area, we computed the average of all urban areas within the State of South Carolina. We continue to believe that this method of establishing a wage index value for areas with no hospital data is the most appropriate method.

We did not receive comments on the proposed continuation of our current policies for rural Massachusetts and Hinesville, Georgia. Therefore, in this

final rule we are finalizing the same methodology we have used for areas with no hospital data in the past, that is, compute the average wage index value of all urban areas within the state and use that value as the wage index.

In the ESRD PPS proposed rule (74 FR 49969), we proposed to eliminate the wage index floor under the ESRD PPS and to use the value for rural Puerto Rico (0.4047) that has been used by other payment systems for rural areas that do not use a wage index floor. In particular, we have previously applied the ESRD wage index floor for rural Puerto Rico, because all areas in Puerto Rico that have a wage index were eligible for the ESRD wage index for the proposed ESRD PPS (74 FR 49969).

We also proposed to use the labor-related share as measured by the proposed ESRD bundled market basket, which was 38.160 percent in the proposed rule (74 FR 49969, 50003). Our proposed adjustment for wages was set forth in § 413.231 (74 FR 50024).

For the proposed rule (74 FR 49969), we used the most current final wage index available at that time to complete the analysis. As we indicated, we anticipated that the proposed CY 2011 ESRD PPS wage index data for purposes of the ESRD PPS (that would not include any wage index budget-neutrality adjustment) along with the CY 2011 proposed update to the existing basic case-mix adjusted composite payment system, would be published in the CY 2011 PFS proposed rule (75 FR 40167 through 40168). We also proposed to publish the final CY 2011 ESRD PPS wage index along with the CY 2011 final rule update to the existing basic case-mix adjusted composite payment system in the CY 2011 Physician Fee Schedule final rule, which we expect would be published in November of 2010 (74 FR 49969).

The comments we received on the wage index proposal and our responses are set forth below.

Comment: One commenter indicated that the CMS' use of the composite rate separately billable wage index listed on the facility level impact file is inaccurate and questioned the accuracy of the spreadsheet used in the proposed rule. Also, the commenter believed that the labor-related share of the proposed bundle would be significantly lower than the share under the current rate.

Response: The labor-related share based on the ESRD PPS bundled market basket ESRDB is lower than the labor-related share under the basic case-mix adjusted composite payment system. This is due to the fact that the labor-related share for the current system does not include the labor-related share component associated with separately billable items and services. The labor-related share in the proposed ESRDB market basket was 38.160 percent (74 FR 50003). This share represents the proportion of an ESRD facility's payment that is adjusted for geographic wage differences. For this final rule, in response to public comment, we made several methodological changes to the ESRDB market basket described in section II.J. of this final rule. The revised labor-related share is 41.37 percent.

Comment: Many of the commenters agreed that for some rural facilities, additional staff must be recruited from nearby large cities, and travel costs and wage premiums are paid to encourage employees to endure the long commutes.

Response: The wage data used to construct the wage index are updated annually, based on the most current data available and are based on OMB's definitions when applying the rural definitions and corresponding wage index values. As a result, the wage index reflects increased efforts by rural ESRD facilities.

Comment: Commenters believed that the wage index floor should be maintained for all rural geographic locations to prevent access barriers and resulting rural disparities. The commenters also expressed concern that the proposed removal of this floor would aggravate disparities in care and would impair access to care at rural facilities.

One commenter believed that the elimination of the wage index floor will result in a decline in a per treatment cost and questioned the adequacy of the methodology used to develop the wage index. Commenters from Puerto Rico strongly urged CMS to retract its proposal to eliminate the wage index floor applicable to dialysis services rendered in Puerto Rico in order to avoid endangering timely and accurate renal dialysis services to their patients. The commenters also believed that the wage index values are flawed because of the use of 4-year-old data to calculate current values in all areas of Puerto Rico.

Response: As stated above, the wage data used to construct the wage index are updated annually, based on the most current data available and are based on OMB's definitions when applying the rural definitions and corresponding wage index values. Since publication of the ESRD PPS proposed rule, we have proposed a CY 2011 wage index floor of 0.60 for the case-mix portion of the blended payment for purposes of the transition in the CY 2011 PFS proposed rule (75 FR 40167).

The only CBSAs that would be affected by the proposal to eliminate the wage index floor value for the ESRD PPS wage index are located in Puerto Rico. In Puerto Rico, the majority of ESRD facilities' wage indices are significantly below the current floor. As a result of public comments, we believe maintaining the wage index floor under the ESRD PPS will benefit ESRD facilities that have low wage index values.

Therefore, for this final rule, we will finalize our proposal regarding the use of the OMB's CBSA-based geographic area designations to define urban/rural areas and corresponding wage index values as proposed. Also, although we proposed to eliminate the wage index floor under the ESRD PPS, we will continue to apply the wage index floor during the transition to the PPS portion of the ESRD PPS payment in 2011. We note that eliminating the wage index floor over the course of the transition, provides an additional cushion to those facilities going through the transition, because they will continue to receive the benefit of the floor as they adjust to payments under the ESRD PPS. Although a commenter suggested that we apply the floor to all rural area values, it is important to note that no rural ESRD facilities outside Puerto Rico would benefit from the current floor because their wage indexes exceed 0.60.

As we indicated in the proposed rule (74 FR 49969), we issued the proposed CY 2011 wage index for the composite rate portion of the blended payment in the CY 2011 PFS proposed rule (75 FR 40167) and will respond to public comments and finalize the CY 2011 ESRD PPS wage index in the CY 2011 PFS final rule later this year. Lastly, we are finalizing 413.231 (Adjustment for wages), however, we are revising the provision to indicate the wage index is applied to the labor-related share of the base rate.

b. Low-Volume Adjustment

Section 1881(b)(14)(D)(iii) of the Act requires a payment adjustment that "reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent."

i. Defining a Low-Volume Facility

As indicated above, section 1881(b)(14)(D)(iii) of the Act authorizes the Secretary to define "low-volume facilities" for purposes of a payment adjustment in the proposed ESRD PPS. As discussed in the proposed rule (74 FR 49969), we believed the low-volume adjustment should encourage small ESRD facilities to continue to provide access to care to an ESRD patient population where providing that care would otherwise be problematic. For the proposed rule, UM–KECC performed analyses using data from CMS Medicare cost reports, SIMS, and OSCAR for years 2004–2006 to assist us in determining what the ESRD facility-level characteristics are that best demonstrate a low-volume facility (74 FR 49969). In the proposed rule, we described the methodology used to define a low-volume facility by setting the parameters for ESRD facility size. We explained that the term 'year' would be established by the ESRD facility's final-settled cost report, where the final-settled cost report reports costs for 12 consecutive months (74 FR 49970).

For purposes of exploring possible definitions for low-volume facilities, we began by developing a measure for facility size. Under the initial categorization, an ESRD facility that furnished less than 5,000 treatments per year was considered small, an ESRD facility that furnished 5,000 to 10,000 treatments per year was considered medium, and an ESRD facility that furnished 10,000 treatments per year or more was considered large. We then categorized all ESRD facilities into four ESRD facility ownership types: (1) Independent, (2) regional chains, (3) Large Dialysis Organizations (LDOs), and (4) unknown ownership type. Of the hospital-based ESRD facilities, we found that 75.5 percent were independent, 10.7 percent were members of a regional chain/other category, 0.7 percent were members of an LDO, and 13.2 percent had unknown ownership status.

The comparison between ESRD facility size and ownership type indicated that ownership varied with ESRD facility size and smaller ESRD facilities, especially those with less than 3,000 treatments, were relatively more likely to be independent than larger ESRD facilities. The comparison also indicated that while smaller ESRD facilities were less likely to be members of an LDO than larger ESRD facilities, a relatively large fraction of smaller ESRD facilities were members of an LDO. As a result of the comparison between ESRD facility size and ESRD facility ownership type, we chose to use ESRD facility ownership type as a variable in a two-equation regression analysis to test whether cost varied by ESRD facility ownership type within an ESRD facility size category (74 FR 49970).

We also looked at the distribution of ESRD facility size across ESRD facilities that have an urban or rural status. We found that nearly half of the small ESRD facilities were rural and larger ESRD facilities were less likely to be rural. The comparison also indicated that because most ESRD facilities were urban, even with the lower percentage of small ESRD facilities in urban areas, more urban ESRD facilities than rural ESRD facilities would benefit from a low-volume payment adjustment. As a result of the comparison between ESRD facility size and urban/rural status, we used urban/rural status as a variable in a two-equation regression analysis to test whether cost varies by urban/rural status within an ESRD facility size category (74 FR 49971).

In the proposed rule, we discussed the methodology used to identify the factors that could be targeted to ensure that we had the right population of ESRD facilities that were low-volume as well as the methodology used to identify the treatment threshold (74 FR 49971 through 49975). We found that the cost multipliers for small ESRD facilities were greater than 1.1 for any of the definitions for small ESRD facility size with respect to number of treatments per year and that the cost multipliers tended to decline for successively higher cutoffs for defining small ESRD facilities. We also noted that if a payment multiplier fully reflected the cost multiplier, there would be a strong disincentive for ESRD facilities to increase volume above the cutoff. However, to the extent that a payment multiplier was smaller than the cost multiplier, this disincentive was somewhat diminished (74 FR 49974).

We explained that since the analyses included data that spanned a 3-year period (2004–2006), we further evaluated the three ESRD facility size categories that we applied in the previous regression analysis, that is, less than 2,000 treatments, less than 3,000 treatments, and less than 4,000 treatments per year. We were interested to see the number of small ESRD facilities that were able to maintain their ESRD facility size status each year of the 3-year period. We proposed to use a threshold of ESRD facilities that provide less than 3,000 treatments per year across the 3-year period because it struck a balance between establishing an increment in payment that reflected the substantially higher treatment costs incurred by low-volume facilities (an increment that tended to decrease as the low-volume threshold was raised) but still applied to a sufficiently large number of ESRD facilities to have an impact (74 FR 49975).

In the proposed rule, we explained that in accordance with the statute, we defined low-volume facilities in § 413.232, as an ESRD facility that meets the following criteria: (1) Furnished less than 3,000 treatments in each of the 3 years preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership during the 3 years preceding the payment year (74 FR 49975).

In the proposed rule, we expressed our awareness that there are Medicare-certified ESRD facilities that solely furnished support services and training for home hemodialysis and home peritoneal dialysis to ESRD beneficiaries. We expressed our concern that it may not be appropriate to extend low-volume eligibility to these types of facilities (74 FR 49975).

In addition, in the proposed rule, we expressed our concerns about potential misuse of the proposed low-volume adjustment. Specifically, our concern was that the low-volume adjustment could incentivize dialysis companies to establish small ESRD facilities in close geographic proximity to other ESRD facilities, thereby leading to unnecessary inefficiencies, in order to obtain the low-volume adjustment. To address our concern, we proposed criteria for ESRD facilities to be eligible for the low-volume adjustment. We proposed that for the purposes of determining the number of treatments under the proposed definition of a low-volume facility, the number of treatments considered furnished by the ESRD facility would be equal to the aggregate number of treatments actually furnished by the ESRD facility *and* the number of treatments furnished by other ESRD facilities that are both: (i) Under common ownership with; and (ii) 25 road miles or less from the ESRD facility in question. However, we proposed to grandfather those commonly owned ESRD facilities that had been in existence and certified for Medicare participation on or before December 31, 2010, thereby exempting them from the geographic proximity restriction (74 FR 49975).

In the proposed rule, we discussed that there would need to be a method in place so that existing ESRD facilities that met the definition of a low-volume facility could be identified. We proposed that ESRD facilities could

attest to the FI/MAC that they qualify as a low-volume facility (74 FR 49975 through 49976).

We solicited comment on the change of ownership element of the proposed definition of a low-volume facility. We did not receive any comments and, therefore, we are finalizing the change of ownership element of the low-volume definition at § 413.232.

We did not receive comments on the proposed grandfathering provision nor the ESRD facilities attestation of low-volume status requirement. Therefore, in this final rule, we are finalizing those provisions as proposed. We received a few comments on the appropriateness of applying the low-volume adjustment to training ESRD facilities as set forth below.

Comment: One commenter was opposed to applying the low-volume adjustment to ESRD facilities that solely furnish support services and training to home patients. The commenter believed that because these facilities do not treat patients, they should not be eligible for the low-volume adjustment. Two commenters believed that it is appropriate to apply the low-volume adjustment to eligible ESRD facilities that solely furnish support services and training to home patients. One commenter explained that allowing these types of facilities to be eligible for the low-volume adjustment is consistent with encouraging home dialysis options. Another commenter provided a detailed explanation as to why small facilities that only furnish PD should qualify for the adjustment. This commenter also asked for clarification as to how CMS would identify facilities that solely furnish support services and training and if these facilities would be excluded from the analysis. One commenter expressed concern about CMS' treatment of home dialysis services in the low-volume policy indicating that CMS does not have the ability to properly identify training programs.

Response: We maintain a database of all ESRD facilities and their respective Medicare certifications. We are able to use this database to develop reports and to analyze and monitor the different facility characteristics and trends. The cost reports used in determining low-volume ESRD facilities for the analyses of costs for composite rate and separately billable services identifies both home and in-facility dialysis treatments, including training treatments.

With regard to the comments concerning the facilities that solely furnish support services and training, in our analysis we controlled for the percentage of training treatments in the facility so that the adjustment for low-volume facilities would be independent of costs associated with home dialysis training. Therefore, we are including ESRD facilities that solely furnish support services and training as being eligible for the low-volume adjustment. We believe that including this type of ESRD facility as being eligible for the low-volume adjustment could encourage ESRD facilities in rural areas, to provide home dialysis training. We will monitor the extent to which facilities that solely furnish home dialysis training support receive the low-volume payment adjustment and whether the number of these facilities increases after implementation of the ESRD PPS.

We received many comments on the possible unintended effects of establishing a treatment threshold and other comments on the definition of a low-volume ESRD facility as set forth below.

Comment: Many commenters expressed concern regarding potential disincentives low-volume facilities could have regarding patient care. The commenters suggested that CMS consider strategies for monitoring the low-volume adjustment in addition to those stated in the proposed rule. The commenters claimed that facilities will not offer additional treatments if it means that those additional treatments will render the facilities ineligible for the low-volume adjustment. The commenters also asserted that dialysis chains will establish facilities in a market where another facility is sufficiently servicing a location just to be able to take advantage of the adjustment. The commenter stated that a dialysis chain could create an artificial low-volume facility that purposely operates below its efficiency level in order to receive the adjustment. The commenters recommended that CMS enact controls and measures to prevent gaming of the low-volume adjustment and to ensure that those facilities which serve disadvantaged areas are correctly identified. One commenter suggested that CMS only apply the adjustment to facilities that are not within 30 road miles of another facility.

Response: We share the commenter's concerns and agree that there is potential for gaming as a result of the low-volume adjustment. At this time, we are not finalizing any additional criteria or requirements. We believe that the geographic proximity restriction, as described in the ESRD PPS proposed rule (74 FR 49975), produces the same effect as the commenter's suggestion of not allowing ESRD facilities that are within 30 road miles of another ESRD facility to be eligible for the low-volume adjustment. We believe that the commenter's suggestion is too restrictive in that there could be independent small ESRD facilities that are servicing areas efficiently even if there are within 30 road miles of another independent ESRD facility. We will monitor payments under the ESRD PPS and the location of new facilities to determine if changes in the criteria that qualify ESRD facilities as being low-volume are warranted.

Comment: Many commenters supported the low-volume adjustment indicating that the adjustment would encourage small ESRD facilities to continue to provide access in areas where the patient base is low.

Response: We thank the commenters for their support.

Comment: A couple of commenters questioned the rationale we used in determining the treatment threshold. Specifically, the commenters stated that CMS used an arbitrary selection of 3,000 treatments, which ignores the real and measurable higher costs per treatment incurred by low-volume facilities performing 4,000 or 5,000 treatments per year. A few commenters requested that CMS provide a detailed explanation of its methodology for selecting facilities as being eligible for the low-volume adjustment and verify that facilities identified as low-volume meet the criteria of providing less than 3,000 treatments.

A few commenters expressed concern that the proposed treatment threshold of less than 3,000 treatments would capture too low of a population of small facilities leaving out many facilities that they believe should receive the adjustment. Several commenters expressed concern that most pediatric facilities may not qualify based on the less than 3,000 treatment threshold. The commenters suggested that CMS raise the treatment threshold portion of the low-volume definition to less than 4,000 treatments.

Response: We disagree with the comment that our proposal to establish a threshold of less than 3,000 treatments was arbitrary. As discussed in the proposed rule, we began the development of the low-volume adjustment by analyzing facility size. We determined facility size by looking at the total number of treatments that a facility furnished annually because that was the basis for which they receive payment. We used the total treatment counts from cost reports for 2004, 2005, and 2006. We carefully assessed treatment counts beginning at less than 1,000 and moved upward to more than 10,000. We performed comparisons of

different facility characteristics against the different treatment thresholds and studied the trends. We found that in each comparison, when the number of treatments increased, the cost that facilities incurred for composite rate services decreased (74 FR 49970).

For this final rule, we repeated the analyses using cost reports for 2006, 2007, and 2008. We also used SIMS data for total treatments for calendar year 2008 to see the change in the percentage of certain ESRD facility types that would be eligible with a less than 4,000 treatment threshold that may not have been eligible with a less than 3,000 treatment threshold. As displayed in Tables 23 and 24, we compared characteristics of facilities eligible for a low-volume adjustment that are based on a 3,000 treatment threshold for determining low-volume status to characteristics of facilities eligible for the low-volume adjustment that are based on a 4,000 treatment threshold. We found the percent of Medicare HD-equivalent dialysis treatments that would qualify for the low-volume adjustment increased from 0.7 percent using a 3,000 treatment threshold to 1.9 percent using a 4,000 treatment threshold. The tables also show that when compared to larger facilities, facilities that would be eligible for the low-volume adjustment are more likely to be located in a rural area, less likely to be part of an LDO, more likely to be hospital based, likely to have a somewhat higher percentage of Medicare patients, more likely to be a pediatric facility, more likely to have previously received an isolated essential facilities (IEF) composite rate payment exception, and more likely to concentrate on home dialysis.

Based on the commenter's arguments and our subsequent analysis regarding the treatment threshold, in this final rule, we are finalizing a threshold of less than 4,000 treatments and we are revising the regulation at § 413.232 to reflect this threshold.

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Table 23: Characteristics of facilities eligible for a low volume adjustment that is based on a 3,000 treatment threshold for determining low volume status, 2008*

Facility type	% of Medicare HD-equivalent treatments**	Rural	Facility ownership: Large dialysis organization	Hospital based	% Medicare (based on Cost Reports)	Facilities with at least 50% of Medicare treatments for pediatric patients	Isolated Essential Facility (IEF) before 2005	Facilities with only home dialysis treatments on Cost Reports
Low volume facility: Did not open or close and reported < 3,000 treatments each year from 2006-08^	0.7%	42.0%	38.1%	42.0%	74.3%	12.2%	2.2%	16.2%
Other facilities that reported < 3,000 treatments during 2008	2.2%	26.1%	31.6%	15.7%	69.1%	2.3%	0.5%	9.7%
Facilities with ≥ 3,000 treatments	97.1%	21.8%	64.4%	9.5%	72.1%	0.3%	0.9%	1.0%

*Data on the total number of treatments for each facility were obtained from SIMS. The reported in-center treatments from SIMS were added to the estimated treatments for home dialysis patients, using the number of home dialysis patients reported in SIMS and the average number of treatments per patient year from Medicare outpatient dialysis claims. Excludes facilities with data on total treatments not available in SIMS for 2008 (n=75).
**Based on 37.4M HD-equivalent treatments on Medicare claims for 5,108 facilities in 2008.
^For hospital-based facilities, eligibility for the low volume adjustment was established based on the combined treatment counts for both the parent facility and any affiliated satellite facilities that were identified

Table 24: Characteristics of facilities eligible for a low volume adjustment that is based on a 4,000 treatment threshold for determining low volume status, 2008*

Facility type	% of Medicare HD-equivalent treatments**	Rural	Facility ownership: Large dialysis organization	Hospital based	% Medicare (based on Cost Reports)	Facilities with at least 50% of Medicare treatments for pediatric patients	Isolated Essential Facility (IEF) before 2005	Facilities with only home dialysis treatments on Cost Reports
Low volume facility: Did not open or close and reported < 4,000 treatments each year from 2006-08^	1.9%	44.5%	48.1%	29.1%	76.7%	7.7%	1.4%	11.1%
Other facilities that reported < 4,000 treatments during 2008	3.5%	28.4%	37.1%	15.6%	69.3%	1.8%	1.4%	7.6%
Facilities with ≥ 4,000 treatments	94.6%	20.3%	65.1%	9.0%	71.9%	0.2%	0.8%	0.8%

*Data on the total number of treatments for each facility were obtained from SIMS. The reported in-center treatments from SIMS were added to the estimated treatments for home dialysis patients, using the number of home dialysis patients reported in SIMS and the average number of treatments per patient year from Medicare outpatient dialysis claims. Excludes facilities with data on total treatments not available in SIMS for 2008 (n=75).
**Based on 37.4M HD-equivalent treatments on Medicare claims for 5,108 facilities in 2008.
^For hospital-based facilities, eligibility for the low volume adjustment was established based on the combined treatment counts for both the parent facility and any affiliated satellite facilities that were identified

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Comment: One commenter recommended that CMS consider a stratified differential payment to all ESRD facilities based on treatment thresholds. The commenter further explained that under a differential payment method, facilities would receive the largest adjusted payment for the first 1,000 treatments and then as the number of treatments increases, the payment amount would decrease.

Response: We thank the commenter for their suggestion. We will monitor the number of facilities that are low-volume throughout the initial years of the ESRD PPS and analyze their behaviors to decide if we should develop a different methodology in determining low-volume eligibility in future refinements.

Comment: We received a few comments objecting to our proposal to use total annual treatments as a criterion in the low-volume definition. The commenters explained that there are too many variables associated with using treatments, such as, patients hospitalized, patients who travel, patient-visitors, and missed treatments. The commenters stated that a stable method of determining the volume of a facility is by patient census or by counting the number of chairs available for furnishing treatments (stations) in the facility.

Response: We disagree that a stable method of determining the volume of an ESRD facility would be by patient census or stations in the facility. In the proposed rule, we explained that in the initial analysis, an ESRD facility size was defined by the number of treatments (74 FR 49970). Payments to ESRD facilities are paid on a per treatment basis and we noted that patient census accounted for by the number of treatments that are furnished. We believe that furnishing care to patients that get hospitalized, patients who travel, patient-visitors, and those patients that miss treatments is a universal occurrence among all ESRD facilities and, therefore, these circumstances neither serve as an advantage nor a detriment in an ESRD facility's eligibility for the low-volume adjustment. We do not consider patient census or number of stations as indicators of low-volume status, because these would not reflect the actual number of treatments provided. In addition, we continue to believe the use of total treatments, including those covered by other payers, is necessary to determine eligibility for low-volume status.

Comment: A few commenters from hospital associations requested clarification on which treatments would count toward the proposed treatment threshold, because they furnish both inpatient and outpatient dialysis services.

Response: Payment for renal dialysis services under the current payment system and under the ESRD PPS is made to Medicare-certified ESRD providers of services or renal dialysis facilities for furnishing outpatient maintenance renal dialysis items and services. Given that the ESRD PPS pertains to outpatient maintenance dialysis, the low-volume adjustment treatment threshold only pertains to outpatient dialysis and therefore, the treatments counted do not include inpatient dialysis treatments.

Comment: One commenter suggested that CMS include payer mix as a criterion in determining the eligibility of a low-volume facility. The commenter expressed concern that facilities that have a higher percentage of Medicare-only patients, or patients that are Medicare and Medicaid eligible, have a high risk of having low profit margins.

Response: We disagree with the commenter that payer mix should be used as a criterion in determining low-volume eligibility. As we stated in the proposed rule (74 FR 49969), we believe the low-volume adjustment is intended to encourage small ESRD facilities to continue to provide access to care to an ESRD patient population where providing that care would otherwise be problematic. Therefore, we will provide an adjustment based on the volume of treatments provided and not on the basis of a payer mix. We note that many ESRD facilities determined eligible for the low-volume adjustment have a high percentage of Medicare patients (see Table 24).

Comment: Some commenters suggested that the implementation of the low-volume criteria should be more specific and clear in stating eligibility for the adjustment. Two commenters questioned how CMS will determine when a facility reaches its 3000th treatment. The commenters suggested that one way we could determine when a facility reached the 3,000 treatment threshold is to use Medicare claims. The commenter explained that if CMS uses Medicare claims to make this determination, then this would suggest that CMS is not including non-Medicare treatments. The commenters suggested that the alternative to using Medicare claims would be to use cost reports. However, the commenters expressed concern that using cost reports would create too long of lag time from when the facility is no longer eligible for the low-volume adjustment and when the FI/MAC would be able to identify total treatments. The commenters expressed concern that using the cost reports to verify that a facility does or does not continue to be eligible for the low-volume adjustment means that CMS would retroactively collect monies paid out on all treatments that exceeded the threshold in that payment year. Other commenters suggested that CMS use cost reports to terminate the application of the low-volume adjuster at the time the cost report is submitted and to not claw back the dollars already paid out.

Response: We believe that we were explicit in our discussion of criteria in the proposed rule (74 FR 49975), but we agree that we did not discuss the implementation in the proposed rule. We will provide additional information on the implementation of the low-volume adjustment in the future. Therefore, we are finalizing the low-volume definition and the applicable criteria as set forth in § 413.232.

We used all treatments including non-Medicare treatments from the cost reports to establish the low-volume threshold, as we believe that inclusion of all treatments regardless of payer type represents the true volume of treatments that are provided to ESRD patients. If we had not included treatments from other payer types, we would have not determined the actual volume of services provided to individuals with ESRD. Therefore, we will use cost reports to confirm facility status as low-volume.

We agree with the commenter that there is a lag time from when the facility may no longer be eligible for the low-volume adjustment and when the FI/MAC finalizes its cost report for that payment year. It is our understanding that ESRD facilities have accounting systems in place that allow them the ability to record the number of patients that they currently care for, and are therefore aware of the number of treatments it furnishes on a monthly basis.

We recommend that once a facility determines it has furnished over 4,000 treatments in the payment year that it would notify its respective FI/MAC that it no longer qualifies as a low-volume facility and request to no longer have the adjustment applied to its treatments. Where a facility no longer meets the eligibility requirements and does not notify its FI/MAC, CMS will develop procedures to ensure that ESRD facilities receive the appropriate payments. We will address these procedures in detail in the future.

Comment: A few commenters stated that they do not believe that the data CMS used to develop the low-volume adjustment was appropriate. The commenters explained that cost reports

have not been used for purposes of setting payment and that their experience with cost reports is that they typically have extreme values/errors that can distort results. The commenters suggested that CMS perform a more detailed review of the individual facilities that it identified as being qualified to receive the low-volume adjustment to ensure that the correct facilities are being identified. The commenters recommended that we consider adhering to the statutory recommendation of a 10 percent adjustment in absence of clear, concrete data.

Response: We use the cost report information to obtain facility level information that includes facility costs for composite rate services and the number of dialysis treatments provided by a facility. Because the low-volume payment adjustment is a facility level adjustment, whereby an ESRD facility would receive a payment adjustment based on the number of maintenance dialysis treatments it furnished, we believe the cost report would be the appropriate source to obtain that information. We agree with the commenter that in our data analysis for the ESRD PPS, we found that there were individual cost reports with extreme values or errors and a methodology has been used to exclude these records from the analyses (discussed further in section II.C. of this final rule). We will be monitoring the use of the low-volume adjustment to ensure that appropriate ESRD facilities, which have not exceeded the 4,000 treatment threshold, will receive the low-volume payment adjustment. In the meantime, we believe using the adjustment derived from the regressions analysis is a better measure of the costs of low-volume facilities.

Comment: We received two comments requesting clarification of why we used 89 low-volume facilities in the low-volume adjustment analysis but listed 166 low-volume facilities in the impact file. The commenters provided examples of facilities that were identified by CMS as low-volume in the impact analysis, but according to their research, did not meet the low-volume criteria, such as (1) 6 facilities closed in 2007 or 2008; (2) 11 facilities had greater than 3,000 total treatments for cost report year 2006; (3) 2 facilities were start-ups or may have changed ownership in 2007; and (4) 30 facilities have zero workstations which would indicate that they appear to be home dialysis programs. The commenters stated that these examples indicate that CMS is incorrectly identifying facilities as low-volume.

Response: As discussed in the proposed rule (74 FR 49969), the data used for the regression analysis which was used to determine the magnitude of the adjustment for low-volume facilities (not to identify the actual ESRD facility), was made from Medicare cost reports, SIMS, and OSCAR for the years 2004, 2005, and 2006. Using the data available at the time the analysis was completed, we estimated that 89 facilities with cost report data available for the regression analysis would qualify as low-volume facilities (74 FR 49975).

However, to assess the impact of the ESRD PPS in 2011, we used the most recent data available to determine total facility treatments. Because cost reports for 2007 were generally not complete at the time of the analysis, we used SIMS data to identify low-volume facilities that would be eligible for the adjustment. The information in SIMS is populated from the Annual Facility Survey which is submitted by all ESRD facilities on a yearly basis. Based on the data available at the time the impact analysis was completed, 166 facilities met the low-volume definition proposed at § 413.232 (74 FR 50018). Therefore, it is possible that there is conflict between CMS's data and the data that was being analyzed by the commenter due to the timing of when the analysis was completed and the difference in data sources.

Comment: One commenter disagreed with the proposed requirement that an ESRD facility must provide less than the treatment threshold for three consecutive years before becoming eligible for the low-volume payment adjustment if the ESRD facility serves a population of patients located in remote areas. The commenter suggested reducing the qualification time period to one year. One commenter expressed concern that limiting the low-volume adjustment to facilities that have been in operation for three years would freeze the number of ESRD facilities in rural areas, thereby causing patient access issues.

Response: We appreciate the commenter's suggestion however we do not have a mechanism in place to determine if a facility is in a remote area. We discuss rural facilities later in this section of this final rule.

We believe that a 3-year waiting period serves as a safeguard against facilities that have the opportunity to take a financial loss in establishing new facilities that are purposefully small. We structured our analysis of the ESRD PPS by looking across data for three years as we believe that the 3-year timeframe provided us with a sufficient span of time to view consistency in business operations.

Comment: Several commenters recommended that the IEF be considered eligible for the low-volume adjustment regardless of the number of treatments they provide each year. Two commenters expressed concern that twelve of the 37 facilities with current IEF Medicare exceptions exceeded the 3,000 low-volume threshold. The commenters believe that the facilities that currently have IEF status have been deemed as an IEF through the exception process by providing evidence of their excess costs due to furnishing dialysis treatments in areas that are isolated. One commenter suggested that CMS review the cost reports for these IEFs and base the adjustment on current and accurate costs. Another commenter suggested the same idea but added that the adjustment be at least 10 percent.

Response: To be eligible for an IEF exception rate under the current basic case-mix adjusted composite payment system, an ESRD facility was required to demonstrate that it met the criteria established by us. As discussed in section II.L. of this final rule, all exceptions currently in place will no longer apply under the ESRD PPS. The IEFs that retained their exception rate after the implementation of the basic case-mix adjusted composite payment system will no longer be able to retain that rate after the implementation of the ESRD PPS. As a result, there is no mechanism to reassess or grant exceptions. However, in the event that an ESRD facility elects to receive payment under the ESRD PPS transition period, any existing exceptions would be recognized for the purpose of the basic case-mix adjusted composite payment system portion of the blended payment through the transition.

In the proposed rule, we indicated that there are currently 37 facilities that retained their exception rates (74 FR 50018). However, the 37 facilities are not exclusively IEFs. The total represents both facilities that met the criteria for an IEF exception and facilities that demonstrated they have atypical service intensity.

We do not believe that IEF facilities should automatically be considered low-volume because the criteria required for the IEF exceptions differ from the criteria established to be eligible for the low-volume adjustment.

Comment: One commenter recommended that CMS develop a methodology similar to the one used to identify critical access hospitals (CAH). The commenter further explained that this would include mileage proximity to

another dialysis facility as well as number of treatments per year.

Response: We appreciate this suggestion; however, we believe that ESRD facilities and CAHs are not comparable provider types. CAHs, defined at section 1820(c)(2)(B) of the Act, furnish a multitude of services and have provider-specific conditions of participation, and therefore, have criteria established to identify them. We believe that we have developed criteria that are appropriate to establish if an ESRD facility is eligible for a low-volume payment adjustment. Therefore, as we indicated in the previous response, we are finalizing the criteria to be used to determine low-volume eligibility in § 413.232. We will monitor the growth of low-volume facilities to see if additional criteria are warranted in the future.

Comment: Several commenters expressed concern that the low-volume adjustment would not "level the marketplace between competitors and therefore would not help the average small dialysis organization (SDO)". Some commenters stated that CMS should support small businesses because most SDOs are dependent on Medicare patients for the majority of their treatments. The commenters further stated that only facilities that are not part of an LDO should receive the low-volume adjustment because in comparison with the LDOs, SDOs furnish a small percentage of the dialysis patient population. As a result, commenters claimed that they are unable to benefit from the economies of scale of LDOs.

Response: We appreciate the commenters' concerns, however, we continue to believe that the definition of a low-volume facility discussed in the proposed rule (74 FR 49975), and subsequently modified by this final rule which increased the treatment threshold from 3,000 treatments to 4,000 treatments, identifies the ESRD facilities that incur high costs for furnishing renal dialysis items and services in areas that would otherwise be problematic. We believe that with our data analysis which provided empirical evidence of higher costs and our selection of criteria, we have identified those facilities that are low-volume. We note that in response to comments from SDOs, we have done an analysis to compare how the smaller dialysis facilities that are neither low-volume nor affiliated with a large dialysis organization will fair after implementation of the ESRD PPS. This analysis is discussed in section IV.B.1. of this final rule.

We received a few comments on the proposed geographic requirements used to determine the number of treatments furnished by an ESRD facility to be eligible for the low-volume payment adjustment as set forth below.

Comment: One commenter expressed concern that the low-volume adjustment should be developed based on the proximity of a facility to all other facilities and the total volume of services a facility furnishes. The commenter suggested that CMS implement a low-volume adjuster that is based on the total volume and proximity of the facility in question to other facilities. Another commenter suggested that CMS consider the regularity and frequency of dialysis care that patients need when determining the distance threshold as most dialysis patients are treated three times weekly. The commenter indicated the 25 road mile standard may not be appropriate and that CMS may want to consider a shorter distance.

Response: In the proposed rule, we explained that we were concerned about the potential misuse of the proposed low-volume adjustment because the low-volume adjustment could incentivize dialysis companies to establish small ESRD facilities in close geographic proximity to other ESRD facilities leading to unnecessary inefficiencies. Therefore, for the purposes of determining the number of treatments, we proposed that the number of treatments considered furnished by the ESRD facility would be equal to the aggregate number of treatments furnished by the other ESRD facilities that are both under common ownership, and 25 road miles or less from the ESRD facility in question. We developed the proximity criteria as a parameter to be used by the FI/MACs when they evaluate eligibility for the low-volume adjustment of new facilities that open in the future (74 FR 49975). We do not believe that the frequency that a patient receives dialysis treatments is relevant to determine the location of a new facility as the distance traveled would be different for each patient.

Therefore, for the reasons above and those set forth in the proposed rule (74 FR 49975), in this final rule we are finalizing the geographic requirements used to determine the number of treatments furnished by an ESRD facility, which is to consider the total number of treatments furnished by an ESRD facility to be equal to the aggregate number of treatments furnished by the other ESRD facilities that are both under common ownership, and 25 road miles or less from the ESRD facility in question, to be eligible for the low-volume payment adjustment at § 413.232.

Comment: One commenter expressed concern that although they agree with the extra monies being allocated to high cost facilities for meeting the low-volume criteria, the effect on the patients that receive care in these facilities will be an increase in their co-insurance amounts.

Response: We agree with the commenter that the ESRD PPS will affect patient co-insurance amounts. However, we note that this adjustment was required under the statute.

ii. Defining the Percent of Increase

Section 1881(14)(D)(iii) of the Act also requires the ESRD PPS include a "payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment not be less than 10 percent." In the proposed rule, we discussed the definition and our analysis for a low-volume facility (74 FR 49969). Based on the definition and the analysis, the resulting low-volume payment adjustment was determined to be 20.2 percent (74 FR 49974). Using our proposed low-volume criteria, we measured the payments received by these ESRD facilities and determined that 76.4 percent of ESRD facilities meeting the proposed low-volume criteria would get an adjustment of 10 percent or more increase in payment relative to what they received under the current system.

In our proposed rule (74 FR 49977), we proposed a 20.2 percent increase to the base rate to account for the costs incurred by low-volume facilities for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014. The proposed low-volume adjustment policy was set forth at proposed § 413.232 (74 FR 49969). We invited comments on the low-volume facility proposed adjustment, which was discussed above.

In addition, for purposes of determining the appropriate adjustment for the low-volume facilities defined above, we considered other options in addition to the 20.2 percent adjustment (74 FR 49978). As mentioned previously, section 1881(14)(D)(iii) of the Act requires the payment adjustment for low-volume facilities be not less than 10 percent during the transition. One alternative we considered in determining the adjustment for low-volume facilities was the minimum statutory adjustment

of 10 percent. We stated that this adjustment would provide relief to low-volume facilities of the costs they incur to provide services. In addition, providing a lower payment adjustment results in less of a decrease in the ESRD PPS base rate that would apply to treatments furnished by all ESRD facilities and less beneficiary co-insurance obligation.

The other alternative we mentioned for the low-volume adjustment was use of the midpoint between the statutory adjustment of 10 percent and the results of our data analysis which was 20.2 percent (74 FR 49978). We stated that we believed that a 15 percent increase could establish an appropriate adjustment amount that would provide low-volume facilities the incentive to utilize resources more efficiently and control their costs.

We invited comments on these alternative options for determining the percent low-volume adjustment.

The comments we received on this proposal and our responses are set forth below.

Comment: Two commenters recommended that we reduce the 20.2 percent increase to the minimum 10 percent permitted by law because at 10 percent, facilities would be less likely to deny treatments to ensure that they remain under the threshold.

Response: For this final rule, we updated our ESRD PPS model with data for 2006, 2007, and 2008 and found that with a treatment threshold of 4,000 treatments, the updated increase to the base rate is 18.9 percent. We believe that since we will be monitoring payments under the ESRD PPS and the location of new facilities as they are established, the 18.9 percent increase to the base rate is an appropriate adjustment that will encourage small facilities to continue to provide access to care. In addition, we believe it is more appropriate to use the regression driven adjustment rather than the 10 percent minimum adjustment mentioned in the statute. We believe that using the regression driven adjustment which is based on empirical evidence allows us to implement a payment adjustment that is a more accurate depiction of higher costs.

Therefore, in this final rule we are finalizing a 18.9 percent increase to the base rate to account for the costs incurred by low-volume facilities for renal dialysis services furnished on or after January 1, 2011.

c. Alaska/Hawaii Facilities

Section 1881(b)(14)(D)(iv) of the Act permits the Secretary to include other payment adjustments as the Secretary determines appropriate. The basic case-mix adjusted composite payment system currently does not provide a separate adjustment for ESRD facilities located in Alaska and Hawaii. However, some prospective payment systems, such as the hospital inpatient PPS and the inpatient psychiatric facility PPS, provide a cost of living adjustment (COLA) for facilities located in Alaska and Hawaii. These COLA adjustments are applied to the non-labor portion of the payment and are based on the rationale that the wage index adjustment to the labor portion of the payment is not sufficient to provide for the higher costs incurred by facilities in Alaska and Hawaii. For example, the same supplies used by an ESRD facility located in Hawaii may cost more because there are additional (higher) transportation costs incurred to receive the same supplies compared to an ESRD facility located in the United States mainland. An analysis completed for the 2008 Report to Congress indicated there was no need for a COLA for these areas. After all adjustments (including wage and other adjustments), our analysis of ESRD facilities located in Alaska and Hawaii did not demonstrate any adverse impact from the ESRD PPS.

In the proposed rule, we stated that our analysis continues to support that the ESRD PPS would adequately reimburse ESRD facilities located in Alaska and Hawaii (74 FR 49978). Therefore, we did not propose to adopt COLA adjustments for ESRD facilities in Alaska and Hawaii under the ESRD PPS. We invited public comments on the proposal.

We received a few comments regarding the COLA for Alaska and Hawaii as set forth below.

Comment: Two commenters believed that the adjustments contained in the proposed ESRD PPS did not adequately address the incremental costs incurred by providing dialysis services and supplies to ESRD patients in Alaska and Hawaii. The commenters urged CMS to reconsider the proposal to not apply a COLA adjustment for these States and indicated that the costs associated with furnishing ESRD treatments in these States remains higher than the cost of providing dialysis services in the contiguous United States.

Response: We recognize the costs incurred by Alaska and the many islands of Hawaii might be attributable to the geographical barriers that may not be a burden to ESRD facilities located in the contiguous United States. However, as we indicated in the ESRD PPS proposed rule (74 FR 49978), the various analyses of ESRD facilities located in Alaska and Hawaii did not demonstrate any adverse impact from the ESRD PPS.

Therefore, we do not believe that application of the COLA would be appropriate. As a result, in this final rule, we are not adopting COLA adjustments for ESRD facilities in Alaska and Hawaii under the ESRD PPS.

d. Rural

Section 1881(b)(14)(D)(iv)(III) of the Act provides that the ESRD PPS may include payment adjustments as the Secretary determines appropriate such as a payment adjustment for facilities located in rural areas. We proposed to define rural facilities at § 413.231(b)(2) as facilities that are outside a Metropolitan Statistical Area or a Metropolitan Division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB (74 FR 49978).

In the proposed rule, we indicated that based on our impact analysis, rural facilities would be adequately reimbursed under the proposed ESRD PPS. Therefore, we did not propose a facility-level adjustment based on rural location and we invited public comments on our proposal (74 FR 49978).

Many of the commenters were concerned about beneficiary access to care that may result from insufficient payment to cover the costs of delivering renal dialysis services to patients in rural areas. This was particularly concerning to commenters who pointed out that ESRD beneficiaries who reside in rural locations already have fewer choices with regard to their care.

We received comments opposing our proposal not to include a facility-level adjustment that is based on rural location, which included the following two assertions: (1) Currently the costs of providing renal dialysis services in rural areas are higher than in urban areas and that costs would further increase by expanding the bundle to include additional medications and laboratory tests; and (2) currently patient access to renal dialysis services in rural areas is limited and insufficient reimbursement would result in closure of these facilities further hindering patient access.

The specific comments that we received on this proposal and our responses are set forth below.

Comment: Several ESRD facilities and health care professionals indicated that rural and small facilities have higher operating cost and lower revenue than the larger, urban or suburban facilities. These facilities are forced to operate at a low margin or at a financial loss. Commenters identified several factors

that contribute to higher costs including: higher recruitment costs to secure qualified staff, a limited ability to offset costs through economies of scale, and decreased negotiating power in contractual arrangements for medications, laboratory services or equipment maintenance. One commenter indicated that compared to the large chains, rural dialysis providers will be unable to compete in negotiating prices for drugs and that this would be especially problematic for the manufacturers' monopoly on EPO and Cinacalcet.

Commenters further noted that the lower revenues among rural ESRD facilities are attributed to serving a smaller volume of patients of which a larger proportion are indigent and lack insurance, and a smaller proportion have higher paying private insurance. Several commenters requested that CMS consider cost differentials in determining whether rural ESRD facilities warrant a payment adjuster. Other commenters requested that small rural facilities be paid based on the cost of providing services to allow them to break even.

Response: As indicated in section II.L. of this final rule, rural facilities are expected to experience a −1.5 percent decline in payments in 2011 due to implementation of the ESRD PPS. We note, however, in accordance with section 1881(b)(14)(A)(ii) of the Act and discussed in section II.E.4. of this final rule, the ESRD PPS base rate was reduced by 2.0 percent so that the estimated total amount of payments in 2011 equals 98 percent of what would otherwise be paid if the ESRD PPS were not implemented. Therefore, rural facilities as a group are projected to receive less of a reduction than urban facilities and many other subgroups of ESRD facilities.

We also note that as described in section II.A.3. of this final rule, implementation of oral-only Part D drugs will be delayed until 2014. This delay will provide small, rural facilities additional time to consider negotiating options for obtaining the most favorable prices on drugs possible. For example, small rural facilities may benefit from joining cooperative arrangements to improve negotiating capacity. We intend to monitor how rural ESRD facilities fare under the ESRD PPS and will consider other options if access to renal dialysis services in rural areas is compromised under the ESRD PPS.

Comment: Some commenters claimed that under the proposed rule, some rural facilities may not receive adequate reimbursement to continue to provide dialysis services in remote areas, resulting in compromised patient access to care. Commenters requested that CMS reassess its data for rural facilities following its reassessment of the data for low-volume facilities.

Response: As the commenter suggested, we reassessed the impact on ESRD facilities based on the final payment adjustments described in this final rule. As mentioned previously, the impact analysis conducted for this final rule indicates a 1.5 percent decrease in total payments to rural ESRD facilities. This small decline reflects the fact that 44.5 percent of low-volume ESRD facilities are located in rural areas (as discussed earlier in this section of this final rule).

Comment: One commenter was concerned that the 3 percent transition budget neutrality adjustment may particularly disadvantage the quality of care for rural dialysis patients, given their higher costs for patient transport, staff salary, and facility maintenance costs.

Response: As described in section II.E.5. of this final rule, we are required by section 1881(b)(14)(E)(ii) of the Act to apply a transition budget neutrality adjustment to account for the effect of the transition on aggregate payments in order to stay within the overall requirement for a 2 percent reduction in expenditures in 2011.

Comment: One commenter questioned whether defining every facility not located within a Metro statistical area (MSA) as rural reflects the variation in the degree of geographical isolation and therefore, cost among providers that are not located within an MSA. The commenter noted that cost differences may exist among facilities classified as rural that are further from an MSA compared to facilities closer to an MSA.

Response: We recognize that there may be differences among rural facilities based on distance from an MSA. However, we do not have a separate mechanism to identify additional variation among facilities in the area outside of a particular MSA.

Comment: A few commenters indicated that in rural settings the nephrologist facilitates care for other specialties by drawing laboratory tests or administering medications for conditions other than ESRD. One commenter stated that because the rural patients often do not have transportation to access these services separately from the dialysis visits, the ESRD facility cooperates by drawing these laboratory tests or administering medications ordered by the nephrologist in the interest of providing the patient with efficient healthcare delivery. The commenter stated that non-ESRD-related laboratory tests and medications ordered by the nephrologist should remain separately payable.

Response: In the interest of patient convenience and in minimizing their transportation burden, we will not preclude ESRD facilities from drawing non-ESRD related laboratory tests on behalf of ESRD patients. As described in section II.K.2. of this final rule, the laboratory tests used for non-ESRD-related purposes would be identified with a modifier and paid separately. Similarly, as described in section II.K.2. of this final rule, there may be instances in which non-ESRD-related medications may be administered in the ESRD facility. These medications would also be identified with a modifier and paid separately.

Comment: Several commenters indicated that ensuring access to home dialysis and home dialysis training is essential to successfully serving a rural area.

Response: We share the commenters' view with respect to the importance of ensuring access to home dialysis and home training. As discussed in section II.A.7. of this final rule, all home dialysis services will be included in ESRD PPS payments to ESRD facilities as of January 1, 2011. In addition, as discussed in section II.A.7. of this final rule, we are finalizing a training add-on adjustment to compensate ESRD facilities for the additional resources associated with home dialysis or self-dialysis training.

For the reasons we explained above in response to the public comments and based on the data analysis conducted for this final rule, we are finalizing the proposed definition of rural facilities at § 413.231(b)(2) of this final rule and we are not implementing a facility-level payment adjustment that is based on rural location.

e. Site Neutral ESRD PPS Rate

For dialysis services furnished before January 1, 2009, the basic case-mix adjusted composite rate differentiated between hospital-based and independent ESRD facilities. That is to say, the composite rate for hospital-based facilities was on average $4.00 more per treatment more than the composite rate for independent dialysis facilities.

Section 1881(b)(12)(A) of the Act, requires a site neutral composite rate so that the payment rate for services furnished on or after January 1, 2009, by hospital-based ESRD facilities is the same as the payment rate paid to independent facilities under the current system. In addition, section 1881(b)(12)(A) of the Act requires that

in applying the geographic index to hospital-based facilities, the labor-related share shall be based on the labor-related share otherwise applied to the renal dialysis facilities. In the CY 2009 final rule (72 FR 69881 and 72 FR 69935), we revised § 413.174, which described the methodology for prospective rates for ESRD facilities, to conform to the statutory requirement.

Section 1881(b)(14)(A)(i) of the Act provides that for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this title to ESRD facilities for renal dialysis services, in lieu of any other payment. Therefore, the site neutral payment provisions discussed above will be incorporated under the ESRD PPS and used to establish a single base rate that will apply to ESRD facilities.

5. Determination of ESRD PPS Payment Adjusters

In the proposed rule, we described the selection of patient characteristics as potential case-mix adjusters using a modeling approach that relied on separate regression equations for CR and SB services (see Table 29 in the proposed rule 74 FR 49979). We stated that the predictive power of the separate estimating equation for CR services in terms of the proportion of variance explained (R^2) was 46.0 percent. The comparable figure for the SB regression equation was 8.7 percent. The overall estimated R^2 for the ESRD PPS payment model is 39.0 percent (74 FR 49978). While the case-mix adjustments were based on separate estimating equations, the equations were combined into a single payment formula for the ESRD PPS. The methodology for combining the separate composite rate and separately billable estimating equations was described in the proposed rule (74 FR 49980 through 49981).

We did not receive any public comments in connection with our methodology for combining the separate composite rate and separately billable estimating equations into a single payment formula for calculating the ESRD PPS payment adjusters. Accordingly, we are using that same methodology to combine the separate composite rate and separately billable payment adjusters using the payment variables adopted for this final rule.

Table A in the Appendix shows how the payment adjusters from the separate CR and SB regressions were combined. The first two columns in Table A in the Appendix represent the CR and SB model results for each of the regression equations, carried to three significant figures. The third column of Table A of the Appendix presents a single payment multiplier for each patient characteristic based on its relationship to resource use for both CR and SB services. The payment adjusters in the third column ($PmtMult_{EB}$) were calculated as the weighted average of the CR and SB multipliers. The weights correspond to each component's proportion of the sum of the average CR costs and SB payments per treatment for CYs 2006–2008, as shown in Table 25.

Table 25—Estimated costs for composite rate and separately billable services, CY 2006-08[1]

	2006		2007		2008		Pooled, 2006-2008	
Measure of resource use	n (facilities or patient months)	Average $ per treatment	n (facilities or patient months)	Average $ per treatment	n (facilities or patient months)	Average $ per treatment	n (facilities or patient months)	Average $ per treatment
Facility composite rate costs[2]	4,158	$173.27	4,331	$177.41	4,485	$182.26	12,974	$177.72
Patient month separately billable Medicare Allowable Payments[3]								
Ages <18	5,907	$51.36	5,491	$52.26	5,744	$46.02	17,142	$49.84
Ages 18 and older	2,833,464	$86.46	2,890,396	$83.99	2,879,465	$81.53	8,603,325	$83.97

[1]Weighted by the number of hemodialysis-equivalent dialysis treatments.
[2]Source: Medicare cost reports for freestanding and hospital-based dialysis facilities.
[3]Source: Medicare dialysis patient claims.

The weights were calculated using the three years of pooled data. Based on this analysis, the average cost for CR services per treatment as computed from the Medicare cost reports was $177.72. The average MAP per treatment for SB services based on Medicare claims for the same period was $83.97. Based on total estimated costs of $261.69 per treatment ($177.72 + $83.97), the relative weights are $weight_{CR} = 0.6791$ for composite rate services ($177.72/$261.69) and $weight_{SB} = 0.3209$ for separately billable services ($83.97/$261.69). The payment multipliers presented in the third column of Table A in the Appendix were calculated as $PmtMult_{EB} = 0.6791 \times PmtMult_{CR} + 0.3209 \times PmtMult_{SB}$. In this manner, the separate case-mix adjusters for composite rate and separately billable services were combined to obtain a single set of multipliers (shown in the third column of Table A in the Appendix) to compute the payment rates under the proposed ESRD PPS.

Six co-morbidities were identified as payment adjusters for separately billable services only, as they did not have a statistically significant association with composite rate costs based on the regression results. These patient characteristic variables have a composite rate multiplier in Table A in the Appendix of 1.000. For these co-morbidities, there is no payment adjuster for composite rate services. Therefore, the payment multiplier is equal to $0.6791 \times 1.000 + 0.3209 \times PmtMult_{SB}$. The payment multipliers in the third column of Table A in the Appendix reflect the combined results from the two-equation model described in this final rule, and represent the case-mix adjustment factors that will be

applied to the base rate to compute the payment amount per treatment under the finalized ESRD PPS.

G. Pediatric Patients

In section IX. of the proposed rule (74 FR 49981 through 49987), we pointed out that section 1881(b)(14)(D)(iv)(I) of the Act gave the Secretary the discretionary authority to develop a pediatric payment adjustment under the ESRD PPS. Consistent with that authority, we proposed our methodology for developing a pediatric payment adjustment and proposed pediatric patient-specific case-mix adjustment factors (74 FR 49987).

Using the same two-equation regression methodology developed for adult patients, the pediatric payment model incorporated the proposed adjustment factor of 1.199 from the adult payment model for patients less than age 18 for the purpose of computing the composite rate portion of the bundled payment for pediatric patients (74 FR 49982). In order to adjust the separately billable portion of the payment rate, we proposed the use of specific adjusters for each of eight pediatric classification categories (*see* Table 32 at 74 FR 49986). These classification groups reflected two age groups (<13 and 13–17), two co-morbidity classification groups (none and one or more) based on the presence of either HIV/AIDS, diabetes, septicemia within 3 months, or cardiac arrest, and two modality groups (PD or HD). The result was a set of eight pediatric classification groups, each of which had its own bundled ESRD PPS payment multiplier. Those multipliers reflected the combined composite rate and separately billable adjustment factors developed in accordance with the two-equation regression methodology used in connection with the adult payment model. These adjustment factors were weighted according to the relative utilization of resources among pediatric patients obtained from the Medicare cost reports for 2004 through 2006 for composite rate services, and 2004 through 2006 claims for separately billable services. The proposed adjustment factors, which would be applied to the base rate under the ESRD PPS, ranged from 0.963 to 1.215 (*see* Table 33 at 74 FR 49987).

We received numerous comments from industry representatives including children's hospitals and other dialysis facilities treating pediatric patients, LDOs, hospital organizations, physician representatives, dialysis industry groups, and laboratories on our proposed pediatric payment model. Commenters were opposed to the methodology used to develop the proposed pediatric payment adjusters. The comments we received and our responses are set forth below.

Comment: Several commenters stated that the proposed methodology underestimated the cost of caring for pediatric patients with ESRD, and that application of the proposed payment adjusters would cause severe financial hardship for facilities treating ESRD pediatric patients. The commenters pointed out that the proposed payment multiplier of 1.199 used to adjust the composite rate portion of the pediatric MAP, as well as the composite rate portion of the MAP, is based on the costs of adult dialysis units, not pediatric specific services. The commenters suggested that the composite rate cost portion of the pediatric MAP, and the composite rate adjustment factor, should be based on actual cost data from pediatric dialysis units.

The commenters believed that the present multiplier of 1.62 applied to the composite rate per treatment for pediatric patients was likely more reflective of actual pediatric costs, not the proposed factor of 1.199. Other commenters recommended that CMS should perform further statistical analysis which uses the actual costs from pediatric ESRD facilities, or the pediatric units of ESRD facilities to determine the composite rate cost portion of the pediatric MAP, and the composite rate pediatric adjustment factor.

Response: In the proposed rule, we pointed out the current pediatric adjustment factor of 1.62 was developed from only those ESRD facilities that sought and obtained an exception to their otherwise applicable composite payment rates (74 FR 49984). This factor only reflected the costs of ESRD facilities which exceeded their composite payment rates. Therefore, the 1.62 adjustment factor was likely biased upward because it was not developed from the costs of ESRD facilities with costs below their composite rates.

However, the commenters raise a valid point. The generally lower payments for treating adult ESRD patients were commingled with pediatric payments in developing the composite rate portion of the proposed base rate. The multipliers from the composite rate and separately billable portions of the proposed pediatric payment adjustments were weighted based on average ESRD composite rate facility costs for 2004 through 2006. The multipliers were developed from data that were not restricted to pediatric ESRD facilities. Similarly, the adjustment factor of 1.199 applied to the composite rate portion of the proposed pediatric payment adjustment factors reflect the composite rate costs of pediatric patients treated in all facilities, not just pediatric ESRD facilities or the pediatric units of dialysis facilities. Because these costs reflect predominantly adult patients, they may be understated if, as is likely, the cost of care for pediatric patients in primarily adult facilities is less than the cost of care for pediatric patients in primarily pediatric facilities. We agree that further additional statistical analysis is warranted to determine whether a robust case-mix adjusted pediatric payment model can be developed based on co-morbid characteristics of pediatric dialysis patients, one which does not dilute the higher composite rate costs of pediatric patients with the generally lower composite rate costs of adult patients.

We agree with the commenters that the proposed pediatric case-mix adjusters reflect composite rate costs that may understate the cost of treating pediatric dialysis patients, because of the predominance of adult patients in ESRD facilities. To respond to the commenters' concern that adoption of the proposed pediatric payment adjusters would not compensate ESRD facilities for the actual costs of furnishing dialysis to pediatric patients, we have modified the proposed payment adjusters applied to pediatric patients (see Table 33 in the proposed rule at 74 FR 49987). The pediatric payment adjusters we have adopted for this final rule reflect the higher average composite rate payment per treatment that we made in CY 2007 for pediatric dialysis treatments compared to those for adult patients and the lower average per treatment payments made for separately billable services furnished pediatric patients in that year. As discussed in section II.E.1. of this final rule, CY 2007 is the year used to develop the ESRD PPS base rate amount. Combined composite rate and separately billable average payments per treatment in CY 2007 for pediatric dialysis patients exceeded the comparable figure for adult patients by 10.5 percent ($264.55 versus $239.39). This differential has been reflected in the pediatric payment adjusters set forth in this final rule.

Comment: Several commenters maintained that the four co-morbidities included in the proposed rule for classifying pediatric ESRD patients into one of eight classification groups (HIV/AIDS, septicemia, diabetes, and cardiac arrest) (74 FR 49987) were not appropriate for the pediatric patient

population and were not frequently encountered. The commenters stated that these co-morbidities, while perhaps relevant in the adult population, do not accurately reflect the complexity and cost of providing dialysis treatments to children. The commenters recommended alternative co-morbidities which they believed would be more reflective of the clinical conditions encountered among pediatric ESRD patients and require more costly resource intensive care. Suggested co-morbidities included developmental delay/mental retardation, growth retardation and renal osteodystrophy, deafness, seizure disorders, anxiety, secondary hyperparathyroidism, and rare genetic disorders such as cystinosis, primary hyperoxaluria, congenital hepatic fibrosis and other congenital diseases, chronic lung disease from hypoplastic lungs, and bone marrow and other solid organ transplants.

Response: We appreciate the commenters' concerns that any co-morbidity used as an ESRD pediatric payment adjustment reflects the cost and intensity of care necessary to provide outpatient dialysis to children. Unfortunately, because ESRD facilities rarely report co-morbidities on the Medicare type 72X claims submitted for payment, we obtained the co-morbidities used to establish the proposed pediatric classification groups from the same Medicare claims data used to identify the co-morbidities in the adult payment model. The small size of the outpatient ESRD pediatric dialysis patient population (about 860 patients in 2008) precluded the development of specific adjusters for individual co-morbidities due to a lack of statistical robustness. Therefore, we used a count of the number of defined co-morbidities in developing the pediatric classification groups.

The commenters' suggestion to use co-morbidities typical of the clinical conditions encountered among ESRD pediatric patients merits consideration, although we believe that it might require a specific data collection effort to obtain the co-morbidities for analysis. Although the co-morbidities in the proposed rule were derived from measures originally developed using claims from the adult population, their inclusion in the pediatric payment model was based on analyses that showed their relationship to cost specifically in the pediatric population. As explained below, we have developed pediatric adjustment factors for this final rule which do not rely on specific co-morbidities. We will consider the commenters' suggested alternative co-morbidities in future refinements to the pediatric payment adjusters adopted in this final rule.

Comment: Several commenters disagreed with the two age classification groups we used in the proposed pediatric payment model (age <13; 13–17). The commenters stated that the use of these two age groups undervalued the complexity and additional facility costs incurred in dialyzing children. Some commenters recommended only one age group (age <18) to simplify the bundle for pediatric dialysis.

Other commenters recommended alternative age groups. One commenter with clinical experience treating pediatric ESRD patients pointed out that dialysis patients under age 5 use one nurse per dialysis station and patients ages 5–12 use one nurse for every two stations. The commenter suggested that adopting age categories using this information would result in three categories for pediatric ESRD patients (<age 5, ages 5–12, and ages 13–18). Another commenter's clinical observations that younger children typically require more staff time than older teenagers or adults, led to a recommendation that we use age groups that match the age groups contained in the codes used for MCPs in Medicare's physician fee schedule (<2, ages 2–11, and ages 12–19).

Response: The two age groups that we used in connection with the proposed pediatric payment adjustments (<13, ages 13–17) reflected the measurable difference in the utilization of separately billable services among ESRD patients due to the onset of adolescence. We found that subdividing these age categories further did not yield statistically significantly more homogeneous groups with respect to separately billable services. As the two age groups presented in the proposed rule were empirically determined, we see no reason to revise them based on the wide range of opinions shown in the comments received. Further, the comments about the nursing intensity of different age groups pertain to composite rate services. For composite rate services, only one age range applies (under 18). Accordingly, in creating pediatric payment adjusters for both composite rate and separately billable services for this final rule, we have adopted the two proposed age groups (<13, ages 13–17) to classify pediatric patients.

Comment: Several commenters acknowledged the difficulty of developing pediatric payment adjustments because of the relatively small number of Medicare ESRD pediatric patients. The commenters stated that because both Congress and CMS have recognized the higher costs of treating children by exempting children's hospitals from the Medicare inpatient PPS, it would be appropriate to exclude pediatric facilities (and by extension, treatments for pediatric patients not treated in pediatric facilities) from the ESRD PPS.

Response: Although we may develop in the future pediatric payment adjusters based on co-morbidities that are prevalent among pediatric dialysis patients after additional research and analysis, we believe the changes we have made with regard to the final pediatric payment adjustments will provide sufficient payment to ESRD facilities that treat pediatric ESRD patients and that excluding pediatric patients from the bundled ESRD PPS would not be appropriate. We have adopted two payment variables from the proposed methodology used to develop the pediatric payment adjusters, that is, age and modality (74 FR 49987). Although, in response to comments, we are no longer adopting co-morbidities with regard to the pediatric payment adjustments, we are using actual payments to ESRD facilities for composite rate services in CY 2007 for treating pediatric dialysis patients to determine payment for pediatric ESRD patients under the ESRD PPS. We believe that modifying the methodology used to develop the proposed pediatric payment adjusters is responsive to commenters' concerns that the proposed composite rate portion of the pediatric payment adjusters predominantly reflected the cost of treating adult patients and understated the composite rate costs of treating pediatric dialysis patients.

Comment: Several commenters opposed the use of modality as a payment variable in the pediatric payment adjustments. The commenters stated that according to the American Society of Pediatric Nephrologists, between 40 and 50 percent of pediatric dialysis patients receive CCPD. They indicated that PD for pediatric ESRD patients is often preferred because it avoids the difficulty of obtaining vascular access in small children, allows fewer dietary restrictions, and permits the ability to attend school regularly because dialysis is provided at home. The commenters maintained that adjusting payment by modality for pediatric patients may undervalue payment for PD and provide a disincentive to provide PD for pediatric patients.

Response: In our proposed rule, we stated that the main problem with a separately billable payment model that does not recognize modality for

pediatric patients is that it results in an underpayment for HD and an overpayment for PD (74 FR 49985). In developing pediatric payment adjustments, analyses that did not differentiate by modality revealed that the average prediction errors (that is, the degree to which the predicted values differed from the actual values) were positive for PD and negative for HD. Moreover, the prediction errors in both directions were large relative to the average predicted values.

By contrast, the prediction errors in alternative analyses that distinguished payment by modality were much smaller and did not consistently favor PD over HD. Payment by modality reduced the difference between the actual and predicted payments. Therefore, use of modality as a payment variable reduced the incentive to steer patients to a particular modality based purely on the payment implications. It also substantially improved the predictive power of the payment models.

We noted that payment by modality in the proposed pediatric payment adjustments was inconsistent with the way modality is treated in the adult payment adjustments, which do not include a modality adjustment (74 FR 49985). We also said that payment by modality was not consistent with the goal of encouraging home dialysis. However, given the already relatively high utilization of PD in the pediatric ESRD population, a point substantiated by the commenters, we pointed out that it may not be necessary to further encourage home therapies for this population.

PD has many advantages for pediatric patients able to utilize that dialysis modality. We do not believe that its prevalence will be diminished by the inclusion of modality as a pediatric payment classification variable. Because the use of modality as a classification variable results in enhanced predictive power, reducing the likelihood of underpaying for pediatric HD patients and overpaying for PD patients, we have retained modality as a payment variable for the pediatric payment adjustments described in this final rule.

Comment: One commenter suggested that CMS undertake a separate rulemaking process to develop a payment model for pediatric patients. The commenter noted the substantially different circumstances in connection with furnishing dialysis to children, and recommended that hospital cost report data and co-morbidity data from claims be used to develop case-mix adjustments that are better reflective of the costs and complexity of treating pediatric dialysis patients.

Response: The Medicare hospital cost reports do not contain patient-specific cost information. Because there are so few pediatric dialysis patients, hospital cost reports, similar to those from independent facilities, largely reflect the total costs of treating adult patients. The co-morbidities in the proposed rule were derived from measures originally developed using claims from the adult population. However, their inclusion in the proposed pediatric payment adjustments was based on analyses that showed their relationship to cost in the pediatric population. Less than 2 percent of dialysis facility claims reflect a co-morbid condition. Therefore, the use of claims data as the commenter suggests based on this current degree of reporting would not be very helpful in developing alternative case-mix adjusters.

Unless ESRD facilities begin to include co-morbid medical conditions on their claims, a separate data collection effort may be necessary to obtain co-morbidities specific to the pediatric dialysis population. Once we have completed the research necessary to determine if co-morbidities prevalent among pediatric dialysis patients can be used to refine the pediatric payment adjusters adopted in this final rule, any proposed revisions would be implemented through rulemaking.

Comment: One commenter noted that training for home dialysis should not be included in a bundled payment system for pediatric patients. The commenter explained that the level and duration of training required varies according to the ability and age of the child and his or her caretaker. Because children rely on adult caretakers, a change in a child's familial or living situation would necessitate one or more periods of retraining. Therefore, training should be reimbursed separately from a bundled ESRD PPS for pediatric patients.

Response: We have developed a separate add-on amount for training that will apply for both adult and pediatric dialysis patients. Although the CY 2007 base rate applicable to both adult and pediatric patients includes payments for training treatments, we point out that training treatments for both adult and pediatric dialysis patients under the ESRD PPS will be increased $33.44, subsequently adjusted for area wage levels using the dialysis facility's applicable wage index, to reflect the additional costs of training. For an explanation of how this adjustment was developed, see section II.A.7. of this final rule.

Comment: One commenter stated that the pediatric case-mix adjusters failed to recognize the unique nature of pediatric facilities by failing to account for higher staffing ratios imposed by state regulatory mandates, additional ancillary and nursing personnel required to treat pediatric ESRD patients, and higher supply costs of these patients.

Response: We agree with the commenter's concerns. As noted previously, the routine operating costs associated with treating pediatric ESRD patients included in the composite rate cost component of the pediatric payment adjustments may be understated because they largely reflect the overhead and operating costs of facilities treating predominantly adult patients. Therefore, in this final rule, we are modifying our methodology for determining the pediatric payment adjustments.

As described later in this section, we have incorporated in the pediatric payment adjusters a 10.5 percent increase (an adjustment of 1.105) to reflect the degree to which total actual CY 2007 payments for composite rate and separately billable services for pediatric ESRD patients exceed the comparable figure for adult patients. In CY 2007, Part B composite rate payments per treatment for pediatric dialysis patients were approximately 38.6 percent higher than those for adult patients ($216.46 versus $156.12), while separately billable payments per treatment were approximately 42.2 percent lower ($48.09 versus $83.27) (see Table 26). The total difference was 10.5 percent ($216.46 + $48.09 = $264.55; $156.12 + $83.27 + $239.39; $264.55/$239.39 = 1.105).

By incorporating this difference in the formula used to develop the pediatric payment adjusters set forth in this final rule, as described in paragraph E below, we believe that we are appropriately reflecting the higher costs for composite rate services furnished to pediatric ESRD patients in the payment adjusters, in response to commenters' concerns that the proposed pediatric payment adjusters would underpay for pediatric patients.

Table 26
Comparison of Pediatric to Adult Payments for Services in an Expanded ESRD PPS, 2007

Service	All ages		Age < 18		Age 18 and older	
	Average per treatment	Total	Average per treatment	Total	Average per treatment	Total
Dialysis patients	--	328,787	--	872	--	328,004
Hemodialysis-equivalent dialysis treatments	--	36,747,662	--	75,478	--	36,672,184
Medicare Allowable Payments for services in the expanded ESRD PPS						
Total for Part B and Part D services	$239.88	$8,809,732,068.05	$267.66	$20,140,444.32	$239.82	$8,789,591,623.73
Total for Part B services	$239.44	$8,799,031,984.47	$264.55	$19,967,531.39	$239.39	$8,779,064,453.08
Composite rate and other dialysis Services	$156.25	$5,741,729,454.44	$216.46	$16,338,032.59	$156.12	$5,725,391,421.85
Composite rate services	$155.65	$5,719,657,831.39	$199.30	$15,043,119.60	$155.56	$5,704,614,711.79
Durable medical equipment and supplies	$0.49	$18,060,482.59	$16.00	$1,207,494.83	$0.46	$16,852,987.76
Dialysis support services	$0.04	$1,447,484.43	$1.08	$81,360.99	$0.04	$1,366,123.44
Ultrafiltration	$0.07	$2,563,656.04	$0.08	$6,057.18	$0.07	$2,557,598.86
Separately billable services (Part B)	$83.20	$3,057,302,530.04	$48.09	$3,629,498.81	$83.27	$3,053,673,031.23
Epogen	$51.08	$1,876,926,573.16	$26.84	$2,026,111.30	$51.13	$1,874,900,461.86
Darbepoetin	$4.57	$167,935,969.83	$1.97	$148,917.20	$4.58	$167,787,052.63
Calcitriol	$0.09	$3,125,612.59	$0.32	$24,190.94	$0.08	$3,101,421.65
Doxercalciferol	$2.09	$76,901,723.05	$0.46	$34,763.13	$2.10	$76,866,959.93
Paricalcitol	$8.79	$322,849,347.85	$5.24	$395,284.33	$8.79	$322,454,063.53
Iron sucrose	$4.52	$166,219,338.55	$1.29	$97,013.96	$4.53	$166,122,324.59
Sodium ferric gluconate	$1.85	$68,086,706.74	$1.00	$75,540.41	$1.85	$68,011,166.33
Levocarnitine	$0.14	$5,026,445.93	$0.18	$13,644.56	$0.14	$5,012,801.36
Alteplase	$0.73	$26,697,321.33	$1.76	$132,629.09	$0.72	$26,564,692.24
Vancomycin	$0.10	$3,583,503.88	$0.16	$11,964.88	$0.10	$3,571,539.00
Daptomycin	$0.03	$1,234,404.70	$0.00	$0.00	$0.03	$1,234,404.70
Other injectables	$0.13	$4,943,934.31	$0.47	$35,594.00	$0.13	$4,908,340.31
Laboratory tests	$8.04	$295,508,409.06	$7.84	$591,436.98	$8.04	$294,916,972.08
Dialysis facility supplies and IV fluids	$1.04	$38,263,239.08	$0.56	$42,408.04	$1.04	$38,220,831.04
Hemodialysis-equivalent dialysis treatments for patients with Part D spending	--	24,737,326	--	55,548	--	24,681,778
Total for Part D services	$0.43	$10,700,083.58	$3.11	$172,912.93	$0.43	$10,527,170.65
Calcitriol (oral)	$0.11	$2,678,711.44	$1.73	$95,936.79	$0.10	$2,582,774.65
Doxercalciferol (oral)	$0.20	$4,965,189.06	$0.56	$31,139.51	$0.20	$4,934,049.55
Paricalcitol (oral)	$0.12	$3,008,544.32	$0.76	$42,381.46	$0.12	$2,966,162.86
Levocarnitine (oral)	$0.00	$47,638.76	$0.06	$3,455.17	$0.00	$44,183.59

1. The Revised Methodology for the Pediatric Payment Adjustments

Section 1881(b)(14)(A)(i) of the Act requires that a single payment apply to "renal dialysis services", including home dialysis, beginning January 1, 2011. These services include composite rate and certain separately billable services. In response to commenters' concerns that the proposed pediatric co-morbidities used to develop the proposed pediatric payment adjusters were not prevalent among pediatric dialysis patients, and that the composite rate costs used to derive the proposed adjusters largely represented the costs of treating adult patients, thereby understating the costs of treating pediatric dialysis patients, we have revised the methodology for calculating the pediatric payment adjusters to reflect the actual average Part B Medicare payment per treatment for pediatric patients in CY 2007. In the following section, we describe the changes.

2. Composite Rate Payments for Pediatric Patients

As part of the basic case-mix adjustment for composite rate services, dialysis treatments furnished to pediatric patients are currently reimbursed at a rate equal to 1.62 percent of the facility's composite payment rate (that is, we use an adjustment factor of 1.62 to the composite rate as the payment for pediatric patients). This composite rate payment adjustment for pediatric patients was established relative to the lowest cost adult age category (age 60–69). The other basic case-mix adjustments for body surface area and body mass index are not applied to claims for pediatric ESRD patients.

In the proposed rule, we described the proposed pediatric payment model which used the two-equation methodology to develop the case-mix adjusters applicable to pediatric patients (74 FR 49982 through 49987). The payment adjustment applicable to composite rate services for pediatric patients was obtained from the facility-level model of composite rate costs for patients less than 18, yielding a regression-based multiplier of 1.199. In response to commenters' concerns that the magnitude of the composite rate portion of the proposed payment multipliers or adjusters for pediatric dialysis patients may be understated, we have revised the methodology for calculating the pediatric composite rate payment amount.

Instead of using the regression-based composite rate multiplier of 1.199, we have incorporated in the pediatric payment adjusters the overall difference in average payments per treatment between pediatric and adult dialysis patients for composite rate services in CY 2007 based on the 872 pediatric dialysis patients reflected in the data. We selected CY 2007 consistent with our determination that 2007 represented the year with the lowest per patient utilization of dialysis services in accordance with section 1881(b)(14)(A)(ii) of the Act, using the methodology previously described in this final rule. Table 26 reveals that the

average CY 2007 MAP for composite rate services for pediatric dialysis patients was $216.46, compared to $156.12 for adult patients. This difference in composite rate payment is reflected in the overall adjustment for pediatric patients calculated below.

3. Separately Billable Services

Based on comments received that our proposed pediatric co-morbidities were not appropriate because they were not prevalent among pediatric dialysis patients, we modified the payment adjusters for separately billable services for pediatric patients to exclude the co-morbidities we proposed. We developed adjustments using the variables of age (<13, 13–17) and modality (PD or HD). As with the methodology described in the proposed rule (74 FR 49984), all of the analyses were performed using log-linear regression models of the average separately billable MAP per treatment for each of three years (CYs 2006, 2007, and 2008). The data were pooled over the 3-year period, resulting in up to three yearly observations for each pediatric patient.

As with the payment multipliers that were developed in connection with the proposed rule, the payment multipliers developed in connection with this final rule using only two variables, age and modality, often required a statistical "smearing" adjustment to improve the accuracy of the payment adjusters upon transformation of the regression model results from the log dollar scale to the dollar scale (that is, to limit retransformation bias).

Under statistical "smearing", a correction factor is applied to the predictions from a model that is estimated on the logarithmic scale (for example, the log of the average MAP per treatment). In the context of examining healthcare cost or payment data that do not follow the normal distribution curve (that is, are not normally distributed), retransformation bias may occur when converting predicted values that are made on the log scale (that is, log dollars) back to the original scale (that is, dollars), yielding biased estimates of the mean cost in dollars. In order to develop valid payment adjusters that reflect the relationships between patient characteristics and the MAPs (that is, in dollars), it is essential that retransformation bias be limited as much as possible. Because the difference between residuals (that is, the difference between the measured MAP and predicted MAP for each observation) did not vary in the desired random pattern, indicating correlation between the variance of the residuals and some of the patient characteristics based on age and modality (statistically known as "heteroscedasticity"), separate smearing adjustments were applied by patient subgroup. The smearing adjustments were based on the average retransformed residual for each patient category. For further information on the use of statistical smearing, retransformation, and heteroscedasticity, *see* Duan, N., *Smearing estimate: a nonparametric retransformation method,* Journal of the American Statistical Association, 78, 1983, pp. 605–610, and Manning, W.G., *The logged dependent variable, heteroscedasticity, and the retransformation problem,* Journal of Health Economics, 17, 1998, pp. 283–295. To develop the pediatric payment multipliers or adjustments for the four pediatric classification groups adopted for this final rule, we similarly performed statistical smearing adjustments to minimize retransformation bias.

4. No Caps Applied to the Separately Billable MAP per Treatment

In the proposed rule, we explained that we capped the separately billable MAP per treatment for pediatric dialysis patients at $289.00 based on the standard outer fence method for identifying statistically aberrant values (*see* 74 FR 49984). The outer fence was defined as the 75th percentile of the separately billable MAP per treatment, plus three times the interquartile range, which is the 75th percentile minus the 25th percentile.

However, we found that capping the separately billable MAP had little effect on the magnitude of the payment multipliers, suggesting that the predicted payments are not biased through the inclusion of valid or invalid values. Accordingly, we have not applied caps to the computation of the separately billable MAPs for pediatric patients in developing the pediatric payment adjusters presented in this final rule, with the exception of EPO and ARANESP®. Payments for these ESAs were capped at the same medically unbelievable thresholds used in connection with the development of adjustments applied to adult patients.

The final pediatric payment adjustments for separately billable services use two age categories (<13, age 13–17) and dialysis modality (PD or HD), as the bases for classifying pediatric patients, consistent with what we proposed and after consideration of public comments. In addition, as we discussed above, in response to public comments, the final pediatric payment adjustments do not use co-morbidity categories based on the number of specified co-morbidities as one of the variables used to classify pediatric dialysis patients. Accordingly, we are finalizing four pediatric classification groups or cells, not eight as originally proposed (74 FR 49987). Using data for CYs 2006–2008, we present the pediatric payment adjuster or multiplier results in Table 27 below.

Table 27

Calculating Combined Payment Multipliers for Pediatric Patients Based on Adjustments for Age and Modality

Cell	Patient characteristics		Separately billable (SB) payment multiplier[1]	Expanded bundle payment multiplier
	Age	Modality		
1	<13	PD	0.319	1.033
2	<13	Hemo	1.185	1.219
3	13-17	PD	0.476	1.067
4	13-17	Hemo	1.459	1.277

[1]Based on a pediatric patient month level regression model of SB MAP/session for 2006-08 (n=17,142 pediatric patient months) that included age (<13 vs. 13-17) and modality (PD vs. HD). An R-squared value calculated at the patient year level was 34.8%. This calculation was based on a regression model that used the average predicted SB MAP per treatment during each patient year (calculated by averaging the monthly predicted values for each patient from the patient-month SB model) to explain variation in the average observed SB MAP per treatment for the patient year. In estimating this R-squared value, a log transformation was applied to both the average predicted and average observed SB values. The R-squared value for the patient month regression model was 32.8%. Subgroup-specific smearing adjustments were applied to the estimated multipliers from the model. The SB payment multipliers presented above were calculated relative to the average SB multiplier among pediatric patients, weighted by treatments, such that the average pediatric SB payment multiplier is 1.000.

For purposes of the payment adjustments, the relevant column is labeled "Separately billable (SB) multiplier". These values reflect the relative costliness of separately billable services for each of the four pediatric patient groups. The SB multipliers were calculated relative to the average SB multiplier among pediatric patients, weighted by treatments, such that the average SB payment multiplier is 1.000.

5. A Combined Composite Rate and Separately Billable Payment Model for Pediatric Patients

Calculation of an overall pediatric adjustment factor reflects the higher payments for composite rate services under the current system, and allows the pediatric payment adjusters for separately billable services to be applied to the total base rate amount. As noted above, the composite rate MAP for pediatric patients is higher than that for adult patients ($216.46 versus $156.12). However, the separately billable MAP is lower for pediatric patients ($48.09 versus $83.27), largely because of the predominance of PD among pediatric patients, in which the utilization of separately billable services is lower, and the smaller body size of younger pediatric patients. The overall difference in the CY 2007 MAP between adult and pediatric dialysis patients is 10.5 percent ($216.46 + $48.09 = $264.55. $156.12 + $83.27 = $239.39. $264.55/$239.39 = 1.105). The use of the 1.105 adjustment to develop the final pediatric adjustment factors set forth in this final rule reflects the higher payment for composite rate services and lower utilization of separately billable services among pediatric dialysis patients.

The pediatric payment adjustments shown in Table B in the Appendix for each of the four classification categories would normally be applied to the separately billable portion of the MAP for pediatric patients. However, for the reasons discussed above, for simplicity of application, we can convert the separately billable pediatric multipliers shown in Table B in the Appendix to values that can be applied to the total base rate amount, reflecting both the composite rate and separately billable components. This can be accomplished as follows:

Let P represent the ratio of the total CR and SB MAP per treatment for pediatric patients relative to adult patients (calculated above to be 1.105), W_{CR} and W_{SB} the proportion of MAP for CR and SB services, respectively, among pediatric patients, C the average case-mix multiplier for adult patients, and $Mult_{SB}$ the SB payment multiplier shown in Table 27. The expanded bundle payment multiplier for CR and SB services for each of the four pediatric classification cells can be calculated as:

$$Mult_{SB} = P * C * (W_{CR} + W_{SB} * Mult_{SB})$$

Based on the average MAP per treatment for CR and SB services of $264.55 for pediatric patients, and $239.39 for adult patients shown in Table 26, P is calculated as:

$$P = \$264.55/\$239.39 = 1.105$$

It should be noted that this method of computing P, which reflects the relative payments for pediatric patients compared to adult patients, is based on CR and SB services covered under Part B only, and does not include payments for oral equivalent drugs under Part D. To be consistent with the two-equation model that is used to determine the payment adjustments for adult patients under the ESRD PPS, the approach that is used to determine the pediatric payment adjustments also reflects comparisons involving Part B services only. This is also consistent with our

proposed pediatric payment methodology (see 74 FR 49986 through 49987).

The CR and SB weights for pediatric patients are calculated as the ratio of the MAP per treatment for CR and SB services relative to the sum of the CR and SB MAP per treatment in 2007, where

W_{CR} = $216.46/$264.55 = 0.8182
and W_{SB} = $48.09/$264.55 = 0.1818

The average case-mix multiplier for adult patients (C = 1.067) is applied to offset the standardization for case-mix adjustments (that is, BSA, low BMI, onset of renal dialysis, and co-morbidities) which are not used for pediatric patients. If this standardization factor of 1.067 were not used to increase the otherwise applicable pediatric payment adjustments or multipliers, those multipliers would be inappropriately understated by 6.7 percent. (For a discussion of how the difference in the case-mix adjustment variables which apply to adult and pediatric dialysis patients result in different standardization factors for adult and pediatric patients in developing the outlier payment thresholds, see section II.H.1.ii. of this final rule.) For example, the expanded payment multiplier for pediatric classification group 1 (cell 1) is calculated as:

$Mult_{EB}$ = 1.105 * 1.067 * (0.8182 + 0.1818 * 0.319) = 1.033

This formula yields the four pediatric payment multipliers shown in Table B in the Appendix that are applied to the overall adjusted base rate amount of $229.63 per treatment, depending upon each pediatric patient's classification cell.

6. Adult Payment Adjustments That Do Not Apply to Pediatric Patients

As explained above, the payment adjustments developed for pediatric dialysis patients do not reflect co-morbidities, which are included as payment adjustments for adult patients. Similarly, the payment adjustments based on BSA, low BMI, and onset of dialysis were developed for adults based on characteristics of adult patients and their relationship with measured costs for services in the ESRD PPS, and, therefore, do not apply to pediatric patients. Pediatric dialysis patients under the ESRD PPS which we are finalizing in this rule will not be eligible for case-mix adjustments based on BSA, low BMI, and the onset of dialysis. In addition, the low-volume adjustment described in section II.F.3. of this final rule will not apply to pediatric patients.

We point out that the payment adjusters for pediatric patients reflect a 10.5 percent increase to account for the overall difference in average payments per treatment for pediatric patients compared to adult patients. While the difference overall is 10.5 percent, payments for composite rate and other dialysis services for pediatric patients exceeded those for adult patients by 38.6 percent ($216.46 versus $156.12; see Table 26). The average composite rate payments for pediatric patients under the current basic case-mix adjusted composite payment system include the 62 percent increase otherwise applied to pediatric patients, plus any exception payments dialysis facilities may have received under § 413.184–§ 413.186 of the Medicare regulations. (It should be noted that the pediatric payment adjustment under the basic case-mix adjusted payment system increased pediatric payments by 62 percent relative to the lowest cost adult age group, ages 60–69, and not relative to the average adult patient overall. Further, pediatric patients were not eligible for other adjustments under the basic case-mix adjusted composite payment system. As a result, the average pediatric payment under this system will be less than 62 percent higher than the average payment for adults.) Both the pediatric basic case-mix adjustment and these facility exception payments were developed to account for the higher costs of facilities that treat pediatric patients.

To the extent the additional payments currently provided for pediatric patients under the basic case-mix composite payment system are likely to reflect higher costs for smaller dialysis facilities otherwise qualifying for the low-volume adjustment under the ESRD PPS, application of the low-volume adjustment for pediatric patients would be duplicative. Therefore, the low-volume payment adjuster of 1.189 that we are finalizing will only be applicable to adult patients, and will not be used in calculating the payment rate per treatment for pediatric dialysis patients. Facilities qualifying for the low-volume adjustment which treat both adult and pediatric patients, may only receive the low-volume adjustment for adult dialysis patients. We point out that the training add-on amount of $33.44 per treatment, subsequently adjusted by the area wage index, is applicable to both adult and pediatric patients.

For comprehensive examples showing the application of the pediatric payment adjusters shown in Table B in the Appendix in connection with computing the payment amounts per treatment for pediatric dialysis patients, *see* section II.I. of this final rule.

Based on the comments received and the responses provided above, we are revising § 413.235(b) to reflect the revised pediatric ESRD patient adjustments of age and modality. In addition, as payment under § 413.235(b) is limited to claims for patients under 18 years of age, we are revising § 413.171 to define a pediatric ESRD patient as an individual less than 18 years of age who is receiving renal dialysis services.

H. Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of ESAs necessary for anemia management. In the proposed rule, we discussed our rationale for outlier payments to facilities under the ESRD PPS (74 FR 49987) and proposed that the ESRD outlier policy parallel the outlier policies adopted under other Medicare PPSs.

We proposed an outlier policy of 1.0 percent of total ESRD expenditures (74 FR 49993). We stated that we believed an outlier percentage of 1.0 percent strikes an appropriate balance between our objective of paying an adequate amount for the most costly resource intensive patients, while providing an appropriate level of payments for those patients who do not qualify for outlier payments. An ESRD facility would be eligible for an outlier payment when its imputed MAP amount per treatment for the outlier services exceeded the outlier threshold, or the facility's predicted MAP amount per treatment for the outlier services plus the fixed dollar loss amount. Finally, we proposed that the outlier payment would be equal to 80 percent of the amount by which the facility's imputed costs exceeds the outlier threshold.

1. Eligibility for Outlier Payment

We proposed that an ESRD facility would be eligible for an additional payment under the ESRD PPS where the facility's imputed, average per treatment costs for ESRD outlier services furnished to a beneficiary exceeded the predicted per treatment MAP amount for outlier services plus the fixed dollar loss amount, as indicated at § 413.237(b) (74 FR 49993 and 50024). We proposed to base eligibility for outlier payments on what we consider ESRD outlier services, that is, only those items and services that are separately billable under Medicare Part B under the current

basic case-mix adjusted composite payment system, and renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Medicare Part D, rather than all items and services comprising the bundled payment under the proposed ESRD PPS (74 FR 49988).

The comments we received in connection with our proposed outlier payment policy and our responses are set forth below.

Comment: Instead of our proposed approach under which outlier payments would be linked to high utilization of specified outlier services, several commenters suggested that we base eligibility for outlier payment on specific conditions or characteristics including patients undergoing home training or self-care training, patients with gastrointestinal bleeding, infections, including vancomycin resistant infections, chronic fluid overload, obesity, or pregnant patients. These commenters suggested that fixed outlier payment amounts could be made on behalf of the patient each month in which the patient condition or characteristic is present.

Response: We disagree with the commenters' suggested alternative approach to establishing outlier eligibility and for making outlier payments. It does not necessarily follow that dialysis patients with specific conditions or characteristics will utilize resources to the extent that they would always qualify for outlier payments. Conversely, it is very likely that patients without the conditions suggested by the commenters could qualify for outlier payments because of the presence of other co-morbidities, the need for particularly expensive ESRD-related drugs and biologicals, more frequent laboratory testing, or other factors. Neither do we believe that paying a fixed outlier payment amount each month in which a specified co-morbid condition or other suggested patient condition is present is an appropriate method for paying for outlier services, as it does not reflect a patient's actual utilization of resources.

The ESRD PPS described in this final rule provides for case-mix payment adjustments which recognize specified co-morbidities which result in higher treatment costs. The ESRD PPS also includes payment variables that reflect differences in patient size and weight through the BSA and low BMI adjustments. All of these payment adjustments result in the application of a targeted or predicted payment rate per treatment for dialysis services reflecting a patient's particular case-mix. In addition, we have also provided an add-on to a patient's otherwise applicable payment rate per treatment for home dialysis training. Notwithstanding a patient's specific case-mix adjustments, where the utilization of resources exceeds the predicted payment amount per treatment beyond a specified threshold, we believe it is appropriate to make outlier payments. Therefore, we are retaining our proposed outlier policy that is based on higher than predicted utilization of outlier services.

Comment: One commenter indicated that certain conditions, such as sepsis, are associated with higher treatment costs. The commenter specified that post-hospitalization antibiotics that are often administered by the ESRD facility and the debility of septic patients contribute to the added cost, and should be considered for outlier payments.

Response: Antibiotics used for the treatment of non-ESRD-related infections are not included in the ESRD PPS bundle. To the extent these injectable drugs are furnished in an ESRD facility, they would continue to be separately payable. The cost of services that are outside of the ESRD PPS payment bundle, and which remain separately billable, are not eligible for outlier payments.

Comment: One commenter stated that the co-morbidities that would trigger outlier payment do not have validity in children.

Response: The presence of a co-morbid condition alone does not trigger outlier payments for either adult or pediatric patients. Rather, it is the provision of additional services that are defined as outlier services that contributes towards outlier eligibility.

Comment: One commenter asserted that the proposed outlier policy would be inadequate to cover the costs associated with home hemodialysis. The commenter believed that the outlier policy would only cover some of the additional expenses incurred as a result of home dialysis patients and providers with a disproportionate number of nursing home hemodialysis patients.

Response: The outlier payment policy is intended to compensate ESRD facilities for treating patients whose consumption of separately billable ESRD-related services results in unusually high costs per treatment beyond a specified threshold which exceeds the predicted cost per treatment. The predicted cost per treatment is determined by multiplying the adjusted base rate by all of the pertinent patient and facility specific payment adjusters that apply.

The payment adjusters do not distinguish between HD furnished in a facility and home HD. Because home HD is provided to only a very small segment of HD patients, the ESRD PPS overwhelmingly reflects the costs of treatment for in-facility patients. Because the availability of compact portable HD machines for home use is a relatively recent phenomenon, we do not yet have sufficient historical data to determine the impact of the predicted payment rates and application of the proposed outlier payment policy on home hemodialysis patients. Therefore, we are unable to determine if the commenter is correct. We point out, however, that our methodology for calculating the amount of outlier payments used the same computation of the separately billable MAP per treatment, regardless of where hemodialysis was performed, and was not biased in favor of any site of service.

a. ESRD Outlier Services

We proposed at § 413.237(a), to base eligibility for outlier payments under the ESRD PPS on a comparison of the predicted MAP amounts and imputed MAP amounts for (1) items and services that currently are separately billable under Medicare Part B, including ESRD-related drugs, ESRD-related laboratory tests, and other ESRD-related services; and (2) renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Medicare Part D (74 FR 50024). We referred to those services as the "ESRD outlier services."

In the proposed rule, we also stated that we were considering the extent to which the 50 percent rule pertinent to the Automated Multi-Channel Chemistry (AMCC) separately billable laboratory tests under the basic case-mix adjusted composite payment system should continue to apply under the ESRD PPS (74 FR 49988). Section 1881(b)(14) prohibits the unbundling of services, including laboratory services. In the proposed rule, we indicated that because Medicare would not make a separate payment for ESRD-related laboratory tests under the ESRD PPS, the 50 percent rule would be rendered irrelevant for payment purposes. We indicated that the 50 percent rule's relevance would be limited to its use in determining eligibility for outlier payments.

We requested public comments on whether or not to include the AMCC tests to which the 50 percent rule applies within the definition of outlier services, and retain the 50 percent rule under the proposed ESRD PPS (74 FR 49988). We also invited comment on our proposal to limit the ESRD outlier services to items and services that were separately billable under Part B, and

those renal dialysis service drugs formerly covered under Part D (74 FR 49988).

The comments we received with respect to the proposed definition of ESRD outlier services and our responses are set forth below.

Comment: Several commenters recommended that laboratory tests should be removed from the definition of outlier services, claiming that such testing does not widely vary based on time on dialysis or type of patient. The commenters maintained that the exclusion of laboratory tests from the definition of outlier services would have a minimal impact on the distribution of outlier payments.

Response: Table 26 reveals that in CY 2007, laboratory tests for Medicare ESRD beneficiaries averaged 3.4 percent or $8.04 of the total MAP amount per treatment of $239.88 for patients of all ages. While this amount is relatively small, we point out that the need for laboratory testing can vary widely depending on changes in a patient's condition. For example, the inpatient hospitalization of an ESRD beneficiary, particularly if the patient does not receive his usual dose of dialysis while hospitalized, can result in severe deviations of dialysis clinical indicators from baseline values upon discharge. This often requires additional laboratory testing and above average doses of ESRD-related drugs and biologicals to return them to normal levels. Such a patient could be costly for the dialysis facility in terms of the additional laboratory testing required.

The additional laboratory tests, coupled with higher utilization of ESRD-related drugs and biologicals, could make the patient eligible for outlier payments. Accordingly, we do not believe that it would be appropriate to exclude ESRD-related laboratory testing services from the separately billable services which comprise the definition of ESRD outlier services.

Comment: Several commenters supported a narrow definition of outlier services limited to intravenous drugs. The commenters believed that utilization of these drugs is the primary driver of variation in patient costs.

Response: While high utilization of injectable drugs, such as ESAs, may largely determine the need for outlier payments for many patients, these drugs and biologicals are not the only reason an ESRD facility incurs unusually high costs in treating patients. A greater need for ESRD-related laboratory testing subsequent to a hospitalization or for other reasons can also contribute to high separately billable expenditures. Oral drugs can also be an important factor. Because it is a patient's total utilization of separately billable items and services that is relevant in determining eligibility for outlier payments, we have not limited these payments to a particular category in this final rule.

Comment: One commenter asserted that to the extent we specify the ESRD-related laboratory tests that would be included in the payment bundle, it would not be necessary to identify these tests on the claim for purposes of the outlier payment computation.

Response: The commenter is incorrect. Laboratory tests included in the ESRD PPS payment bundle represent laboratory tests that were included in the composite rate of the basic case-mix adjusted composite payment system, and tests that prior to January 1, 2011, were separately billable under Part B. To establish whether a laboratory test qualifies as an eligible outlier service, it is necessary to determine whether the test had been (or would have been for new ESRD-related laboratory tests) separately billable under Part B prior to January 1, 2011.

Despite the list of laboratory tests considered ESRD-related included in Table F of the Appendix to this final rule, all laboratory tests furnished an ESRD beneficiary must be specified on the facility claim in order that we can determine which meet the definition of a separately billable service and determine any potential outlier payments. We recognize that some laboratory tests that would otherwise be considered ESRD-related may be ordered for ESRD beneficiaries for purposes other than ESRD. These tests will be excluded from the ESRD PPS payment bundle, will remain separately billable, and would not be considered an eligible outlier service.

Comment: One commenter suggested that given the high cost of blood transfusions and their unpredictable rate of utilization, blood transfusion procedures should be classified as outlier services.

Response: As explained elsewhere in this final rule, blood and blood products have been excluded from the ESRD PPS payment bundle and remain separately billable. Items and services excluded from the payment bundle are not considered outlier services.

Comment: Several commenters favored broadening the definition of outlier services, while others suggested narrowing the definition, claiming that a smaller list of services would simplify the administrative burden associated with billing. One commenter in favor of a broader definition of outlier services maintained that all renal dialysis services should be considered within the definition of outlier services, not only items and services that were previously separately billable. The commenter stated that the separately billable designation, a feature of the basic case-mix adjusted composite payment system, is obsolete under the ESRD PPS because all items and services within the payment bundle, including composite rate services, are classified as renal dialysis services.

Response: Cost information regarding ESRD-related services considered to be composite rate services are not available on a patient-specific basis, only at the ESRD facility level, based on average costs collected from the Medicare cost reports. Neither do the Medicare claims identify specific composite rate items and services for ESRD patients. Therefore, if all renal dialysis services included in the ESRD PPS payment bundle were considered under the definition of outlier services, variation in the patient-specific utilization of resources would reflect only differences in non-composite rate services (that is, separately billable drugs and biologicals, laboratory tests, and medical supplies). This would occur because in the cost report, facilities identify the average of all composite rate costs across all patients treated at the ESRD facility.

We stated in the proposed rule that if we were to include all ESRD-related items and services in our definition of outlier services, including composite rate services, we would need to collect patient-level data on composite rate items and services utilized, and modify the ESRD facility claim form (74 FR 49989). Such an undertaking is not possible prior to the January 1, 2011 implementation of the ESRD PPS. Accordingly, we have developed our outlier payment policy based on the utilization of separately billable items and services.

The commenter who pointed out that the distinction between composite rate and separately billable services will become irrelevant under the ESRD PPS, in which bundled services are classified as Part B renal dialysis services, is correct. However, we find that it is necessary to maintain the distinction at this time in order to identify ESRD-related items and services eligible for outlier payments. Based on the commenter's suggestion, however, we have revised the definition of "separately billable items and services" as defined in § 413.171 to clarify that outlier services include items and services that were, or would have been, prior to January 1, 2011, separately payable.

With respect to the commenter's suggestion that a smaller list of outlier services would simplify the administrative burden associated with billing, we point out that ESRD facilities currently are required to report all separately billable items and services furnished each ESRD beneficiary. We did not propose revisions to the ESRD facility claim form. Therefore, for purposes of determining eligibility for outlier payments, separately billable items and services would continue to be reported on ESRD facility claims.

Comment: Several commenters stated that removing laboratory tests from the definition of outlier services would render the 50 percent rule unnecessary and relieve some of the reporting burden. Another commenter maintained that the 50 percent rule is based on a panel of AMCC tests included in the composite rate in 1983 and no longer reflects current medical standards.

Response: The specification of all ESRD-related laboratory tests as either composite rate or separately billable for the purpose of determining outlier eligibility renders the 50 percent rule moot. However, we cannot, as the commenter suggests, eliminate the 50 percent rule at this time, because it is necessary in order to calculate the basic case-mix adjusted composite rate portion of the blended payment during the three year transition period.

As described in section 40.6 of the Medicare Claims Processing Manual, Publication 100–04, chapter 16—*Billing for End Stage Renal Disease (ESRD) Related Laboratory Tests,* for a particular date of service to a beneficiary, if 50 percent or more of the covered laboratory tests are noncomposite rate tests, Medicare allows separate payment beyond that included in the composite rate. If 50 percent or more of the covered tests are included under the composite rate payment, then all submitted tests are included within the composite payment and no separate payment in addition to the composite rate is made for any of the separately billable tests. If less than 50 percent of the covered tests are composite rate tests, all AMCC tests submitted for the date of service for that beneficiary are separately payable.

Because we need to retain the 50 percent rule to compute the basic case-mix adjusted portion of the blended payment during the ESRD PPS transition and, we believe that it is appropriate to also retain the 50 percent rule to determine whether AMCC panel tests would be considered composite rate or separately billable for the ESRD PPS portion of the blended payment, we are retaining the 50 percent rule and laboratory tests as outlier services. Individual laboratory tests comprising an AMCC panel in which the majority of the laboratory tests are separately billable, would be considered all separately billable for the purpose of determining outlier eligibility.

In order to consistently apply this policy during the transition period, both ESRD facilities that opt out of the transition period and those that go through the transition, will be required to follow the 50 percent rule until the transition period ends January 1, 2014. With respect to a commenter's concern that the 50 percent rule was based on a panel of AMCC tests that no longer reflects current medical standards, once the transition period ends, we will reevaluate the application of the 50 percent rule and determine its future status in relation to laboratory tests which qualify as outlier services.

Comment: One commenter believed that we should replace the 50 percent rule with a reasonable alternative. Specifically, the commenter recommended that we determine the dollar value of the AMCC tests in the current composite rate. The commenter asserted that for purposes of calculating outlier payments, the imputed value of these tests performed above the composite rate value should be calculated based on the same AMCC panel rates that apply to all clinical laboratories.

Response: We believe the commenter is suggesting an approach in which the dollar value of the composite rate laboratory tests included in an AMCC panel would need to be determined. The laboratory fee schedule value in excess of this amount, regardless of the number of composite rate or separately billable individual laboratory tests comprising the panel, would then be considered eligible for outlier payments. Determining the composite rate "payment" value of all individual composite rate laboratory tests which are part of AMCC panel tests for the purpose of the commenter's suggested calculation would be problematic.

In addition, we do not believe we should create an alternative policy for distinguishing composite rate laboratory tests at this time. Once the transition is over and we no longer need to use the 50 percent rule to compute blended payments under the ESRD PPS, we plan to reconsider continuation of the 50 percent rule in connection with our outlier payment policy. Accordingly, we have not adopted the commenter's suggestion.

Comment: Several commenters asserted that outlier payments on behalf of patients with higher drug costs may not be enough to prevent ESRD facilities from withholding non-calcium phosphate binders and cinacalcet.

Response: As indicated in section II.A.3. of this final rule, we are delaying the implementation of oral-only ESRD-related drugs until January 1, 2014, after the transition period ends. We intend to further assess this concern in a future notice of proposed rulemaking.

Comment: One commenter believed that the additional cost of providing extra treatments and supplies should be accounted for within the outlier payment policy.

Response: As discussed elsewhere in this final rule, with medical justification, payments will continue to be made for additional treatments required beyond the usual three per week under the ESRD PPS. Most medical supplies associated with furnishing dialysis treatments are currently included in the composite rate of the basic case-mix adjusted composite payment system. However, medical/surgical supplies used to administer ESRD-related drugs that prior to January 1, 2011, were separately billable, but are included in the ESRD PPS payment bundle, would be included in the definition of outlier services. These supplies would count towards outlier eligibility and potential outlier payments.

Comment: One commenter requested that CMS provide guidance as to how it intends to deal with the allocation of services that occur at infrequent, but routine and predictable intervals (for example, monthly), and that appear on a claim with a high imputed value on one day in a claim.

Response: The commenter is correct that we described much of the outlier methodology in terms of per treatment amounts consistent with the per treatment unit of payment under the ESRD PPS (74 FR 49993 through 49994). In other words, we have not developed individual outlier adjustments applicable to infrequently furnished costly items and services.

We believe that our methodology is consistent with a bundled payment approach that takes into account the aggregate monthly use of resources. We clarify that in instances in which a facility's imputed costs exceed the proposed outlier threshold plus the fixed dollar loss amount, outlier payments would apply to all treatments the ESRD facility furnished the patient that month, and reported on the monthly claim, regardless of the frequency with which these services were provided.

Comment: One commenter requested clarification as to whether we will make

outlier payments to ESRD facilities that do not line item bill outlier services on the monthly claim.

Response: To calculate outlier eligibility and payments, ESRD facilities must identify which outlier services have been furnished. To the extent that an ESRD facility fails to identify outlier services on the monthly claim, we would have no way of making outlier eligibility determinations or any potential corresponding outlier payments. We view this billing approach as similar to the way in which ESRD facilities currently bill under the basic case-mix adjusted composite payment system. That is, currently ESRD facilities identify by line item date of service all separately billable items and services. Because our definition of ESRD outlier services is based on ESRD-related items and services that were or would have been, prior to January 1, 2011, separately billable, we believe that ESRD facilities are well positioned to identify outlier services on their monthly claims and this reporting should not result in substantial burden.

Comment: Several commenters asserted that our approach for determining outlier payment adjustments is too complex, and will increase administrative costs as facilities will need to submit itemized summaries of formerly separately billable expenses and analyze whether each treatment meets the criteria for outlier payments. Specifically, the commenters pointed out that the timely transfer of information on oral drugs dispensed or purchased from pharmacies will need to occur in order for the ESRD facility to itemize these drugs on the monthly claim. Another commenter stated that the outlier policy could harm small ESRD facilities lacking the resources to properly evaluate and bill for high cost patients.

Response: We believe that ESRD facilities are currently well positioned to continue the reporting of all separately billable items and services used by ESRD patients in order to determine their eligibility as outlier services, and potential for triggering outlier payments. CMS will automate the pricing and calculation of outlier payments to the maximum extent feasible. We agree that ESRD facilities will need to report the purchase and payment for the oral drugs and biologicals (excluding oral-only drugs until 2014) for ESRD beneficiaries as soon as practicable for reporting on the monthly claim. Although we appreciate the commenters' concerns with respect to the need to report all outlier eligible services on the monthly claim, this is necessary in order to calculate any potential outlier payments.

Once claims data can be collected which reflect the utilization of outlier services under the ESRD PPS, we intend to analyze those data to identify which outlier services are associated with the greatest proportion of outlier payments. We intend to weigh those results against the administrative burden of continuing to collect and record each outlier eligible service on the claim. We would propose any alterations to the definition of outlier services in a future notice of proposed rulemaking.

Comment: MedPAC recommended that CMS develop clinical criteria, similar to the ESA Claims Monitoring Policy, for the utilization of drugs and laboratory tests under our outlier payment policy to ensure their appropriate use.

Response: At this point, we believe it is premature to determine whether a monitoring policy is necessary to determine the appropriate utilization of separately billable services under our outlier payment policy. If we determine based on data analysis of the consumption of outlier eligible services under the ESRD PPS that inappropriate use of outlier services is leading to excessive outlier payments, we will reconsider MedPAC's suggestion and propose revisions to the outlier policy in the future.

After consideration of all public comments received, we are modifying our proposed definition of ESRD outlier services set forth in proposed § 413.237 (74 FR 50024) in order to clarify our definition of eligible outlier services. That section references proposed § 413.171 (74 FR 50022) with respect to the definition of separately billable items and services that will be considered eligible outlier services. We are revising the definition of separately billable services set forth in proposed § 413.171 to read as follows: "Separately Billable Items and Services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of individuals with ESRD that were or would have been, prior to January 1, 2011, separately payable under Title XVIII of the Act and not included in the payment systems established under section 1881(b)(7) and section 1881(b)(12) of the Act".

We are finalizing the definition of outlier services to include the following items and services that are included in the ESRD PPS bundle: (1) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (4) renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, notwithstanding the delayed implementation of ESRD-related oral-only drugs effective January 1, 2014.

We point out that with respect to the former Part D drugs, other than the oral-only drugs that are delayed for inclusion in the ESRD PPS payment bundle until January 1, 2014, the current outlier eligible drugs are limited to drugs and biologicals required to regulate bone and mineral metabolism and cellular metabolism. Currently these drugs are calcitriol, paracalcitol, doxercalciferol, and levocarnitine. The list of separately billable items and services that will be considered ESRD outlier services is dynamic. If new ESRD-related laboratory tests or new oral drugs emerge within the classifications noted, they will be considered eligible for outlier payments, provided they would have been considered separately billable under Part B or covered under Part D prior to January 1, 2011. We intend to publish a list of currently eligible separately billable outlier services in a subsequent administrative issuance.

We are revising § 413.237 of the regulations to define outlier services as separately billable items and services as defined in § 413.171 of this part and renal dialysis service drugs and biologicals proposed for inclusion in the ESRD PPS that currently are covered under Medicare Part D (including those Part D oral-only drugs that are bundled but for which implementation is delayed until after the ESRD PPS transition period ends).

b. Predicted ESRD Outlier Services MAP Amounts

We proposed that predicted outlier services MAP amounts for a patient would be determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments (74 FR 49989).

The predicted separately billable MAP amounts in the proposed rule were based on the patient-level regression for separately billable services. Thus, it was possible to predict patient-specific separately billable MAP amounts for

these services by multiplying the average separately billable MAP amounts by the separately billable case-mix adjusters.

We provided tables that listed the case-mix adjustment multipliers for outlier services for adult and pediatric patients (74 FR 49989 through 49990) and described the process for calculating the adjusted average outlier services MAP amount (74 FR 49990). The proposed adjusted average outlier services MAP amount was $64.54 (74 FR 49991). That amount was multiplied by the product of the patient-specific outlier services payment multipliers to yield the predicted outlier services MAP amount. Lastly, the fixed dollar loss amount was added to this amount.

In the proposed rule, we stated that we intended to include former Part D drugs and biologicals into the separately billable services regression model that generates the case-mix payment adjusters (74 FR 49989). However, for reasons set forth in section II.F. of this final rule, we have been unable to include payments for former Part D drugs in the regression model used to develop the separately billable case-mix adjusters. Payments for these drugs, however, have been included in the computation of the CY 2007 base rate to which the case-mix adjustments are applied.

Accordingly, effective January 1, 2011, the outlier services payment adjustments are based solely on the items and services that, prior to January 1, 2011, were separately billable under Medicare Part B. Therefore, in this final rule, the outlier services multipliers are represented by the separately billable services payment multipliers. The updated list of outlier services payment multipliers on behalf of adult patients is presented in Table A of the Appendix under the heading "separately billable services." The updated list of outlier services payment multipliers on behalf of pediatric patients is presented in Table B of the Appendix under the heading "SB payment multiplier."

The average outlier services MAP amount per treatment in this final rule is based on payment amounts reported on 2007 claims and adjusted to reflect projected prices for 2011. In the proposed rule, we used a single outlier services MAP amount based on the average utilization of separately billable services for all Medicare ESRD patients (74 FR 49991). For this final rule, we have adopted separate outlier services MAP amounts for adult and pediatric patients. We did this because of the change in methodology for developing the final pediatric payment adjustments, and to ensure that the outlier thresholds for determining outlier payments for pediatric patients were not inappropriately high, resulting in fewer outlier payments. This change in methodology is appropriate because of the lower utilization of separately billable dialysis services among pediatric patients compared to adult patients. The final average outlier services MAP amounts are $54.14 for patients < 18, and $86.58 for patients age 18 and older.

In the proposed rule, we described how the average MAP amount per treatment for outlier services was adjusted by the case-mix and wage index standardization factor in order to avoid duplicate payments, because adjustments for case-mix and the wage index are applied to the adjusted MAP amount per treatment to compute the ESRD PPS payment amount for each patient (74 FR 49990). Although the standardization factor cited in the proposed rule reflected low volume payments, we inadvertently omitted stating that this standardization factor also included any estimated low-volume payments. After application of this standardization factor (0.7827 in the proposed rule), we also applied the 1.0 percent reduction for total estimated outlier payments (0.99 outlier reduction) and the 2.0 percent reduction mandated under MIPPA (MIPPA reduction factor of 0.98) (74 FR 49990 through 49991). After application of reductions described above, the resulting adjusted average outlier services MAP amount would be multiplied by the applicable patient-specific case-mix adjustments to obtain the predicted outlier services MAP amount (74 FR 49991). As described further in section d., "Outlier Percentage and Fixed Dollar Loss Amounts" below, the fixed dollar loss amount would be added to this amount to obtain each patient's outlier threshold. Total separately billable payments per treatment will have to exceed this amount in order for outlier payments to apply.

In the proposed rule, the standardization factor reflected all of the proposed case-mix and facility-level adjustment variables, including estimated low-volume payments (74 FR 49991). Because we have revised the proposed payment methodology for adult patients to reflect a patient month approach to determine the separately billable regression adjustments and excluded certain case-mix adjustments as described below, and eliminated co-morbidities entirely from the proposed pediatric payment methodology as discussed in section II.G. of this final rule, we have recomputed the proposed standardization factor (0.7827) for case-mix and the wage index to reflect the following final patient characteristics for adult patients: Age, BSA, underweight (BMI < 18.5), time since onset of renal dialysis < 4 months, pericarditis (acute), bacterial pneumonia (acute), gastro-intestinal tract bleeding (acute), hereditary hemolytic or sickle cell anemia (chronic), myelodysplastic syndrome (chronic), monoclonal gammopathy (chronic), and the low-volume adjustment as discussed in section II.E.3. of this final rule.

For pediatric patients, no standardization for outlier services is necessary since the final pediatric adjustments for outlier services were calculated such that the average overall pediatric multiplier is 1.000. The final adjustments are based on age (< 13 and 13–17) and modality (PD or HD) as discussed in section II.G. of this final rule. It should be noted that the low-volume adjustment will not apply to pediatric dialysis patients for reasons explained in section II.G. of this final rule.

As shown in Table 28 below, the average outlier service MAP amount per treatment, adjusted for the standardization, MIPPA reduction, and outlier payment factors just described for adult and pediatric patients, results in the adjusted average outlier services MAP amounts, which are multiplied by the patient-specific case-mix adjustments, to yield a patient's predicted outlier services MAP amounts. As described further in section "d. Outlier Percentage and Fixed Dollar Loss Amounts" below, the fixed dollar loss amounts for adult and pediatric patients will be added to these amounts to obtain each patient's outlier threshold for separately billable services. This is the amount which must be exceeded on a per treatment basis in order for outlier payments to apply.

Table 28--Adjusted Average Outlier Services MAP Amount

Adjusted Average Outlier Services MAP Amount		
	Patient age	
	< 18	18 and older
Average outlier services MAP amount per treatment[1]	$54.14	$86.58
Adjustments		
Standardization for outlier services[2]	1.000	0.9756
MIPPA reduction	0.98	0.98
Adjusted average outlier services MAP amount[3]	$53.06	$82.78
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold[4]	$195.02	$155.44

[1]Excludes patients for whom not all data were available to calculate projected payments under an expanded bundle. The outlier services MAP amounts are based on 2007 data. The medically unbelievable edits of 400,000 units for EPO and 1,200 mcg for Aranesp that are in place under the current ESA Claims Monitoring Policy were applied. The outlier services MAP amounts were also inflation adjusted to reflect projected 2011 prices for outlier services.

[2] Applied to the average outlier MAP per treatment. For patients 18 and older the standardization for outlier services is based on the following patient characteristics: Age, BSA, underweight (BMI < 18.5), time since onset of renal dialysis < 4 months, pericarditis (acute), bacterial pneumonia (acute), gastro-intestinal tract bleeding (acute), hereditary hemolytic or sickle cell anemia (chronic), myelodysplastic syndrome (chronic), monoclonal gammopathy (chronic) and the low volume adjustment. For patients ages <18, no standardization for outlier services is necessary since the pediatric adjustments for outlier services were calculated such that the average overall pediatric multiplier based on age (<13 and 13-17) and modality (PD or Hemo) is 1.000.

[3]This is the amount to which the separately billable (SB) payment multipliers are applied to calculate the predicted outlier services MAP for each patient.

[4]The fixed dollar loss amounts were calculated using 2007 data to yield total outlier payments that represent 1% of total projected payments for an expanded ESRD PPS.

We received the following comments in connection with our proposed outlier payment methodology. The comments received and our responses are set forth below.

Comment: One commenter expressed concern that the outlier services MAP amount would be decreased by 25 percent as a result of the standardization for case-mix and wage adjustments, the MIPPA reduction, and the outlier policy reductions.

Response: We believe the commenter was concerned about the magnitude of the reduction. Under the proposed rule, the standardization for case mix, low-volume payments, area wage level adjustments, the 2 percent reduction required by MIPPA, and the 1 percent outlier policy, resulted in a 24.1 percent reduction from the base rate. Based on the revisions to the payment models used to develop the payment adjustments finalized in this rule, application of the revised standardization factor (for case-mix, low-volume payments, and area wage levels), the MIPPA reduction, and outlier policy reduction factors, has reduced the reduction to the outlier services MAP amount to 6.9 percent for pediatric patients, and 4.4 percent for adult patients. Based on our updated analyses conducted for purposes of this final rule, we are finalizing the adjusted average outlier services MAP amounts of $53.06 for pediatric patients and $82.78 for adult patients.

c. Estimating the Imputed ESRD Outlier Services MAP Amounts

As discussed above, we proposed to base eligibility for outlier payments on a comparison of an ESRD facility's predicted MAP amount per treatment for ESRD outlier services to the facility's imputed MAP amount per treatment for those same services. In the proposed rule, we discussed our proposed methodology for determining the predicted outlier services MAP amounts for a patient (74 FR 49988) and the imputed outlier services MAP amounts for a patient (74 FR 49991). We proposed to estimate an ESRD facility's imputed costs for the ESRD outlier services based on the actual utilization of separately billable services.

We noted that although ESRD facilities currently identify costs associated with certain outlier services such as EPO and vaccines, our analysis revealed that other ESRD-related drugs and biological appear to be under-reported or not reported. For this reason, we did not believe that a cost-to-charge ratio that would be based on such reported information would accurately reflect an ESRD facility's cost

for drugs. As a result, we proposed to estimate a provider's costs based on available pricing data rather than applying a cost-to-charge ratio to facility charges to impute their cost (74 FR 49991).

i. Data Used To Estimate Imputed ESRD Outlier Services MAP Amounts

With respect to estimating the imputed MAP amounts of ESRD outlier services that are separately billable under Part B, we proposed to use ASP data for the Part B ESRD-related drugs (which is updated quarterly), and the annual laboratory fee schedule for the previously separately billable laboratory tests (74 FR 49991). We proposed to use various pricing mechanisms for the other separately billable ESRD-related services. Specifically, for medical/surgical supplies used to administer separately billable drugs, we proposed to estimate MAP amounts based on the predetermined fees that apply to these items under the current base case-mix adjusted composite payment system. For example, we pay $0.50 for each syringe identified on an ESRD facility's claims form.

For other medical/surgical supplies such as IV sets and gloves, the Medicare Claims Processing Manual (CMS Pub. 100–04) currently allows Medicare contractors to elect among various options to price these supplies, such as the Drug Topics Red Book, Med-Span, or First Data Bank (CMS Pub. 100–04, Chapter 8, Section 60.2.1). We proposed that the FI/MAC would continue to use the pricing mechanisms that are currently in place for items and services that currently are separately billable under Part B to estimate costs for these other medical/surgical supplies.

We proposed to estimate hospital-based and independent ESRD facilities' costs for blood, supplies used to administer blood, and blood processing fees using the pricing mechanisms that are currently in place for items and services that currently are separately billable under Part B (74 FR 49991). We did not propose a specific mechanism for estimating the imputed MAP amounts for drugs formerly covered under Medicare Part D but that would become renal dialysis service drugs when the ESRD PPS would be implemented in 2011. Rather, we requested public comments on the five potential approaches for estimating the imputed MAP amounts of these drugs and on alternative approaches. In the proposed rule, we discussed our rationale for each approach (74 FR 49992).

To summarize, we considered the following pricing mechanisms: (1) ASP, (2) national average Part D plan prices, (3) wholesale acquisition cost (WAC), (4) national average prescription drug event (PDE) Part D claims data, and (5) ESRD facility costs net of manufacturer rebates, discounts, and other price concessions.

The comments received on the pricing data proposed for use in estimating imputed ESRD outlier services MAP amounts and our responses are set forth below.

Comment: Several commenters requested that we clarify the specific pricing mechanism that will be used in estimating the imputed outlier services MAP amounts for separately billable drugs within the outlier calculation. Several commenters believed that ASP+6 would be a reasonable approximation of average acquisition, preparation and handling costs for the Part B separately billable drugs that are included in the definition of outlier services.

Response: We solicited public comments on the various pricing approaches that we proposed (74 FR 49992), but received very few comments, each of which are addressed below. As discussed below, only one commenter cited a preference for a particular pricing methodology among those presented. Because ASP data for the Part B ESRD-related drugs and biologicals are updated quarterly, and is the current basis for payment for these drugs, in this final rule we are finalizing the use of ASP pricing for these drugs and biologicals for the purpose of determining outlier eligibility and payments. The prices for estimating payments for Part B drugs and biologicals that were separately billable prior to January 1, 2011, will be determined by continuing to apply ASP+6 pricing for these drugs as we do currently under the basic case-mix adjusted composite payment system.

Comment: One commenter expressed concern that the separately billable prediction equation predicts 8.7 percent of the payment model's variance. The commenter believed that it would be better to pay providers based on actual spending on high cost outliers.

Response: We believe that by referring to actual spending, the commenter meant their cost for outlier services. We appreciate the commenter's input on the pricing scheme for outlier services, as noted above, we are not using provider cost for pricing of outlier services. As we explained in the proposed rule (74 FR 49991), although ESRD facilities currently identify costs associated with certain ESRD outlier services such as EPO and vaccines, our analysis revealed that charges for other ESRD-related drugs and biologicals appear to be under-reported or not reported. For this reason, we do not believe that a cost-to-charge ratio that would be based on such reported information would accurately reflect an ESRD facility's cost.

After implementation of the ESRD PPS, we intend to analyze the extent of outlier payments under the ESRD PPS and may reconsider the commenter's suggestion that we use actual provider cost (net of rebate, discounts, or other reductions) for high cost patients. We note that the updated analysis using 2006–2008 data yielded an R-squared value for the patient-level separately billable payment model of 3.3 percent due to revisions in the payment adjustments described in section II.F.3. and 4, and II.G. of this final rule.

Comment: A drug manufacturer stated that it would be willing to voluntarily report its ASP for ESRD-related drugs. One commenter encouraged CMS to rely on current Part D pricing information as a basis for calculating outlier eligibility. The commenter recommended that payment for oral ESRD-related drugs be based on the price at which the SDO would need to buy the drug from a pharmacy under arrangements. The commenter stated that contract pharmacies will expect a profit on contracting arrangements, thus penalizing SDOs. Another commenter suggested that in light of the difficulties in attempting to impute Part D drug costs for purposes of the outlier calculation, it would be best to limit the payment bundle to only those Part D covered drugs that are the oral equivalent form of an intravenous drug now covered under Part B, and separately billed by ESRD facilities.

Response: We appreciate the drug manufacturer's willingness to report ASP pricing for drugs that are covered under Part D. Although CMS does not have the authority to compel drug manufacturers to submit such data, we are encouraged by the willingness of some manufacturers to report such data, and may consider the use of ASP data in the future, including whether a voluntary reporting approach would be appropriate or feasible to determine pricing for ESRD-related drugs formerly covered under Part D. Although one commenter suggested using wholesale acquisition cost (WAC)(*see* comment below), with the exception of the use of ASP pricing, no other commenters expressed a preference for a particular pricing approach among the ones proposed.

We have elected to adopt the national average drug prices based on the Medicare Prescription Drug Plan Finder.

Similar to acquisition costs, the prices retrieved from the Medicare Prescription Drug Plan Finder reflect pharmacy dispensing and administration fees. Those prices also reflect the negotiated prices of both large and small prescription drug plans. We urge ESRD facilities to indicate on the claims their acquisition costs for ESRD-related oral drugs that are used as substitutions for injectable drugs. In this way, we can compare acquisition costs to the prices from Medicare Prescription Drug Plans.

We share the commenter's concern about imputing oral drug costs and note that, as described previously, the implementation of oral-only Part D drugs within the ESRD PPS is delayed until after the transition period ends and will be discussed in a future notice of proposed rulemaking.

Comment: One commenter requested clarification as to whether blood, blood products and blood transfusion procedures are included in calculating eligibility for outlier payments. The commenter requested that we specify the pricing mechanism that would be used to estimate the imputed MAP amounts for blood and blood products.

Response: As indicated in section II.A.3. of this final rule, we are not finalizing the bundling of blood, blood products, and blood transfusion procedures in the ESRD PPS payment. These services will continue to be separately payable. Therefore, these services do not meet the definition of ESRD outlier services and the imputed MAP amounts for use in the outlier calculation will not include payments for these services.

Comment: One commenter stated that payment for outpatient medications should be based on evidence-based guidelines. This commenter asserted that because there is no evidence supporting the superiority of brand name Vitamin D receptor drugs, the reasonable cost of generic equivalents would be an appropriate basis for pricing these and other drugs.

Response: The listing of ESRD outlier service drugs and their corresponding prices is not limited to brand name-only drugs.

Comment: One commenter requested that new technologies be included in the definition of outlier services suggesting that we consider paying for the full cost of any innovative drug or technology when an outlier payment is triggered. The commenter believed that this approach could serve as an interim measure until CMS and ESRD facilities acquire experience with the new drug or technology.

Response: We appreciate the commenter's suggestion for assessing outlier eligibility and calculating potential outlier payments for new technologies. We intend to publish a list of ESRD outlier services for implementation on January 1, 2011, in a subsequent administrative issuance along with the methodologies for updating the list. We plan to continue to assess options for accounting for the cost of new technologies within the ESRD PPS, whether through the outlier payment policy or some other feature of the ESRD PPS. We would include our assessment and any proposed options in future notices of proposed rulemaking.

Comment: One commenter suggested that CMS use wholesale acquisition cost (WAC) for purposes of pricing new drugs.

Response: Although the commenter suggested the use of WAC for pricing new drugs, no reason was given. With respect to new Part D drugs, we would rely on the national average drug price by NDC code based on data from the Medicare Prescription Drug Plan Finder as discussed previously in this section. As such, we will be unable to establish prices for new drugs that would meet the definition of ESRD outlier services until prices for those drugs are included in the Prescription Drug Plan Finder and we have updated the ESRD outlier services list to reflect the new drug and established the price in CMS systems that price ESRD claims. We point out that although new drugs would only be eligible for outlier payment after the outlier services list has been updated, the otherwise applicable ESRD PPS bundled payment rate would still apply to any new drugs within the classification categories. We intend to update the ESRD outlier services list annually to reflect new prices and new drugs within our classification categories described in section II.A.3. of this final rule.

As a result of the public comments received, we are finalizing the bases for estimating imputed outlier services MAP amounts as follows: "(1) Part B drugs that were or would have been separately billable prior to January 1, 2011, will continue to be priced based on the most current ASP pricing plus 6 percent". (2) Laboratory tests that were or would have been separately billable prior to January 1, 2011, will continue to be priced based on the most current laboratory fee schedule amounts. (3) ESRD-related supplies used to administer separately billable Part B drugs (for example, syringes) that prior to January 1, 2011, were or would have been separately billable, will continue to be priced as they are currently. (4) Renal dialysis drugs and biologicals that prior to January 1, 2011, were or would have been separately covered under Part D, including ESRD-related oral-only drugs and biologicals for which we have delayed implementation until January 1, 2014, will be priced by NDC code based on the national average pricing data retrieved from the Medicare Prescription Drug Plan Finder".

ii. Determining the Imputed per Treatment ESRD Outlier Services MAP Amount

In the proposed rule, we indicated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient (74 FR 49992). We proposed that the ESRD facility would identify by line item on the monthly claim, all ESRD outlier services furnished to the patient. We would then estimate the imputed MAP amount for these services applying one of the proposed pricing methodologies discussed above. The imputed outlier services MAP amounts for each of these services would be summed and divided by the corresponding number of treatments identified on the claim to yield the imputed outlier services MAP amount per treatment. An ESRD facility would be eligible for an outlier payment if the imputed average outlier services MAP amount per treatment exceeded the sum of the predicted outlier services MAP amount per treatment and the fixed dollar loss amount.

We did not receive comments on our proposed methodology for determining the imputed ESRD outlier services MAP amounts per treatment, beyond those already addressed in the previous section. For this reason and because it is a reasonable method to determine the amount that would have been paid for these services absent the ESRD PPS, we are finalizing our methodology for imputing an outlier services MAP amount per treatment.

d. Outlier Percentage and Fixed Dollar Loss Amounts

In the proposed rule, we indicated that payments under section 1881(b)(14)(D)(ii) of the Act for outlier cases would be applied in a budget neutral manner (74 FR 49992). Therefore, we proposed to reduce the base rate by the proposed outlier percentage (that is, 1.0 percent), reflecting the total amount of estimated payments for outlier cases, as discussed in section II.E.4. of this final rule. In the proposed rule, we discussed our rationale for determining outlier

payments and outlier percentages for the ESRD PPS (74 FR 49992).

We proposed that the outlier percentage would be 1.0 percent of total ESRD PPS payments (74 FR 49993). We stated that we believed an outlier percentage of 1.0 percent struck an appropriate balance between our objectives of paying an adequate amount for for the most costly patients, while providing an appropriate level of payment for those patients who did not qualify for outlier patients. We also said that this percentage is consistent with other Medicare PPSs, such as the 1 percent outlier policy under the outpatient PPS (74 FR 49993). We also proposed that the fixed dollar loss amounts that would be added to the predicted, outlier services MAP amounts would differ for adult and pediatric patients due to differences in the use of separately billable services among adult and pediatric patients, particularly drugs (74 FR 49993). We proposed separate fixed dollar loss amounts, defined in proposed § 413.237(a), of $134.96 for adult patients and $174.31 for pediatric patients (74 FR 49993, 50024).

We received the following comments on our proposals pertaining to these features of the outlier policy.

Comment: Many commenters supported the proposed features of the outlier policy including the 1.00 percent outlier percentage, indicating that it will assist all facility types including independent, hospital-based, and pediatric facilities in providing adequate care to complex and costly patients. However, to maximize the base rate amount, commenters urged CMS to keep the outlier percentage as small as possible.

Another commenter urged us to eliminate the outlier policy and pay the same bundled rate for all patients asserting that the 1.0 percent outlier reduction from the base rate for small and midsized dialysis facilities would have a punitive impact, because these facilities are not able to spread their outlier risk over a large patient population.

Response: As indicated in the proposed rule, we believe that a 1.00 percent outlier percentage strikes an appropriate balance between our objectives of paying an adequate amount for the most costly patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. We have updated the information in the Table 37 that appeared in the proposed rule (74 FR 49993) based on the ESRD PPS adopted in this final rule to show how outlier payment reductions in the base rate beyond 1 percent would revise the number of estimated patient months that would qualify for outlier payments for both adult and pediatric patients. *See* Table 29 below.

Table 29: Impact of Outlier Percentage on Patient Months Qualifying for Outlier Payment

	Outlier percentage				
	1%	1.5%	2%	2.5%	3%
Age 18 and Older: Patient Months Qualifying for Outlier Payment	4.7%	6.4%	8.2%	10.0%	11.9%
Age < 18: Patient Months Qualifying for Outlier Payment	2.2%	3.5%	5.0%	6.7%	9.0%
Age 18 and Older: Fixed Dollar Loss Amount*	$155.44	$127.41	$106.13	$89.02	$74.84
Age < 18: Fixed Dollar Loss Amount*	$195.02	$140.88	$103.19	$76.16	$56.29

*The fixed dollar loss amounts were calculated using 2007 claims data to yield total outlier payments that represent a certain percentage (e.g., 1%) of total projected payments in an expanded ESRD PPS, and reflect an outlier loss sharing percentage of 80%. In determining the fixed dollar loss and outlier payment amounts, EPO and darbepoetin payments were capped to reflect the medically unbelievable edit thresholds in place under the ESA monitoring policy starting January 1, 2008 (400,000 units for EPO and 1,200 mcg for darbepoetin). The outlier payment would be based on 80% of the outlier services Medicare Allowable Payment (MAP) that exceeds the sum of the predicted outlier services MAP for each patient and the fixed dollar loss amount for the patient's age group (<18 or 18 and older).

As with Table 37 in the proposed rule (74 FR 49993), we believe that Table 29 continues to support our belief that a 1 percent outlier payment percentage balances the need for paying for unusually costly resource intensive cases, while at the same time ensuring an adequate base rate for patients who do not qualify for outlier payments. Based on the updated analysis, a 1.0 percent outlier policy results in 4.7 percent of patient months qualifying for outlier payment compared to 5.3 percent based on the analysis conducted for the proposed rule. An increase in the outlier percentage would result in a lower fixed dollar loss threshold and more patient months qualifying for outlier payment.

However, each percent increase in the outlier percentage decreases the base rate applied to all patient months. Public comments addressed in previous sections of this final rule advocating for fewer adjustments, a lower standardization reduction, and a higher base rate provide additional support for a 1.0 percent outlier policy.

With respect to the commenter who urged us to eliminate the outlier payment policy, we point out that section 1881(b)(14)(D)(ii) of the Act requires us to have an outlier payment

adjustment. Accordingly, we are finalizing the 1.0 percent outlier percentage.

Comment: One commenter stated that an independent analysis revealed that an outlier payment policy similar to that proposed by CMS was "optimal" in that it resulted in minimal reduction to the base rate and provided a reasonable distribution of outlier payments to providers. The commenter found that outlier payments were distributed in higher proportion to African American patients than for other racial groups.

Response: We note that the outlier percentage of 1.0 percent which we have adopted in this final rule comports with our analysis and the commenter's analysis.

Comment: Several commenters recommended that we re-evaluate outlier payments and the outlier percentage on an ongoing basis and adjust it periodically as needed, adding back any excessive reduction in the base rate if projected outlier payments exceed actual outlier payments. Similarly, another commenter believed that because ESRD facilities may not receive adequate payment for outlier expenses, we should return any unanticipated decrease in reimbursement to providers on a pro rata basis at the end of the year. The commenter asserted that this would ensure budget neutrality, not budget negativity.

The commenters concluded that adjustments must reflect the changes in the reported cost of care for the outlier patient population to ensure equity in access for all ESRD patients.

Response: We disagree with the commenters' recommendations. We have put forth our best effort to project the impact of a 1.0 percent outlier payment policy on the magnitude of the fixed dollar lost amounts for adult and pediatric patients in order to calculate the outlier payment thresholds. The ESRD PPS is intended to provide a fixed reliable payment rate per treatment for the cost of furnishing outpatient dialysis services.

While we intend to update the fixed dollar loss amounts on an annual basis in order to maintain a 1.0 percent outlier percentage, and evaluate the degree to which our estimated projections of outlier payments match actual outlier expenditures, we do not intend to adjust the base rate in future years to reflect the difference between actual and projected outlier payments. We have taken the same position in connection with other PPSs, and do not believe a departure from this policy would be appropriate. Therefore, we have not adopted the commenters' suggestion that we make prospective corrections in the base rate amounts to correct for over/underestimates in projected outlier payments for prior years.

Based on our review of all public comments received, the updated data analyses conducted for purposes of this final rule, and for the reasons discussed above, we are finalizing the fixed dollar loss amounts and outlier percentage as set forth in proposed § 413.237(a). Specifically, we are finalizing fixed dollar loss amounts of $155.44 and $195.02 for adult and pediatric patients, respectively, and a 1.0 percent outlier percentage.

2. Outlier Payments

In the proposed rule, we proposed an 80 percent loss sharing percentage as the percentage of costs exceeding the fixed dollar loss amount that would be paid by Medicare (74 FR 49993). We conveyed our interest in preserving the efficiency incentives inherent under a PPS, stating that an 80 percent loss sharing percentage would strike a reasonable balance between the policy objective of paying an adequate amount for high cost cases, while at the same time preserving the efficiency incentives inherent in a PPS. We also stated that an 80 percent loss sharing percentage was consistent with that used in other Medicare payment systems. We also proposed to implement an annual monitoring process that would identify patterns of increased utilization of outlier services, and any associated outlier payments across ESRD facilities (74 FR 49993).

For treatments eligible for outlier payments, we proposed that the per treatment outlier payment equal 80 percent (the loss sharing percentage) of the imputed average ESRD outlier service MAP amounts in excess of the sum of the predicted, outlier services MAP amount per treatment, and the fixed dollar loss amount, as specified in proposed § 413.237(c). We indicated that for treatments eligible for the outlier payments, the outlier payment would be added to each ESRD PPS per treatment payment amount.

The comments we received on our outlier payment proposal and our responses are set forth below.

Comment: One commenter stated that to facilitate cost containment, outlier payments, by design, do not cover all losses. This commenter asserted that ESRD facilities pay for the treatment of infections in the interest of continuity of care when these infections may have little to do with dialysis care. The commenter estimated an outlier payment for a high cost patient based on AWP pricing for daptomycin and concluded that the facility would lose $1,600 in one month after accounting for the outlier policy's loss sharing feature. The commenter believed that to compensate for this loss, ESRD facilities would either reduce the provision of medications to other patients, defer this treatment to be provided at home or in infusion centers, or turn the patient away.

Response: As discussed in section II.A.3. of this final rule, we will provide a mechanism whereby an ESRD facility can identify and be paid separately for antibiotics (and other drugs and biologicals) that are administered in the ESRD facility, but are not renal dialysis services. Because non-renal dialysis services do not meet the definition of an outlier service, they would not be included in the calculation of outlier eligibility or payments.

Comment: One commenter stated that pay for performance does not clearly define how to prevent penalty for non-compliant patients or patients with underlying disease as related to adequacy or anemia. The commenter considered these cases to be "outliers."

Response: The commenter is apparently using the term "outliers" in a manner different than that addressed in the proposed and final rules with respect to our establishment of an outlier payment policy. The types of cases which the commenter cites may be aberrant or unusual, but they would not necessarily qualify as outlier cases in the context of this final rule. We refer readers to section II.M. of this final rule for more information about the pay-for-performance element of the ESRD PPS, referred to as the QIP.

As a result of the public comments and for the reasons we have explained above and in the proposed rule, we are finalizing § 413.237(c) of the regulations to provide that the per treatment outlier payment equal 80 percent (the loss sharing percentage) of the imputed average ESRD outlier service MAP amounts in excess of the sum of the predicted, outlier services MAP amount per treatment and the fixed dollar loss amount.

3. Hypothetical Outlier Payment Examples Hypothetical Example—Adult Patient

Martha, a 66 year old female who is 167.64 cm. tall, weighs 105 kg., and has a recent diagnosis of GI bleeding. A patient of this weight and height is not below the threshold for underweight status and thus would not qualify for a low BMI adjustment.

The formula for calculation of a patient's BSA is:

$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$

Martha's BSA is calculated as:

$BSA_{Martha} = 0.007184 * 167.64^{.725} * 105^{.425} = 0.007184 * 40.9896 * 7.2278 = 2.1284$

Table 29 reveals that the separately billable multiplier for BSA is 1.014. Martha's case-mix adjustment based on her BSA of 2.1284 would be:

$= 1.014^{(2.1284 - 1.87/0.1)}$

$= 1.014^{2.584}$

= 1.037

Step 1: Determine the predicted, ESRD outlier services MAP amount using the product of all applicable case-mix adjusters.

The product of the patient-level outlier services case-mix adjusters as identified in Table 29:

= 66 year old: 1.000, BSA: 1.037, and GI bleeding: 1.571:

= 1.000 * 1.037 * 1.571

= 1.6291

The adjusted, average, ESRD outlier services MAP amount = $82.78

The adjusted, average ESRD outlier services MAP amount * product of the outlier services case-mix adjusters:

= $82.78 * 1.6291

= $134.86

Step 2: Determine the imputed average, per treatment, ESRD outlier services MAP amount based on utilization of all separately billable services on the monthly ESRD facility bill.

Assume the imputed monthly ESRD outlier services amount = $4,000 and that the corresponding total number of treatments in the month = 10

The imputed, average, per treatment, outlier services MAP amount

= $4,000/10

= $400

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount.

The fixed dollar loss amount = $155.44

The predicted, ESRD outlier services MAP amount = $134.86

= $134.86 + $155.44

= $290.30

Step 4: Calculate outlier payment per treatment.

Outlier payment = imputed average, per treatment, outlier services MAP amount − (predicted, ESRD outlier services MAP amount plus the fixed dollar loss amount) * loss sharing percentage:

= ($400.00 − $290.30) * .80

= $109.70 * .80

= $87.76

Hypothetical Example—Pediatric Patient:

John, is a 13 year old HD pediatric patient.

Step 1: Determine the predicted, ESRD outlier services MAP amount.

As specified in Table 29, determine the patient-level ESRD outlier services case-mix adjuster:

= 13 year old HD patient = 1.459

The adjusted, average, ESRD outlier services MAP amount = $53.06

The adjusted, average, ESRD outlier services MAP amount * the product of the outlier services case-mix adjusters:

= $53.06 * 1.459

= $77.41

Step 2: Determine the imputed, average, per treatment, ESRD outlier services MAP amount.

The imputed monthly ESRD outlier services amount = $4,000

Assume the corresponding total number of treatments = 10

The imputed, average, per treatment, outlier services MAP amount =

= $4,000/10

= $400

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount.

The fixed dollar loss amount = $195.02

The predicted, ESRD outlier services MAP amount = $77.41

= $77.41 + $195.02

= $272.43

Step 4: Calculate outlier payment per treatment.

Outlier payment = imputed, average, per treatment, outlier services MAP amount − (predicted, ESRD outlier services MAP amount plus the fixed dollar loss amount) * loss sharing percentage:

= ($400.00 − $272.43) * .80

= $127.57 * .80

= $102.06

The outlier payment amount would be added to the ESRD PPS payment amount, per treatment. For a detailed description of calculating the ESRD PPS payment amount per treatment, please refer to the hypothetical examples in the Comprehensive Payment Examples presented later in this section of this final rule.

4. Application of Outlier Policy During the Transition and in Relation to the ESA Monitoring Policy, Other Claims Processing Tools, and Other CMS Policies

In the proposed rule, we indicated that the outlier payment policy would be limited to the proposed ESRD PPS (74 FR 49994). We proposed that for those ESRD facilities that do not elect to be excluded from the three year transition, outlier payments would be limited to the portion of the blended rate based on the payment rates under the proposed ESRD PPS.

We also indicated that nothing within the proposed outlier payment policy would replace the claims monitoring implications related to the utilization of separately billable ESAs including currently available epoetin alfa (EPOGEN®, or EPO), darbepoetin alfa (ARANESP®) or any ESAs that may be developed in the future and used by beneficiaries receiving renal dialysis services (74 FR 49994).

The comments received on application of our proposed outlier policy during the transition and in relation to the ESA Claims Monitoring Policy and our responses to them are set forth below. Approximately half of the commenters supported and half opposed the continuation of our claims monitoring policy with respect to the utilization of ESAs.

Comment: Some commenters stated that they believed there would be no incentive to overuse ESAs once the ESRD PPS is implemented in 2011 and, therefore, the ESA Claims Monitoring Policy should be discontinued. Other commenters supported continuing to apply the ESA Claims Monitoring Policy under the ESRD PPS, maintaining that it would help ensure that ESAs would not be overutilized in order to obtain outlier payments. One commenter suggested that in instances where the patient's ESA and iron therapies are within the QIP parameters, then CMS should provide outlier payments. The commenter believed that it would be appropriate to include the costs of ESA therapy while the patient's hemoglobin remained at 13 or lower and the patient's iron stores were adequate, but exclude from the outlier calculation the costs of ESA therapy in instances where a patient's hemoglobin exceeded 13, or if the patient's iron level was above an adequate level.

Response: Currently there are two claims processing edits associated with the ESA Claims Monitoring Policy—the reduction in the payable ESA amount based on reported hemoglobin (or hematocrit) level, and medically unbelievable edits (MUEs) based on the ESA total administered dose. During the transition, ESRD facilities will be expected to meet our quality measures under the QIP, notwithstanding that the implementation of the QIP does not occur until January 1, 2012, in addition to complying with other policies for coverage and claims processing.

With respect to the basic case-mix adjusted composite payment system portion of the blended payment during the transition, we will continue to apply

both ESA Claims Monitoring Policy processing edits and implement any corresponding payment reductions. Although several commenters believed that the implementation of the ESRD PPS would provide sufficient incentives not to overutilize ESAs, obviating the need for continuation of the ESA Claims Monitoring Policy, we believe that the continued application of this policy will help ensure the proper dosing of ESAs, and provide an added safeguard against the overutilization of ESAs, particularly where the consumption of other separately billable services may be high, in order to obtain outlier payments.

With respect to the commenter's suggestion that payments for ESAs should only be considered outlier eligible payments when a patient's hemoglobin is at 13 or lower, and excluded when the value exceeds 13, this recommendation does not consider the fact that hemoglobin levels can be volatile even when proper doses are administered. Fluctuations will occur because of the time required to titrate levels in response to the patient's specific condition. Therefore, linking ESA eligibility for outlier payments to a patient's achieved hemoglobin level is not a feasible payment option.

With respect to the ESRD PPS portion of the blended payment, we will apply dosing reductions resulting from the application of the ESA Claims Monitoring Policy prior to any calculations of outlier eligibility. We believe that continuation of this policy is necessary in order to provide a disincentive for overutilization of ESAs in order to receive outlier payments, notwithstanding that the implementation of the ESRD PPS will tend to discourage overuse of ESAs, as ESAs are part of the payment bundle.

The ESA dose edits will be applied prior to pricing so that we do not overvalue these services in determining eligibility for outlier payments. We note that the ESA Claims Monitoring Policy provides an opportunity for appeal to address those situations where there might be medical justification for higher hematocrit or hemoglobin levels. Beneficiaries, physicians, and dialysis facilities may submit additional documentation to justify medical necessity, and any payment reduction amounts may be subsequently reinstated when documentation supports the higher hematocrit or hemoglobin levels. To the extent successful appeals impact the amount of outlier payments on behalf of beneficiaries, those claims will be reprocessed to reflect the correct amount of outlier payments.

Comment: One commenter believed that EPO dosing among ESRD patients has been historically high and recommended that we cap the EPO contribution in the base rate at 14,000 units per week. Similarly, the commenter questioned whether the inclusion of current ESA dosing parameters within the outlier calculation would be in the best interest of the patient and suggested that high doses related to hyporesponsiveness should be further investigated. The commenter recommended that we cap ESA dosing at 160,000 units per month (IV administration) until further valid studies have determined safer dosing levels.

Response: With respect to the commenter's specific concern about the extent to which the cap on ESA dosing is appropriate, we note that this concern is beyond the scope of this rule. We appreciate the commenter's concern about potential excess ESA dosing of ESRD patients but, as discussed in section II.E. of this final rule, the amount of ESA payment included in the base rate comports with limits established under the ESA Claims Monitoring Policy.

We stated in the proposed rule that both the base rate and the features of the outlier policy, including the outlier percentage and fixed dollar loss thresholds, were based on 2007 claims data (74 FR 49990). In developing the base rate for the proposed rule we applied a medically unbelievable EPO limit of 30,000 units per treatment. This edit contributed to lower fixed dollar loss amounts. For purposes of the final rule, we have revised the ESA medically unbelievable edits to comport with CMS's own ESA Claims Monitoring Policy. Specifically, in 2007, the ESA claims monitoring policy included a monthly medically unbelievable edit threshold of 500,000 for EPO and 1,500 mcg. for ARANESP®. The medically unbelievable edit thresholds were reduced to 400,000 units for EPO and 1,200 mcg. for ARANESP® in 2008 (Transmittal 1307, Change Request 5700 (July 20, 2007)).

For purposes of this final rule, the base rate and the features of the outlier policy, including the outlier percentage and the fixed dollar loss thresholds as reflected in Table 28 were based on 2007 data. Although the medically unbelievable edits that were in place for EPO and ARANESP® were 500,000 units and 1,500 mcg., respectively in 2007, we chose to apply the edits that are currently in place. That is, we applied medically unbelievable edits of 400,000 units for EPO and 1,200 mcg. for ARANESP® in establishing the outlier policy's fixed dollar loss amounts. We believe that this edit is necessary for purposes of reflecting current CMS policy and to bring the projected fixed dollar loss amounts into line with ESA dosing that is consistent with the current ESA Claims Monitoring Policy. We point out that we applied a similar edit to the calculation of the base rate, in that the medically unbelievable edits that were in place for EPO and ARANESP® in 2007 were also used to calculate the components of the base rate that reflect payments for ESAs.

Comment: One commenter responded to our request for identifying potential safeguards against the overuse of ESAs under the ESRD PPS. This commenter noted that there are certain diseases in which ESAs should not serve as the primary treatment approach for anemia where transfusion may be the better choice. This commenter suggested that we could implement measures to ensure that ESAs are not administered or reimbursed in the absence of evidence of iron depletion.

Response: We agree with the commenter that there are multiple causes (for example, iron deficiency anemia, vitamin B12 deficiency, or folic acid deficiency) and treatment approaches for anemia. We expect that patients will be evaluated to determine the cause of their anemia and treated appropriately. We would also expect that ESRD facilities that administer ESAs in accordance with their patients' plans of care would do so in accordance with the FDA's approved indications.

Comment: One commenter requested that we do further research into higher hemoglobin levels because the commenter believes that some patients do not do well with lower hemoglobin levels and therefore need more EPO.

Response: Although we are not performing such research, we would agree that any research that attempts to examine the relationships among hemoglobin levels, ESA utilization, and clinical outcomes is welcome and should be encouraged.

Comment: One commenter expressed concern that establishing reimbursement policy based on what the commenter believed are "misguided/unguided and perhaps dangerous treatment patterns," eroded the opportunity to improve quality of care and establish a financially sound policy. The comment included a copy of a report from the Department of Health and Human Services' Office of the Inspector General (US DHHS OIG) which described inconsistencies in ESRD facilities' policies and protocols for administering ESAs. Other commenters submitted comments indicating that there have not been studies that have reported an

appropriate target hematocrit and expressed concern that the proposed rule might encourage underutilization of EPO.

Response: We are closely following the growing body of scientific evidence that describes the usage patterns of ESAs, as well as their potential benefits and harm. In order to further evaluate this body of evidence, CMS held a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting on March 24, 2010. The purpose of the MEDCAC was to provide independent guidance and expert advice to us about the evidence on the use of ESAs in the management of anemia in patients with chronic kidney disease and end-stage renal dialysis disease. On June 16, 2010, we formally opened a new National Coverage Determination (NCD) regarding ESAs.

Comment: Several commenters questioned specific features of the ESA Claims Monitoring Policy and ESA dosing of patients with chronic kidney disease (CKD).

Response: We thank the commenters for stating their concerns. However, we solicited public comments on the extent to which we should continue to apply the ESA Monitoring Policy under the proposed ESRD PPS, which is a payment system applicable to Medicare beneficiaries with end-stage renal disease, not CKD. Comments concerning the ESA Claims Monitoring Policy and ESA dosing of patients with CKD are beyond the scope of this final rule.

In developing this final rule, we have considered the extent to which it would be appropriate to extend the ESA Claims Monitoring Policy to include home dialysis patients who self-administer ESAs. Currently, the ESA Claims Monitoring Policy does not apply to ESA claims for patients who receive their dialysis at home and self-administer their ESAs and we will continue this policy in 2011.

We expect ESRD facilities managing home dialysis patients to use prudent judgment in ESA dosing and monitoring hemoglobin levels. Because outlier payments may be made on behalf of home dialysis patients as well as in-facility ESRD patients, we intend to monitor outlier payments for any unusual trends in outlier payments for all patients, including home dialysis patients who self-administer ESAs. We will continue to evaluate outlier payments and, if necessary, will address changes in the future.

As a result of the public comments received and for the reasons we addressed above, we will continue to apply the ESA Claims Monitoring Policy edits on ESRD facility claims for purposes of calculating the basic case-mix adjusted composite payment system portion of the blended payment during the transition period, and in connection with determining the eligibility of ESA payments for outlier payments.

I. Comprehensive Payment Model Examples

In section II.D. of this final rule, we demonstrated how the case-mix adjustments based on separate estimating equations for CR and SB services (that is, the two equation model) were combined to obtain a single payment formula under the ESRD PPS. Table A in the Appendix contains the case-mix adjustments applicable to adult patients. In section II.G. of this final rule, we addressed the pediatric payment adjustments under the ESRD PPS. Table B in the Appendix contains the four pediatric classification categories and corresponding case-mix adjusters that will be applied to pediatric patients. In this section, we explain how the area wage index and case-mix adjustments will be applied to the adjusted base rate amount described in section II.E.4. of this final rule, reflecting combined CR and SB services, resulting in a patient-specific per treatment payment amount under the ESRD PPS, as set forth in § 412.56. We demonstrate how the case-mix adjustments presented in Tables A and B in the Appendix would be applied for eight hypothetical ESRD patients to obtain the per treatment payment amounts under the ESRD PPS. We refer to the product of the applicable case-mix adjustment factors as the patient multiplier or PM. The ESRD PPS case-mix adjusters are shown in Table A in the Appendix for adult patients and Table B in the Appendix for pediatric patients.

Each example uses the adjusted base rate of $229.63, covering Part B renal dialysis services and self-care home dialysis services as set forth under section 1881(b)(4) of the Act. Each example also assumes an ESRD wage index value of 1.1000. The labor-related share derived from the ESRD PPS market basket, described in section II.J. of this final rule, is 41.737 percent. Therefore, the starting point in each example prior to determining the patient-specific PM is a wage index adjusted base rate of $239.21. This amount was computed as follows:

Base rate $229.63
Labor-related share of base rate ($229.63 * .41737 = $95.84) $95.84
Wage index adjusted labor-related share ($95.84 * 1.1000 = $105.42) $105.42
Non labor-related share of base rate ($229.63 * (1 − .41737) = $133.79 $133.79
Wage index adjusted base rate ($105.42 + $133.79 = $239.21) $239.21

We also point out that each case-mix adjusted payment amount is reduced by 3.1 percent through the application of an adjustment factor of .969 to account for budget neutrality during the transition period. This is referred to as the transition budget neutrality adjustment, and is included as the last item in the computation of the payment amount for each patient, after application of all other case-mix adjustment factors (that is, all PMs), including any applicable add-on amounts for training treatments. It also applies to any outlier payments.

Example 1—Relatively Healthy ESRD Patient With No ESRD Payment Co-Morbidities; No Outlier Payments Apply

John, a 45 year old male Medicare beneficiary, is 187.96 cm. (1.8796 m.) in height and weighs 95 kg. John was diagnosed with ESRD in early 2010 and has been on HD since July 2010. He has chronic glomerulonephritis and hypertension, and has an AV fistula. The patient also has secondary hyperparathyroidism. John's payment rate for treatments furnished in January 2011 would be calculated as follows.

Table A in the Appendix reveals that none of John's co-morbidities is among those for which a case-mix adjustment applies. The only pertinent factors to adjust the base rate amount are age, height, and weight. Using the formula for BMI, we see that John is not underweight, having a BMI of 26.89 kg/m^2, which is greater than the threshold value of 18.5, the cut-off for underweight status:

$BMI_{John} = weight_{kg} / height\ (m^2)$
$= 95/1.8796^2$
$= 95/3.5329$
$= 26.89$

Therefore, there is no case-mix adjustment for low BMI. The formula for calculation of a patient's BSA is:

$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$

John's BSA is calculated as:

$BSA_{John} = 0.007184 * 187.96^{.725} * 95^{.425}$
$= 0.007184 * 44.5346 * 6.9268$
$= 2.2161$

Using the Table A in the Appendix multiplier of 1.020, John's case-mix adjustment or payment multiplier (PM) based on his BSA of 2.2161 is computed as follows:

$PM_{BSA} = 1.020^{(2.2161-1.87)/0.1}$
$= 1.020^{3.461}$

= 1.0709

John's PM would reflect the applicable case-mix adjustments from Table A in the Appendix for both age and BSA and may be expressed as:

$PM_{John} = PM_{age} * PM_{BSA}$
= 1.013 * 1.0709
= 1.0848

John's ESRD payment rate for treatments furnished in January 2011 would be:

$239.21 * 1.0848 * .969 = $251.45

Example 2—Same as Example 1, Except Dialysis Began November 15, 2010

John's PM would have to include the adjustment for the onset of dialysis, because the treatments for which we are calculating the payment amount occur within 4 months of November 15, 2010. Because the onset of dialysis adjustment is limited to a maximum of 120 days, this particular adjustment would apply for treatments furnished between January 1, 2011 and March 15, 2011. John's applicable case-mix adjustments would be for a patient new to dialysis, age, and BSA, and may be expressed as:

$PM_{John} = PM_{DialQuest} * PM_{Age} * PM_{BSA}$

Using the adjustment factors from Table 10, John's PM is:

$PM_{John} = 1.510 * 1.013 * 1.0709 = 1.6381$

For treatments furnished between January 1, 2011 and March 15, 2011, John's payment rate per treatment would be:

$239.21 * 1.6381 * .969 = $379.70

After March 15, 2011, when the onset of dialysis adjustment has expired, the payment would be $251.45, as calculated in Example 1.

Example 3—ESRD Patient With Multiple Co-Morbidities

Mary, a 66 year old female, is 167.64 cm. (1.6764 m.) in height and weighs 105 kg. She has diabetes mellitus and cirrhosis of the liver. Mary was diagnosed with ESRD in 2006, and has been on HD since that time. Mary was admitted for a two week hospitalization from January 2–16, 2011 due to gastrointestinal tract bleeding, a diagnosis confirmed upon discharge. Mary's hemorrhaging due to her GI bleeding ceased during her hospitalization. While in the hospital, Mary received inpatient dialysis. Mary was also discharged with a diagnosis of monoclonal gammopathy. After convalescing at home for 3 days, she resumed HD at an ESRD facility on January 20, 2010. The facility records the GI bleeding and monoclonal gammopathy diagnoses using the relevant ICD–9–CM codes for treatments received during the month of January. For claims submitted beginning with the month of February and continuing thereafter, the facility reports only the monoclonal gammopathy diagnosis, a chronic condition.

The BMI calculation is:

$BMI = weight_{kg}/height(m^2)$
$BMI_{Mary} = 105/1.6764^2$
= 105/2.8103
= 37.3626

Table A in the Appendix reveals that the PM in this example must be considered using the case-mix adjustments for gastrointestinal tract bleeding, monoclonal gammopathy, age, and BSA. Although Mary has diabetes and cirrhosis of the liver, these co-morbidities are not used in determining the case-mix adjusters under the ESRD PPS. The formula for calculation of a patient's BSA is:

$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$
$BSA_{Mary} = 0.007184 * 167.64^{.725} * 105^{.425}$
= 0.007184 * 40.9896 * 7.2278
= 2.1284

Using the Table A in the Appendix multiplier of 1.020, Mary's case-mix adjustment or PM based on her BSA of 2.1284 is computed as follows:

$PM_{BSA} = 1.020^{(2.1284 - 1.87)/0.1}$
$= 1.020^{2.584}$
= 1.0525

Although Mary has both an acute co-morbidity (GI bleeding) and a chronic co-morbidity (monoclonal gammopathy) for the month of January, the facility may only be paid using the condition with the higher adjustment factor for the maximum number of 4 consecutive claim months in which payment for both co-morbidities must be considered. Because the case-mix adjustment for GI bleeding (1.183) exceeds that for monoclonal gammopathy (1.024), Mary's case-mix adjustment for co-morbidities will reflect GI bleeding only for treatments received in January 2011 through April 2011. Therefore, for these treatments, Mary's PM may be expressed as:

$PM_{Mary} = PM_{age} * PM_{BSA} * PM_{GIBleed}$
= 1.000 * 1.0525 * 1.183
= 1.2451

For treatments received from January 20, 2011 through April 2011, Mary's payment rate per treatment is:

$239.21 * 1.2451 * .969 or $288.61

Beginning with claims for May, only one co-morbidity applies for payment purposes, monoclonal gammopathy, for which the PM is 1.024. As this is a chronic condition, beginning with treatments furnished in May and continuing thereafter, Mary's PM may be expressed as:

$PM_{Mary} = PM_{age} * PM_{BSA} * PM_{Mono}$
= 1.000 * 1.0525 * 1.024
= 1.0778

For treatments received in May 2011 and thereafter, provided no other co-morbidities apply, Mary's payment rate per treatment would be:

$239.21 * 1.0778 * .969 or $249.83

Example 4—ESRD Patient With Multiple Co-Morbidities, Onset of Dialysis Adjuster, Training Treatments, and Acute Co-Morbidity Recurrence Apply

Ted, a 30-year-old male, began in-center HD on March 20, 2011. Ted has type II diabetes mellitus, sickle cell anemia, and was diagnosed on March 2 with bacterial pneumonia, which was treated with antibiotics. After completing his course of treatment with antibiotics, Ted was declared free of pneumonia on April 15. Because the patient has family caregivers available to assist him, Ted expressed a desire to become a PD patient. His nephrologist agreed that Ted was a suitable candidate for CAPD. On June 20, 2011, Ted began a series of 12 training treatments at his dialysis facility (one which does not qualify for the low-volume adjustment, but which is certified to provide home dialysis training) to transition to CAPD. These training treatments ended on July 21, 2011. Between July 18 and July 21, Ted had 2 training treatments. Ted successfully began CAPD on July 23, 2011, but was again diagnosed with bacterial pneumonia on August 10. After prolonged treatment with antibiotics, Ted was declared free of pneumonia on November 15, 2011.

Ted is 170 cm. (1.70 m.) in height and weighs 78 kg. Table A in the Appendix reveals that the case-mix adjusters which must be considered in this case are those for age, BSA, onset of dialysis, bacterial pneumonia, and sickle cell anemia. As will be shown Ted does not qualify for the low BMI adjustment. In addition, the training add-on of $33.44 per treatment (prior to adjustment for area wage levels) must also be considered in the payment computations.

$BMI_{Ted} = weight_{kg}/height\ (m^2)$
$= 78/1.70^2$
= 78/2.89
= 26.99

Because Ted's BMI exceeds the required threshold value of 18.5, there is no case-mix adjustment for low BMI. The formula for the calculation of a patient's BSA is:

$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$

Ted's BSA is calculated as:

BSA_{Ted} 0.007184 * $170^{.725}$ * $78^{.425}$
= 0.007184 * 41.4072 * 6.3700
= 1.8949

Using the Table A in the Appendix multiplier of 1.020, Ted's case-mix adjustment based on his BSA of 1.8949 is computed as follows:

$PM_{BSA} = 1.020^{1,8949-1.87)/0.1}$
$= 1.020^{.249}$
= 1.0049

The onset of dialysis adjustment is applicable in Ted's case, and extends from March 20, 2011 through July 17, 2011 (120 days). During this period, no case-mix adjustments for co-morbidities may be applied because the onset of dialysis adjustment supersedes the application of case-mix adjusters for co-morbidities. Neither may the training add-on be paid for the 10 training treatments furnished during the period the onset of dialysis adjustment is in effect. The only pertinent case-mix adjustments are those for age, BSA, and the onset of dialysis. For the 120 day period from March 20, 2011, through July 17, 2011, Ted's PM is calculated as follows:

$PM_{TED} = PM_{age} * PM_{BSA} * PM_{Dial/Onset}$
= 1.171 * 1.0049 * 1.510
= 1.7769

Ted's ESRD payment rate per treatment from March 20, 2011 through July 17, 2011 would be:
$239.21 * 1.7769 * .969 = $411.88

For the 2 training treatments furnished between July 18 and July 21, the dialysis facility would receive a training add-on for each treatment, computed as follows:

Training rate—$33.44
Wage index—1.10
Training payment—$33.44 * 1.10 = $36.78

Because Ted has a chronic co-morbidity, sickle cell anemia, the payment rate per treatment for dialysis treatments beginning July 18 must reflect case-mix adjustments for age, BSA, and sickle cell anemia:

$PM_{Ted} = PM_{age} * PM_{BSA} * PM_{Sickle}$
= 1.171 * 1.0049 * 1.072
= 1.2615

Ted's ESRD payment rate per treatment (excluding the training add-on amount for 2 training treatments) would be:

$239.21 * 1.2615 = $301.76

Total payments for each of the 2 training treatments provided between July 18 and July 21 would be:

($301.76 + $36.78) * .969 = $328.05

For claims submitted beginning August 2011, Ted's dialysis facility correctly reported the co-morbidities of sickle cell anemia and bacterial pneumonia. Because payment can only be made for the condition which yields the highest payment where two or more co-morbidities apply, Table A in the Appendix reveals that bacterial pneumonia is the condition with the higher case-mix adjuster (1.135). Therefore, this is the co-morbidity that will be reflected in the computation of Ted's PM as follows for claims submitted for the 4 months of August 2011 through November 2011 (the maximum number of claim months an acute co-morbidity case-mix adjuster can be applied without a subsequent recurrence):

$PM_{Ted} = PM_{age} * PM_{BSA} * PM_{Pneum}$
= 1.171 * 1.0049 * 1.135
= 1.3356

Ted's ESRD payment rate per treatment for the months of August 2011 through November 2011 would be:

$239.21 * 1.3356 * .969 = $309.58

After November 2011, the only co-morbidity that would apply in computing the payment rate is Ted's chronic sickle cell anemia, for which the PM is 1.072. Beginning with claims submitted for the months of December 2011 and thereafter, assuming no other changes in Ted's condition, the payment rate per treatment would be based on the following case-mix adjusters:

$PM_{Ted} = PM_{age} * PM_{BSA} * PM_{Sickle}$
= 1.171 * 1.0049 * 1.072
= 1.2615

Beginning with monthly claims for December 2011 and thereafter, Ted's ESRD payment rate per treatment would be:

$239.21 * 1.2615 * .969 = $292.41

Example 5—Aged ESRD Patient With Low BMI (< 18.5kg/m_2), History of Hospitalization, Multiple Co-Morbidities, and Treatment in a Facility Qualifying for the Low-Volume (LV) Adjustment

Agnes, an 82 year old female, is 160.02 cm. (1.6002 m.) in height and weighs 45.36 kg. She has longstanding type II diabetes mellitus and was diagnosed with ESRD in 2008. The patient has coronary artery disease and peripheral vascular disease. In January 2009, Agnes began dialyzing with an upper arm AV fistula which had been created the previous year. In March 2010, after an unsuccessful attempt to declot the AV fistula during hospitalization, Agnes experienced additional bleeding complications and has been dialyzed using a catheter ever since. In December 2010, the patient was admitted to the hospital after fainting during an outpatient dialysis treatment. She was diagnosed with pericarditis and discharged January 11, 2011. She resumed outpatient dialysis on January 13, 2011 at a facility which qualifies for the LV adjustment, because it has never had a treatment volume exceeding 3500 treatments since it opened in 2005. Her treating physician declared her free of pericardial inflammation on February 12, 2011. On April 10, 2011, Agnes was hospitalized with bacterial pneumonia and remained hospitalized until April 25. She resumed outpatient dialysis on April 28. Agnes was declared free of bacterial pneumonia on May 15, 2011, after post-hospitalization treatment with antibiotics. The facility submitted monthly claims for the months of January and February 2011 with the reported diagnosis of pericarditis. For dialysis treatments furnished during the month of March, the facility submitted a monthly claim reporting no co-morbidities. For dialysis treatments furnished Agnes during the months of April and May, the facility reported on the monthly claims the co-morbidity of bacterial pneumonia.

We must first use Agnes' height and weight to determine if a case-mix adjustment for low BMI applies and determine Agnes' BSA. BMI is computed as follows:

$BMI_{Agnes} = weight_{kg}/height(m^2)$
$= 45.36/1.6002^2$
= 45.36/2.5606
= 17.71

Agnes' BMI is less than 18.5. Therefore, her PM must include the 2.5 percent case-mix adjustment for underweight status.

The BSA formula is:

$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$

Agnes' BSA is calculated as:

$BSA_{Agnes} = 0.007184 * 160.02^{.725} * 45.36^{.425}$
= 0.007184 * 39.6302 * 5.0592
= 1.4404

Using the Table A in the Appendix multiplier of 1.020, Agnes' case-mix adjustment based on her BSA of 1.4404 is calculated as follows:

$PM_{BSA} = 1.020^{(1.4404-1.87)/0.1}$
$= 1.020^{-4.296}$
= .9184

The applicable factors that should be used to calculate Agnes' PM are the case-mix adjusters for age, BSA, low BMI, pericarditis, bacterial pneumonia, and the facility adjuster for LV.

For the months of January and February 2011, Agnes' ESRD facility reported on her monthly claims the pericarditis co-morbidity. Using the

Table A in the Appendix adjusters, Agnes' PM for the months of January and February may be expressed as:

$PM_{Agnes} = PM_{age} * PM_{BSA} * PM_{BMI} * PM_{Pericard} * PM_{LV} = 1.016 * .9184 * 1.025 * 1.114 * 1.189 = 1.2668$

Agnes' ESRD payment rate for treatments furnished in January, February, and March 2011 would be:

$\$239.21 * 1.2668 * .969 = \$293.64$

Although Agnes no longer had pericarditis as of February 12, 2011, her facility is entitled to payments for treatments furnished in March which reflect a case-mix adjustment for this acute co-morbidity, because case-mix for an acute co-morbidity may be applied for claims submitted for four claim months unless another co-morbidity yields a higher payment amount. Agnes' PM for April 2011 reflecting pericarditis is as follows:

$PM_{Agnes} * PM_{age} * PM_{BSA} * PM_{BMI} * PM_{Pericard} * PM_{LV} = 1.016 * .9184 * 1.025 * 1.114 * 1.189 = 1.2668$

Her PM reflecting the co-morbidity of bacterial pneumonia is:

$PM_{Agnes} = PM_{age} * PM_{BSA} * PM_{BMI} * PM_{Pneum} * PM_{LV} = 1.016 * .9184 * 1.025 * 1.135 * 1.189 = 1.2907$

Agnes' dialysis facility normally would be entitled to a payment adjustment for treatments reflecting the pericarditis co-morbidity for 3 claim months after February 2011, because a payment adjustment reflecting a co-morbidity may be paid for 4 claim months, including the month in which the diagnosis was present and dialysis treatments were furnished. However, in April Agnes was diagnosed with bacterial pneumonia. Because Agnes' PM based on pneumonia is higher than that for pericarditis, her payment rate for April 2011 will be based on the bacterial pneumonia co-morbidity as follows:

$\$239.21 * 1.2907 * .969 = \$299.18$

Because Agnes' dialysis facility is entitled to payments reflecting the bacterial pneumonia co-morbidity for claims for 4 claim months, the payment rate of $299.18 per treatment would apply for all treatments furnished in April through the month of July 2011, provided there are no other changes in Agnes' condition.

Example 6—Same as Example 1, With Outlier Payments (For a Description of the Outlier Payment Methodology, *See* Section II.H. of This Final Rule)

John receives HD 3 times weekly. However, in January 2011 he suffered a compound ankle fracture and was hospitalized for 4 days from January 10 through 14. During the hospitalization John did not undergo any dialysis treatments. After discharge John resumed his dialysis treatments, but it was noted that his dialysis clinical indicators were markedly perturbed from baseline values, requiring additional laboratory testing and above average doses of several injectable drugs, particularly EPO, to return them to normal levels. During January 2011 John received 9 outpatient HD treatments at his usual facility. The facility submitted a claim for allowable outlier services including drugs and biologicals, laboratory tests, and supplies totaling $3,000.00

Using Table A in the Appendix, we begin by computing the predicted outlier services MAP per treatment based on the SB case-mix adjustment factors for the PM variables applicable to John, age and BSA:

$SBPM_{John} = PM_{ageSB} * PM_{BSASB}$

John's BSA from Example 1 is 2.2161. Applying the SB adjustment factor from Table 10 for BSA, John's outlier services PM for BSA is computed as follows:

$SBPM_{BSA} = 1.014^{(2.2161 - 1.87)/0.1} = 1.014^{3.461} = 1.0493$

John's outlier services PM is calculated as:

$SBPM_{John} = .992 * 1.0493 = 1.0409$

From Table 28, we determine that the outlier services MAP per treatment for adult patients is $82.78. Therefore, the case-mix adjusted predicted outlier services MAP per treatment for John is:

$\$82.78 * 1.0409 = \$86.17$

Next, we determine the imputed outlier services MAP amount per treatment which reflects the cost of outlier services actually incurred by the ESRD facility. John's outlier services imputed amount averaged $3000.00/9 or $333.33 per session.

Next, we must determine if John's dialysis facility is entitled to outlier payments by comparing the predicted outlier services MAP amount to the imputed outlier services MAP amount. But first, we must add the fixed dollar loss amount to the predicted outlier services MAP amount.

The fixed dollar loss (FDL) amount for the predicted outlier services MAP, reflecting the case-mix adjustments for John for age and BSA is:

$John_{FDL} = \$86.17 + \$155.44 = \$241.61$

Because John's average outlier services MAP for the outlier services services received was $333.33, which exceeds the outlier services MAP plus the FDL totaling $241.61, John's ESRD facility is eligible for outlier payments beyond the otherwise applicable ESRD PPS payment amount of $251.45.

The outlier payments are calculated as follows:

Amount by which the imputed amount exceeds the predicted amount plus the FDL— $333.33 − $241.61 = $91.72

Loss sharing ratio—80%

Outlier payments per treatment—$91.72 * .80 = $73.38

Outlier payments—$73.38 * 9 treatments * .969 = $639.95

Regular ESRD payments for January 2011—$251.45 * 9 = $2263.05

Total ESRD PPS payments for January 2011—$2263.05 + $639.95 = $2903.00

Example 7—Pediatric ESRD Patient Receiving Treatments in a Low-Volume (LV) Facility; Outlier Payments Apply

Timmy is a 16 year old male with ESRD due to renal hypoplasia. The patient was on PD until 2009, when he received a deceased donor kidney transplant. Timmy's transplant failed in August 2010, and he has been on HD since that time. The patient receives dialysis through an AV graft. Timmy has a history of post-transplant lymphoma, which is in remission. He also has diabetes mellitus, which developed after the kidney transplantation. Timmy weighs 66.2 kg. and is 161.6 cm. in height. He was hospitalized in December 2010 with Staph bacteremia. As part of his HD, Timmy receives ARANESP® 60 mcg. IV q 2 weeks, paracalcitol 4 mcg. IV 3 times a week, and iron dextran 100 mg. IV every 2 weeks. The patient also takes 2 tablets, 667 mg. each of calcium acetate 3 times per day. Timmy had 12 HD treatments in January 2011. The ESRD facility, which qualifies for the LV adjustment for adult patients, submitted a January claim for allowable outlier services including drugs and biologicals, laboratory tests, and supplies totaling $3800.00.

Co-morbidities are not used to determine a pediatric patient's ESRD payment rate because these factors have been taken into account in the pediatric payment adjustments. Neither is the LV adjustment applicable to pediatric dialysis patients. The only variables relevant in determining Timmy's payment amount per treatment, without regard to outlier payments, are age and dialysis modality. Because Timmy is 16 and undergoes HD, Table B in the Appendix reveals that his pediatric classification group is category 4, for which the PM is 1.277. Timmy's payment rate per treatment, without regard to outlier payments, is:

$\$239.21 * 1.277 * .969 = \$296.00$

Timmy's dialysis facility would receive $296.00 for each of the 12

treatments it furnished in January 2011. Table B in the Appendix reveals that the SB case-mix adjustment factor for Timmy's pediatric classification group (cell 4) is 1.459.

From Table 28, we determine that the outlier services MAP per treatment for pediatric patients is $53.06. Therefore, the case-mix adjusted predicted outlier services MAP per treatment for Timmy is:

$53.06 * 1.459 = $77.41

Next, we determine the imputed outlier services MAP amount per treatment which reflects the cost of outlier services actually incurred by the ESRD facility. Timmy's outlier services imputed amount averaged $3800.00/12 or $316.67 per treatment.

We then determine if Timmy's dialysis facility is entitled to outlier payments by comparing the predicted outlier services MAP amount to the imputed outlier services MAP amount. But first, we must add the fixed dollar loss amount to the predicted outlier services MAP amount. The fixed dollar loss (FDL) amount for the predicted outlier services MAP, reflecting Timmy's pediatric classification group, is:

$Timmy_{FDL}$ = $77.41 + $195.02 = $272.43

Because Timmy's average outlier services MAP for the outlier services received was $316.67, which exceeds the outlier services MAP plus the FDL totaling $272.43, Timmy's ESRD facility is eligible for outlier payments beyond the otherwise applicable ESRD PPS payment amount of $296.00.

The outlier payments are calculated as follows:

Amount by which the imputed amount exceeds the predicted amount plus the FDL—$316.67 − $272.43 = $44.24
Loss sharing ratio—80%
Outlier payments per treatment—$44.24 * .80 = $35.39
Outlier payments—$35.39 * 12 treatments * .969 = $411.51
Regular ESRD payments for January 2011—$296.00 * 12 = $3552.00
Total ESRD PPS payments for January 2011—$3552.00 + $411.51 = $3963.51

Example 8—Pediatric ESRD Patient Receiving Training Treatments in a Low-Volume Facility

Andrew, a 12 year old male with diabetes mellitus, has been on CCPD since June 2010. Andrew's father has been deceased for 5 years. His mother, who assists him with his dialysis at home, will be unable to assist Andrew with dialysis beginning on February 10, 2011, because of major surgery which will leave her physically unable to participate in her son's care for an extended period of time. Andrew's Aunt Millie, who lives nearby, has agreed to be Andrew's caregiver and assist him with his dialysis. Millie required 17 training sessions at Andrew's dialysis facility, which is certified to provide home dialysis training, in order to become knowledgeable and skilled sufficiently to perform this role. These training sessions began February 16 and ended March 10. Andrew's dialysis facility, which has been open for 5 years, has never furnished more than 3100 treatments in a year, and qualifies for the low-volume (LV) adjustment.

Table B in the Appendix reveals that Andrew's pediatric dialysis classification group is cell 1, with an associated PM of 1.033. Although Andrew's dialysis facility is eligible for the LV adjustment for its adult patients, the LV multiplier does not apply to pediatric patients. During the months of January and February 2011, Andrew's ESRD payment rate per HD-equivalent treatment would be:

$239.21 * 1.033 * .969 = $239.44

However, Andrew's dialysis facility is entitled to receive payment for a maximum of 15 training treatments furnished in connection with Andrew's new caregiver, Aunt Millie. Because the amount of the training add-on is adjusted by the dialysis facility's wage index (1.10), the amount of the training add-on is calculated as follows:

Training rate—$33.44
Wage index—1.10
Training payment—$33.44 * 1.10 = $36.78

For the maximum number of 15 training treatments for which the training adjustment may be provided in connection with a PD patient, Andrew's payment rate, including the training add-on, would be:

($239.21 * 1.033 + $36.78) * .969 = $275.08

J. ESRD Bundled Market Basket

Under section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401 of Public Law 111–148, beginning in 2012, the ESRD bundled payment amounts are required to be annually increased by an ESRD market basket increase factor that is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute further provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services. Under section 1881(b)(14)(F)(ii) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of Public Law 111–148, the ESRD bundled rate market basket increase factor will also be used to update the composite rate portion of ESRD payments during the ESRD PPS phase-in period from 2011 through 2013, though beginning in 2012, such market basket increase factor will be reduced by the productivity adjustment. We intend to address in future rulemaking the productivity adjustment that will be applicable beginning in 2012. With regard to application of the ESRD bundled rate market basket in CY 2011, we note that as a result of amendments by section 3401(h) of Public Law 111–148 to section 1881(b)(14)(F) of the Act, a full market basket will be applied to the composite rate portion of the blended payment during the first year of the transition (*i.e.,* 1.0 percentage point will not be subtracted). Therefore, we have modified § 413.196 by making conforming changes as a result of the Affordable Care Act.

As required under section 1881(b)(14) of the Act, effective for CY 2012 (and for purposes of the first year of the transition, CY 2011), CMS has developed an all-inclusive ESRD bundled rate (ESRDB) input price index. Although "market basket" technically describes the mix of goods and services used to produce ESRD care, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from that market basket. Accordingly, the term "ESRDB market basket" as used in this document refers to the ESRDB input price index.

A market basket has historically been used under the Medicare program to account for the price increases of the requisite inputs associated with the services furnished by providers. The percentage change in the ESRDB market basket reflects the average change in the price of goods and services purchased by ESRD facilities in providing renal dialysis services. Since a single payment rate exists for both operating and capital-related costs, the ESRDB market basket for ESRD facilities includes both operating and capital-related costs.

In the proposed rule (74 FR 49997 through 50003), we discussed the development of the proposed cost categories and their respective weights for the ESRDB market basket using CY 2007 as the base year, the choices of price proxies, and an explanation of the methodology and results of the proposed ESRDB market basket. As described in the proposed rule (74 FR 49997), using a base year of CY 2007 and Medicare cost report data, we first

computed cost shares for the following nine major expenditure categories: (1) Wages and Salaries, (2) Employee Benefits for direct patient care, (3) Pharmaceuticals, (4) Supplies, (5) Laboratory Services, (6) Blood Products, (7) Administrative and General and Other (A&O), (8) Housekeeping and Operations, and (9) Capital-Related costs. We then supplemented the Medicare Cost Report data with additional data sources and expanded these cost categories to ultimately derive the 16 proposed ESRDB market basket cost categories and weights (74 FR 49998 through 50001). Also in the proposed rule, we described our selection of, and the rationale for, the appropriate price proxies to measure the rate of price change for each category (74 FR 50001 through 50002), as well as provided the projected annual rates of growth in the ESRDB market basket for CY 2009 through CY 2019 based on the most recent forecast available at the time. Additionally, we proposed that the ESRDB labor-related share equal 38.160 percent, which represented the sum of the weights for the following cost categories: Wages and Salaries, Benefits, Housekeeping and Operations, All Other Labor-related Services, 87 percent of the cost weight for Professional Fees, and 46 percent of the weight for Capital-related Building and Equipment expenses (74 FR 50003).

The comments we received on these proposals and the responses are set forth below.

Comment: A commenter expressed concern that the proposed ESRD bundled PPS suggests that 42.8 percent of the facility's ESRD treatment costs are labor-related. The commenter was concerned that staff levels will be reduced to compensate for the revenue loss realized by the regressive formula of the proposed payment system.

Response: The labor-related share in the ESRD bundled proposed rule was 38.160 percent (74 FR 50003). We are uncertain how the commenter calculated 42.8 percent. To provide clarification for the commenter, we note that the labor-related share of the ESRDB market basket is defined as the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. This share represents the proportion of an ESRD facility's payment that is adjusted for geographic wage differences. As discussed below, we have made several methodological changes to the ESRDB market basket based on the public comments received. The new labor-related share is 41.737 percent. We will closely monitor the cost structure of the ESRD industry and the labor-related share of the ESRDB market basket, following implementation of the ESRD PPS. If new data show material shifts in the average cost structure for ESRD providers, including changes in the labor-related share, we will propose to rebase the ESRDB market basket, as technically appropriate.

Comment: Several commenters recommended using 2008 or 2009 as the base year for the ESRDB market basket in order to more accurately represent the changes in facility operating costs that resulted from the compliance with the Conditions for Coverage and other trends. Commenters stated that cost reports from 2008 are available for CMS to use, and although they are not settled, MedPAC analysis found little difference between submitted and settled cost reports.

Response: We agree with the commenters with regard to the issue of using more updated data for the base year for the development of the CY ESRDB market basket. As we indicated in the proposed rule, we proposed to use CY 2007 because it was the most recent year that both relatively complete Medicare cost report data and supplemental data from the Census' Business Expenditure Survey (BES) were available (74 FR 49997). That is, the proposed ESRDB market basket was developed over the winter of 2008 and spring of 2009. At that time, 2007 Medicare cost reports (MCR) represented the most complete set of data available. Therefore, the methodology used to finalize the proposed ESRDB market basket estimates was completed well in advance. The 2007 MCR data are comprised of financial data for ESRD facilities reporting on different fiscal years, including but not limited to federal fiscal, calendar, and "state" fiscal year (July 1 to June 30). A facility's MCR data are typically available between nine months and one year from the end of the facility's fiscal period. Since publication of the proposed rule, we have reviewed the 2007 MCR data using a complete sample and found that the cost weights are not materially different relative to those found in the proposed 2007 ESRDB market basket.

The agency monitors market basket cost weights regularly to determine if significant changes have occurred from one year to the next. To that end, and based on public comment, we have constructed and analyzed cost weights from the newly available 2008 MCRs and determined there has been a material shift in the cost structure of ESRDs from 2007 to 2008. Specifically, there was a notable decrease in the Pharmaceuticals cost weight for 2008 compared to 2007 (as discussed in more detail below). Therefore, we believe it is appropriate to use the 2008 MCR data for the base year cost weights of the ESRDB market basket. We will continue to closely monitor the cost report data as the ESRD PPS is implemented; and should we observe any additional material changes in the cost structure of the industry, we will propose to rebase and revise the ESRDB market basket accordingly.

Comment: Several commenters applauded CMS's decision to use the Producer Price Index (PPI) for prescription drugs as the price proxy for measuring price growth in ESRD drugs in the proposed ESRDB market basket.

Response: We appreciate commenters' support for using the PPI for prescription drugs as the price proxy for measuring price growth for the ESRD drugs cost category. In this rule, we are finalizing the selection of this proxy for the following three reasons:

(1) *Relevance:* This index contains an appropriate level of aggregation for use in the Medicare market baskets (including former Part D drugs covered in the ESRD bundle), as well as reflects competitive pricing observed in efficient markets.

(2) *Reliability:* This index represents a consistent time series and allows for projections of future price changes that are based on technically sound econometric modeling techniques that are widely accepted.

(3) *Timeliness/Public Availability:* The Bureau of Labor Statistics independently publishes this data on a monthly basis with no significant methodological changes.

Comment: Several commenters believe that a better price proxy for drugs in ESRD facilities is the National Health Expenditure (NHE) estimate of prescription drug spending.

Response: We believe the NHE estimate of prescription drug spending growth is not an appropriate price proxy for use in the ESRDB market basket. NHE growth rates reflect changes in total spending (that is, prices and quantities). The ESRDB market basket is intended to only reflect price changes, holding quantities fixed in a base year. For the reasons outlined above, we believe the PPI for prescription drugs is the appropriate price proxy to apply to the drugs cost category in the ESRDB market basket.

Comment: Several commenters opposed the use of the Employment Cost Index (ECI) for Health Care and Social Assistance as the price proxy for Wages and Salaries. These commenters recommended that CMS use the ECI for Hospitals as the price proxy because

they claim it more accurately reflects the occupational mix in ESRD facilities than the ECI for Health Care and Social Assistance.

Response: In the proposed rule, we proposed to use the ECI for Health Care and Social Assistance to proxy the Wages and Salaries cost category (74 FR 50001). That selection was largely driven by the ESRD industry's inclusion in the North American Industry Classification System's (NAICS) category 621, Ambulatory Health Care Services, which is one component that makes up the ECI for Health Care and Social Assistance (NAICS 62).

In response to commenters' concerns, we have reviewed the occupational mix of ESRD facilities and compared it in detail to that of hospitals (found in NAICS category 622), nursing and residential care facilities (found in NAICS category 623), and the compilation of industries contained in the Health Care and Social Assistance category (NAICS category 62). To do this, we compared Full Time Equivalent (FTE) data from the ESRD Medicare cost reports with occupational composition data found in the Occupational Employment Statistics produced by the Bureau of Labor Statistics (BLS). We found that ESRD facilities have a somewhat unique occupational mix that differs, to varying degrees, from hospitals, nursing and residential care facilities, and the compilation of industries found in the health care and social assistance classification. These three comparisons were selected as they represent the health industries for which ECIs are available.

Based on our analysis, we agree with the commenters that it would be appropriate to consider the use of the ECI for Hospitals as a price proxy for this category. In our follow-up analysis, we noted that the ESRD industry's occupational and skill mix (including physicians, registered nurses (RN), licensed practical nurses (LPN), and a variety of technicians) is not fully represented in NAICS category 62 (Health Care and Social Assistance). In comparing the ESRD occupational mix to the occupational mix of hospitals, we found that for many of the higher skilled occupations, the ESRD industry did bear certain similarities to that of the hospital industry. As a result, we have determined it would be appropriate to account for the unique occupational mix in ESRD facilities by utilizing a blended price proxy for the Wages and Salaries cost category. The blended proxy will incorporate the Wages and Salaries ECI for Health Care and Social Assistance (representing 50 percent of the blend) and the Wages and Salaries ECI for Hospitals (representing the other 50 percent of the blend). In addition to using a blended ECI as the price proxy for Wages and Salaries, we will also use a blended ECI as the price proxy for the Benefits cost category using the same 50/50 ratio. Those ECIs include the Benefits ECI for Health Care and Social Assistance (50 percent) and the Benefits ECI for Hospitals (50 percent).

Comment: Several commenters requested that CMS provide additional detail on the ESRDB market basket, stating that there were holes in documenting the methodology for its development. Particularly, the commenters stated that CMS omitted a significant amount of detail on the price proxies and did not provide the prospective reference data from which the price proxies are extracted. These commenters requested that CMS put the detailed forecast of the price proxies on the CMS Web site for public view. They noted that the information provided should be available to replicate the results of the ESRDB market basket, as proposed.

Response: We agree that the public should be able to replicate the methodology used to construct the ESRDB market basket. We disagree, however, with the commenters' claim that the proposed rule lacked significant documentation regarding the methodology used to construct the ESRDB market basket. The proposed rule provided a detailed description of the data sources used to develop the ESRDB market basket cost weights (74 FR 50001). Likewise, as indicated in the proposed rule, the price proxies used in the ESRDB market basket were listed for each cost category and are based on data maintained and published by the BLS (74 FR 50001 through 50002). We would refer the commenter to BLS regarding any specific information on the detailed price proxies.

To assist the commenter and other interested stakeholders in locating these price proxies on the BLS Web site, we have provided the individual BLS series codes for the indexes in the price proxy discussion of this final rule (below). The price proxies can be obtained by entering these codes at the BLS Web site (*http://data.bls.gov/cgi-bin/srgate*). Regarding the individual forecasts of the price proxies used to develop the CY 2011 ESRDB market basket update factor, these forecasts are developed by IHS Global Insight, Incorporated (IGI), a nationally recognized economic and financial forecasting firm. We purchase IGI's detailed price proxy projections for use in the Medicare market baskets. As a matter of practice, we publish all of the underlying detail for each price proxy for the historical period. However, because the projections of each individual price proxy are proprietary, we typically aggregate those projections into higher level categories and then publish the results with usually a one-quarter lag. Since the ESRDB market basket is a new market basket that is still progressing through the rule-making process, we have not published additional detail other than what has been published in the proposed rule. Following implementation of this PPS, we will begin publishing the ESRDB market basket, including the detail as described above, on the CMS Web site (*http://www.cms.hhs.gov/MedicareProgramRatesStats/04_MarketBasketData.asp#TopOfPage*).

Comment: Several commenters stated that CMS did not specify a plan for the frequency of rebasing and revisions of the ESRDB market basket. Commenters stated that CMS usually rebases on a 4-year cycle in other provider indexes. They noted that this is an appropriate timeframe for the rebasing of the ESRDB market basket.

Response: We monitor the market basket cost weights regularly to determine if significant changes have occurred from one year to the next. In general, we have typically proposed to rebase and revise the market baskets roughly every five years; although we have proposed alternatives to that rate when technically appropriate or when mandated by law (for example, the Inpatient Hospital Prospective Payment System (IPPS) market basket is required to be rebased more frequently than every five years, in accordance with Section 404 of Pub. L.108–173). We are unable to provide a specific rebasing schedule for the ESRDB market basket, in part, because this is a new payment system that is being implemented making it particularly difficult to say with certainty how frequently rebasings would be technically appropriate. In general, we do not explicitly state how often any market basket will be rebased or revised, unless there is a mandated rebasing schedule. As is the agency's practice, we will continuously monitor the composition of the new ESRDB market basket to determine the next technically appropriate time to rebase and revise the index. At that time, the agency will go through the notice and comment rulemaking process including proposing and finalizing any changes after consideration of public comments.

Comment: One commenter believes that the ESRDB market basket update will not address the low margins for small dialysis organizations (SDOs), especially in the context of a two

percent reduction in payments under the ESRD PPS. The commenter stated that ESRDB market basket updates to payments in the following years should reflect increases in costs, and that it will likely not be enough to increase the SDO margins even to current levels.

Response: The impact on SDOs is addressed in section IV.B of this final rule. The ESRDB market basket calculations produced by the Office of the Actuary in CMS are constructed entirely independent from any margins analysis. The ESRDB market basket updates represent the net result of combining price projections for each individual cost category with that category's respective cost weight.

Notably, the CMS market baskets are not intended to update payments based on projected costs, which are equal to prices multiplied by quantities. The purpose of the ESRDB market basket, rather, is to update the base payment rate to account for the projected input price inflation associated with the goods and services required to provide ESRD bundled services while holding that market basket of goods and services constant.

As a result of public comments, we have made several methodological changes to the proposed ESRDB market basket. First, as discussed above, we are using a 2008 base year rather than a 2007 base year for the ESRDB market basket. This year represents the latest year for which appropriately complete data are available. Second, we have changed the price proxies for the Wages and Salaries and the Benefits cost categories from ECIs for Health Care and Social Assistance (NAICS category 62) to blended indexes of the ECIs for Hospitals and the ECIs for Health Care and Social Assistance (as detailed above). Third, we are no longer including blood and blood products in the ESRDB market basket.

In the proposed rule, blood and blood products were included in the proposed ESRDB market basket (74 FR 49999) since these products were included in the proposed ESRD bundled payment. However, as explained in section II.A.4. of this final rule, we have decided to remove blood and blood products from the bundled payment in response to public comment. Therefore, since blood and blood products are no longer included in the ESRD bundled payment, it is no longer appropriate to include that category in the ESRDB market basket.

Lastly, we are delaying the inclusion of costs associated with oral-only drugs and biologicals formerly covered under Part D that have no injectable equivalents (or other form of administration) in the ESRDB market basket. Similar to blood and blood products, these costs were included in the ESRDB market basket in the proposed rule (74 FR 49999) due to these products being included in the proposed ESRD bundled payment. However, in response to public comment, CMS has decided to delay implementation of including ESRD-related oral-only Part D drugs (without injectable equivalents or other forms of administration) in the bundled payment, as stated in section II.A.3. of this final rule. Therefore, it is no longer appropriate to include the costs associated with these products in the ESRDB market basket for this final rule.

Below we discuss the ESRDB market basket we are finalizing, including the changes noted above. Additionally, in response to public comments, where relevant, we include the applicable BLS series code for the various price proxies. We believe this provides added transparency for the new ESRDB market basket.

Cost Category Weights

The ESRDB market basket cost weights in this final rule are based on the CY 2008 cost report data for independent ESRD facilities. We refer to the ESRDB market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2008 = 100. Source data included CY 2008 Medicare cost reports (Form CMS–265–94), supplemented with 2002 data from the U.S. Department of Commerce, Bureau of the Census' Business Expenditure Survey (BES). The BES data were aged to 2008 using appropriate price proxies to estimate price growth. The price proxies used for the aging of the BES data come from publicly available price indexes such as various producer price indexes (PPI), consumer price indexes (CPI), or employment cost indexes (ECI). All of these price proxies are based on data published by the U.S. Department of Labor, Bureau of Labor Statistics (BLS).

Using Worksheets A, A2, and B from the CY 2008 Medicare cost reports, we first computed cost shares for eight major expenditure categories: Wages and Salaries, Employee Benefits for direct patient care, Pharmaceuticals, Supplies, Laboratory Services, Administrative and General and Other (A&O), Housekeeping and Operations, and Capital-Related costs. In the proposed rule, we had initially computed cost shares for nine major expenditure categories (74 FR 49997); however, as stated earlier, we are now removing blood and blood products from the ESRDB market basket for this final rule, and therefore, we now yield one less major expenditure category than stated in the proposed rule. Edits were applied to include only cost reports that had total costs greater than zero. In order to reduce potential distortions from outliers in the calculation of the cost weights for the major expenditure categories, cost values for each category less than the 5th percentile or greater than the 95th percentile were excluded from the computations. The resulting data set included information from approximately 3,869 independent ESRD facilities' cost reports from an available pool of 4,299 cost reports. Expenditures for the eight cost categories as a proportion of total expenditures are shown in Table 30 below. We note that the values calculated for the cost weights in this table differ from those that were published in the proposed rule (74 FR 49998). This is a result of several factors including: The use of 2008 Medicare cost report data rather than 2007 Medicare cost report data, the removal of blood and blood products costs from the ESRDB market basket, and the removal of costs associated with ESRD-related oral Part D drugs without injectable equivalents from the ESRDB market basket. While some of these changes in the cost weights are minor, we discuss the more notable differences in the CY 2007 and CY 2008 cost weights in the text below.

Table 30—Initial 2008-Based End-Stage Renal Disease Bundled Rate Major Cost Categories and Weights Determined from the Medicare Cost Reports

Expense Category	CY 2008-Based Weights
Wages and Salaries	26.338%
Benefits for Direct Patient Care	5.163%
Pharmaceuticals	26.358%
Supplies	9.726%
Laboratory Services	0.356%
Housekeeping and Operations	3.604%
Administrative and General, and Other	17.594%
Capital-Related Costs	10.861%
Total	100.000%

Note: Totals may not sum to 100 percent due to rounding

Some costs that are required to be included in the ESRD bundled payment are not reported on the Medicare cost report. As a result, we supplemented Medicare cost report data with expenditure estimates for various ESRD-related oral drugs with injectable equivalents that are currently covered by Medicare Part D, as well as with additional lab expenses. The estimates for both of the aforementioned expenditures were provided by Kidney Epidemiology and Cost Center of the University of Michigan (UM–KECC). There are also costs that are reported on the Medicare cost report that are not included in the ESRD bundled payment. For instance, expenses related to vaccine costs were removed from total expenditures since these are excluded from the ESRD bundled payment.

We expanded the expenditure categories developed from the Medicare cost reports to allow for a more detailed expenditure decomposition. To expand these cost categories, BES data were used as the Medicare cost reports do not collect detailed information on the items in question. Those categories include: Benefits for all employees, professional fees, telephone, utilities, and all other services. We chose to separate these categories to more accurately reflect changes in ESRD facility costs. We describe below how the initially computed categories and weights were modified to yield the final ESRDB market basket expenditure categories and weights presented in this final rule.

Wages and Salaries

The weight for Wages and Salaries that was initially computed was derived from Worksheet B of the Medicare cost report. However, because Worksheet B only includes direct patient care salaries, it was necessary to derive a methodology to include all salaries, not just direct patient care salaries, in order to calculate the appropriate ESRDB market basket cost weight. This was accomplished in four steps, as follows:

(1) From the trial balance of the cost report (Worksheet A), we computed the ratio of salaries to total costs in each cost center. The cost centers for which we calculated this ratio were drugs, housekeeping and operations, A&O, supplies, laboratories, capital-related machinery, and EPO.

(2) We then multiplied the ratios computed in step 1 by the total costs for each corresponding cost center from Worksheet B. This provided us with an estimate of non-direct patient care salaries for each cost center.

(3) The estimated non-direct patient care salaries for each of the cost centers on Worksheet B estimated in step 2 were subsequently summed and added to the direct patient care salary figure (resulting in a new total salaries figure).

(4) The estimated non-direct patient care salaries (*see* step 2) were then subtracted from their respective cost categories to avoid double-counting their values in the total costs.

As a result of this process, we moved from an estimated Wages and Salaries cost weight of 22.297 percent (as estimated using only direct patient care salaries as a percent of total costs found on the Medicare cost report) to a weight of 26.338 percent (capturing both direct and non-direct patient care salaries and, again, dividing that by total costs found on the Medicare cost report), as seen in Table 30. For comparison purposes, we note that the Wages and Salaries cost weight in the proposed rule was 25.106 percent (74 FR 49998).

When we add the expenditures related to laboratory expenses that were previously paid for under the Medicare fee schedule, and are not included in the Medicare cost report, the expenditures for ESRD-related oral drugs with injectable equivalents that are currently covered under Part D that are not included in the Medicare cost report, and remove the estimated vaccine costs that are to be paid outside of the bundle, then the cost weight for the Wages and Salaries category falls to 24.965 percent.

The final adjustment made to this category is to include contract labor costs. These costs appear on the Medicare cost report; however, they are embedded in the Administrative and General and Other category and cannot be disentangled using the Medicare cost reports alone. To move the appropriate expenses from the A&O category to Wages and Salaries, we used data from the BES. We first summed total contract labor costs in the survey. We then took 80 percent of that figure and added it to Wages and Salaries. At the same time, we subtracted that same amount from A&O. The 80-percent figure that was used was determined by taking salaries as a percentage of total compensation (excluding contract labor). The resulting cost weight for Wages and Salaries increases to 26.755 percent.

Benefits

The Benefits weight was derived from the 2002 BES data aged forward to 2008 as a benefit share for all employees is not available from the ESRD Medicare cost report. Due to the change in the base year from CY 2007 (used in the proposed rule (74 FR 49998)) to CY 2008 (used in this final rule), the 2002 BES data for each of the appropriate cost categories were aged to 2008 as opposed to 2007. The cost report only reflects benefits associated with direct patient care. In order to include the benefits related to non-direct patient care, we estimated this marginal increase from

the BES Benefits weight. This resulted in a Benefits weight that was 1.143 percentage point larger (6.306 vs. 5.163) than the Benefits weight for direct patient care calculated directly from the cost reports. To avoid double-counting and to ensure all of the market basket weights still totaled 100 percent, we removed this additional 1.143 percentage point for Benefits from Pharmaceuticals, Administrative and General and Other, Supplies, Laboratory Services, Housekeeping and Operations, and the Capital-related Machinery components. This calculation reapportions the benefits expense for each of these categories using a method similar to the method used for distributing non-direct patient care salaries as described above.

The final adjustment made to this category is to include contract labor costs. Once again, these costs appear on the Medicare cost report; however, they are embedded in the Administrative and General and Other category and cannot be disentangled using the Medicare cost report alone. To move the appropriate expenses from the A&O category to Benefits, we followed the same methodology used to apportion contract labor wages and salaries noted immediately above. For Benefits, we applied the remaining 20 percent of total contract labor costs, as estimated using the BES, and included that in the Benefits cost weight. At the same time, we subtracted that same amount from A&O. The 20-percent figure that was used was determined by summing direct patient care benefits (as estimated using the Medicare cost report) and non-direct patient care benefits (as estimated using the BES) and taking that sum as a percentage of total compensation (excluding contract labor). The resulting cost weight for Benefits increases to 6.754 percent.

Utilities

We developed a weight for Utility expenses using the 2002 BES data, as utilities are not separately identified on the Medicare cost report. We aged these 2002 BES-based utility expenditures to 2008. We then disaggregated the Utilities category to reflect three subcategories: Electricity, Fuel (Natural Gas), and Water and Sewerage. We computed the ratio of each BES category to the total BES operating expenses. We then applied each ratio to the total operating expense percentage share as calculated from the cost reports, including the additions of ESRD-related oral drugs with injectable equivalents that are currently covered under Part D and additional lab expenses, to estimate the ESRD facility weight for each utility expenditure category. These amounts were then deducted from the share of the combined Operation & Maintenance of Plant and Housekeeping cost category, where the expenses are included on the Medicare cost report (but cannot be separately identified). The resulting Electricity, Fuel (Natural Gas), and Water and Sewerage ESRDB market basket weights are 0.621, 0.127, and 0.516 percent, respectively, yielding a combined Utilities cost weight of 1.264 percent.

Pharmaceuticals

The ESRDB market basket includes expenditures for all drugs included in the ESRD bundled payment, including separately billable drugs and ESRD-related oral drugs with injectable equivalents that are currently covered under Medicare Part D. We were able to calculate an expenditure weight for pharmaceuticals directly from the Drugs cost center on Worksheet B plus the expenditures of EPO which are reported on worksheet A2 of the Medicare cost reports. Vaccine expenditures, which are mandated as separately reimbursable, were excluded when calculating this cost weight. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, and hepatitis B vaccines described in subparagraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the drug. Since these drugs are excluded from other prospective payment systems, we exclude them from the ESRDB market basket, as well. We estimate that expenditures for these three vaccines are approximately 1 percent of the total Medicare-allowable payments for separately billable drugs. The resulting cost weight determined from the Medicare cost report for Pharmaceuticals is 26.358 percent, as seen in Table 30. For comparison purposes, we note that this cost weight in the proposed rule was 28.775 percent (74 FR 49998).

Expenditures in 2008 for ESRD-related oral drugs with injectable equivalents that are currently covered under Part D were added to cost report totals. The estimate we used for these ESRD-related Part D drugs with injectable equivalents, provided by UM–KECC, is approximately $15 million for 2008. Finally, to avoid double-counting, the weight for the Pharmaceuticals category was reduced to exclude the estimated share of non-direct patient care salaries and benefits associated with the Drugs and Epoetin cost centers. This resulted in an ESRDB market basket weight for Pharmaceuticals of 25.52 percent. EPO expenditures accounted for 17.359 percentage points of the Pharmaceuticals weight, ESRD-related oral drugs with injectable equivalents that are currently covered under Part D accounted for 0.153 percentage point of the Pharmaceuticals weight, and all other drugs accounted for the remaining 7.541 percentage points of the Pharmaceuticals weight.

Supplies

We calculated the weight for Supplies included in the bundled rate using the reimbursable and separately billable expenditure amounts for the Supplies cost center on Worksheet B of the Medicare cost report. Supplies that are separately billable are reported as a separate line item on the cost reports and were also included. This total was divided by total expenses to derive a weight for the Supplies component in the ESRDB market basket. The computed weight for this category was reduced by the non-direct patient care salaries and benefits associated with the Supplies cost center. The resulting ESRDB market basket weight for Supplies is 9.216 percent.

Laboratory Services

We calculated the weight for Laboratory Services included in the bundled rate using the reimbursable and separately billable expenditure amounts for the Laboratory cost center on Worksheet B of the Medicare cost report. The cost report expenditures do not include laboratory services paid for under the Medicare fee schedule, only facility-furnished laboratory tests. Since a large majority of laboratory tests are paid via the fee schedule, we adjusted the laboratory fees upward. The inflation factor was computed from the ratio of ESRD facility Medicare laboratory payment data to the other facility Medicare laboratory payment data. This provides a measure of the extent to which laboratory services fall under the Medicare fee schedule. The weight for this category was similarly reduced by the non-direct patient care salaries and benefits associated with the Laboratory cost center. The resulting ESRDB market basket weight for Laboratory Services is 5.497 percent.

Housekeeping and Operations

We developed a market basket cost weight for this category using data from Worksheet A of the Medicare cost reports. Worksheet B combines the capital-related costs for buildings and fixtures with the Operation and Maintenance of Plant (Operations) and Housekeeping cost centers, so we were unable to calculate a weight directly from Worksheet B. We separated these

expenses from capital-related costs because we believe housekeeping and operations expenditures, such as janitorial and building services costs, are largely service-related and would be more appropriately proxied by a service-related price index. To avoid double-counting, we subtracted from the Housekeeping and Operations weight the utilities proportion described above, as well as the non-direct patient care salaries and benefits share associated with the Operations and Housekeeping cost center. The resulting ESRDB market basket cost weight for Housekeeping and Operations is 2.029 percent.

Administrative and General and Other (A&O)

We computed the proportion of total A&O expenditures using the A&O cost center data from Worksheet B of the Medicare cost reports minus the A&O expenditures related to the Blood Products and Vaccine categories. As described above, we exclude contract labor from this cost category and apportion these costs to the salary and benefits cost weights. Similar to other expenditure category adjustments, we then reduced the computed weight to exclude salaries and benefits associated with the A&O cost center. The resulting A&O cost weight is 13.899 percent. This A&O cost weight is then fully apportioned to derive detailed cost weights for Professional Fees, Telephone, All Other Labor-Related Services, and All Other Nonlabor-related Services.

Professional Fees

A separate weight for Professional Fees was developed using the 2002 BES data aged to 2008. Professional fees include fees associated with the following: advertising, accounting, bookkeeping, legal, management, consulting, administrative, and other professional services fees. To estimate professional fees, we first calculated the ratio of BES professional fees to a total of administrative and other expenses from BES. We applied this ratio to the A&O total cost weight to estimate the proportion of ESRD facility professional fees. The resulting weight is 1.773 percent. This cost weight is then separated into Labor-related Professional Fees (1.549 percent) and Nonlabor-related Professional Fees (0.224 percent), which is described in more detail below.

Telephone

Because telephone service expenses are not separately identified on the Medicare cost report, we developed a Telephone Services weight using the 2002 BES expenses aged to 2008. We estimated a ratio of telephone services expenses to total administrative and other expenses from BES. We applied this ratio to the total A&O cost weight to estimate the proportion of ESRD facility telephone expenses. The resulting ESRDB market basket cost weight for Telephone Services is 0.597 percent.

All Other Labor-Related Services

A separate weight for All Other Labor-related Services was developed using the 2002 BES data aged to 2008. All other labor-related services include repair and maintenance fees. We estimated a ratio of all other labor-related services expenses to total administrative and other expenses from BES. We applied this ratio to the total A&O cost weight to estimate the cost weight for ESRD facility All Other Labor-related Services. The resulting ESRDB market basket cost weight is 1.219 percent.

All Other Nonlabor-Related Services

A separate weight for All Other Nonlabor-related Services was developed using the 2002 BES data aged to 2008. Non labor-related services include insurance, transportation, shipping, warehousing, printing, data processing services, and all other operating expenses not otherwise classified. We estimated a ratio of all other nonlabor-related services expenses to total administrative and other expenses from BES. We applied this ratio to the total A&O cost weight to estimate the cost weight for ESRD facility All Other Nonlabor-related Services. The resulting ESRDB market basket cost weight is 10.311 percent.

Capital

We developed an ESRDB market basket cost weight for the Capital category using data from Worksheet B of the Medicare cost reports. Capital-related costs include depreciation and lease expense for buildings, fixtures, movable equipment, property taxes, insurance, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. Because housekeeping and operations costs are included in the Worksheet B cost center for Buildings and Fixtures capital-related expense, we excluded these costs and developed a separate expenditure category as noted above. Similar to the methodology used for other ESRDB market basket cost categories with a salaries component, we computed a share for non-direct patient care salaries and benefits associated with the Capital-related Machinery cost center. We used Worksheet B to develop two capital-related cost categories, one for Buildings and Fixtures, and one for Machinery. We reasoned this was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with Buildings and Fixtures could move differently than those associated with Machinery, we believe that separate price proxies would be more appropriate to track price changes for the different capital-related categories over time. The resulting ESRDB market basket cost weights for Capital-related Buildings and Equipment and Capital-related Machinery are 7.459 and 2.074 percent, respectively.

Table 31 lists all of the expenditure categories in the ESRDB market basket and their corresponding CY 2008 cost weights and proxies, as developed in accordance with the methodology described above. For comparison purposes, we have added the corresponding CY 2007 cost weights as published in the proposed rule (74 FR 50010).

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Table 31—ESRDB Market Basket Cost Categories, Price Proxies, and Cost Weights

Cost Category	Price/Wage Variable	ESRDB Market Basket CY 2008 Weights (Percent)	ESRDB Market Basket CY 2007 Weights (as proposed) (Percent)
Total Compensation		33.509	30.693
Wages and Salaries	Blend of Wages and Salaries ECI for Hospitals and Wages and Salaries ECI for Health Care and Social Assistance	26.755	24.516
Employee Benefits	Blend of Benefits ECI for Hospitals and Benefits ECI for Health Care and Social Assistance	6.754	6.177
Utilities		1.264	1.180
Electricity	PPI - Commercial Electric Power	0.621	0.586
Natural Gas	PPI - Commercial Natural Gas	0.127	0.111
Water and Sewerage	CPI - Water & Sewerage Maintenance	0.516	0.483
All Other Materials		39.765	44.161
Pharmaceuticals	PPI – Pharmaceuticals for Human Use (Prescription)	25.052	30.743
Supplies	PPI- Medical, Surgical, and Personal Aid Devices	9.216	8.543
Laboratories	PPI- Medical and Diagnostic Laboratories	5.497	4.875
All Other Services		15.929	15.383
Telephone	CPI - Telephone Services	0.597	0.590
Housekeeping and Operations	PPI – Janitorial Services	2.029	1.766
Labor-related		2.768	2.641
Professional fees Labor-related	ECI - Compensation for Professional and Related Occupations (Priv.)	1.549	1.478
All Other Labor-related Services	ECI - Compensation for Service Occupations (Priv.)	1.219	1.163
Nonlabor-related		10.535	10.386
Professional fees Nonlabor-related	ECI- Compensation for Professional and Related Occupations (Priv.)	0.224	0.214

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Price Proxies

Once we determined the CY 2008 ESRDB market basket expenditure categories and weights, appropriate wage and price series or proxies were selected to measure the rate of price change for each category. All of the proxies are based on BLS data, and are grouped into one of the following three BLS categories:

(1) *PPIs:* PPIs measure changes in the prices producers receive for their outputs. PPIs are the preferable price proxies for goods and services that ESRD facilities purchase as inputs in producing dialysis services, since these facilities generally make purchases in the wholesale market. The PPIs that we use measure price change at the final stage of production.

Cost Category	Price/Wage Variable	ESRDB Market Basket CY 2008 Weights (Percent)	ESRDB Market Basket CY 2007 Weights (as proposed) (Percent)
All Other Nonlabor-related Services	CPI - All Items Less Food and Energy	10.311	10.172
Capital Costs		9.533	8.547
Capital Related-Building and Equipment	CPI – Owner's Equivalent Rent	7.459	6.653
Capital Related-Machinery	PPI - Electrical Machinery and Equipment	2.074	1.894

Note: Detail may not add to total due to rounding. The detailed cost weights for the proposed ESRDB CY 2007 Market Basket in this table do not sum to 100 percent since the Blood and Blood Products cost category is not listed. As described above, we are no longer including these costs in the ESRDB market basket.

(2) *CPIs:* CPIs measure changes in the prices of final goods and services purchased by the typical consumer. Because these indexes may not reflect the prices faced by a producer, we used CPIs only if an appropriate PPI was not available, or if the expenditure more closely resembled a retail rather than wholesale purchase. For example, we used the CPI for telephone services as a proxy for the Telephone cost category because there is no corresponding PPI, and we reasoned that commercial and residential rates change similarly.

(3) *ECIs:* ECIs measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. They are fixed-weight indexes that strictly measure changes in wages and benefits per hour, and are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs we use meet these criteria.

Wages and Salaries

As discussed above, we use a blend of the Wages and Salaries ECI for Hospitals (Civilian) (50 percent)(series code CIU1026220000000I) and the Wages and Salaries ECI for Health Care and Social Assistance (Civilian) (50 percent) (series code CIU10262000000000I) as the measure of price growth for Wages and Salaries in ESRD facilities. This particular blend was chosen to—(1) account for the presence of ESRDs in NAICS 62 (Health Care and Social Assistance), and (2) reflect the similarities observed in the occupational mixes between the ESRD industry and the hospital industry. We believe this approach results in an appropriate price index that reflects changes in the price of wages and salaries in the ESRD industry.

Benefits

As discussed above, we use a blend of the Benefits ECI for Hospitals (Civilian) (50 percent) and the Benefits ECI for Health Care and Social Assistance (Civilian) (50 percent) as the measure of price growth for Benefits in ESRD facilities. We believe this approach results in an appropriate price index that reflects changes in the price of benefits in the ESRD industry.

Professional Fees

We use the Compensation ECI for Professional and Related Occupations (Private) (series code CIU2010000120000I) as the proxy for professional fees. We selected this price proxy because it includes occupations such as lawyers, accountants, and bookkeepers that are represented in this cost category.

Utilities

We use the PPI for Commercial Electric Power (series code WPU0542) and the PPI for Commercial Natural Gas (series code WPU0552) as the proxies for the Electricity and Natural Gas cost categories, respectively. We use the CPI for Water and Sewerage Maintenance (series code CUUR0000SEHG01) as the price proxy for the Water and Sewerage cost category.

Capital-Related—Building and Equipment

We use the CPI for Owner's Equivalent Rent of Residences (series code CUUR0000SEHC) as the price proxy for the Capital-related Building and Equipment cost category. We refer to this price proxy generally as the CPI for Residential Rent. As described earlier, this cost category includes building and fixtures, leased buildings, fixed equipment, and moveable equipment. Because machine equipment, particularly dialysis machines, is reflected in a separate cost category, the bulk of the expenditures captured here are for building and fixed equipment. Therefore, we would prefer to have a proxy that captures the price change associated with this type of capital expense. While there can sometimes be differences in the price levels for residential and commercial rent, we believe the CPI for Residential Rent approximates the change in the underlying costs associated with ESRD facilities' capital costs such as depreciation, interest, taxes, and other capital costs. Given the lack of an ESRD-specific proxy for capital costs, we believe that the CPI for Residential Rent represents the best available proxy for the changes in capital costs facing ESRD facilities.

Capital-Related—Machinery

We use the PPI for Electrical Machinery and Equipment (series code

WPU117) as the price proxy for the capital-related machinery cost category. This PPI includes dialysis machines, which are a significant component of machine equipment costs reported by ESRD facilities. Therefore, we believe that this price proxy is the best measure of the price growth of this cost category.

Pharmaceuticals

ESRD facilities use a variety of drugs during dialysis treatment including EPO which is currently a separately billable drug and accounts for the majority of ESRD facility drug expenses. We pay for erythropoietic agents to treat chronic anemia in ESRD patients. At present, Epogen© and ARANSP© (both manufactured by a single supplier) are two of the prevailing erythropoietic drugs available to treat anemia in ESRD patients. Medicare is the dominant purchaser of EPO since it is mainly used to treat kidney dialysis patients. For the ESRDB market basket, we use the PPI for Pharmaceuticals for Human Use (Prescription) (series code WPUSI07003) as the price proxy for the Pharmaceuticals category. We refer to this price proxy generally as the PPI for Prescription Drugs. We use this proxy for a variety of reasons. First, all of the market baskets that we produce include price proxies that are intended to reflect the efficient average price increase associated with the purchase of the particular input category. Accordingly, we have chosen to proxy the Pharmaceuticals cost category in the ESRDB market basket, which includes the mix of all prescription drugs purchased by dialysis facilities, by the PPI for Prescription Drugs because it reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. Second, we anticipate the price changes associated with the assortment of drugs administered in ESRD facilities should, over time, be similar to the average prescription drug price changes observed across the entire economy. Finally, this price series was chosen as it is both publicly available and regularly published.

Supplies

We use the commodity-based PPI for Medical, Surgical, and Personal Aid Devices (series code WPU156) as a proxy for changes in ESRD supply prices. Many of the supplies used in dialysis are included in this PPI, such as dialyzers, catheters, I.V. equipment, syringes, and other general medical supplies used in dialysis treatment.

Laboratory Services

We use the PPI for Medical and Diagnostic Laboratories (series code PCU6215—6215—) as the price proxy for the ESRD Laboratory Services cost category. Most of the laboratory tests used in dialysis are blood chemistry tests (a covered component of the PPI for Medical and Diagnostic Laboratories). Additionally, some ESRD facilities are using diagnostic imaging services to monitor patient site access, and the points where waste exchange takes place (also a covered component of this price proxy).

Telephone

We use the CPI for Telephone Services (series code CUUR0000SEED) as the price proxy for the Telephone cost category. This index is used as the price proxy for Telephone Services in other market baskets produced by CMS.

Housekeeping and Operations

We use the PPI for Janitorial Services (series code PCU561720561720) as the price proxy for the Housekeeping and Operations cost category. This is the same price proxy that was used in the proposed rule; however, we referred to this proxy as the PPI for Building, Cleaning and Maintenance in the proposed rule (74 FR 50002). This PPI includes housekeeping, janitorial, and maintenance (excluding repairs) services, and is representative of the types of costs included in this cost category.

All Other Labor-Related Services

We use the Compensation ECI for Service Occupations (Private) (series code CIU2010000300000I) as the price proxy for the All Other Labor-Related Services cost category. This category includes expenses related to repair services. We feel that the service occupations most accurately reflect the costs for these types of repair and maintenance services purchased by ESRD facilities.

All Other Nonlabor-Related Services

We use the CPI for All Items Less Food and Energy (series code CUUR0000SA0L1E) as the price proxy for the All Other Nonlabor-Related Services cost category. This category includes costs such as data processing, purchasing, taxes, home office costs, and malpractice costs. The costs represented in this category are diverse and are primarily associated with the purchase of services. These costs are best represented by a general measure of inflation such as the CPI for All Items Less Food and Energy. Food and energy are excluded from the index to remove the volatility associated with those items. Additionally, energy prices are already captured in the utility price proxies.

ESRDB Market Basket Increases

The final ESRDB market basket reflects the combination of cost weights and price proxies discussed above. As explained above, under section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of Public Law 111–148, for 2012 and each subsequent year, the Secretary shall reduce the market basket increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, 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)". For purposes of providing a forecast, Table 32 contains the projected rate of growth for CY 2011 through CY 2020 for the ESRDB market basket (adjusted, where applicable, based on the estimated productivity adjustment for a given year). Although we provide a forecast here, we will address in future rulemaking the implementation and application of the productivity adjustment to the ESRDB market basket increase factor that will be required beginning in 2012. Also, as we indicated above, in CY 2011, we note that as a result of amendments by section 3401(h) of Public Law 111–148 to section 1881(b)(14)(F) of the Act, a full market basket will be applied to the composite rate portion of the blended payment during the first year of the transition.

Table 32--Forecast of the 2008-Based ESRDB Market Basket Percent Change, Adjusted for Productivity, where applicable, for CY 2011 and Beyond

CY beginning January 1st	ESRDB Market Basket Percent Change - Unadjusted	ESRDB Market Basket Percent Change – Adjusted for Productivity
CY2011	2.5	N/A
CY2012	2.7	1.3
CY2013	2.7	1.5
CY2014	2.6	1.6
CY2015	2.6	1.9
CY2016	2.6	2.0
CY2017	2.6	1.9
CY2018	2.6	1.8
CY2019	2.6	1.9
CY2020	2.6	1.9

Note: The market basket changes adjusted for productivity will be used for update purposes for CY 2012 through CY 2020, as mandated by the Affordable Care Act.
Source: 2010 1st Quarter Forecast from IHS Global Insight

ESRD Labor-Related Share

The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share is typically the sum of Wages and Salaries, Benefits, Professional Fees, Labor-related Services, and a portion of the Capital share from a given market basket. We used the 2008-based ESRDB market basket cost weights to determine the labor-related share for ESRD facilities under a bundled system. Under the ESRDB market basket, the labor-related share for ESRD facilities is 41.737 percent; as shown in Table 33 below. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping and Operations, All Other Labor-related Services, 87 percent of the weight for Professional Fees (details discussed below), and 46 percent of the weight for Capital-related Building and Equipment expenses (details discussed below).

Table 33—ESRDB Market Basket Labor-Related Share

Cost Category	2008-based ESRDB Labor-Related Share (Percent)
Wages and Salaries	26.755%
Benefits	6.754%
Housekeeping and Operations	2.029%
All Other Labor-related Services	1.219%
Professional Fees Labor-related	1.549%
Capital Labor-related	3.431%
Total	41.737%

The labor-related share for Professional Fees (87 percent) reflects the proportion of ESRD facilities' professional fees expenses that we believe varies with local labor market. As stated in the proposed rule (74 FR 50003), we recently conducted a survey of ESRD facilities to better understand the proportion of contracted professional services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD's local labor market. Therefore, we are including 87 percent of the cost weight for

Professional Fees in the labor-related share.

The labor-related share for capital-related expenses (46 percent of ESRD facilities' adjusted Capital-related Building and Equipment expenses) reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages. Capital-related expenses are affected in some proportion by variations in local labor market costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local labor market costs, such as interest rates. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

K. Implementation

1. Transition Period

Section 1881(b)(14) of the Act replaces the current basic case-mix adjusted composite payment system with a case-mix adjusted bundled ESRD PPS, for Medicare outpatient ESRD facilities beginning January 1, 2011. Section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide "a four-year phase-in" of the payments under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011. Although the statute uses the term "phase-in", other Medicare payment systems use the term "transition" to describe the timeframe during which payments are based on a blend of the payment rates under the prior payment system and the new payment system. For purposes of this ESRD PPS final rule, we use the term "transition" to describe this timeframe.

Section 1881(b)(14)(E)(i) of the Act further requires that the transition occur "in equal increments," with payments under the ESRD PPS "fully implemented for renal dialysis services furnished on or after January 1, 2014." In addition, section 1881(b)(14)(E)(ii) of the Act permits an ESRD facility to make a one-time election to be excluded from the transition from the current basic case-mix adjusted composite payment system, with its payment amount for renal dialysis services based entirely on the payment amount under the ESRD PPS. This election must be made prior to January 1, 2011. Lastly, section 1881(b)(14)(E)(iii) of the Act requires that we make an adjustment during the transition so that payments during the transition equal the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. The transition budget-neutrality adjustment policy is set forth at § 413.239 and is discussed further in section II.E.5. of this final rule.

In accordance with section 1881(b)(14)(E) of the Act, we proposed to implement the transition from the current basic case-mix adjusted composite payment system in equal increments, so that renal dialysis services furnished on or after January 1, 2014, would be paid entirely based on the payment amount under the ESRD PPS. Specifically, we proposed that for renal dialysis services provided during the transition period beginning January 1, 2011 and ending December 31, 2013, ESRD facilities would receive a blended payment for each dialysis treatment consisting of the payment amount under the basic-case mix adjusted composite system and the payment amount under the ESRD PPS (74 FR 50003). We noted that, because ESRD facilities would receive an all-inclusive payment during the transition period for all renal dialysis services, other entities, such as Method II DME suppliers and laboratories would no longer bill Medicare beginning January 1, 2011 for renal dialysis services furnished to ESRD patients. These entities would need to seek payment from the patient's ESRD facility (74 FR 50003).

The comments we received and our responses are set forth as follows:

Comment: Many commenters suggested that we consider implementing Part D drugs in the bundled payment during the last year of the transition and, indicated that the inclusion of these drugs would impact an ESRD facility's decision of whether to elect to go into the transition period or to receive full payment under the ESRD PPS. The commenters believed that we should collect accurate data on the costs of Part D drugs before they are implemented as part of the ESRD PPS bundle.

Response: In this final rule and in response to public comment, we are delaying implementation of payment under the ESRD PPS of ESRD-related oral-only drugs that are currently separately paid under Part D until January 1, 2014. The decision to delay implementation of oral-only drugs is discussed in section II.A.3.a. of this final rule. The implementation of ESRD-related drugs and biologicals under the ESRD PPS is discussed in section II.A.3. of this final rule. Because we are implementing all other ESRD-related former part D drugs and biologicals effective January 1, 2011, we included a $0.49 adjustment to the portion of the blended payment amount related to the basic case-mix adjusted composite payment system to account for those drugs. To derive the $0.49 adjustment, we used the 2011 price inflated payment amounts divided by the Part D HD-equivalent treatments for Part D enrollees as discussed in section II.F.5. of this final rule. We will continue to analyze the prices paid under Part D for oral-only ESRD-related drugs so that we are able to appropriately price these drugs in the ESRD PPS base rate.

Comment: Many commenters suggested that we consider implementing laboratory tests in the bundled payment during the last year of the transition. The commenters explained that there will be administrative burden in contracting for laboratory services during the transition period. The commenters indicated that even if laboratories are willing to enter into a contract, they are concerned about their ability to negotiate reasonable prices given the low volume of services that they would request from the laboratories.

Response: Section 1881(b)(14)(A)(i) of the Act requires CMS to include all renal dialysis services, which include ESRD-related diagnostic laboratory tests, into one single payment effective January 1, 2011. Section 1862(a)(24) of the Act prohibits unbundling of expenses for renal dialysis services (as defined in section 1881(b)(14)(B) of the Act). Therefore, we do not have the authority to pay laboratories directly for ESRD-related diagnostic laboratory tests. We note, under the current basic case-mix adjusted composite payment system, certain ESRD-related laboratory tests are included in the composite rate. ESRD facilities would have been required under the current basic case-mix adjusted composite payment system to establish arrangements with laboratories to perform these laboratory tests and receive payment from the ESRD facility. Therefore, we do not agree that bundling all ESRD-related laboratory tests under the ESRD PPS will pose a significant burden.

For CY 2011, we proposed to make payments based on 75 percent of the payment rate under the basic case-mix adjusted composite payment system and 25 percent of the payment rate under the ESRD PPS. For CY 2012, we proposed to make payment based on 50 percent of the payment rate under the basic case-mix adjusted composite payment system and 50 percent of the payment rate under the ESRD PPS. For

CY 2013, we proposed to make payment based on 25 percent of the payment rate under the basic case-mix adjusted composite payment system and 75 percent of the payment rate under the ESRD PPS. For renal dialysis services furnished on or after January 1, 2014, we proposed that payment to ESRD facilities would be based on 100 percent of the payment amount under the ESRD PPS (74 FR 50003).

We did not receive public comments on the proposed blending methodology for the transition from the basic case-mix composite payment system to the ESRD PPS bundled payment system and, therefore, we are finalizing the blending methodology as proposed in § 413.239(a).

We proposed that the portion of the blended rate based on the payment amount with regard to the basic case-mix adjusted composite payment system would be comprised of the composite payment rate (which is adjusted by the basic case-mix adjustments and a wage index), the drug add-on amount, and payment amounts for items and services furnished to dialysis patients that are currently separately paid under Part B by Medicare to entities other than the ESRD facility. We also proposed to include a $14 adjustment to the portion of the blended payment amount related to the basic case-mix adjusted composite payment system during the transition to account for the ESRD-related drugs and biologicals that are currently separately paid under Part D and were proposed to be included in the ESRD PPS base rate (74 FR 50004). Because we are delaying payment under the ESRD PPS for former Part D oral-only drugs, the proposed $14 adjustment will be $0.49 for this final rule, as discussed in section II.E.5. of this final rule.

We did not receive comments on the composition of the portion of the blended rate based on the basic case-mix adjusted composite payment system. Therefore, we are finalizing our proposal that the portion of the blended rate based on the basic case-mix adjusted composite payment system will be comprised of the composite payment rate (which is adjusted by the basic case-mix adjustments and a wage index), the drug add-on amount, and payment amounts for items and services furnished to dialysis patients that are currently separately paid under Part B. We will include a $0.49 adjustment to the portion of the blended payment amount related to the basic case-mix adjusted composite payment system during the transition to account for the ESRD-related drugs and biologicals (currently separately paid under Part D), but effective January 1, 2011, will be bundled under the ESRD PPS, (as discussed in section II.E.5. of this final rule).

In the proposed rule, we discussed that for the years during which the transition is applicable, section 1881(b)(14)(F)(ii) of the Act requires the Secretary to annually increase the portion of the ESRD PPS that is based on the composite rate that would otherwise apply if the ESRD PPS had not been enacted (74 FR 50004). In particular, at the time the ESRD PPS proposed rule was published, section 1881(b)(14)(F)(ii)(II) of the Act required the composite rate portion of the blended payment to be updated annually by the ESRDB market basket update minus 1.0 percentage point. Therefore, for each year of the transition, to maintain the 98 percent budget-neutrality amount, we proposed that the composite payment rate portion of the blended amount would be updated by the applicable case-mix adjustments, the drug add-on adjustment, the current wage index, and the ESRDB market basket update minus 1.0 percentage point.

We also proposed that payments for items and services furnished to dialysis patients that are paid separately under Part B under the current composite payment rate methodology, that is, ESRD-related laboratory tests, ESRD-related drugs, and ESRD-related supplies, blood, and blood products would no longer be paid separately. Instead, those items and services would be priced to reflect how they are currently paid (for example, using a fee schedule or ASP amount) (74 FR 50004).

We address comments related to the market basket in section II.J. of this final rule; laboratory tests in section II.A.4; ESRD-related drugs in sections II.A.2. and II.A.3.; ESRD supplies in section II.A.4; and, blood and blood products in section II.A.6. of this final rule. As discussed in these respective sections, for this final rule, ESRD-related blood and blood products will not be included in the ESRD PPS bundle and ESRD-related laboratory tests and ESRD-related drugs will no longer be separately paid. In addition, in accordance with section 3401(h) of the Affordable Care Act, which revised section 1881(b)(14)(F) of the Act, for CY 2011, the full ESRDB market basket update will apply and, for CY 2012, the ESRDB market basket update reduced by a productivity adjustment would apply as discussed in section II.J. of this final rule.

In the proposed rule, we noted that there are ESRD facilities that have existing exception amounts that are used for payment in lieu of the composite rate, drug add-on payment, and basic case-mix adjustments. Any existing exception amounts would not be updated by the ESRDB market basket throughout the transition (74 FR 50004). Finally, in the proposed rule, we discussed that the portion of the blended rate based on the ESRD PPS would include the base rate and all applicable patient-level, facility-level adjustments, and outlier payments as set forth in proposed § 413.231, § 413.232, § 413.235 and § 413.237. We respond to comments regarding exceptions in section II.L.1; the ESRD PPS base-rate in section II.E; patient-level adjusters in section II.F.3; and, facility-level adjusters in section II.F.4. of this final rule.

As noted in the proposed rule, section 1881(b)(14)(E)(ii) of the Act gives an ESRD facility the option to make a one-time election to be excluded from the four-year transition from the current basic case-mix adjusted composite payment system in the form and manner specified by the Secretary (74 FR 50004). Once made, this election may not be rescinded. ESRD facilities may choose to be paid the blended rate under the transition period in order to give them time to determine the impact of the ESRD PPS on their operations and to make necessary adjustments. We indicated in the ESRD PPS proposed rule that we believed ESRD facilities would choose to be excluded from the transition if they concluded that they would benefit financially from the payment amount under the ESRD PPS (74 FR 50004).

Section 1881(b)(14)(E)(ii) of the Act requires that ESRD facilities wishing to be excluded from the transition must make an election to be excluded and their election must be made prior to January 1, 2011, in the form and manner specified by the Secretary. We proposed that ESRD facilities notify their FI/MAC of their election choice in a manner established by the FI/MAC no later than November 1, 2010, regardless of any postmarks or anticipated delivery dates. We proposed that ESRD facilities that become certified for Medicare participation and begin to provide renal dialysis services between November 1, 2010 and December 31, 2010, would notify their FI/MAC of their election choice at the time of enrollment. Once an ESRD facility notifies its respective FI/MAC of their election choice, on or before November 1, 2010 (or at the time of enrollment for newly-certified ESRD facilities that begin to provide renal dialysis services between November 1, 2010 and December 31, 2010), the ESRD

facility's election cannot be rescinded (74 FR 50004).

We also proposed that ESRD facilities that fail to affirmatively make an election by November 1, 2010, would be paid based on the blended amount during the transition. We proposed that elections submitted by ESRD facilities that wish to be excluded from the transition that are received, postmarked, or delivered by other means after November 1, 2010, would not be accepted. Thus, we proposed that all ESRD facilities wishing to be excluded from the transition should submit their election choice by the proposed deadline. ESRD facilities electing to be excluded from the transition will receive full payment under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011 (74 FR 50004).

We did not receive any comments regarding the proposed one-time election process and, therefore, in this final rule we are finalizing § 413.239 with modifications to indicate that the FI/MAC will establish the manner in which an ESRD facility will indicate its intention to be excluded from the transition, consistent with our proposal.

We received the following general comments regarding the transition period.

Comment: Most of the commenters appreciated the transition period and agreed that the time from 2011 through 2014 allows them time to make adjustments to their operations. One commenter requested that we allow the SDOs the time to consider the final rule so that they can make informed decisions regarding transitioning. Another commenter suggested that we eliminate the transition period, continue to pay ESRD facilities based on the current composite rate system, and then implement the ESRD PPS fully in 2014. The commenter explained that this approach would simplify the implementation and remove the need for a complex dual payment system during the transition period.

Response: The statute requires a 4-year transition period for ESRD facilities that do not opt to be excluded from the transition. In addition, after January 1, 2011, the statute requires that a single payment for renal dialysis services be made to ESRD facilities for renal dialysis services furnished to ESRD beneficiaries.

a. New ESRD Facilities

Section 1881(b)(14)(E)(i) of the Act permits a provider of services or a renal dialysis facility to make a one-time election to be excluded from the transition, it also provides that this election must be made prior to January 1, 2011. As a result, we proposed that ESRD facilities that are certified for Medicare participation and begin providing renal dialysis services or home dialysis services on or after January 1, 2011, would not have the option to choose whether to be paid a blended rate under the transition or the payment amount under the ESRD PPS. Rather, we proposed in § 413.239(c) that new ESRD facilities would be paid based on 100 percent of the payment amount under the ESRD PPS (74 FR 50004). As we did not receive any public comments regarding this proposal, we are finalizing § 413.239(c) as proposed.

We proposed to define a new ESRD facility as an ESRD facility that is certified for Medicare participation on or after January 1, 2011 in § 413.171. We did not receive any public comments regarding this proposal. Accordingly, for the reasons we set forth in the proposed rule, we are finalizing § 413.171 as proposed.

b. Limitation on Beneficiary Charges Under the ESRD PPS and Beneficiary Deductible and Co-Insurance Obligations

Section 1833 of the Act governs payments of benefits for Part B services and the cost sharing amounts for services that are considered medical and other health services. In general, many Part B services are subject to a payment structure that requires beneficiaries to be responsible for a 20 percent co-insurance after the deductible (and Medicare pays 80 percent). With respect to dialysis services furnished by ESRD facilities to individuals with ESRD, under section 1881(b)(2)(a) of the Act, payment amounts are 80 percent (and 20 percent by the individual) (74 FR 50005).

We proposed the items and services that would be considered renal dialysis services included in the ESRD PPS payment, such as composite rate services, certain separately billable ESRD-related injectable drugs, ESRD-related drugs and biologicals currently covered under Part D, laboratory testing, etc. We acknowledged that certain items and services such as laboratory tests and Part D drugs currently have different beneficiary co-insurance structures. However, we indicated that these items and services would be considered renal dialysis services after the ESRD PPS is implemented when furnished by an ESRD dialysis facility to an ESRD beneficiary. Therefore, we proposed that a 20 percent beneficiary co-insurance would be applicable to the ESRD PPS payment for these services including any adjustments to the ESRD PPS payment such as adjustments for case-mix, wage index, outlier, etc. (74 FR 50005).

We proposed that an ESRD facility receiving an ESRD PPS payment could charge the Medicare beneficiary or other person only for the applicable deductible and co-insurance amounts as specified in proposed § 413.176. Therefore, the beneficiary co-insurance amount under the ESRD PPS would be 20 percent of the total ESRD PPS payment (including payments made under the transition). We noted that the amount of co-insurance is based on the proposed ESRD PPS payment for renal dialysis services and home dialysis in 42 CFR Part 413. We explained that, in general, ESRD facilities are paid monthly by Medicare for the ESRD services they furnish to a beneficiary even though payment is on a per treatment basis. We proposed to continue this practice to pay ESRD facilities monthly for services furnished to a beneficiary beginning January 1, 2011 (74 FR 50005).

During the transition period before January 1, 2014, ESRD facilities that do not elect to go 100 percent into the ESRD PPS in 2011 would receive a blended payment amount. We proposed that the blended monthly payment amount would be subject to a 20 percent beneficiary co-insurance (74 FR 50005).

Additionally, in accordance with section 1881(b)(1) of the Act, we proposed in § 413.172(b) that an ESRD facility may not charge a beneficiary for any service for which payment is made by Medicare. This policy would apply, even if the ESRD facility's costs of furnishing services to that beneficiary are greater than the amount the ESRD facility would be paid under the proposed ESRD PPS (74 FR 50005).

We received about 230 comments on beneficiary co-insurance obligations which are summarized below.

Comment: A number of commenters believed dialysis facilities would be burdened by collecting the beneficiary coinsurance, especially co-insurance associated with the Part D oral drugs. The commenters stated that ESRD facilities are caregivers and not pharmacies and, therefore, their staff does not currently collect co-insurance and that if staff had to collect co-insurance, it would interrupt patient care. Other commenters expressed concern about the burden associated with collecting co-insurance liabilities because they would have to develop new systems.

Response: We do not agree with the commenters that collecting co-insurance would be a new requirement for ESRD

facilities because there has been a beneficiary co-insurance liability on the composite payment system as well as the basic case-mix adjusted composite rate payment. As discussed in section II.A.3. of this final rule, implementation of oral-only drugs will be delayed until January 1, 2014. Therefore, we do not believe that ESRD facilities will experience additional burden as a result of the implementation of the ESRD PPS effective January 1, 2011.

Comment: A number of commenters were concerned about the financial affects on beneficiaries with ESRD due to the copays that would result from the new bundled PPS. The commenters believed the new bundled PPS would increase beneficiary co-insurance and, therefore, would be a financial burden on patients, many who have limited income. Some commenters believed CMS should do an analysis of the impact of the increased beneficiary co-insurance on patients since there is no data available. A number of commenters with ESRD were worried about being able to pay for their dialysis treatment.

Response: Under the current basic case-mix adjusted composite system, there has been an incentive for excess use of separately billable items and services and patients have been responsible for a 20 percent co-insurance liability on most of these separately billable. For this reason, in addressing co-insurance obligations under the current composite payment methodology, it is important to consider not only the co-insurance associated with the composite rate itself, but also the 20 percent co-insurance obligation for most separately billed drugs and biologicals.

Under the ESRD PPS, the base rate (which includes composite rate services as well as items and services that are currently separately billable) reflects the average cost for furnishing dialysis services to patients. For this reason, if patients use less than the average of separately billable items and services (that is, items and services that were separately paid under the current basic case-mix adjusted composite payment system), they can expect an increase in their co-insurance obligation. However, if patients use more than the average of separately billable items and services, they should pay less in co-insurance under the ESRD PPS. The amount of the difference in co-insurance under the current basic case-mix adjusted composite payment system and the ESRD PPS for an individual patient is directly related to how their use of separately billable services compares to the average amount. We acknowledge that this comparison does not reflect that under the ESRD PPS, beneficiaries will assume a 20 percent co-insurance liability for non-routine laboratory tests that was not assumed under the current basic case-mix adjusted composite payment system. However, we note that under the current basic case-mix composite rate system, certain routine laboratory tests are included in the composite rate. Therefore, beneficiaries have been responsible for co-insurance associated with ESRD-related laboratory tests that are included in the composite rate.

A bundled PPS allows patients to pay co-insurance based upon the bundled rate for all items and services needed for their treatment without additional co-insurance costs if more separately billed items or services are needed.

Comment: Many commenters raised concerns about the financial burden for patients under the ESRD PPS because patients would have to pay co-insurance for oral drugs and laboratory tests. The commenters stated that shifting the oral drugs from Part D to Part B could result in significant increases in out-of-pocket costs for beneficiaries. Other commenters indicated that some ESRD patients currently have high out-of-pockets costs for their oral drugs and believed bundling the oral drugs would cause this cost to be even higher. Some commenters indicated that beneficiaries would not have the option to use generics or less expensive drugs in order to save money. Other commenters indicated that some ESRD patients would not reach catastrophic coverage under Part D with the new bundled system because they will be in the coverage gap for a longer time.

Some commenters were concerned that beneficiaries who have the low-income subsidy under Part D will have to pay higher co-pays for these drugs. Some commenters stated that data presented at the recent American Society of Nephrology meeting, showed that 68 percent of dialysis patients are enrolled in Medicare Part D and 76 percent of these patients have the low-income subsidy. A few commenters were concerned that States' Medicaid programs may not cover the 20 percent co-insurance for oral drugs for dual-eligibles, which they would have received under Part D. One commenter stated that including Part D drugs in the bundle could eliminate access to financial programs that assist patients with co-pays, such as Medicare Low Income Assistance programs as well as program such as the American Kidney Fund's Part D Program for Prescription Bone Medication. Some commenters suggested that CMS should delay the inclusion of the oral drugs specifically the ones with no injectable equivalent because of the lack of data available on the use of these drugs so that CMS can obtain data to assess the financial impact on beneficiaries and facilities. A few commenters requested that CMS assess the possible negative effects on beneficiaries who would now be responsible for co-insurance payments for both oral drugs and laboratory tests.

Response: As discussed in section II.A.3.a. of this final rule, we are delaying the implementation of oral-only drugs currently covered under Part D under the ESRD PPS until January 1, 2014. In section II.A.3. of this final rule, we discuss the inclusion of a limited number of ESRD-related oral drugs and biologicals with other forms of administration. Therefore, the oral-only drugs will continue to be covered under Medicare Part D until January 1, 2014. At that time, when oral-only drugs are paid under the ESRD PPS, the same co-insurance structure described in this section will apply for oral-only drugs. We plan to collect data on the oral-only ESRD-related drugs to assess the impact on beneficiaries and ESRD facilities. We will address the implementation of the oral-only drugs in the ESRD bundle in future notice of proposed rulemaking.

Comment: A few commenters were concerned about the negative impact the additional co-insurance would place on beneficiaries which may contribute to decisions to discontinue treatment, medications, etc. The commenters stated that many patients have difficulty in meeting the co-pays under the current system. The comments believe that if there is an increase in beneficiaries' payments, there is the possibility of beneficiaries missing treatments that would affect their quality of care. A few commenters were specifically concerned about patient noncompliance with taking their medications due to higher out-of-pocket costs. One commenter expressed concern that facilities would be held responsible for the drop in the compliance rates under the QIP.

Response: We appreciate the commenters' concerns about the affects of the co-insurance liability on patients. However, as we discussed in the proposed rule (74 FR 50005), section 1833 of the Act governs payments of benefits for Part B services and the cost sharing amounts for services that are considered medical and other health services. We also explained that with respect to dialysis services furnished by ESRD facilities to individuals with ESRD, under section 1881(b)(2)(a) of the Act, payment amounts are 80 percent (and 20 percent by the individual). Therefore, we do not have the authority

to eliminate the beneficiary co-insurance liability.

As we have discussed in previous responses, beneficiaries have been responsible for co-insurance under the current basic case-mix adjusted composite payment system. Under the ESRD PPS, beneficiaries will continue to assume the co-insurance liability for the renal dialysis services provided by ESRD facilities. However, rather than a co-insurance for each separately billable item and for the basic case-mix adjusted composite rate under the current system, beneficiaries will pay co-insurance on the ESRD PPS payment amount which includes the ESRD PPS base rate and all applicable payment adjustments under the ESRD PPS.

We discuss the applicable adjustments which would be applied to the ESRD PPS base rate and subject to the beneficiary co-insurance liability in sections II.F.3. of this final rule. As discussed in section II.A.3.a. of this final rule, oral-only ESRD-related drugs will not be implemented under the ESRD PPS until January 1, 2014. Therefore, we do not believe that implementation of the ESRD PPS effective January 1, 2011, will cause patients to make decisions to discontinue any medications or treatment because of their co-insurance liability.

Comment: Many commenters expressed concern that ESRD facilities would need to develop systems for collecting medication co-payments. Other commenters expressed concern for the safety of ESRD facility staff stating that ESRD facilities maintaining cash on hand from patients' medication co-payments would place their staff and patients at risk for crime and theft. The commenters also stated they would need to hire additional security to protect against crime and theft. Another commenter stated that there is currently no billing mechanism in place between ESRD facilities and pharmaceutical companies nor is there a mechanism by which the pharmaceutical company could collect the patient's co-payment obligation for drugs included in the ESRD PPS bundle.

Response: Because ESRD-related drugs are included in the ESRD PPS bundle and, therefore, are in the ESRD base rate, the ESRD facility is responsible for obtaining any applicable co-insurance from their beneficiaries. A beneficiary would not have a co-insurance liability on each prescription, but rather on the bundled ESRD PPS payment amount. Beneficiaries have a co-insurance liability under the current basic case-mix adjusted composite rate. Therefore, we do not understand the concerns being raised about the need to collect co-insurance payments under the ESRD PPS, as this responsibility exists under the current payment system. We expect that ESRD facilities will employ any necessary measures that they require to ensure their staff's safety. We believe that because collection of co-insurance payments exist under the current ESRD payment system, the same safety concerns exist and the same measures to address these concerns are in place.

Comment: A number of commenters expressed concern that under the ESRD PPS, beneficiaries will have to pay co-insurance on laboratory tests. The commenters noted that beneficiaries currently have no financial responsibility to pay for their laboratory tests because Medicare pays 100 percent. The commenters believed the inclusion of laboratory tests in the ESRD PPS bundle would lower Medicare's obligation to only 80 percent of the payment and require beneficiaries to pay the 20 percent co-insurance for associated costs, resulting in increased out-of-pocket costs for beneficiaries. The commenters indicated that both beneficiaries and dialysis facilities would be penalized financially for laboratory services.

A few commenters complained about the burden and cost of collecting co-insurance for laboratory tests because most facilities do not have their own laboratories. One commenter indicated that according to the proposed rule, Medicare beneficiaries with ESRD who require dialysis will not have access to needed laboratory tests, which will be discriminatory. The commenter further believed patients who currently do not have a co-insurance obligation for laboratory tests, will now be responsible for 20 percent which might result in financial burden for many patients who already might be on limited or fixed incomes. Another commenter noted that those with limited or fixed incomes may be subject to an additional $300 to $400 per year for co-insurance on laboratory tests. One commenter believed the additional co-insurance would presumably be covered by Medicare Supplemental plans but could not predict the effects of the bundle for the costs of Medicare supplemental insurance. One commenter noted that Congress in MIPPA did not indicate that the longstanding policy that Medicare paying 100 percent for laboratory tests would change under the ESRD bundled system. Another commenter stated that historically CMS recognized the difficulty of placing a co-insurance on laboratory tests on facilities and patients and excluded diagnostic testing from beneficiary co-insurance obligations.

Response: As we discussed in section II.A.4. of this final rule, ESRD-related laboratory tests are considered renal dialysis services and are included in the ESRD PPS bundled base rate, and therefore, as part of the ESRD base rate after applicable adjustments are applied, would be subject to the 20 percent co-insurance (that is, individual laboratory services would not be subject to a separate beneficiary co-insurance liability). In other words, under the ESRD PPS, beneficiaries will not have a co-insurance liability for each laboratory test, but rather beneficiaries will have a co-insurance liability on the total payment that Medicare makes to an ESRD facility on their behalf. This is analogous to the beneficiary co-insurance liability under the current basic case-mix adjusted composite rate where beneficiaries have a co-insurance liability for the composite payment made to ESRD facilities on their behalf and not co-insurance liability on each composite rate service they receive.

We note that most routine laboratory tests for ESRD-related purposes are currently included in the basic case-mix adjusted composite rate. This means that currently, beneficiaries with ESRD have a co-insurance liability for the composite rate, which includes laboratory tests. We do not see the inclusion of ESRD laboratory tests in the ESRD PPS as being any different than what occurs currently under the basic case-mix adjusted composite rate system.

Comment: One commenter expressed concern that the implementation of the bundled ESRD PPS presents a substantial risk to ESRD facilities because of the potential for non-recovery of co-insurance payments for patients who are dually eligible under Medicare and Medicaid. The commenter recommended that CMS should create a new billing code for the bundle of services under the ESRD PPS and require States to recognize the new Medicare payment system. The commenter stated that CMS could work through the National Association of State Medicaid Directors to educate the States well in advance of the implementation of the PPS to provide ample time for them to adjust their co-insurance amounts, as required.

Response: We have already begun outreach efforts with the States to ensure that State Medicaid Agencies understand their responsibilities to adjust their systems so that co-insurance amounts are properly determined and paid appropriately for dually-eligible

beneficiaries upon implementation of the ESRD PPS.

Although an ESRD PPS billing code may make it easier for States to determine whether they have an obligation to pay co-insurance on behalf of a patient with ESRD, line item billing by date of service (where each renal dialysis service is itemized on the claim) will continue to be necessary in order for blended payments to be made during the transition and for identification of outlier services.

Comment: Several commenters were concerned about dialysis beneficiaries who have Medigap supplemental plans because oral drugs and laboratory tests have not previously been covered under Medigap. The commenters were specifically concerned about how Medigap plans will adjust to the inclusion of oral drugs in the ESRD PPS. A commenter questioned if Medigap plans would consider drugs as renal dialysis services. Several commenters stated that Medigap insurers may deny payment of the beneficiary co-insurance because statute prevents them from coordinating benefits for oral drugs. Several commenters believed that Medigap premiums would increase significantly and would financially burden patients.

One commenter stated that CMS should take into consideration that Medicare is the only insurance available to stage 5 chronic kidney disease patients (that is, ESRD patients). Another commenter believed that the ESRD PPS will target patients with private insurance and their co-insurance for additional revenue which would be an unfair burden on those that pay their insurance and co-insurance out-of-pocket. A commenter with private drug insurance was concerned about the costs and processes to pay two sets of premiums and co-insurance. Another commenter stated that the copayment under Medicare could significantly exceed the current copayments for those with private insurance.

Response: We believe that generally, Medigap and other private insurance plans cover co-insurance and copayment obligations for Medicare Part B services after the beneficiary meets the Part B deductible amount. We do not expect this to change under the ESRD PPS bundle. We are unable to address if these plans will continue to cover the co-insurance under the ESRD PPS. As we discussed in a previous response, ESRD-related oral drugs and laboratory tests included in the ESRD PPS bundle are considered renal dialysis services under the Part B benefit. Therefore, we do not believe there should be issues with Medigap plans because such oral drugs are renal dialysis services. We reiterate that payment under the ESRD PPS for oral-only drugs currently covered under Part D will be delayed until January 1, 2014.

We do not agree with the comments that Medicare will target patients with private insurance and their copays for additional revenue. The ESRD PPS, as a Medicare Part B payment system for outpatient maintenance dialysis, provides payment on behalf of Medicare beneficiaries to ESRD facilities that provide home dialysis and renal dialysis services. Therefore, beneficiary's co-insurance liability is not based on the absence or presence of private insurance.

We also do not anticipate any change with regard to beneficiaries with private drug insurance and the costs and processes to pay two sets of premiums and co-insurance under the ESRD PPS. As we discussed in previous responses, under the current basic case-mix adjusted composite payment, beneficiaries are subject to co-insurance liability for composite and separately billable payments made to ESRD facilities. We acknowledge that this co-insurance obligation changes under the ESRD PPS because the Medicare payment made to ESRD facilities will include items and services that are separately billable under the current basic case-mix adjusted composite payment system.

Comment: A few commenters expressed concern that the wide array of case-mix adjusters would create an inequity for patients, especially the sicker patients, because their bundled payment rate will be higher due to the adjustments with sicker patients having higher co-insurance. Other commenters stated that the proposed adjusters like age, health history, and clinic size would add extra work and complexity to reimbursement and would increase the co-payment. Another commenter was concerned that patients would not withstand the additional out-of-pocket costs associated with the ESRD bundle and the case-mix adjusters. One commenter opposed the application of beneficiary co-payment amounts to outlier payments asserting that this would set a dangerous precedent for discrimination on the basis of patient characteristics. The commenter recommended that CMS limit all patients' co-payment responsibility to 20 percent of the base rate payment amount.

Response: We do not have the authority to determine how the beneficiary co-insurance liability is applied. Section 1881(b)(2)(A) of the Act requires payments for dialysis services furnished by ESRD facilities to individuals with ESRD for which payments may be made under Part B to be equal to 80 percent of the amounts determined. The statute further requires that payments from individuals are to be 20 percent of the amount for such services after the deductible. Therefore, Medicare is required by statute to pay 80 percent and the beneficiary's responsibility is 20 percent of the amounts established for ESRD PPS renal dialysis services. This would include applying the beneficiary co-insurance liability to the ESRD PPS base rate and all applicable adjustments, including the outliers.

We do not agree that applying the beneficiary co-insurance liability based on characteristics is discriminatory. We discuss the patient characteristics that have demonstrated higher usage of separately billable items in section II.F.3. of this final rule. Because these characteristics (such as age, BSA and BMI) result in higher resource utilization and therefore higher costs, ESRD facilities will receive a payment adjustment to the ESRD PPS base rate and beneficiaries will be required to assume 20 percent of the costs. We note that under the current basic case-mix adjusted composite payment system, many of the same patient characteristics have been applied to the composite rate (age, BMI and BSA) and beneficiaries have been required to assume 20 percent of those payments.

Payments under the ESRD PPS reflect the extent to which additional resources are utilized. In situations where a patient with ESRD is sicker and, therefore, utilizes more resources, the payment to the ESRD facility providing renal dialysis services to that patient would reflect the higher resource use. Under the current basic case-mix adjusted composite payment system, greater resource utilization is reflected by greater use of separately billable items that are subject to a beneficiary co-insurance liability. In other words, patients have been subject to paying co-insurance under the current payment system based on the use of resources.

Therefore, based on the comments and the reasons discussed above, we are finalizing the beneficiary co-insurance liability of 20 percent applied to the ESRD PPS payment inclusive of all applicable payment adjustments.

2. Claims Processing

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made for renal dialysis services and other items and services (for example, supplies and equipment

used to administer dialysis, drugs, biologicals, laboratory tests, and support services) related to home dialysis. In the proposed rule, we noted that implementation of the ESRD PPS will require changes to the way we process claims. Some of the changes we proposed may involve establishing consolidated billing rules and edits and changes to the data elements reported on claims (74 FR 50005).

The consolidated billing approach essentially confers to the ESRD facility the Medicare billing responsibility for all of the renal dialysis services that its patients receive. The consolidated billing rules and edits that are being set forth in this final rule are described further below.

a. Consolidated Billing Rules and Edits

In the proposed rule (74 FR 50005), we explained that since the ESRD PPS payment model represents an all-inclusive payment for renal dialysis services and home dialysis items and services, the ESRD facility is responsible for all of the ESRD-related services that its patients receive. Items and services that are paid separately under the current basic case-mix adjusted composite rate (such as laboratory tests), would no longer be billed for by entities (such as laboratories and DME suppliers), and therefore, payment for these services would be made only to the ESRD facility so that duplicate payment is not made by Medicare. Although DME suppliers and laboratories may not bill Medicare for ESRD-related services paid under the ESRD PPS beginning January 1, 2011, in the event an erroneous bill is submitted, consolidated billing edits will prevent payment for those services under the ESRD PPS.

In the proposed rule, we also discussed the difficulty in differentiating between a renal dialysis service and a service furnished for other non-ESRD conditions (74 FR 50005). In order to ensure proper payment in all settings, we explored the use of modifiers to identify those services furnished that are not ESRD-related (74 FR 50005).

We received one comment regarding consolidated billing.

Comment: One commenter expressed concern that consolidated billing would require entirely new billing and payment arrangements for dialysis facilities and for the suppliers under arrangement. The commenter explained that building these relationships may be particularly challenging for SDOs. Further, the commenter stated that the proposed consolidated billing arrangement is similar to the provisions applicable to skilled nursing facilities (SNF). However there is a large difference in volume of administrative employees that can implement the new set of business practices necessitated by consolidated billing.

Response: We do not expect that the billing requirements under the ESRD PPS will require substantial changes in billing. Under the current basic case-mix adjusted composite payment system ESRD facilities that do not provide laboratory testing services, drugs, DME and supply services directly, would have to provide these items and services under arrangements. However, under the ESRD PPS there may be more services furnished than those under existing arrangements.

With respect to changes to the claims, under the ESRD PPS, there are requirements for ESRD facilities to provide additional information in existing fields. For example, ESRD facilities will be required to (1) itemize all drugs and biologicals provided to each individual patient; (2) itemize all laboratory tests provided to each individual patient; (3) place a modifier for non-ESRD related laboratory tests, drugs and biologicals, and supplies and equipment for the purpose of receiving separate payment; and (4) enter a co-morbidity ICD–9–CM diagnostic code (as described in section II.A.3. of this final rule) recognized for purposes of the co-morbidity payment adjustment. Because ESRD facilities have been required to line itemize under the current basic case-mix adjusted composite payment system and as ESRD facilities had been encouraged to enter co-morbidities on ESRD claims, we do not consider any of these reporting requirements to be an additional burden.

We are not requiring ESRD facilities to itemize supplies and equipment that are ESRD-related and are therefore paid through the bundle. However, in the event that supplies or equipment are not ESRD-related, ESRD facilities will place a modifier for those supplies and equipment signifying that they were used for services that are not ESRD-related and eligible for separate payment.

Comment: One commenter suggested that we consider deferring the consolidated billing edits for laboratory tests, drugs, and DME equipment and supplies until the full implementation of the ESRD PPS. The commenter also requested that we ensure that all interested parties receive adequate provider education regarding the changes implemented with the final rule.

Response: We are unable to delay implementation of the consolidated billing rules and edits because, as mentioned above, the ESRD PPS is an all-inclusive payment for home dialysis and renal dialysis services and ESRD facilities are responsible for all ESRD-related services furnished to their patients. Because it is a bundled payment system for which a single payment is made the ESRD facility, we are required to ensure that payment for these services is made only to the ESRD facility so that duplicate payment is not made by Medicare. We intend to issue educational materials regarding the implementation of the ESRD PPS to all interested parties in the near future.

i. Laboratory Tests

Section 1881(b)(14)(B)(iv) of the Act requires that ESRD-related diagnostic laboratory tests not included under the current basic case-mix composite payment system must be included as part of the ESRD PPS payment bundle. In the proposed rule, we explained that patients with ESRD often have co-morbid conditions which would require many of the same laboratory tests as those required to monitor the patients' ESRD (74 FR 50005). Therefore, we acknowledged that it may be difficult to differentiate between an ESRD-related laboratory test and tests ordered for non-ESRD-related conditions. We indicated that to ensure proper payment in all settings, we were exploring the use of modifiers to identify laboratory tests furnished for ESRD-related conditions from those furnished for non-ESRD-related conditions.

We received numerous comments regarding the proposed inclusion of laboratory tests in the ESRD PPS bundled payment which are set forth below.

Comment: Many commenters expressed concern that it is common for a patient's nephrologist to act as their primary care physician (PCP) and monitor all of the patient's medical conditions. The commenters expressed concern that there would be unintended consequences if the non-ESRD-related laboratory tests ordered by the nephrologists are included in the ESRD PPS bundle. Commenters were concerned that patients would be referred to medical specialists which would fragment care and require additional travel for medical appointments. Commenters were also concerned that patients would require more needle sticks if non-ESRD-related laboratory tests were included in the ESRD PPS bundle.

Some commenters indicated that it is common for physicians other than the

nephrologist to order laboratory tests from the ESRD facility. The commenters explained that the ESRD facility draws the specimen and then either furnishes the testing, if they are qualified to do so, or sends the specimen to a laboratory. The commenters believed that it is helpful for the patient and their continuity of care, if other physicians have this type of service (courtesy draws) available to them. Several patients requested that CMS continue to allow courtesy draws because it protects patients' vascular access site and saves patients from making multiple trips.

Response: As we discussed in a previous response, ESRD facilities will be able to identify laboratory tests, drugs, biologicals, and other items that are not ESRD-related by utilizing a modifier on claims. Therefore, in this final rule, we are finalizing a consolidated billing approach that gives the ESRD facilities and laboratories the ability to identify non-ESRD-related laboratory tests, by using a modifier, which allows for separate payment.

With regard to the commenters who indicated that providers other than the patient's nephrologist may order non-ESRD-related laboratory tests in order to preserve patient's vascular access and to mitigate multiple medical visits, physicians or other practitioners that directly submit orders to the ESRD facility to furnish a laboratory test or draw a specimen to send to an independent laboratory will be able to continue to do so. However, we remind ESRD facilities that they would still be subject to the following rules: (1) ESRD facilities are expected to furnish such services in accordance with the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 provided at § 493; and (2) physicians are required to order the diagnostic tests in accordance with the conditions provided at § 410.32.

Comment: We received numerous comments requesting that we implement a specific listing of routine ESRD-related laboratory tests that are included in the ESRD PPS bundle. Many commenters identified laboratory tests they believed belong in the listing. Some of the commenters referred to the laboratory tests that are currently paid under the composite payment system, while other commenters referred to a list that State and Federal surveyors use as guidance while conducting audits of the ESRD facilities. Two LDOs and two other dialysis advocacy associations provided a listing of approximately 50 laboratory tests. Another commenter suggested that we use a listing of laboratory tests that were developed through the Kidney Disease Outcomes Quality Initiative. We also received requests to omit diagnostic tests used for kidney transplants, bacteriology tests, and tests furnished specifically for travelling patients.

Response: We agree with the commenters that there should be a specific list indentifying laboratory tests that are furnished for ESRD patients. We believe that a listing of laboratory tests can be used as part of a consolidated billings strategy to mitigate duplicate payment. We also believe that ESRD facilities can use this list in developing contractual relationships with laboratories. However, in developing a listing of laboratory tests that are considered to be ESRD-related, we found that there are some laboratory tests that are specifically necessary for monitoring a patient's ESRD condition. We also found that there are numerous laboratory tests that are used by physicians not only for ESRD-related conditions, but also for other reasons. Therefore, a clinical review of the laboratory tests suggested by the commenters was performed by CMS physicians and other medical professionals.

As a result of this review, we have compiled a listing of laboratory tests that are used to diagnosis or monitor ESRD-related conditions which is presented in Table F of the Appendix. The laboratory tests listed, if furnished to ESRD patients by the ESRD facility directly or under arrangement, will be considered renal dialysis services (unless otherwise specified as being performed for non-ESRD-related conditions) and will be covered under the ESRD PPS bundled payment. If a laboratory test is furnished by the ESRD facility or by an independent laboratory for reasons that are not ESRD-related, then that laboratory tests can be billed with a modifier which would allow for separate payment. We acknowledge that the list of ESRD-related laboratory tests displayed in Table E of the Appendix is not an all-inclusive list and we recognize that there are other laboratory tests that may be ESRD-related. We will monitor claims to see if additional laboratory tests should be added.

Comment: Commenters expressed concern that there are many ESRD facilities that do not own their own laboratories and those ESRD facilities would experience high costs implementing new billing systems. The commenters further explained that the laboratories will need to bill the ESRD facilities making the ESRD facilities responsible for additional documentation and claims processing. One commenter argued that the proposed effective date of January 1, 2011, does not allow time to implement the contract changes that will be required.

Response: We do not understand the commenters' concerns. Currently, ESRD facilities that do not own their own laboratories must have contracting arrangements with a laboratory for the laboratory tests included in the current basic case-mix adjusted composite payment system. Section 494.130 provides that, "ESRD facilities must provide, or make available, laboratory services (other than pathology and histocompatibility) to meet the needs of the ESRD patients. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter." Therefore, we do not see the implementation of the ESRD PPS as requiring any changes from existing practices, with the exception of the inclusion of additional laboratory tests under the ESRD PPS.

ii. Drugs and Biologicals

As we discussed in the proposed rule, section 1881(b)(14)(B) of the Act defines renal dialysis services to include, among other things, certain drugs and biologicals, including drugs and biologicals that were separately payable under Part B and Part D. Under the current ESRD basic case-mix adjusted composite payment system, ESRD facilities generally do not furnish oral drugs to their ESRD patients. ESRD patients currently acquire these drugs and biologicals either through Medicare Part D, private insurance, or independently.

We proposed to include renal dialysis service drugs formerly covered under Part D under the ESRD PPS. We further proposed that ESRD facilities furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement. We explained that regardless of the mechanism by which these drugs would be furnished (directly or under arrangement), we believed that some of the Part D provisions set forth in the 42 CFR Part 423, would become relevant for ESRD facilities. We requested public comments on the extent to which Part D requirements should apply to ESRD-related oral drugs (74 FR 50006).

We also stated in the proposed rule that we expected ESRD facilities to update their grievance processes to account for all self-administered ESRD-related drugs (74 FR 50006). Patients would continue to have access to both

internal and external grievance processes including the ESRD Network and the State survey agency.

We indicated in the proposed rule that in the case of any ESRD facility that would seek to furnish drugs directly, those facilities would have to comply with state pharmacy licensure requirements. We noted that, as an alternative, many ESRD facilities would forego the process of becoming licensed as a pharmacy and instead, furnish renal dialysis service drugs formerly covered under Part D under arrangement with a licensed pharmacy. We indicated that the ESRD facility would provide their patients with a listing of pharmacies with which it would have arrangements with to dispense the renal dialysis service drugs (74 FR 50006).

As indicated in proposed § 413.241, we further expected that the ESRD facilities would establish arrangements with pharmacies in a manner that would facilitate beneficiary access to renal dialysis service drugs. That is to say, at a minimum, we expected that the arrangement would take into account variables like the terrain, whether the patient's home is located in an urban or rural area, the availability of transportation, the usual distances traveled by patients in the area to obtain health care services, and the pharmacy's capability to provide all classes of renal dialysis service drugs to patients in a timely manner. In addition, we expected that ESRD facilities would coordinate the provision of renal dialysis service drugs on behalf of traveling patients to facilitate ongoing compliance with the plan of care during periods of travel (74 FR 50006–50007).

To prevent duplicate payment under both Part D and Part B for bundled drugs and biologicals formerly covered under Part D, we indicated in the proposed rule that we were considering the incorporation of an ESRD indicator on the Part D eligibility information that would prevent Part D drug payments for bundled ESRD drugs and biologicals at the pharmacy. We proposed that the pharmacy would bill the ESRD facility for all renal dialysis service drugs and biologicals included in the proposed ESRD PPS that were dispensed, but would not be permitted to bill the patient for the usual Part B co-insurance amount, nor treat these drugs in accordance with the Part D rules. The ESRD facility would collect applicable beneficiary co-insurance based on the ESRD PPS per treatment payment amount (74 FR 50007).

In the proposed rule, we noted that the cost of the drugs and biologicals currently separately payable under Part D that we proposed to be designated as Part B renal dialysis services for purposes of the proposed ESRD PPS, would be reflected in the ESRD PPS portion of the blended payment (74 FR 50007).

The comments we received on these proposals and our responses are set forth below.

Comment: Many commenters requested that oral medications not be bundled but rather, should continue to be obtained through Part D. The commenters believed that bundling the oral drugs into the ESRD PPS would eliminate patient protections that are currently in place under Medicare Part D such as drug utilization review, medication therapy management, beneficiary choice in drugs within each drug class, geographic access standards and reduced co-insurance levels for low-income subsidy eligible patients.

To the extent oral medications are bundled, some commenters believed that we should implement similar Part D protections into the ESRD PPS. Other commenters asserted that bundling oral medications into the ESRD PPS would result in a duplication of the Medicare Part D system, questioning CMS for considering the imposition of a system similar to Part D asserted that doing so would increase inefficiencies and cost.

Response: We appreciate the commenters interest in maintaining patient protections that ensure access to drugs. As discussed in section II.A.3. of this final rule, although ESRD-related oral drugs and biologicals are included in the ESRD PPS bundle as of January 1, 2011, we are delaying payment under the ESRD PPS of ESRD-related oral-only medications until January 1, 2014. Therefore, because the majority of the oral drugs currently paid under Part D are oral-only drugs and payment under the ESRD PPS for oral-only drugs has been delayed until January 1, 2014, we intend to further evaluate beneficiary protections under the ESRD PPS related to oral drugs. We note that we are developing monitoring procedures that we will discuss in the future.

We acknowledge that as discussed in section II.A.3. of this final rule, there are a limited number of ESRD-related oral drugs and biologicals with other forms of administration which will be implemented January 1, 2011 and therefore, ESRD facilities will be required to ensure that patients have access to these drugs. Consequently, ESRD facilities will need to address their concerns in order to be able to furnish ESRD-related oral drugs and biologicals with other forms of administration, prior to January 1, 2011. With regard to the oral drugs that are being bundled in 2011, we believe these concerns can be alleviated and/or gradually addressed because such drugs have some other forms of administration.

Comment: Many commenters opposed the bundling of oral medications citing logistical and operational concerns associated with furnishing drugs either directly or under arrangement. The commenters believed that activities associated with furnishing these drugs directly would necessitate infrastructure and staffing changes that would drive up costs. These commenters stated that developing expertise in meeting pharmacy requirements and in hiring additional personnel, adopting technology and creating space for the storage and distribution of self administered drugs would require a great deal of effort and resources. The commenters stated that pharmacists would need to be hired to comply with dispensing requirements under State and Federal law. Other commenters believed that nursing and social work staff would be expected to distribute the self-administered drugs and that this task would detract from their nursing and social work duties.

Other commenters believed that clinical care staff such as registered nurses and personal care attendants would be cut to fund the additional cost of bringing pharmacy staff on board. Several commenters indicated that ESRD facilities currently in operation will be constrained in their ability to create in-house pharmacies or to store additional bundled drugs in instances where they have already maximized their square footage.

Similarly, commenters were also concerned about the additional burden ESRD facilities that elect to furnish these drugs under arrangement would experience such as establishing and maintaining pharmacy contracts. Commenters identified pros and cons of contracting with a large number of pharmacies versus contracting with a few pharmacies. The commenters believe that large numbers of contracts would promote convenient patient access but ESRD facilities' administrative costs would increase proportionally according to the number of pharmacies with which they contract. Overall, commenters asserted that payment under the ESRD PPS would not cover the additional costs of administrative burdens and increased staffing needs that will result from the bundling of oral drugs.

One commenter supported the option to allow facilities to choose between furnishing oral drugs directly or under arrangement. This commenter further noted that by allowing this choice, CMS

did not directly impose a requirement that a facility become a licensed pharmacy or have a pharmacist on staff. This commenter believed that beneficiary access to drugs would be preserved through facility arrangements with contracted pharmacies much like facilities currently contract with clinical laboratories.

Response: As we discussed in detail in section II.A.3.a. of this final rule, we are delaying payment for oral-only drugs under the ESRD PPS until after the ESRD PPS transition. We agree with the comment that ESRD facilities will have choices regarding whether and how to furnish ESRD-related oral drugs and biologicals that have other forms of administration. For example, an ESRD facility may continue to furnish the injectable and other forms of iron or may elect to furnish the oral forms of these drugs (and biologicals), as determined by the patients' plans of care. ESRD facilities will need to determine how they will obtain and furnish these drugs and biologicals (for example under arrangement or mail order). We note that ESRD facilities currently furnish drugs and biologicals to patients and, therefore, would have experience and arrangements under the current basic case-mix adjusted composite payment system. We acknowledge that these experiences and arrangements may only address the injectable drugs and biologicals and, that given the inclusion of the other ESRD-related drugs and biologicals under the ESRD PPS beginning January 1, 2011, additional arrangements may be needed.

Comment: One commenter was concerned that the bundling of oral drugs would result in an automatic shift of patients' drug coverage to Medicare. The commenter believed that patients who currently rely on drug coverage from private retiree or employer health plans with little or no cost sharing will be disadvantaged under the ESRD PPS. Another commenter believed that the ESRD PPS may benefit uninsured patients who currently either cannot receive these drugs or have difficulty getting to a pharmacy.

Response: We do not agree with the commenter that bundling oral drugs will shift patients' drug coverage to Medicare. Under the ESRD PPS, Medicare coverage for some ESRD-related drugs and biologicals will shift from Medicare Part D to Part B and, therefore, would be included in the ESRD PPS. The statute does not govern private insurance or require that drug coverage shift from private insurance to Medicare Part B. Furthermore, the statute does not change private insurance or incorporate coverage of services paid for by private insurers.

We do not believe that the ESRD PPS will have any effect with regard to benefiting patients who are currently having difficulty getting to a pharmacy. Under the ESRD PPS, patients may still need access to a pharmacy for their ESRD-related oral drugs and biologicals if the ESRD facility provides drugs and biologicals under arrangement.

With regard to the comment that uninsured patients will benefit under the ESRD PPS, we agree that patients who currently do not have drug coverage (either privately or through Part D) will benefit from the inclusion of ESRD-related oral drugs and biologicals under the ESRD PPS. However, as these drugs and biologicals have been included in the ESRD PPS base rate, patients will have a co-insurance liability.

Comment: Several commenters stated that bundling of oral drugs provides an unfair advantage to LDOs which the commenters believed control the market for certain ESRD-related drugs. Commenters also believed that LDOs have a further advantage because they have developed in-house pharmacies.

Other commenters stated that small ESRD facilities would not have the resources to develop in-house pharmacies and would need to contract for oral medications. One commenter asserted that SDOs that opt to furnish drugs under arrangement would not reach the volume necessary to contract with pharmacy benefit managers (PBMs) and would need to contract with smaller pharmacies at less favorable rates. Another commenter asserted that small and rural facilities and their local pharmacy partners will be disadvantaged because they are less capable of aggressively negotiating drug prices.

Several commenters urged CMS to propose a standard national method for dialysis facilities to establish prospective contracts with multiple traditional and mail-order pharmacies for the furnishing of dialysis-related drugs, regardless of the size of the dialysis provider. Other commenters suggested that CMS negotiate with pharmaceutical manufacturers on behalf of ESRD facilities to establish prices for ESRD-related drugs. Another commenter suggested that as an alternative to furnishing medications directly, ESRD facilities could rely on a third party Competitive Acquisition Program (CAP) vendor to purchase and distribute Part B renal dialysis service drugs to ESRD patients.

Response: We thank the commenters for expressing their concerns about the advantages and disadvantages that they believe exist between large and small dialysis organizations and for providing suggestions for ways in which ESRD facilities could obtain ESRD-related drugs and biologicals. However, we are not specifying in this rule how ESRD facilities are to obtain ESRD-related drugs and biologicals.

Thus, we are not adopting a national method for establishing contracts with pharmacies, nor will we negotiate with drug manufacturers on behalf of ESRD facilities to establish ESRD-related drug prices. We note that CAP participation is limited to Medicare physicians who administer drugs in their offices. However, we will take these suggestions into consideration when we implement ESRD-related oral-only drugs under the ESRD PPS. In the meantime, we encourage ESRD facilities to pursue group purchasing arrangements with similarly situated organizations to secure the most favorable drug prices possible.

Comment: One commenter stated that organizations with demonstrated pharmacy capabilities can help ESRD facilities minimize potential operational and administrative burdens of managing pharmacy care. The commenter further stated that mail order pharmacies provide ESRD patients with consistency of care and ease of access to their necessary medications while also saving payers and patients money.

Response: We appreciate the commenter's input and believe that ESRD facilities that elect to furnish drugs under arrangement will seek contracts with pharmacies on the basis of competitive pricing and on the value that contracted pharmacies can offer to the ESRD facilities' patients in terms of convenient access.

Comment: Several commenters requested clarification as to whether the ESRD facility will be required to hire a pharmacist or if the nurses will be required to dispense the oral drugs. An ESRD facility nurse expressed concern that she would be forced to act as a pharmacist, performing duties that would be beyond the scope of nursing practice.

Response: We do not require that ESRD facilities hire a pharmacist nor do we require that ESRD facilites dispense oral drugs. Rather, under the ESRD PPS, ESRD facilities will be required to provide ESRD-related drugs and biologicals (including ESRD-related drugs and biologicals with other forms of administration). ESRD facilities will need to determine how they will obtain and dispense drugs and biologicals (that is, directly or under arrangements). However, ESRD facilities and the

professional staff associated with these facilities will continue to be required to comply with State and Federal laws pertaining to dispensing of prescription drugs and biologicals.

Comment: One commenter requested clarification as to how oral medications would be dispensed and charted; on a per treatment, weekly or monthly basis. Several commenters believed that oral drugs covered under the ESRD PPS (such as phosphate binders), would only be provided on the days that the patient is in the facility and during the dialysis treatment itself. Other commenters stated that phosphate binders should be given with meals and that administering phosphate binders during dialysis could result in patients experiencing nausea, vomiting, choking or altered blood pressure.

Several commenters expressed concern that ESRD facilities may have difficulty recouping the full payment amount for oral medications that are taken outside the ESRD facility, particularly in instances where multiple days, weeks or months-worth of medications are prescribed. The commenter provided an example in which an ESRD facility provided a patient with a month's supply of a drug but, as a result of missed treatments, the facility would only receive payment for a partial month worth of treatments and would not recoup the full cost of the medication furnished.

Other commenters were concerned that patients may encounter additional burden if ESRD facilities do not approve 30 day supplies of drugs. The commenters stated that smaller prescribed quantities of drugs would increase the number of trips that patients would need to make to the pharmacy, which would be particularly burdensome for patients with limited transportation.

Response: ESRD facilities will be required to record the quantity of oral medications provided for the monthly billing period. In addition, ESRD facilities would submit claims for oral drugs only after having received an invoice of payment. We will address recording of drugs on an ESRD claim in future guidance.

We appreciate the commenter's concern that ESRD facilities believe they will be at risk for drug costs incurred but for which payment may not be recouped as a result of missed treatments. Under the ESRD PPS, payments are made on a treatment basis. However, some ESRD-related oral drugs and biologicals may be required to be taken on days that do not correspond with a treatment. We will be providing instruction on how these medications are to be entered on the ESRD claim. We believe that ESRD facilities will need to ensure, to the best of their ability, that patients do not miss treatments. ESRD facilities will need to determine the most appropriate way to furnish drugs and biologicals that ensures that patients receive their required medications, while mitigating the facilities' risk for drug costs.

Comment: One commenter stated that hospital-based ESRD facilities meet their patients' medication needs through the use of intravenous medications prepared by the hospital's on-site pharmacy. One commenter indicated that state pharmacy licensure requirements do not permit the hospital pharmacy to dispense outpatient medications. The commenter further noted that hospital-based ESRD facilities would need to establish a contract with an outside pharmacy to furnish the necessary oral medications.

Response: We want to clarify that in bundling ESRD-related injectable and oral drugs and biologicals with other forms of administration, we are not mandating that ESRD facilities change from intravenous to oral or other forms of these drugs. As indicated in the proposed rule, we would expect that any ESRD facility that provides outpatient maintenance renal dialysis items and services, would either establish their own licensed pharmacies or contract with licensed pharmacies.

Comment: Several commenters asserted that bundling oral medications into the ESRD PPS would create confusion between Part B and Part D for patients, ESRD facilities, pharmacies and Part D sponsors. One commenter supported our proposal to create an ESRD indicator as a way of preventing duplicate payment of drugs under Part B and Part D. Other commenters stated that Part D plans would bear much of the burden of ensuring that ESRD patients do not receive drugs under Part D coverage that have been bundled into the ESRD PPS as ESRD-related services. The commenter stated that because Part D already has effective cost control mechanisms in place, it is not necessary to bundle Part D drugs into the ESRD PPS for purposes of controlling costs. Another commenter believed that where an ESRD-related drug is indicated for non-ESRD-related indications, the ESRD indicator would not provide all the information necessary to prevent duplicate payment.

Response: We intend to implement an ESRD indicator that will store a beneficiary's ESRD status in Part D systems. Part D sponsors would be expected to share the information with their claims processing contractors for purposes of claims adjudication. This indicator will allow contracted pharmacies to correctly bill ESRD-related drugs to the ESRD facility and non-ESRD-related drugs to Part D.

We do not agree with the commenter that it is not necessary to bundle Part D drugs in the ESRD bundle because Part D has mechanisms to control costs. We discuss the interpretation of the definition for renal dialysis services and the inclusion of Part D drugs in the ESRD bundle in section II.A.3. of this final rule.

With regard to the commenter's concern that an ESRD indicator would not provide necessary information to prevent duplicate payment, when a drug is indicated for non-ESRD-related conditions, as we discuss later in this section, ESRD facilities will be able to identify drugs and biologicals used to treat non-ESRD conditions with a modifier and will be paid separately for these items.

Comment: One commenter expressed concern about potential administrative complexities that may be associated with furnishing drugs that are on the Drug Enforcement Agency's (DEA) list of controlled substances. This commenter further specified that the process of securing and renewing a DEA license would add to the administrative complexity of implementing the ESRD PPS.

Response: We expect that ESRD facilities are currently complying with any applicable requirements associated with controlled substance administration if they provide controlled substances to their patients. While there is no requirement under the ESRD PPS for ESRD facilities to administer controlled substances, if an ESRD elects to provide them, they would be required to comply with State and Federal requirements.

Comment: One commenter requested clarification as to how antitrust laws would be applied in the context of ESRD facilities that may seek to contract with one or more pharmacies for the provision of oral drugs. The commenter suggested that to the extent an ESRD facility were to contract with one pharmacy but not another, this may violate antitrust laws.

Response: Antitrust laws are beyond the scope of this final rule. However, to the extent an ESRD facility opts to furnish drugs under arrangement, we would expect that the facility would conduct an independent compliance review of antitrust and any other applicable Federal or State laws.

Comment: One commenter stated that OIG, MedPAC, or the Institute of Medicine should conduct studies two

years after implementation of the ESRD PPS to ensure proper implementation of oral-only drugs into the ESRD PPS bundle has occurred and that Medicare beneficiaries have not been adversely impacted.

Response: We thank the commenter for this recommendation and note that to the extent these entites were to conduct such studies we would support those efforts. As discussed in this final rule, oral-only drugs PPS will not be paid under the ESRD PPS until January 1, 2014. We note that section 10335 of the Affordable Care Act requires the GAO to conduct a study and submit a report to Congress on Medicare beneficiary access to high quality dialysis services, including specific oral drugs (oral-only).

As a result of the public comments and for the reasons discussed above, we are revising § 413.241. The revised § 413.241 will read as follows: "Effective January 1, 2011, an ESRD facility that enters into an arrangement with a pharmacy to furnish renal dialysis service drugs and biologicals must ensure that the pharmacy has the capability to provide all classes of renal dialysis drugs and biologicals to patients in a timely manner."

iii. Home Dialysis

In the proposed rule, we discussed that section 1881(b)(14)(A)(i) of the Act requires the costs of home dialysis supplies and services furnished under Method I and Method II, regardless of home treatment modality, be included in the ESRD PPS bundle. We proposed that the Method II home dialysis approach in its present form would no longer exist under the ESRD PPS effective January 1, 2011, but our proposal did not eliminate Method I in its present form (74 FR 50006). Therefore, a supplier could only furnish, under an arrangement with the ESRD facility, home dialysis equipment and supplies to a Medicare home dialysis patient and the supplier would have to go to the ESRD facility for payment. As discussed in section II.A.4. of this final rule, under the ESRD PPS, all home dialysis items and services are covered under the ESRD PPS payment and no separate payment will be made. In the event supplies or equipment are used for non-ESRD-related purposes, those supplies or equipment could be billed separately by utilizing a modifier which indicates that the supply or equipment is not ESRD-related.

The comments we received regarding Method II can be found in section II.A.7. of this final rule.

b. Expansion of the Data Elements Reported on Claims

In the proposed rule, we explained that currently the services that are billed on the ESRD claim do not provide any detail of the composite rate items and services that are furnished to the patient beyond the treatment itself (74 FR 50006). We did not propose additional reporting requirements in regards to collecting data for composite rate items and services, but we noted that collecting additional data at the patient-level is necessary for refinements to the case-mix adjustments of the ESRD PPS's payment model. We provided examples of items and services, such as time on machine, nutritional services, social work services, and nursing services included in the current basic case-mix adjusted composite payment system, but are not captured on the claim. We requested public comment on possible data elements and other claim-based information that would identify patients who are high cost (74 FR 50006).

We received comments regarding the expansion of the data elements reported on claims as described below. The comments and our responses are set forth below.

Comment: All commenters agreed that it is important to expand the data elements required on ESRD claims in order to effectively make refinements to the ESRD PPS payment model in the future. Some commenters agreed with the examples of services in the proposed rule. Two commenters stated that therapeutic nutritional services are critical for ESRD patients who cannot swallow or digest and absorb adequate nutrition from traditional nutrient formulas. One of the commenters suggested that we specifically collect data from ESRD facilities to assess the frequency and duration of nutrition services. Another commenter suggested that we collect drug data with applicable laboratory results that examine physiological responses to each drug.

Response: We thank the commenters for their suggestions and will consider them when we initiate changes to the data elements required on claims. Further direction will be provided in the future.

3. Miscellaneous Comments

We also received general comments related to the ESRD PPS, which are included below. The comments and our responses are set forth below.

Comment: Several commenters requested that there be a payment adjustment for nursing home staff providing care to beneficiaries with ESRD.

Response: The ESRD PPS will provide a bundled payment for renal dialysis services provided by a Medicare-certified ESRD facility. The case-mix payment adjustments are provided to account for the additional costs associated with separately billable items and services, of providing dialysis related services for patients with certain characteristics. The facility payment adjustments, including the outlier payment, are provided to account for the additional composite costs of providing dialysis related services. A payment adjustment for nursing home staff services would not be available under the ESRD PPS because payment for nursing home staff is covered separately outside of the ESRD PPS and, such services do not meet the definition of renal dialysis services for which ESRD facilities are paid a single rate.

Comment: One commenter was concerned that the proposed ESRD PPS would violate State and Federal anti-kickback and physician self-referral laws. The commenter believed that under the proposed ESRD PPS, an ESRD facility would be required to bill directly for laboratory tests that currently, are billed by the laboratory. The commenter believed that in cases where ESRD facilities have physician ownership, this arrangement would result in the ESRD facility sharing in profits of self-ordered laboratory tests. The commenter was concerned that physician-owned ESRD facilities, may be in violation of physician self-referral rules, and that these facilities would not be permitted to submit bills for laboratory charges. The commenter concluded that under the ESRD PPS, laboratories, as the provider of laboratory services, should continue to bill Medicare to avoid potential anti-kickback or Stark violations. Another commenter expressed concern that to the extent the ESRD facility would omit laboratory services from the ESRD facility claim in an attempt to adhere to physician self-referral rules, the services would not count towards the outlier eligibility calculation rendering the ESRD facility ineligible for potential outlier payment for laboratory services. Another commenter stated that to the extent that hospital-based ESRD facilities choose to enter into arrangements with community pharmacies for self-administered ESRD drugs, the facility would have to initiate a Stark law compliance review in the event that the community pharmacy has physician owners.

Response: Because all renal dialysis services, including ESRD-related laboratory services and drugs (with the exception of oral-only drugs), will be

paid under the ESRD PPS beginning January 1, 2011, these services as described 42 CFR § 411.351, would not be considered designated health services subject to physician self-referral requirements. If ESRD facilities have arrangements that they believe may be subject to the Federal anti-kickback statute, these facilities should contact the OIG. (Information about the Federal anti-kickback statute is available on the OIG's Web site at *http://oig.hhs.gov*.)

Comment: One commenter indicated the importance of monitoring fluid status and the need to develop strategies and practices for effective and safe fluid removal.

Response: We agree that fluid management is important; however, methods for monitoring fluid status are beyond the scope of this final rule.

Comment: Several commenters offered suggestions for additional collection of data and analyses which they believed would be helpful in connection with improving and refining the ESRD PPS. Suggestions were wide-ranging and included additional analyses showing beneficiary out-of pocket expenses under the PPS, collection of data to determine how dialysis practice patterns change under the new system, analyses for additional performance measures that could be integrated into the QIP, analysis on changes in the utilization of drugs subsequent to PPS implementation, refinement of data sources to evaluate race as a potential case-mix adjuster, collection of data on home dialysis training services and analysis of the effect on home dialysis, and collection of data and analysis to incorporate new drugs, technologies, and advances in clinical protocols into the ESRD PPS.

Response: We appreciate all of the commenters' suggestions on the collection of data and recommendations for subsequent analyses we could undertake to monitor and refine the ESRD PPS. As we gain experience with the new system, certain policy issues may emerge requiring more immediate attention for data collection and analysis. We recognize that we must balance the need for additional data and the potential for improvements and revisions to the ESRD PPS with the administrative burden that may be created. We will take all of these suggestions and recommendations under advisement for consideration of future refinements to the ESRD PPS.

Comment: Commenters expressed concern that we did not include information on how we intend to identify ESRD-related items and services after 2011. The commenters requested that we establish a periodic review process to add or remove items and services in the ESRD PPS bundle such as laboratory tests and drugs as well as update the reimbursement allocated to those services as market conditions change. Other commenters pointed out that we made policy determinations related to a number of specific items and services under the ESRD PPS based upon the current clinical practice for ESRD. The commenters requested that we specify an appropriate process for updating policies under the ESRD PPS as clinical treatments evolve and new technologies emerge.

Other commenters expressed concern that there will be little incentive for innovation from the medical products industry for new therapies and that CMS should encourage investment and innovation to improve patient outcomes. One commenter stated they believed we have the flexibility to provide for a separate payment for new and innovative drugs and technologies for a defined period of time while determining the appropriate costs of the new therapies for inclusion in the ESRD PPS bundle.

Response: We do not agree that the ESRD PPS will inhibit the development of new technologies or treatment. The ESRD PPS does not dictate, limit or prescribe any treatment or technologies used for ESRD patients. Rather, the ESRD PPS provides a payment for the average patient as well as adjustments to that payment rate to account for increased resource utilization. We have determined that several aspects of the ESRD PPS will need to be updated annually to keep current with new renal dialysis services. As we discussed in section II.A.3 of this final rule, we have not specified drugs and biologicals that would be renal dialysis services, but rather we specified categories by mode of action to provide for any new drugs or biologicals that may be developed or used in the future. For example, for anemia management, new drugs that constitute renal dialysis services that are approved for the treatment of anemia and are furnished by an ESRD facility, would be reported on the ESRD facility claims and paid under the ESRD PPS. We will use this information to update the list of ESRD-related drugs and biologicals, including the drug categories each January 1 for purposes of the outlier policy (see section II.H. of this final rule).

In a similar manner to drugs, we will need to keep the list of ESRD-related laboratory tests up-to-date for purposes of the outlier policy. The clinical laboratory fee schedule is updated annually to reflect updates in Medicare payment as well as to reflect new tests. We will be reviewing on an annual basis the new tests that are being added to the clinical laboratory fee schedule so that we can determine whether any of them are ESRD-related so they can be recognized under the outlier policy.

With regard to new technology, the payment structure under the ESRD PPS does not specify the type of modality (and therefore, the type of technology) that should be used for dialysis. Rather, the per-treatment payment provides for ESRD facilities to use the modality they believe is best, as determined by the individual plan of care. We believe that under the ESRD PPS, ESRD facilities will have the opportunity to utilize any new technology that arises.

We believe that these mechanisms of updating ESRD-related drugs and biologicals and laboratory tests, will address any changes that may arise in the future. However, should the technologies and treatments for ESRD change significantly at some point in the future, we could consider whether other mechanisms may need to be incorporated through future rulemaking to ensure that Medicare ESRD patients continue to have access to important advances in care.

Comment: One commenter suggested that we update the ESRD PPS base rate, patient-specific adjusters, co-morbidity case-mix adjusters and facility-level adjusters no later than CY 2013 because by that time we should have adequate data. The commenter expressed concern that if the ESRD PPS is not updated annually, the adjusters could remain unchanged over an extended period of time and would not reflect changes in the costs of provided ESRD care.

Response: We plan to implement payment for oral-only ESRD-related drugs under the ESRD PPS base rate after the ESRD PPS transition in 2014. In order to do so, we anticipate that the rulemaking to implement oral-only drugs under the ESRD PPS in 2014 would take place during 2013.

After that refinement, we expect to update periodically the regression analysis using the most recent claims and cost report data to determine if changes to the type and amount of payment adjustments are warranted. In addition, we will update the ESRD PPS annually to reflect the latest market basket forecast with adjustments for productivity, geographical variations in wages to reflect the most current hospital wage data and CBSA definitions, and appropriate changes to the fixed-dollar loss threshold amounts to maintain the 1 percent outlier policy.

As we proposed, we have codified these annual updates in § 413.196

(Notification of changes in rate-setting methodologies and payment rates). However, we have revised the language to reflect that the market basket update could result in a negative update. Therefore, we replaced reference to the market basket percentage increase with the market basket update factors.

Comment: Some commenters expressed concern about the role of the ESRD Networks. The commenters stated that there is a need to implement an ESRD Network Program that will effectively protect and support patients. The commenter suggested that the Network Program include mandatory best practice quality standards for all Networks to ensure that the quality of ESRD care is being judged consistently throughout the country. Other commenters expressed concern that the ESRD Networks are not accessible or attentive to patient concerns. Another commenter stated that the ESRD Networks should be tasked with monitoring and reporting involuntary discharges. Several commenters asked what role the ESRD Networks will have in implementing the ESRD PPS.

Response: We promote high value quality healthcare for beneficiaries and utilizes a variety of approaches to meet this goal. Examples of these approaches include contemporary quality improvement, coverage and payment policy, public reporting, and regulatory enforcement. The 18 ESRD Networks are contracted by us to oversee and facilitate high quality ESRD care, promote quality improvement, evaluate and resolve patient grievances, and assist ESRD facilities in meeting Network goals. The Networks monitor and report information related to complaints and grievances and involuntary discharges. We are currently assessing the role of the ESRD Network Program as it relates to the ESRD PPS and the QIP and how to optimize the expertise of the Networks to accelerate improvements in dialysis care.

Comment: Several commenters suggested a patient representative panel to monitor how the ESRD PPS will affect dialysis treatment and patient care. One commenter stated that there is little mentioned in the proposed rule with regards to patient satisfaction and that patient satisfaction is an important qualifier for future refinements to the system. Other commenters suggested that we establish a review process for evaluating the impact of the new PPS on patients and providers to ensure that the changes in payment do not result in clinical practice changes that adversely affect patients.

Response: We are concerned about how the ESRD PPS affects beneficiaries and has aimed to identify and mitigate potential negative effects. The way beneficiaries experience dialysis care is important to us. The QIP provides a method to ensure quality dialysis care and refers to patient satisfaction (information regarding the QIP is found in section II.M. of this final rule). Because the statute indicates that the quality measures should include patient satisfaction measures to the extent feasible, we are assessing the dialysis facility Consumer Assessment of Healthcare Providers and Systems (CAHPS tool), to determine the feasibility and readiness of use within the QIP in future years. In addition, as an integral part of the QIP, a program monitoring plan is in development to identify indicators useful in determining adverse effects on vulnerable (high risk) populations. Patient input is an important component of our monitoring plan development activities.

Comment: Some commenters expressed concern about non-compliant patients and gave suggestions for initiatives for incentivizing them to comply with their care plans. One example provided by the commenters was a "pay less for performance" incentive under which patients would be rewarded with a deduction in premiums if they follow their care plan. The commenters indicated that non-compliant behavior is very expensive in terms of furnishing healthcare.

Response: We encourage a patient-centered care approach in which the patient is included as a multidisciplinary team member (*see* § 494.80 of the ESRD Conditions for Coverage). We also encourage sharing of best practices among ESRD facilities including best practices regarding patients compliance with their care plans. While we recognize the role a dialysis patient plays into the success of their own care, Medicare is paying dialysis facilities to provide dialysis services and as such, the dialysis facility is ultimately responsible for ensuring that patients participate in their plan of care. We note that we do not have the authority to reduce patient premiums (Part B premium or co-insurance liability) to reflect patient compliance with their care plans.

Comment: One commenter noted that the proposed ESRD PPS did not inform patients adequately about effects on their costs and indicated that patients need to be informed in a clearly understood manner about how the ESRD PPS will affect their costs.

Response: We appreciate the commenter's concern about informing patients about the changes of the new ESRD PPS. We plan to outreach and educate facilities, providers and beneficiaries after this final rule is released.

Comment: One commenter supported including drugs in the bundle and believed that having drugs covered by ESRD facilities will be helpful for many patients. This commenter noted that her drug use decreased since going on home hemodialysis and she was able to stop some medications which helped lower her copayments for drugs.

Response: We thank the commenter for supporting our proposal to include drugs in the bundle.

Comment: We received several comments regarding the need for updating the Medicare cost report for ESRD facilities. Commenters stated that in order to accurately determine how facilities will fare over time under the new payment system and in order to evaluate cost trends, cost report reform is required. The commenters further explained that all of the changes that will occur under the ESRD PPS will not be properly captured in the cost report in its current form. Some commenters argued that Medicare cost reports for ESRD facilities do not offer a resource for an accurate estimation of costs associated with home hemodialysis or other home modalities. One commenter stated that if payment adequacy and other benchmarking of costs associated with current and new ESRD modalities are to be possible, cost report instructions at the modality level will need substantial revision.

Response: We agree that changes to the cost report are necessary to reflect the ESRD PPS and to improve the accounting of ESRD facility costs. Any changes in cost reporting will be addressed in the future.

Comment: Commenters indicated that the proposed ESRD PPS will give dialysis facilities an incentive not to support their dialysis patients' efforts to travel. These commenters indicated that dialysis providers often require transient patients to submit Hepatitis B, Surface Antigen and Surface Antibody results which are more recent than required by the Centers for Disease Control and Prevention (CDC) guidelines. Under current practice, the patient is generally responsible for the cost of the testing; the proposed rule will shift the cost to the home dialysis facility.

Response: Hepatitis B testing is included in the basic case-mix adjusted composite payment rate, and therefore, payments for these tests were included

in the ESRD PPS base rate. As a result, we expect that ESRD facilities will require Hepatitis B testing only when appropriate to meet CDC guidelines. The patient will have a 20 percent co-insurance liability on the ESRD PPS per treatment payment amount and does not have a financial liability specifically for Hepatitis B testing. As a result, we do not believe that the treatment of Hepatitis B under the ESRD PPS will affect or prohibit patients from traveling.

Comment: Commenters indicated that patients who travel represent an administrative burden and economic loss to the patient's home facility and bundling will make traveling patients less attractive. A few commenters had concerns about how payment will be made for the administration of medications to traveling dialysis patients. Commenters believed that dialysis facilities will be cautious of arranging transient treatment if there is no established means of reimbursement between the patient's home facility and the transient facility. One commenter indicated that transient facilities will have no incentive to administer injectable medications or higher dosages of ESAs to traveling patients. The commenter also questioned which dialysis facility would be responsible for administering necessary medications to the traveling patient under the bundled ESRD PPS. Other commenters indicated that laboratory tests required by traveling patients should be specifically excluded from the bundled ESRD PPS. If the laboratory testing required by a destination unit are not separately billable, it will complicate and perhaps, compromise the ability of beneficiaries to travel for work, family and pleasure.

Response: ESRD facilities that accept responsibility for a transient ESRD patient must furnish all necessary ESRD-related care. We expect the home dialysis facility and the transient dialysis facility to work together and exchange patient information regarding co-morbid medical conditions and drug dosing to accommodate dialysis patients who travel because of work, family or for pleasure. Given that beginning January 1, 2011, the bundled ESRD PPS base rate and adjustments include payments for laboratory tests, ESAs and other ESRD-related drugs and biologicals (other than oral-only ESRD-related drugs), dialysis facilities furnishing these services to the traveling patients will receive payment for these services through their bundled ESRD PPS payment.

Comment: Several commenters offered views regarding the imprudence of not having an ESRD PPS demonstration project or pilot testing of the proposed ESRD payment approach before going forward with national implementation.

Response: The MMA included a provision for a demonstration project to test the ESRD PPS prior to full implementation. However, that provision was repealed.

4. Comments Regarding Monitoring

We received many comments, primarily from patients and health care practitioners expressing concerns about monitoring the effects of the ESRD PPS. Comments that pertain to the QIP are addressed in section II.M. of this final rule. Other comments and our responses are discussed below.

Comment: Many commenters expressed concern about the need to monitor the impact of bundling ESRD drugs based on patient outcomes. Others questioned if there will be tracking mechanisms to see how payment changes will affect patient health. Some commenters cited particular areas of concern such as an increase in the number of parathyroidectomies being performed; iron use; bone mineral metabolism; hospitalization and vascular access.

Response: We understand the concerns raised and have indicated throughout this final rule that we will be monitoring the outcomes and effects of the ESRD PPS. While virtually all commenters expressed concerns about the potential negative effects of the PPS, we believe that the ESRD PPS provides opportunities for positive outcomes as well. Therefore, we plan to look at positive effects as well as areas of vulnerabilities. We are in the process of identifying those areas including those expressed by commenters. For example, as we discussed in section II.A.3. of this final rule, we have identified ESRD-related categories of drugs rather than specific drugs that will allow us to identify trends or changes in the drugs utilized by outcome such as anemia management. Also, as discussed earlier in this section, ESRD facilities will be required to indicate ESRD-related drugs and biologicals with other forms of administration on their claims. Because we have information on Part B on the ESRD claims and Part D separately payable drugs and biologicals, we will have a baseline from which to compare future drug usage and can monitor for changes in drug substitutions and dosing. We are also able to monitor for changes in inpatient hospital admissions and outpatient services for ESRD patients to determine if there are increases in ESRD-related procedures such as parathyroidectomies.

Comment: Some commenters questioned how changes from the ESRD PPS will be monitored for errors or fraud attempts.

Response: We have identified a number of measures in this final rule that address potential errors or fraud attempts. For example, in section II.K.2.a. of this final rule, we have described how ESRD facilities and MCPs will be required to utilize a modifier to identify items and services that they attest are not renal dialysis services. In the low-volume facility discussion in section II.F.4. of this final rule, we identified criteria that ESRD facilities will be required to meet in order to be eligible for the low-volume payment adjustment. In section II.A.3. of this final rule, we indicated that specific criteria will be required to be documented for the co-morbidity categories eligible for a payment adjustment. These can be monitored or verified. In addition, as discussed in the previous response to comments, we are in the process of identifying areas of concern (for example, drug utilization). We will be issuing specific instructions and corresponding manual changes in the future.

Comment: Some commenters indicated that oversight is needed to prevent ESRD facilities from "cherry picking" patients. One commenter expressed concern that the ESRD facility conditions for coverage allows patients to be involuntarily discharged for non-payment.

Response: We appreciate the concerns expressed that there may be ESRD facilities that will select patients based on higher payments. We will require information on the ESRD claims that will allow us to identify patient characteristics that result in eligibility for payment adjustments. For example, in the discussion under the onset of dialysis found in section II.F.3. of this final rule, we indicated that we would be looking at the number of beneficiaries who become eligible for Medicare due to a shortened coordination of benefit period. We will monitor very closely, potential access concerns and could make adjustments to the PPS in future years. We expect that ESRD facilities and providers will not "cherry Pick" patients.

We appreciate the commenters' concerns about patients being involuntarily discharged from an ESRD facility and note that, we intend to monitor for changes in the number and characteristics of patients who have been involuntarily discharged from their ESRD facility.

Comment: Several commenters indicated that there could be an increase in negative outcomes because the ESRD PPS does not apply limits on payment for preventable errors or outcomes. One commenter recommended that ESRD facilities not receive payment for preventable negative outcomes.

Response: We agree that other than the QIP discussed in section II.M. of this final rule, there is no payment reduction for negative outcomes. However, as we discuss in section II.F.3. of this final rule, we did not include certain co-morbidities, such as septicemia, as being eligible for a payment adjustment because we believe that it could be an incentive for poor outcomes. By not providing an opportunity to receive additional payment, we believe that we have mitigated payment incentives for poor outcomes.

Comment: A few commenters expressed concern that CMS should be able to determine if patients are not receiving adequate amounts of Epogen®. One commenter recommended that CMS also monitor blood transfusions administered to beneficiaries with ESRD.

Response: The commenters are correct that we collect hemoglobin information on ESRD claims. As we noted earlier, we will require ESRD facilities to indicate all renal dialysis-related drugs such as Epogen®, including dosages on the ESRD claim. We will explain this in more detail in the future. We are also planning to monitor blood transfusions for ESRD patients in our monitoring plans. We note, as discussed in section II.M. of this final rule, hemoglobin is a measure under the QIP.

Comment: One commenter recommended the establishment of an independent panel of stakeholders and experts to evaluate tracking of drugs. Another commenter suggested establishing an external oversight board comprised of dialysis community stakeholders including patients, physicians, nurses and providers to review monitoring reports to ensure transparency of data. The commenter believes the oversight board should have the authority to influence CMS policy to remediate any negative changes in availability or quality of patient care.

Response: We thank the commenters for these suggestions and will take them into consideration as we develop our monitoring plan for the ESRD PPS.

Comment: One commenter believed that it is extremely important to set up a monitoring system that ensures that under the ESRD PPS, patients and physicians maintain access to a wide range of available drugs. The commenter also stated that a process to monitor medication use in real-time using clearly delineated metrics more inclusive than quality measures, to "ensure that no adverse effects of the bundle on patient care and outcomes."

Response: We have discussed that we are requiring ESRD facilities to identify on the ESRD claims, renal dialysis related drugs. We discussed in section II.A.3. of this final rule that we identified categories of renal dialysis related drugs using claims data for drugs which received separate payment. We expect that ESRD facilities will, therefore, ensure that their patients receive the drugs (and biologicals) that they require. At the current time, we are unable to monitor medication use in real time as we are dependent on information on ESRD claims submitted by the ESRD facilities.

Comment: A few commenters were in favor of retaining the ESA Claims Monitoring Policy. These commenters suggested that similar monitoring policies be created for dosage administration and physiological response, for other drug classes (such as antibiotics, thrombolytics, vitamins and minerals).

Response: We thank the commenters and will take the suggestions into consideration as we develop our monitoring policies.

5. Comments Beyond the Scope of This Final Rule

We also received many comments that were beyond the scope of the ESRD PPS final rule, including comments the following topics: Educating patients on the importance of compliance with their prescribed treatment plan and expanding funding for educating people on strategies for the prevention of kidney disease; end of life care for dialysis patients; cost containment or price ceilings on pharmaceuticals and equipment; the need for financial planning for death and financial assistance to bereaved families in need, to deal with outstanding funeral and medical bills; consideration for studying the potential future of stem cell treatments; the need to be more progressive in offering cutting-edge options to beneficiaries; the need to establish criteria such as morbidity, prognosis, age and family support to determine a beneficiary's appropriateness for dialysis; consideration for a payment adjustment for beneficiaries with ESRD who are employed or attending school; concern that the surveyors from the Department of Health are not encouraging best practices and no longer pursue the goal of identifying ways to improve care for patients; and the need for disaster planning for the provision of dialysis treatments.

Other commenters raised issues related to post-transplant coverage of immunosuppressive drugs, stating that coverage of post-transplant immunosuppressive drugs should be extended for the life of the transplant because oftentimes patients have difficulty affording these medications when Medicare coverage runs out. One commenter requested that Medicare preserve access to brand name post-transplant medications. A patient commenter requested help paying for a transplant and for post-transplant medical care. Another patient commenter wanted to know whether they could get a kidney. One commenter stated that it is unfortunate that nephrologists spend minimal time in training on home dialysis modalities. Another commenter stated that greater emphasis should be placed on long-term rehabilitation such that ESRD patients can enjoy active lifestyles, employment and community involvement. Another commenter believed that CMS should develop a plan to encourage and track employment status among patients with ESRD.

Because the above issues are beyond the scope of this final rule, we have not addressed them in this final rule.

L. Evaluation of Existing ESRD Policies and Other Issues

In the proposed rule, we reviewed existing ESRD policies to determine their applicability to the ESRD PPS. We proposed to eliminate the exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities that exist under the basic case-mix adjusted composite payment system (74 FR 50007). We proposed to evaluate the current ESA monitoring policy (EMP) and the operational issues for circumstances in which Medicare is the secondary payer (MSP). We also proposed to maintain the bad debt policy and the 50-cent per treatment deduction to fund the ESRD Networks (74 FR 50007). We also proposed to set forth in § 413.195 the limitation on review with regard to the ESRD PPS (74 FR 50007). In addition, we explained that we were considering the extent to which the laboratory services 50 percent rule would continue to apply under the ESRD PPS (74 FR 50008).

1. Exceptions Under the Case-Mix Adjusted Composite Payment System

Section 1881(b)(7) of the Act and § 413.182 generally address exceptions to the composite payment rates. Section

422(a)(2) of BIPA prohibited the granting of new exceptions to the composite payment rates after December 31, 2000. Section 623(b) of the MMA amended section 422(a)(2) of BIPA to restore composite rate exceptions for pediatric facilities that did not have an exception rate in effect as of October 1, 2002. Section 422(a)(2)(D) of BIPA defined a pediatric facility as a renal dialysis facility at least 50 percent of whose patients are under 18 years of age.

In the proposed rule (74 FR 50007), we noted that in the CY 2005 PFS proposed rule (69 FR 47535), we explained that section 422(a)(2)(C) of BIPA provided that any ESRD composite rate exception in effect on December 31, 2000, would continue as long as the exception rate exceeds the applicable composite payment rate. We further explained the methodology that would be employed to compute the exception amount, and that we were proposing to allow each dialysis facility the option of continuing to be paid at its exception rate or at the basic case-mix adjusted composite rate. On April 1, 2004, we opened the exception window for pediatric facilities and noted that the window would close in September 27, 2004. We further explained that in the CY 2005 PFS final rule with comment period (69 FR 66332), we stated that the exception process was opened each time there is a legislative change in the composite payment rate or when we open the exception window, including our intent to open the pediatric exception windows on an annual basis. We also noted that we would provide for the continuation of the home training exception, to allow for facilities with home training exceptions to retain their current training exception rates as well as take advantage of the case-mix adjusted rates for non-training dialysis (74 FR 50007).

In the proposed rule, we indicated that while section 153 of MIPPA does not directly address exceptions, section 1881(b)(14) of the Act creates an ESRD bundled prospective payment in lieu of payment under previous ESRD payment systems, and given that the ESRD PPS no longer directly addresses changes in the ESRD composite rate, we believe that the exceptions currently in place would no longer apply (74 FR 50007). We also noted we addressed the higher costs relating to case-mix through the patient characteristic adjustments and outlier payments (74 FR 49949 and 49987). We proposed the elimination of the isolated essential facility, self dialysis training costs, atypical service intensity (patient mix) and pediatric facility exceptions, effective for ESRD renal dialysis services furnished on or after January 1, 2014 (at the conclusion of the phase-in). In other words, any existing exceptions would terminate effective for ESRD treatment on or after January 1, 2014. Additionally, no further exception windows would be open effective for ESRD treatment furnished on or after January 1, 2011, the effective date of the ESRD PPS. In the event that an ESRD facility elected to receive full payment under the ESRD PPS for renal dialysis services on or after January 1, 2011, any existing exceptions would no longer be recognized. In the event that an ESRD facility elected to receive payment under the transition period, any existing exceptions would be recognized for purposes of the basic case-mix adjusted composite payment system portion of the blended payment through the transition. We proposed to include the periods of exceptions and the elimination of the exceptions to the composite payment rates in § 413.180 of the regulations. With respect to appeals under § 413.194(b), we pointed out that such appeals apply only to exceptions to the composite rate granted before January 1, 2011 (74 FR 50007).

We received comments from three children's hospitals and one from the American Academy of Pediatrics concerning pediatric exceptions and these comments are described below. We did not receive any comments on our proposal to eliminate the isolated essential facility, self-dialysis training costs, and atypical service intensity (patient mix) exceptions.

Comment: One commenter indicated that the proposed pediatric case-mix adjusters and elimination of the pediatric facility exceptions would reduce the costs adjustments needed by many pediatric facilities to remain operational. The commenter believed that the proposed pediatric case-mix adjusters and the elimination of the pediatric exceptions would result in children and adolescents with ESRD not having access to specialized dialysis care. Other commenters believed that these proposals fail to recognize the uniqueness of pediatric facilities that have State mandated higher staff ratios, additional staff required such as teachers and child life specialists, and higher supply costs associated with treating pediatric ESRD patients.

Response: We believe that the changes we have made in this final rule with regard to the pediatric model address the specific needs of pediatric patients and the care that they require. We discuss these changes in detail in section II.G. of this final rule. With regard to the pediatric exceptions, as we discuss in greater detail below, we believe that our proposal to eliminate such exceptions is appropriate and warranted under the statute.

Comment: One commenter indicated that the MIPPA legislation did not specifically eliminate the existing pediatric exceptions to the composite rate and believes that our interpretation of the MIPPA "is a stretch."

Response: We do not agree with the commenter with regard to our interpretation of the MIPPA legislation and section 1881 of the Act. As we discussed in the proposed rule, we continue to believe that the ESRD PPS under section 1881(b)(14) of the Act creates an ESRD prospective payment system in lieu of payments under previous ESRD payment systems. Given that these exceptions pertain to the prior composite rate payment systems under section 1881(b) of the Act, we do not believe that such exceptions would carry forward or be appropriate under the ESRD PPS. After the ESRD PPS transition, no portion of the ESRD PPS payments will be based on the composite rate. As a result, we do not believe it would be appropriate to continue composite rate exception payments after January 1, 2014. We also believe that we have addressed the higher costs of pediatric patients in the final pediatric model discussed in detail in section II.G. of this final rule.

We are finalizing the elimination of the isolated essential facility, self-dialysis training costs, atypical service intensity (patient mix)and pediatric facility exceptions effective for ESRD renal dialysis services furnished on or after January 1, 2014 (at the conclusion of the phase-in). We are also finalizing our proposal that no further exception windows would be open after January 1, 2011, the effective date of the ESRD PPS. In the event that an ESRD facility elects to receive full payment under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011, existing exceptions would no longer be recognized. In the event that an ESRD facility elects to receive payment under the transition existing exceptions would be recognized for the purpose of the basic case-mix adjusted composite payment system portion of the blended payment. We are finalizing the inclusion of the periods of exception and the elimination of the exceptions to the composite payment rates in § 413.180 of the regulations. We note that appeals under § 413.194(b) apply only to exceptions to the composite rate granted before January 1, 2011.

2. Erythropoiesis Stimulating Agent (ESA) Claims Monitoring Policy

In the proposed rule, we discussed the historic development of the ESA Claims Monitoring Policy. We noted that we were evaluating the extent to which we could continue the ESA Claims Monitoring Policy for renal dialysis services furnished on or after January 1, 2011. Specifically, at that time it was not known how the reduction in payment that is currently applied to the separately billed ESAs would be applied under the proposed ESRD PPS (74 FR 50008).

In the proposed rule, we noted that we would continue to evaluate how to establish eligibility for outlier payments in instances where the ESA Claims Monitoring Policy is implicated. CMS is adopting the EMP under the ESRD PPS in computing basic case-mix adjusted composite payments amounts during the transition and it will be taken into account when determining eligibility for outlier payments. We have included the comments and responses pertaining to this policy in section II.H. of this final rule.

3. ESRD Facility Network Deduction

In the proposed rule, we indicated that pursuant to section 1881(b)(7) of the Act, to fund the ESRD Networks, 50 cents is deducted from the amount of each payment for each treatment (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis). The reduction amount applies to all treatment modalities. We sited the Medicare Claims Processing Manual, Public Law 100–04, Ch. 8, section 110 for information on the methodology for calculating the reduction.

We proposed to continue this deduction under the ESRD PPS with a 50-cent reduction per treatment from the payment made to ESRD facilities under the ESRD PPS for facilities that elect to receive payment under the ESRD PPS. For facilities that elect the ESRD PPS transition, we would apply the 50-cent reduction the blended payment amount (74 FR 50008).

We did not receive any comments opposing the continuation of the ESRD network deduction. Therefore, we are finalizing that we will continue the 50-cent deduction under the ESRD PPS.

4. Bad Debt

In the proposed rule, we explained that § 413.89 and Chapter 3 of the Provider Reimbursement Manual, Part 1 (PRM)(CMS Pub. 15–1) set forth the general requirements and policies for payment of bad debts attributable to unpaid Medicare deductibles and coinsurance amounts. Additional requirements for ESRD facilities are set forth at § 413.178. We further explained that under the basic case-mix adjusted composite payment system Medicare pays ESRD facilities 80 percent of a prospectively set composite rate for outpatient dialysis services. The Medicare beneficiary is responsible for the remaining 20 percent as co-insurance, as well as any applicable deductible amounts as set forth in § 413.176 of the regulations. If the ESRD facility makes reasonable collection efforts, as described in section 310 of the PRM, but is unable to collect the deductible or coinsurance amounts for items or services associated with the composite rate, we consider the uncollected amount to be a "bad debt", if the facility meets the requirements at proposed § 413.178 and proposed § 413.89 of the regulations. We also explained that at the end of the ESRD facility cost reporting period, Medicare recognizes a facility's Medicare bad debts. However, § 413.178(a) requires CMS to reimburse ESRD facilities for its allowable bad debt up to the facility's costs as determined under Medicare principles (74 FR 50008).

We explained in the proposed rule that in developing the proposed changes to the ESRD payment system, section 153(a)(4) of MIPPA states, as a Rule of Construction, that, "nothing in this subsection or the amendments made by this subsection shall be construed as authorizing or requiring the Secretary of Health and Human Services to make payments under the payment system implemented under paragraph (14)(A)(i) of section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)), as added by paragraph (1), for any unrecovered amount for any bad debt attributable to deductible and coinsurance on items and services not included in the basic case-mix adjusted composite rate under paragraph (12) of such section as in effect before the date of the enactment of this Act." Therefore, we stated that bad debt payments would continue to be made for the unpaid Medicare deductibles and coinsurance amounts for only those items and services associated with the basic case-mix adjusted composite rate. However, since the proposed single ESRD payment rate is for items and services included in the composite rate and for drugs and laboratory tests, we proposed to use only the composite rate portion of the proposed single ESRD payment rate to determine bad debt payments. We also proposed that bad debt payments for ESRD facilities would continue to be capped as required under § 413.178(a). We also indicated that the Medicare cost report and instructions in the PRM, Part 2 (CMS Pub. 15–2) might be revised to report the case mix adjusted composite rate payment and associated cost data necessary to compute the ESRD facility bad debt payments.

In addition, we proposed to make a conforming change to regulation text at § 413.178(d) regarding ESRD bad debt payment under the proposed ESRD payment system and include a cross-reference to § 413.178 in § 413.89(h) and (i).

We received several comments on bad debt. The comments and our responses are set forth below.

Comment: One commenter questioned how dialysis-related bad debts would be determined under the ESRD PPS. The commenter also questioned if unreimbursed co-payments for laboratory services and Part D drugs would be reimbursed. The same commenter believes that if these services are in the bundle, then they should be included in the bad debt reimbursement and if they are not, then this would result in a financial burden for providers.

Response: As we discussed above, section 153(a)(4) of MIPPA states, as a Rule of Construction, that, "nothing in this subsection or the amendments made by this subsection shall be construed as authorizing or requiring the Secretary of Health and Human Services to make payments under the payment system implemented under paragraph (14)(A)(i) of section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)), as added by paragraph (1), for any unrecovered amount for any bad debt attributable to deductible and co-insurance on items and services not included in the basic case-mix adjusted composite rate under paragraph (12) of such section as in effect before the date of the enactment of this Act." Therefore, we stated that bad debt payments would continue to be made for the unpaid Medicare deductibles and co-insurance amounts for only those items and services associated with the basic case-mix adjusted composite rate. However, since the single ESRD payment rate is for items and services included in the composite rate and for drugs and laboratory tests, we would use only the composite rate portion of the single ESRD payment rate to determine bad debt payments. As oral drugs were not included in basic case-mix adjusted composite rate, they would not be subject to bad debt reimbursement.

In order to determine bad debt amounts for only the basic case-mix adjusted composite rate portion of the

bundled ESRD PPS payment, we will utilize data from the Medicare ESRD cost report to determine the percentage of basic composite rate costs to total costs on a facility-specific basis. The current ESRD cost report Form CMS 265–94 for freestanding facilities and Form CMS 2552–96 for hospital-based facilities, contain data that can be used to compute a facility's percentage of composite costs to total costs. We will apply that facility-specific composite rate percentage to the facility's total bad debt amount associated with the bundled ESRD PPS payment. The resulting bad debt amount will be used to determine the allowable Medicare bad debt payment in accordance with § 413.89 and § 413.178. During the transition period, a facility will apply the facility-specific composite cost percentage to the bad debt amounts associated with only the transition composite rate portion of the bundled ESRD PPS payment. The resulting bad debt amount will be added to the bad debt amount associated with the transition portion of the facility's ESRD reasonable costs to determine the total allowable Medicare bad debt payment in accordance with § 413.89 and § 413.178.

Comment: One commenter believed that section 153(a)(4) of MIPPA is silent with regard to bad debt reimbursement for ESRD services and that the statute does not imply that bad debts for non-composite rate related services should or should not be covered. The commenter further believed that under the ESRD PPS, ESRD bad debts should be reported in the same manner as bad debts for other outpatient PPS services.

Response: We believe that the Rule of Construction included in section 153(a)(4) of MIPPA, as stated above, would allow for the payment of bad debt amounts that are only associated with the basic case-mix adjusted composite rate. Thus, any bad debt amounts associated with drug and laboratory tests or with any non-composite rate amounts will not be allowed. We also note that under § 413.89(i) and § 413.178(d), bad debts arising from covered services paid under a reasonable charge-based methodology, or a fee schedule are not reimbursable under Medicare. Thus, if a Medicare PPS or a portion of a Medicare PPS has its basis in reasonable charges or a fee schedule then, any associated bad debt amounts are not reimbursable.

Comment: One commenter believed that certain proposals, specifically the inclusion of laboratory services in the co-insurance calculation, contravenes the MIPPA statute which, prohibits opening the bad debt issue and increases bad debt costs for ESRD facilities. The commenter further suggested that until oral drugs are accurately accounted for, they should not be in the bundle, to ensure that additional bad debt is not imposed on facilities. The commenter recommended that CMS use caution until meaningful tracking and compliance tools for States, secondary insurers, and beneficiaries be in place. The commenter also recommended that ESRD facilities not be left with additional bad debt resulting from a new payment system.

Response: We believe that the method described above of applying a facility-specific composite rate percentage to the bad debt amounts associated with the ESRD PPS allows us to compute a facility's allowable bad debt payments in accordance with the Rule of Construction included in section 153(a)(4) of MIPPA.

Comment: One commenter noted that it was burdensome to require hospitals to calculate bad debt under a composite rate definition that will no longer exist. The commenter urged CMS to have this policy modified to relate bad debt payments to the new payment system.

Response: We believe that utilizing data that are already reported on the facility's current Medicare cost report to compute the allowable bad debt payment under the ESRD PPS, will mitigate the reporting burden to the provider. ESRD facilities will be required to continue to complete the appropriate cost report worksheets with the data necessary to compute the composite cost percentage and compute the allowable bad debt payment under the ESRD PPS.

Based on the comments received, we are finalizing that bad debt payments will continue to be made for the unpaid Medicare deductibles and coinsurance amounts for only those items and services associated with the basic case-mix adjusted composite rate. However, since the single ESRD payment rate is for items and services included in the composite rate and for drugs and laboratory tests, we will use only the bad debt amounts associated with the composite rate portion of the single ESRD payment rate to determine a facility's allowable bad debt payments. We will use the methodology described above to apply a facility-specific composite cost percentage to the total bad debt amount associated with the bundled ESRD PPS payment to compute the bad debt amount for only the basic case-mix adjusted composite rate. Bad debt payments for ESRD facilities will continue to be made in accordance with § 413.89 and § 413.178 of the regulations, including the requirement to cap ESRD bad debt payments under § 413.178(a). We will revise and publish the appropriate cost reporting worksheets and instructions in the PRM, Part 2 (CMS Pub. 15–2) along with any other necessary administrative issuances, to implement the computation of Medicare ESRD bad debt payments through to the cost report, as described above, for services rendered on or after January 1, 2011.

In addition, we are finalizing the conforming change to regulation text at § 413.178(d) regarding ESRD bad debt payment made under the ESRD payment system described in this final rule. We are also including a cross-reference to § 413.178 in § 413.89(h). In the proposed rule, we erroneously indicated that we were proposing to add a cross-reference in § 413.89(i). However, we did not make any proposed revisions to § 413.89(i). Therefore, for this final rule, we are not revising § 413.89(i).

5. Limitation on Review

As discussed in the proposed rule, section 153(b) of MIPPA amends section 1881(b) of the Act to provide for a limitation on review. Specifically, section 1881(b)(14)(G) of the Act provides the following: "There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act or otherwise of the determination of payment amounts under [section 1881(b)(14)(A)], the establishment of an appropriate unit of payment under [section 1881(b)(14)(C)], the identification of renal dialysis services included in the bundled payment, the adjustments under [section 1881(B)(14)(D)], the application of the phase-in under [section 1881(b)(14)(E)], and the establishment of the market basket percentage increase factors under [section 1881(b)(14)(F)]." We proposed to codify this limitation on review in § 413.195 of the regulations (74 FR 50008).

We received several comments concerning the limitation on review. The comments and responses are set forth below.

Comment: Given the limitation of review clause, one commenter was concerned that it would impose a limit on payment for dialysis services of three treatments per week. The commenter believed that payment should be given for any treatments beyond the three treatments per week without requiring medical justification.

Response: The limitation of review clause would prohibit review of our determination of the number of treatments that would be eligible for payment. We explain how the number of ESRD treatments eligible for Medicare

payment (that is, three treatments per week), was derived in section II.E. of this final rule. We do not agree that we should abolish the medical justification requirement for treatments that exceed the threshold because this process provides a mechanism to allow additional payment beyond the established treatment threshold.

Comment: Several commenters requested we issue an ESRD PPS interim final rule to allow for additional comments or to challenge payments for Part D drugs, because the limitation on review would not allow for administrative or judicial review of the final rule.

Response: Given that we have issued a proposed rule containing a detailed proposal for an ESRD PPS, allowed for an extended 90-day public comment period, and carefully considered the comments received, we believe that a final rule is appropriate. The ESRD PPS bundle is discussed in section II.A. of this final rule and we note that oral-only drugs currently covered under Part D will not be paid under the ESRD PPS until January 1, 2014.

As we proposed, we are codifying the limitation on review in § 413.195 of the regulations. However, we have revised the language to reflect that the market basket update could result in a negative update. Therefore, we replaced reference to the market basket percentage increase with the market basket update factors.

6. 50 Percent Rule Utilized in Laboratory Payments

In the proposed rule (74 FR 50008), we discussed that as specified in CMS Pub 100–04, Chapter 16, Sect. 40.6, for a particular date of service to a beneficiary, if 50 percent or more of the covered laboratory tests within an Automated Multi-Channel Chemistry (AMCC) test are included under the composite rate payment, then all submitted tests are included within the composite payment and no separate payment is made for any of the AMCC tests. If less than 50 percent of the covered laboratory tests within the AMCC are composite rate tests, then all AMCC tests submitted are separately payable. We also described how ESRD facilities were to identify each test that is included in the composite rate and each test that is not included. We further explained that during the transition period, the 50 percent rule would continue to apply to the basic case mix adjusted composite payment system portion of the blended payment. We also stated that under the proposed consolidated billing provisions, the ESRD facility would assume the responsibility for all of the renal dialysis services that its patients receive, including laboratory tests. As a result, the ESRD facilities would apply the 50 percent rule billing procedures including application of the relevant modifiers. Medicare would not make separate payment for laboratory tests, rendering the 50 percent rule irrelevant for payment purposes. The 50 percent rule's relevance would be limited to its use in determining eligibility for outlier payment (74 FR 50008).

In the proposed rule, we noted that preliminary analyses revealed a small impact upon removing from eligibility for outlier services the AMCC tests to which the 50 percent rule applies. As a result, we considered excluding AAMC tests from the definition of outlier services, thus negating the need to apply the 50 percent rule under the proposed ESRD PPS (74 FR 50009). We also noted that we planned to continue to evaluate the impact of this approach and include further discussion in the final rule. We requested public comments on whether or not to include the AMCC tests in the definition of outlier services and retain the 50 percent rule under the proposed ESRD PPS.

Because we are finalizing the use of the 50 percent rule with regard to determining eligibility for outlier payments, we have included our discussion of this issue, along with the comments and responses that we received pertaining to the 50 percent rule, in section II.H. of this final rule.

7. Medicare as a Secondary Payer

In the proposed rule, we stated that Medicare may be a secondary payer (MSP) when the primary payer is a group health plan for ESRD items and services furnished to Medicare beneficiaries during the 30-month Medicare coordination of benefit period (74 FR 50009). We further stated that at that time, we were unable to identify the systems operations and billing procedures impact of this relationship under the current basic case-mix adjusted composite payment system, and we were exploring how it would be utilized and managed under the proposed ESRD PPS. We stated that we believed that while there may need to be system changes in order to process MSP claims under the proposed ESRD PPS, there should be no impact on ESRD providers and on primary payers. We stated our intent to issue through administrative issuance, any changes in the manner of reporting information, should that be required. We solicited public comments on the operational issues of MSP under the proposed ESRD PPS.

We received a few comments on MSP. The comments and our responses are set forth below.

Comment: One commenter questioned what would prevent his secondary payer from dropping him or increasing his premiums. Another commenter suggested changing the MSP period for employed, child-rearing, in-school, or under 25 years of age dialysis patients from 30 months to a continuous period.

Response: Questions concerning premiums or other issues pertaining to secondary insurers are beyond the scope of this final rule. In addition, recommendations concerning changes to the coordination of benefits period are beyond the scope of this final rule.

We believe that the implementation of the ESRD PPS will have no effect on MSP rules. We will continue to evaluate the need for changes to MSP systems, operations and billing procedures under the ESRD PPS and we will issue through administrative issuance any changes in the manner of reporting information should that be required.

8. Conforming Regulation Changes

We proposed to amend 42 CFR Chapter IV. Specifically, we proposed conforming changes to existing regulations to reflect the current basic case-mix adjusted composite payment system and the ESRD PPS. We did not receive any public comment on these changes. Therefore, we are finalizing these conforming changes, along with the technical changes noted in the final rule, as follows:

- Section 413.170(a)—setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system;
- Section 413.170(b)—providing procedures and criteria under which a facility may receive a pediatric exception;
- Section 413.171—defining base rate, composite payment system, basic case-mix adjusted composite payment system, ESRD facility;
- Section 413.172(a)—setting forth that payment for renal dialysis services and home dialysis services are based on prospective payment rates:
- Section 413.172(b)—requiring that all prospective payments to approved ESRD facilities as payment in full and defines approved ESRD facility;
- Section 413.174(a)—establishing prospective payment rates for hospital-based and independent ESRD facilities prior to January 1, 2009;
- Section 413.174(f)—establishing payment for separately billable ESRD-related drugs and biological prior to January 1, 2011;

- Section 413.176(a) and (b)—establishing the beneficiary deductable;
- Section 413.178(d)—establishing bad debt under reasonable charge-based methodology or fee schedule are not reimbursable;
- Section 413.180(1),(2), and (3)—establishing the periods of exceptions to payment rates;
- Section 413.231(a)—establishing the adjusted labor portion of the base rate to account for geographic differences in area wage levels;
- Section 413.231(b)—defining urban and rural areas;
- Section 414.330(a)(2)—establishing exception for equipment and supplies furnished prior to January 1, 2011;
- Section 414.330(b)(2)—establishing exception for home support services furnished prior to January 1, 2011;
- Section 414.330(c)—establishing payment limits for support services, equipment and supplies furnished prior to January 1, 2011; and
- Section 414.335(a)—establishing payment home EPO use prior to January 1, 2011.

M. Anemia Management and Dialysis Adequacy Measures

In the September 29, 2009 proposed rule (74 FR 50009), we proposed to adopt three measures by which the quality of dialysis services furnished by ESRD providers participating in Medicare would be measured.

Section 1881(h)(2)(A) of the Act requires that the measures specified for the Quality Incentive Program (QIP) include measures on anemia management that reflect the labeling approved by the Food and Drug Administration (FDA) for such management, measures on dialysis adequacy, and such other measures the Secretary specifies. To implement this section, we proposed (74 FR 50011) that for the first QIP performance period we would adopt the two anemia management measures and one hemodialysis adequacy measure that are currently used for Dialysis Facility Compare (DFC). Data needed to calculate these measures can be collected from Medicare claims submitted by ESRD providers/facilities on a patient-specific basis.

The anemia management measures used for DFC assess the percentage of patients at a facility whose anemia was not controlled at both the high and low ends of the FDA-recommended hemoglobin levels. Specifically, these measures are: (1) The percentage of patients treated at a provider/facility with a Hemoglobin Less Than 10 g/dL and treated with erythropoiesis stimulating agents (ESAs), and (2) the percentage of patients at a provider/facility with a Hemoglobin Greater Than 12 g/dL and treated with erythropoiesis stimulating agents (ESAs).

The current FDA labeling guideline released November 8, 2007 for the administration of ESAs to patients with chronic kidney disease, including ESRD patients, states, "The dosing recommendations for anemic patients with chronic renal failure have been revised to recommend maintaining hemoglobin levels within 10 g/dL to 12 g/dL."

As we stated in the proposed rule (74 FR 50011), we believe that the proposed anemia management measures reflect the approved FDA labeling for anemia management because they assess the number of patients whose hemoglobin levels are at the low and high end of the FDA label recommendation. In addition, we believe that it is more appropriate to adopt two measures which together assess the high and low ends of the FDA recommended hemoglobin level range, rather than a single measure that reflects the percentage of patients who have hemoglobin levels within the 10 through 12 g/dL range, because two measures will provide a richer picture of provider/facility performance. Additionally, the low and high ends for anemia management have been of particular concern for the treatment of vulnerable patients and these measures will allow for monitoring for this potential outcome. These data will also allow us to calculate the percentage of patients who have hemoglobin levels within the 10 through 12 g/dL range. Therefore, we proposed to adopt these two anemia management measures for the QIP (74 FR 50011).

Anemia data have been reported on DFC since January 2001. As we noted above, we updated the reporting of anemia data for DFC in November of 2008 to be consistent with the new FDA labeling guideline released in November 2007; however, the methodology for calculating the provider/facility, State, and national averages for anemia measures has not changed since the initial release of DFC. We proposed to use the same methodology we use to calculate the anemia management measures for purposes of DFC to calculate the measures for purposes of the QIP because the methodology is consistent with how we have calculated that data since 2001 (74 FR 50011). Under this methodology, we will calculate the measures using hemoglobin data for Medicare patients who have been diagnosed with ESRD for at least 90 days and whose Medicare claims submitted by providers/facilities indicated the use of an ESA during that 90-day period. Data from patients whose first ESRD maintenance dialysis starts before day 90 or who have hemoglobin values of less than 5 g/dL or greater than 20 g/dL will be excluded from the measure calculation. In addition, there must be for the same patient at least 4 claims meeting this criteria for that data to be included in the data for a specific provider or facility.

Technical details on the methodology used to calculate the anemia measures are available on the Arbor Research Collaborative for Health and University of Michigan Kidney Epidemiology and Cost Center Web site: *http://www.dialysisreports.org/Methodology.aspx.*

The Hemodialysis Adequacy Measure (urea reduction ratio (URR)) that we proposed to adopt (74 FR 50011) is also used for DFC and assesses the percentage of patients at a provider or facility that get their blood cleaned adequately (blood urea is removed during in-center hemodialysis). Specifically, this measure assesses the percentage of in-center hemodialysis patients at a provider or facility whose urea reduction ratio (URR) is 65 percent or greater, a standard based on the National Kidney Foundation's Kidney Disease Quality Initiative Clinical Practice Guidelines (NKF–KDOQI). These guidelines are widely used and generally accepted throughout the ESRD community. More information on the calculation of the URR is available at *http://www.dialysisreports.org/Methodology.aspx.*

The methodology for calculating the provider/facility, State, and national averages for the in-center hemodialysis measure has been used since January 2001 with the initial release of DFC; we proposed to use the same methodology to calculate the measure for purposes of the QIP to be consistent with how that data has been calculated since 2001 (74 FR 50012). Under this methodology, we will calculate URR data only for Medicare patients who have been diagnosed with ESRD and received in-center maintenance hemodialysis for at least 183 days from the date that they received their first maintenance dialysis treatment, and whose Medicare claims submitted by providers/facilities included a value for the URR. In addition, there must be for the same patient at least four claims meeting the criteria above for that data to be included in the data for a specific provider or facility. Technical details about the methodology we proposed to use to calculate the hemodialysis adequacy measure are available on the University of Michigan Kidney Epidemiology and Cost Center Web site

at: *http://www.dialysisreports.org/Methodology.aspx.* We note that the data we need to calculate the proposed anemia management and hemodialysis adequacy measures described above can be collected through ESRD claims, which is the only complete provider/facility level data set available to CMS at this time. For this reason in the September 29, 2009 proposed rule published in the **Federal Register** (74 FR 50012), we proposed to adopt only the two anemia management measures and one dialysis adequacy measure described above.

Although we recognize that section 1881(h)(2)(A)(i)(ii) states that the measures shall include "measures on dialysis adequacy," only one dialysis adequacy measure is collected nationally and available to determine provider/facility-specific values. For this reason, we proposed to adopt only one dialysis adequacy measure. We also note that section 1881(h)(2)(A)(iii) of the Act states that the measures shall include, to the extent feasible, other measures as the Secretary specifies, including measures on iron management, bone mineral metabolism, and vascular access (intended to maximize the placement of arterial venous fistula). CMS did not propose in the September 29, 2009 proposed rule, to adopt any measures in these categories for the QIP payment consequence year 2012 since we are not currently collecting data in a manner that would allow determination of provider/facility-specific performance with respect to these categories of measures (74 FR 50012). We are working to identify appropriate sources from which we can adequately capture data to support the future adoption of additional measures. Finally, as we stated in the ESRD PPS proposed rule (74 FR 50012), it is not feasible to propose a patient satisfaction measure at this time because the data collection tool has not been fully validated for the collection of relevant and industry accepted patient satisfaction data. Therefore, we believe it is not feasible to propose more than the aforementioned measures for the QIP payment consequence year 2012 because of the lack of complete and accurate data. We will address other measures in future rulemaking.

In the September 29, 2009 proposed rule (74 FR 50012 through 50016), we also outlined a conceptual model describing various components of the QIP under consideration, such as the weighting of measures and scoring methodology for determining payment reductions. The purpose of the conceptual model was to notify the public regarding what we believe to be essential components of the QIP and obtain detailed comments on those components for purposes of future rulemaking. Our previous discussion of the measures and the conceptual model may be found in the ESRD PPS proposed rule (74 FR 50009).

We received approximately 194 comments on the proposed measures. Many commenters agreed that we should adopt the three proposed measures, although many also suggested that additional measures be included in the ESRD QIP to ensure a robust measurement of the quality of services furnished by dialysis providers/facilities. Commenters also noted the importance of including measures for pediatric, peritoneal and home hemodialysis patients to assure that quality care is provided to these populations.

In response to public comments received about the inclusion of younger patients, we have decided that patients < 18 years of age will not be included in the final calculation of the anemia measures because at this time there is no consensus on the appropriate hemoglobin range for this age group. Further, using this exception makes these measures more consistent with the target age used in the clinical performance measures (CPMs) which have been used by providers/facilities for several years. Therefore, we will use the same methodology for data collection and analysis as used for calculation of the anemia measures reported to the DFC with the exception of not including patients < 18 years of age in the final calculation of provider/facility performance on the measures.

In response to a number of public comments received on these measures and in recognition of a number of concerns related to the exclusion of home hemodialysis patient data from the Hemodialysis Adequacy measure, we are clarifying that home hemodialysis patient data will be included in the calculation of the anemia management measures. Home hemodialysis patients have been included in the anemia management measures currently reported; however, there are different frequencies of treatment for the Home Hemodialysis population that makes the currently accepted measure of Hemodialysis Adequacy of a URR Greater than 65 percent invalid at this time. CMS is currently working with stakeholders to establish a measurement of the adequacy of a hemodialysis treatment that is accurate for this population. This is CMS' basis for excluding this population from the initial year of the QIP. Below we provide a brief summary of each measure proposed, a summary of the public comments received, and our responses to the comments.

We also received comments on the weighting and scoring of measures and the setting of the national performance standard described in the conceptual model. Comments received on components of the conceptual model not related to these measures will not be addressed in this rule. As stated in the proposed rule, we intend to use these comments to inform future rulemaking.

1. Anemia Management Measures: Hemoglobin Less Than 10 g/dL and Hemoglobin Greater Than 12 g/dL

As stated above, we proposed to use the anemia management measures as used in the current DFC database since January 2001 and as required by section 1881(h)(2)(A)(i) of the Act. The anemia management measures proposed for the QIP include two measures on anemia management that reflect the labeling approved by the FDA for such management (74 FR 50011). Data for these measures can be collected from Medicare claims currently submitted by ESRD providers/facilities as required in the initial year. The anemia measures that were proposed are as follows:

- Percentage of Medicare patients at a provider/facility who have an average hemoglobin value less than 10.0 g/dL (referred to in this final rule as the "Hemoglobin Less Than 10 g/dL").
- Percentage of Medicare patients at a provider/facility who have an average hemoglobin value greater than 12.0 g/dL (referred to in this final rule as the "Hemoglobin Greater Than 12 g/dL").

We proposed to calculate these measures using hemoglobin data for Medicare patients who have been diagnosed with ESRD for at least 90 days and whose Medicare claims submitted by providers/facilities indicated the use of an ESA during that 90-day period. Data from patients whose first ESRD maintenance dialysis starts before day 90 or who have hemoglobin values of less than 5 g/dL or greater than 20 g/dL will be excluded from the measure calculation. In addition, there must be, for the same patient, at least 4 claims meeting this criteria for that data to be included in the data for a specific provider or facility. However, as described, ESRD patients less than 18 years of age will not be included in the measure calculation. (Technical details on the methodology we proposed to use to calculate the anemia measures are available on the Arbor Research Collaborative for Health and University of Michigan Kidney Epidemiology and Cost Center Web site: *http://*

www.dialysisreports.org/Methodology.aspx.)

Comment: A few commenters voiced concern about the lack of measures specific to home hemodialysis. Because this modality is being advanced within the ESRD community and Medicare, commenters wished to ensure that measures for this patient population are incorporated in the QIP.

Response: We agree that inclusion of home dialysis modalities (that is, home hemodialysis and peritoneal dialysis) data is important to ensure providers/facilities are incentivized to include these populations in quality improvement efforts. To that end, home hemodialysis patient data will be used to calculate provider/facility scores on the anemia management measures in the QIP payment consequence year 2012. However, due to the varying frequencies of treatments for the home hemodialysis population the use of the currently accepted measure of Hemodialysis Adequacy of a URR greater than 65 percent is invalid at this time. For this reason we will not include home hemodialysis patient data in the calculation of the Hemodialysis Adequacy measure at this time. We are currently working with stakeholders to establish a measurement of the adequacy of a hemodialysis treatment that is accurate for this population. Beyond anemia management and dialysis adequacy, we are continuing to work with the ESRD stakeholders to develop new quality measures for use in future years of the QIP that are applicable, relevant, and provide a means to assess the quality of care that is being delivered to the home hemodialysis population.

Comment: Some commenters questioned the value of the Hemoglobin Greater Than 12 g/dL measure because they believe that the bundled payment should reduce the incidence of overutilization of erythropoiesis stimulating agents (ESAs). The commenters also stated that the percentage of patients with hemoglobin in the range of >10 g/dL and <12 g/dL would be a more effective measure for the QIP.

Response: Hemoglobin values at either end of the spectrum have adverse consequences for the ESRD patient population. We believe that focusing on the population that falls within the range of 10–12 g/dL will not provide the necessary information to evaluate the percentage of patients whose anemia is either inadequately treated or overtreated.

A Hemoglobin Less Than 10 g/dL may be the result of inadequate administration of ESAs, inadequate iron stores, blood loss (gastrointestinal bleeding), an infectious process, or other clinically significant causes. Hemoglobin Less Than 10 g/dL can result in poor oxygenation, decreased activity, increased hospitalizations, need for blood transfusions, and death. We believe that the threat of such adverse consequences should prompt ESRD facilities to take steps to increase patients' average Hemoglobin to greater than 10 g/dL.

On the other hand, a Hemoglobin Greater Than 12 g/dL may result from the overtreatment of anemia with ESAs. A Hemoglobin Greater Than 12 g/dL while a patient is being treated with ESAs has been associated with an increased incidence of death in the ESRD population.

By focusing solely on the percentage of patients that fall between 10–12 g/dL, we believe that important clinical indicators of inadequate or overaggressive treatment of anemia would be lost. A summary of evidence regarding the importance of these measures may be accessed at: *http://www.cms.gov/CPMProject/Downloads/ESRDAnemiaSummary05212008.pdf.*

Comment: Two commenters noted that patients who are active or younger may have higher average hemoglobin levels because higher hemoglobin supports their energy levels. Using the Hemoglobin Less Than 10 g/dL and Hemoglobin Greater Than 12 g/dL for the first QIP performance period, according to the commenters, will force dialysis centers to prescribe less erythropoietin and maintain these patients' average hemoglobin levels closer to 10 g/dL, thereby reducing these patients' ability to continue working and greatly affecting their quality of life. Another commenter stated that patients who live at high altitudes may have higher average hemoglobin levels which should be accounted for in the QIP.

Response: Section 1881(h)(2)(A)(i) of the Act requires that the measures on anemia management specified for the QIP reflect the labeling approved by the Food and Drug Administration (FDA) for such management. The current FDA guidance may be found at: *http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126481.htm.*

We also note that due to the lack of scientific evidence indicating that anemia management for the pediatric population should be the same as the adult population, we do not believe it is appropriate to include the ESRD population under the age of 18 years in the final calculation of the two anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL) that we are finalizing for the QIP payment consequence year 2012. However, the data collection and measure calculation will remain consistent with that used for the DFC since 2001 as described in the current methodology at: *http://www.dialysisreports.org/Methodology.aspx*.

Lastly, guidelines for the administration of ESAs, along with dose adjustments are included along with the ESA packaging that is approved by the FDA. Dose adjustments are made at the discretion of the clinician, based on the needs of the individual patient in order to achieve the desired hemoglobin. This rationale is equally applicable to the population that lives at higher altitudes mentioned by the other commenter and is reported in Brookhard M.A., *et al. Journal of American Society of Nephrology* 19(7): 1389. 2008. In considering the commenters concerns for patients living in high altitude areas, we have determined, based on clinical studies, that while patients living at high altitudes may require less or lower doses of ESA to maintain hemoglobin levels at the appropriate level, they should not be excluded from the measure.

Comment: One commenter recommended that patients not on ESAs be excluded from the Hemoglobin Greater Than 12 g/dL.

Response: Patients who are not receiving ESAs are excluded from the Hemoglobin Greater Than 12 g/dL measure. The purpose of this measure is to monitor high hemoglobin that may be directly attributed to the use (possible overutilization) of ESAs and not attributed to other causes. Therefore, patients not receiving ESAs are excluded from Hemoglobin Greater Than 12 g/dL. Specifications for this measure may be found at: *http://www.dialysisreports.org/Methodology.aspx*.

Comment: Two commenters had a concern about the specifications for the anemia management measures, particularly the time window for measurement. One of the commenters had concerns about the proposal to use the DFC specifications for the Hemoglobin Less Than 10 g/dL because, under those specifications, we calculate a yearly average for the hemoglobin level. The commenter recommended that CMS calculate a 3-month average and then average these 3-month averages over a 12-month period (for example, create a 12-month average using 4 averaged patient quarters). The other commenter believed that the use of 12-month averaging to calculate the anemia management measures would

decrease the public's ability to separate good performers from poor performers. According to this commenter, when 12-month averages are used, clinical performance in most providers/facilities approximates the national average for performance on the anemia management measures. The commenter recommended that for purposes of the QIP, we calculate a 3-month average based on a monthly assessment of lab results.

Response: We proposed to calculate the proposed anemia management measures using the same specifications that we currently use for DFC because the methodology is consistent with how we have calculated those measures since 2001. Details and an explanation for the use of and planned continued use of the existing calculation used for the calculation of the anemia percentages are available on the following Web site: *http://www.dialysisreports.org/Methodology.aspx*.

We believe that using the specifications currently in use for these measures will create minimal data collection disruptions for providers/facilities because they are already submitting data in accordance with these specifications. However, as we review the data from the initial year of the ESRD QIP, we will use findings from this data review to determine whether or not specifications for this measure should be changed. We believe we have the authority to update specifications of quality measures in appropriate cases, such as when selected specifications do not result in useful or accurate information in comparing ESRD providers/facilities. However, we will use the rulemaking process to adopt any changes to measures or new measures into the QIP.

After consideration of the comments received on the Anemia Management Measures and for the reasons stated above, we are finalizing the two anemia measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL) as proposed for the QIP payment consequence year 2012 with one change to these measures. As noted above, patients < 18 years of age will not be included in the final measure calculation of the two anemia measures because of lack of scientific evidence to support the appropriate hemoglobin range for this population and concerns voiced through public comment. Further, excluding the population less than 18 years of age is consistent with the target age for the Anemia Management CPMs in current use. However, we are finalizing the data collection process and calculation of the facility level measures consistent with what has been used for the DFC since 2001. Once testing of data collection for additional measures is completed and such measures prove to be feasible and reliable measures, we will consider adding those measures in future years of the QIP.

2. Hemodialysis Adequacy Measure: Urea Reduction Ratio (URR)

The Hemodialysis Adequacy Measure—Urea Reduction Ratio (URR)—is a nationally reported measure used in the DFC database since January 2001 and can be calculated from claims data currently submitted by ESRD providers/facilities. The hemodialysis adequacy measure that we proposed to adopt (74 FR 50011) is the percent of hemodialysis patients with URR ≥ 65 percent (referred to in this final rule as the "Hemodialysis Adequacy Measure"). We proposed to calculate URR data only for Medicare patients who have been diagnosed with ESRD and received maintenance dialysis for at least 183 days from the date that they received their first maintenance dialysis treatment, and whose Medicare claims submitted by providers/facilities included a value for the URR. In addition, there must be for the same patient at least 4 claims meeting the criteria above for that data to be included in the data for a specific provider or facility. In the proposed rule (74 FR 50013), we proposed that this measure would only apply to facility-based hemodialysis and patients > 18 years of age. As we explain in detail below, peritoneal and home hemodialysis patients will not be included in this measure because, based on the clinical evidence, we have determined that the existing Hemodialysis Adequacy Measure of (URR) > 65 percent is not applicable to these patients.

Comment: Several commenters stated that the Hemodialysis Adequacy Measure is not an accurate measure of dialysis adequacy and that the measure Kt/V is the more accurate and better measure. Additionally, one commenter stated that URR specifications should be adjusted for patients receiving short, daily dialysis (that is, dialysis received 5 or more times per week for 2 to 3.5 hours as required to ensure adequate dialysis).

Response: We currently use ESRD claims for quality data and the URR is one of the measures on the claims. However, the collected URR is only reported for patients receiving in-center hemodialysis and those above the age of 18 years (approximately 96 percent of hemodialysis patients). Accordingly, we believe it is appropriate to use this measure initially for the QIP. The use of URR ≥ 65 percent for the measurement of adequacy with peritoneal dialysis, home hemodialysis, and pediatric dialysis is not a valid measurement of dialysis adequacy because of the unique variations that exist with each different type of dialytic modality and patient population (that is, pediatric patients or adults). Starting July 2010, however, providers are required to submit both URR (in-center hemodialysis patients) and Kt/V (all modalities) on all ESRD claims as reported through CMS Change Request (CR 6782). Given that Kt/V will soon be submitted on claims and that it has become a more widely accepted measurement of the adequacy of dialysis and the National Quality Forum has endorsed quality measures using Kt/V for hemodialysis and peritoneal dialysis, we anticipate that the URR may be replaced by Kt/V in future program years.

Comment: One commenter expressed concern about the Hemodialysis Adequacy Measure proposed for the QIP payment consequence year 2012 as a valid measure of quality. The claims data used for this measure reports the Hemodialysis Adequacy Measure as a range and does not require the number of treatment sessions. The commenter recommended that CMS require that providers/facilities report the specific URR value and the number of treatments to ensure that the measure captures only those patients receiving three treatments per week. Additionally, a commenter recommended that we calculate the measure using patient quarters rather than a 12-month average.

Response: ESRD providers/facilities are required to submit the number of treatments and the specific URR value on each claim submitted for payment. The measure is currently calculated for purposes of DFC using data from patients that have three treatment sessions per week. Patients included in the measures are those receiving in-center hemodialysis. As noted previously, peritoneal and home hemodialysis patients are excluded as well as pediatrics because clinical evidence demonstrates that this is not a valid measure for these patients; however it is an accepted measure for in-center hemodialysis patients. Patients included in this measure must be greater than 18 years of age, have at least 4 claims and have been on dialysis for at least 183 days. Full details and technical specifications for this measure can be accessed at: *http://www.dialysisreports.org/Methodology.aspx*. It is important to note that initially for the QIP all

measures will be claims-based since that is the only complete facility level source of data available for this population. URR is being used in the QIP payment consequence year 2012 because it is a standard measure used in ESRD practice for in-center hemodialysis and has been publicly reported in the DFC since January 2001. We believe this will avoid confusion in the data collection process. We have analyzed the existing claims data to see if there was a significant variance in calculating the URR based on patient quarters rather than a 12-month average and found that there is no difference that would warrant a change in the current methodology that uses a 12-month average.

Comment: A few commenters agreed that the proposed Hemodialysis Adequacy Measure should continue to exclude patients on peritoneal dialysis or home hemodialysis because this measure is not an accurate reflection of the effectiveness of these two modalities. Additionally, some of the commenters recommended that Kt/V be implemented to include peritoneal dialysis and home hemodialysis. Other commenters expressed concerns about the timing of laboratory testing for dialysis adequacy. Another commenter recommended that both the number of treatments prior to measurement of URR and when tests should be taken should be made clear. Lastly, there was concern among the commenters about the impact of residual renal function, which contributes to overall renal clearance and thus, would increase the measure score.

Response: We agree with the commenters that the existing Hemodialysis Adequacy Measure of URR >65 percent should be excluded for home hemodialysis, pediatric dialysis and peritoneal dialysis patients, since it is not a valid measurement of the adequacy of treatment for those modalities based on treatment characteristics. We are in the process of working with the stakeholder community to develop consensus based measurements of adequacy for these modalities.

With regard to the URR measure and number of treatments per week, the specifications state that the measure is based on thrice-weekly hemodialysis treatments. Those receiving more than three treatments per week are excluded from the current measure. Measure specifications may be accessed at: *http://www.dialysisreports.org/Methodology.aspx*. Additionally, we anticipate dialysis providers/facilities to use recommended KDOQI guidelines for laboratory testing for the calculation of Dialysis Adequacy. Guidelines can be accessed at: *http://www.kidney.org/professionals/kdoqi/pdf/12–50–0210_JAG_DCP_Guidelines-HD_Oct06_SectionA_ofC.pdf*.

In terms of patients with residual renal function, residual renal function usually drops off after about 6 months on hemodialysis therefore, dialysis adequacy (URR) for patients are excluded until patients have been on hemodialysis for 6 months. As we indicated, starting July 2010, providers/facilities are required to submit both URR (hemodialysis patients) and Kt/V (all modalities) on all ESRD claims. Given that Kt/V will be submitted on all ESRD claims, and that Kt/V has become a more widely accepted measurement of the adequacy of dialysis and the National Quality Forum has endorsed quality measures using Kt/V for hemodialysis and peritoneal dialysis, we anticipate that the URR may be replaced by Kt/V in future program years which will allow for inclusion of these modalities as well as pediatric patients.

Comment: One commenter noted that the use of 12-month averaging for the Hemodialysis Adequacy Measure diminishes the public's ability to discern performance differences between providers/facilities because, when 12-month averages are used, clinical performance in most providers/facilities approximates the average. The commenter recommended that we calculate the measure by using a three-month average based on a monthly assessment of lab results.

Response: We appreciate the comment. To avoid any confusion in data collection, in the initial year of the QIP we will use the technical specifications used for the DFC. To date, the current specifications and data publicly reported on DFC have been viewed as accurate. However, if data in the initial year of the QIP demonstrate that specifications should be changed, we will take this recommendation under consideration.

After consideration of the comments received on the Hemodialysis Adequacy measure (URR) and for the reasons discussed above, we are finalizing the Hemodialysis Adequacy measure for the QIP payment consequence year 2012. Once testing of data collection for Kt/V is completed and if Kt/V proves to be a feasible and reliable measure, we will consider replacing the URR measure with Kt/V in the future.

3. Additional Comments

In the September 29, 2009 proposed rule (74 FR 50009), we did not propose to include any additional measures beyond the two anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL) and the Hemodialysis Adequacy Measure (URR) both of which will exclude ESRD patients less than 18 years of age for the QIP payment consequence year 2012. Section 1881(h)(2)(A)(iii)of the Act states that the measures shall include, to the extent feasible, such other measures as the Secretary specifies, including measures on iron management, bone mineral metabolism, vascular access (intended to maximize the placement of arterial venous fistula) and patient satisfaction measures. CMS did not propose to adopt any measures in these categories since we are not currently collecting data that would allow determination of provider/facility-specific performance with respect to these categories of measures. We are working to identify appropriate sources from which we can adequately capture data to support the future adoption of additional measures. We anticipate that measures such as Kt/V, vascular access and vascular access infections will be included in future program years when data sources prove valid. Finally, we believe it is not feasible to include a patient satisfaction measure at this time because there is no fully validated data collection tool available to collect relevant and industry accepted patient satisfaction measure data. Additional measures will be addressed in future rulemaking.

Comment: A significant number of commenters expressed concern about the lack of mineral metabolism measures in the list of measures proposed for 2012, with particular concern for the monitoring of parathyroid hormone levels (PTH), Phosphate (PO4) and calcium levels. Commenters noted that the inclusion of calcimimetics and phosphate binders in the bundled payment could result in the underutilization of these effective medications, and some commenters were also concerned about the potential for overutilization of parathyroidectomies as a less expensive option to the medications.

Response: On April 15, 2008, we published in the **Federal Register** the Medicare Conditions for Coverage (CfC) for End-Stage Renal Disease Facilities final rule (73 FR 20370). These Medicare CfCs are enforced by periodic site visits by state survey agencies and specifically require the development and execution of Patient Plans of Care to "provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease." (*See* 42 CFR § 494.90(a)(3).) In addition, § 494.110(a)(2)(iii) requires dialysis facilities to include bone and mineral

metabolism outcomes as part of their ongoing Quality Assessment and Performance Improvement Programs. We consider the mineral metabolism and renal bone disease measure as measures that will be considered for future years of the QIP; however, for the reasons we discussed above, these measures will not be included for 2012.

Comment: We received several comments stating that the three performance measures we proposed for the QIP payment consequence year 2012 were not adequate for evaluating the quality of care offered by ESRD providers/facilities. Several commenters recommended that we also adopt outcome measures for the QIP specifically dealing with hospitalizations, infections, vascular access and iron management. A few commenters also suggested that measures on transfusion and transplant rates be included.

Response: We agree that the measure topics suggested by these commenters would allow us to more fully assess the quality of care provided to Medicare ESRD beneficiaries. As stated above, we are in the process of developing additional quality measures that we will consider for use in future years of the QIP. At this time, ESRD Medicare claims are the only complete provider/facility-level data set available to us. The three measures that we are finalizing for the first year of the QIP—two anemia management measures (Hemoglobin less than 10 g/dL and Hemoglobin more than 12 g/dL) and one Hemodialysis Adequacy Measure (URR)—focus on core aspects of the medical management of ESRD Medicare beneficiaries and have significant implications for their quality of life, morbidity and mortality. Further, observational studies and practice pattern analyses have shown that providers/facilities that perform well on these three measures also experience better patient outcomes in terms of reduced hospitalizations and reduced risk of heart attack, stroke and other adverse events.

Comment: Recognizing that CMS is not proposing at this time to include other measures in the QIP such as iron management, bone mineral metabolism, and vascular access and that CMS has concluded that it is not feasible to propose a patient satisfaction measure at this time, one commenter requested a detailed plan for incorporating these measures into the ESRD QIP. Additionally, the commenter emphasized the importance of establishing a tracking system to ensure baseline values for bone and mineral metabolism markers because these may be significantly impacted by the incorporation of oral medications in the bundled payment.

Response: We are dedicated to the ongoing process of developing additional quality measures, refining existing quality measures and identifying complete and accurate data sources for use in future years of QIP including measures addressing the commenter's concerns regarding bone mineral metabolism and the potential impact with bundled payment. Currently, ESRD claims provide the only complete set of facility level quality data to support the existing measures. We will be monitoring the data to ensure that the ESRD QIP is achieving the desired quality clinical outcomes. We plan to use the rulemaking process as the way to propose the incorporation of new measures currently under development such as hospitalizations, mineral metabolism, vascular access infections, iron management and fluid volume weight management as well as pediatric measures. In addition, we will have a comprehensive monitoring plan in place when the new PPS begins that ensures access and quality care are furnished to ESRD beneficiaries.

Comment: Several commenters expressed support for inclusion of patient-centered measures in the QIP, such as patient quality of life, ability to return to work or whether patients are in rehabilitation. One commenter supported the implementation of a measure of patient awareness of ESRD treatment options (such as transplant and different dialysis modalities). The commenter also noted that for patients, these types of measures may often be more useful to patients in their decision making than clinical measures.

Response: We agree that patient-centered measures, such as awareness of treatment options, are important for the ESRD population in making decisions such as where they wish to seek care. We appreciate the recommendation to incorporate measures evaluating patient outcomes from a patient's perspective, including patient awareness of treatment options, percentage of patients working or in rehabilitation, and quality of life surveys into the QIP. The NQF has endorsed measures of this type, and we are actively seeking a data source for such data as well as developing a means to collect these data. We intend to use such measures in future payment years and will do subsequent rulemaking on these additional measures.

Comment: One commenter recommended the inclusion of a Practice-related Risk Score (PRS) and a patient-level all Clinical Performance Measure (CPM) index as QIP measures, stating that these types of measures may be better for establishing a facility or provider's quality of care. Composite measures are made up of discrete quality measures that, when calculated together, provide a score that assesses more than one aspect of patient care. According to the commenter, the recommended PRS would be a composite, facility-level index of four key dialysis quality measures, including the percent of patients with: (1) Kt/V >1.2; (2) Hemoglobin >11g/dL; (3) Albumin >4.0g/dL; and (4) A central venous catheter for dialysis access. The commenter noted that the score for the PRS may be a good predictor of mortality. The commenter also recommended a patient-level CPM index that would be similar to the PRS and would be composed of dialysis adequacy (single-pooled Kt/V urea of >1.2); Anemia (Hemoglobin >11g/dL); albumin (>40g/L with bromcresol green or >37g/L with bromcresol purple); and access (that is, use of an arteriovenous fistula). The commenter noted that patient risk for hospitalization and/or death increases, according to their studies, with each unmet target (component) of the CPM index.

Response: We appreciate this recommendation. Measures development is already underway in the areas the commenter recommends such as vascular access measures. Technical Expert Panels (TEP) were convened in Spring 2010 to begin development of these additional measures, and subsequent to these initial TEPs, more work on measures development will take place. As stated above, we intend to fully test all measures before proposing to adopt them for the QIP in order to assure that they are reliable indicators of the quality of care and feasible for data collection. Because measures we are adopting at this time are limited to data available on ESRD claims, we would not have the specificity needed to calculate the composite measures presented by the commenter. However, we will continue to consider and evaluate component measures such as those suggested by the commenter as more data resources become available.

Comment: One commenter wrote that CMS must understand and create a category for mortality rates within long term care hospital (LTCH) settings separate from outpatient clinics and other home dialysis settings. Commenters stated that a facility may have greater than 50 percent of its patients with an end of life care option, such as hospice, when such patients can

no longer care for themselves and are thus compromised on many levels. Commenters stated that the other 50 percent of patients may be in LTCH rehabilitation settings and are admitted only a short time, but come to the facility after a lengthy hospitalization in a compromised condition that in many cases includes life threatening morbidity.

Response: We appreciate the recommendation. For the initial year of the QIP, we have decided to limit the measures to the Anemia Management and the Dialysis Adequacy Measures because they go to the core of ESRD patient care, are feasible to collect, and reliably reflect the quality of patient care. However, as we evaluate and refine the mortality measures currently used for the DFC, these issues will be considered.

Comment: Two commenters recommended that there should be measures of fluid balance (overload) in the measure set.

Response: Appropriate and effective fluid management reduces the risk of congestive heart failure, hospitalizations and premature death, and therefore we believe that measures of fluid management are important for evaluating another aspect of ESRD patient care. We are in the process of developing additional quality measures for possible use in future years of the QIP and will be researching the feasibility of including fluid balance as a measure.

Comment: One commenter recommended that the QIP should include measures of treatments, laboratory testing, medications and other clinical care services included in the new bundled payment to evaluate potential impact on patient care (for example, phosphate binders for mineral metabolism).

Response: The selection of the anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL) and the Hemodialysis Adequacy Measure (URR) was driven by what is required in section 153(c) of MIPPA, as well as the limitations of complete facility-level data currently available to us. Patient outcomes are a key focus of the ESRD QIP. Therefore, we are developing or identifying performance measures that will assess the quality of care delivered to the ESRD patients under the bundled payment. For example, we are currently developing measures of bone mineral metabolism, an important clinical issue with ESRD patients. Implementation of the ESRD bundled payment system may have the impact of providers/facilities decreasing use of medications used to treat clinical conditions associated with the appropriate management of bone mineral metabolism therefore measures to address these issues are important.

Comment: One commenter recommended an approach to monitoring quality by analyzing the drug utilization data that providers/facilities report on Part B claims submitted for Medicare payment. It was further recommended that CMS continue to collect information on the volume and use of drugs and other services included in the broader bundled ESRD payment.

Response: We will monitor drug utilization data to the extent that reliable data is available. However, we note that the linkage between drug utilization patterns and patient quality outcomes needs further exploration. Therefore, we are in the process of identifying possible quality measures related to drug utilization and identifying pertinent drug utilization data sources for potential use in future years of the QIP.

Comment: One commenter suggested that CMS develop quality measures that use a real-time system for reporting rates of hospitalization, emergency department use, and mortality for the dialysis population. The commenter further suggested that such information could help CMS and researchers monitor unintended effects of the new bundled payment method.

Response: We agree that real-time data would be beneficial for tracking in a timely manner, clinical outcomes and the quality of care being delivered, and that more timely access to data would further advance the goals of the QIP to improve the quality of care delivered to ESRD patients. While this type of data source is not currently available, we plan to have a comprehensive monitoring strategy in place that will provide the necessary information to evaluate the quality of care being delivered to Medicare patients with ESRD as the bundled payment system is implemented. Along with the development of additional measures, we are seeking data sources that will allow for more timely assessment and reporting of the data.

Comment: Two commenters requested that CMS add venous access flow surveillance to the measure set. One of the commenters offered that, in addition to the three measures proposed in the ESRD QIP conceptual model, vascular access surveillance metrics be added to include metrics for: (1) Assessment of patient condition; (2) treatment interventions; and (3) thrombotic events. Commenters recommended use of electronic surveillance devices for venous access flow monitoring.

Response: We appreciate the comment and agree that the development of venous access monitoring strategies and the development of measures are important for optimizing outcomes within the ESRD population because decreased venous access flow has implications for hospitalizations, potential stroke and other adverse patient outcomes. We are dedicated to the ongoing process of developing additional quality measures, refining existing quality measures and identifying complete and accurate data sources for use in future years of QIP.

Comment: One commenter recommended the development and use of a list of "Never Events" in the ESRD QIP.

Response: We appreciate the recommendation because these types of events are ones that are avoidable. We will consider the potential development and use of sentinel events (never events)—in future years of the ESRD QIP.

Comment: A commenter requested that CMS act with all due speed to ensure that quality of care for vulnerable patients may be measured and facilities may be held accountable.

Response: We agree that monitoring the quality of care for vulnerable populations under the QIP is critical. A program monitoring and evaluation program is being developed to track impact on vulnerable populations and will be addressed in future rulemaking. The current measures, to the extent that relevant data are available (for example, socio-demographics), will be evaluated for potential disparities in future years. Data on the socio-demographics of the ESRD population might be collected from patient, facility/provider enrollment forms; however, we would need to ensure that data analysis methodologies in use would be able to accurately identify these populations and monitor effectively.

Comment: One commenter urged CMS to verify that all quality data aggregated through the ESRD Clinical Performance Measurement Project and used to calculate the QIP performance measures is case-mix and severity adjusted; further, the commenter asked that special consideration be given for hospital-based units.

Response: We acknowledge that some patients may present additional challenges for the treatment of anemia and achieving adequate dialysis because of existing co-morbid conditions, but we do not believe that the anemia management or dialysis adequacy measures should be risk-adjusted for the

ESRD population. The specifications for these measures may be found in the Dialysis Facility Report instructions and descriptions. Patients with hemoglobin <5 g/dL and >20 g/dL are excluded from the measured population as are patients who are less than 18 years of age. Further, to be included in the measurement population (for both anemia management and dialysis adequacy) patients must have received dialysis for at least 90 days and have had four claims submitted. Additionally, these claims must indicate the use of erythropoiesis-stimulating agents (ESAs) for at least 90 days. These exclusions and inclusions from the measurement population act to adjust the measures for certain patient aspects. However, regardless of the type of unit or patient acuity, all patients should receive the appropriate level of care.

Comment: One commenter noted that, because nursing home patients have a higher patient acuity, the national standards may not be achievable by these facilities, resulting in unfair payment reductions.

Response: We agree that this patient population may have multiple co-morbid conditions that make achieving the national standard difficult. However, given the practice guidelines recommended for all ESRD patients, we would expect a majority of ESRD patients in nursing homes to meet or exceed the national average.

Comment: One commenter noted that by using Kt/V in the CPM program and URR in the QIP, Medicare is targeting the mortality rates from a model that was developed over thirty years ago that has also proven no more predictive of morbidity and mortality than patient self-reported physical and mental functioning scores. The commenter recommended that CMS consider mix adjusted physical and mental functioning scores from patient self-report data and expect dialysis providers to improve the scores that indicate higher risk of hospitalization or death.

Response: We will consider this comment as we develop new measures for use in the QIP in the future. We agree that there are challenges related to different levels of patient acuity within the ESRD population that may have an impact on morbidity and mortality beyond URR. Even though these measures are not risk-adjusted, the specifications for the three measures we are finalizing provide exclusions that act as a level of risk-adjustment. Exclusions remove from the denominator a population with a higher than normal severity of illness or have conditions that prevent them for receiving "normal" treatment and therefore, may unfairly impact on performance measurement scores.

Comment: One commenter noted that the quality baseline year should be aligned with the payment baseline year for calculating the payment rate. The commenter recommended that to prevent "gaming" the agency should provide clear and unambiguous requirements surrounding the manner and timing of laboratory measurements (that is, when during the dialysis process laboratory samples are collected for analysis).

Response: The baseline year for performance measurement the commenter referred to is the performance period for the QIP payment consequence year 2012 which is being proposed in the QIP proposed rule published on **August 12, 2010** in the **Federal Register**. Currently, ESRD claims provide the only complete set of facility level quality data to support the existing measures. With regard to the timing of laboratory testing (time of specimen collection on day of patient visit), KDOQI provides guidelines for the timing of laboratory testing. The guidelines may be accessed at: *http://www.kidney.org/professionals/kdoqi/pdf/12-50-0210_JAG_DCP_Guidelines-HD_Oct06_SectionA_ofC.pdf.* We support the KDOQI guidelines and measure specifications which provide the parameters for the timing of testing. Additionally, there will be monitoring and evaluation of the QIP to track and, where, necessary, take action to prevent "gaming" of data.

Comment: One commenter voiced concern that the three proposed measures may not be an accurate reflection of the quality of care. The commenter further stated that the proper goal for the anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin Greater Than 12 g/dL) and the Dialysis Adequacy Measure (URR) may change over time, and that having the measures written in regulations may make it difficult to update to new standards. The commenter also offered that the skill of dialysis staff (measured through turnover rates) may be a better measure of quality of care and that measures of importance to patients (for example, dialysis-induced hypotension) should be used rather than measures such as urea kinetics.

Response: The selection of the proposed measures was driven by what is required in section 153(c) of MIPPA 2008 as well as the limitations of the complete facility-level data currently available to us. In addition, appropriate anemia management and providing adequate dialysis are important to the assessment of care provided to the ESRD population because these measures evaluate the core clinical issues for ESRD patients especially those on in-center hemodialysis. However, we are in the process of developing additional quality measures and identifying data sources for use in future years of QIP. Lastly, we acknowledge that the skill of a facility's staff can have an impact on the quality of care provided to dialysis patients and look forward to gathering more evidenced-based information that we can use to develop appropriate and valid measures in this area.

Comment: One commenter recommended that, for measures related to immunization and vascular access, a one-month, end-of-year value should be considered since these facility outcomes are cumulative.

Response: We are in the process of considering additional quality measures and potentially including measures of immunization and vascular access. We will consider the validity of using a one-month, end of the year value as these measures are developed and tested.

Comment: One commenter voiced concern that the two-year lag between data collection for the performance measures and measure reporting will not allow for facilities to be measured on improvements that may occur during that lag time. The commenter recommended that the QIP measures use Elab data as a source of more current data.

Response: We are seeking data sources that will allow for more timely assessment and reporting of the data in future years of QIP. We are working towards the timely assessment and reporting of data sources that will close the two-year lag in the data. However, we will use the data collection methodology used by the DFC since 2001 for the first year of the QIP.

Comment: One commenter suggested that facilities and providers be rewarded for proactive, real-time monitoring of plasma water volume, vascular compartment refilling and use of techniques that assure optimal fluid volume management.

Response: MIPPA section 153(c) does not grant us the authority to reward providers/facilities on their performance. At most, the statute allows us to provide full ESRD payments to providers/facilities that satisfy the QIP. We view quality as the standard of care that all provider/facilities should strive for and not as an extra that needs to be rewarded. The ESRD QIP will provide those providers/facilities that meet or exceed the performance standard full ESRD payment. With regard to the

commenter's suggestion to measure plasma water volume, vascular compartment refilling and use of techniques assuming optimal fluid volume management, this is an area that experts in the renal community are currently evaluating in the ESRD population because of poor fluid management's implications for hospitalizations, development of congestive heart failure and other avoidable adverse events.

Comment: One commenter requested a detailed outline of the process for measure development.

Response: We use a standardized process for developing measures which can be found at: *http://www.cms.hhs.gov/QualityInitiativesGenInfo/downloads/QualityMeasuresDevelopmentOverview.pdf.* Tested measures are then submitted to the NQF for endorsement.

After careful consideration of the comments, we have decided that for the QIP payment consequence year 2012, we are finalizing the three proposed measures; the two anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL) and the Dialysis Adequacy Measure (Urea Reduction Rate (URR) ≥65 percent) as proposed with one change. As described above, we will not include ESRD patients less than 18 years of age in the measure calculation of the two anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and 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.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding a Low-volume adjustment. (§ 413.232(f))

As discussed in section VIII.A.2.b. of the proposed rule (74 FR 49975), to receive the low-volume adjustment, we proposed that an ESRD facility must provide an attestation to the Medicare administrative contractor or fiscal intermediary that it has met the criteria to qualify as a low-volume facility. The Medicare administrative contractor or fiscal intermediary would verify the ESRD facility's attestation of their low-volume status using the ESRD facility's final-settled cost reports.

In the proposed rule, we indicated that the burden associated with the requirement would be the time and effort necessary for an ESRD facility attesting as a low-volume facility to develop an attestation and submit it to the Medicare administrative contractor or fiscal intermediary (74 FR 50016). In the 2006 data analysis conducted by our contractor, UM–KECC, 489 ESRD facilities were identified as below the low-volume threshold of 3,000 treatments per year. Of these 488 facilities, 166 met the additional low-volume criteria as specified in § 413.232 of this proposed rule. We estimated that it would require an administrative staff member from each low-volume facility 5 minutes to develop the attestation and a negligible amount of time to submit it to the Medicare administrative contractor or fiscal intermediary (74 FR 50016). We further estimated several dozen additional ESRD facilities may meet the criteria of a low-volume facility prior to implementation of the ESRD PPS and therefore, we rounded the total number of estimated low-volume facilities to 200 (74 FR 50016). Therefore, we estimated that the total initial ESRD facility burden would be 16.6 hours (74 FR 50017).

We did not receive any public comments related to this information collection. However, as discussed in section II.F.4. of this final rule, we are finalizing a threshold of 4,000 instead of 3,000 treatments. Therefore, we identified 857 ESRD facilities as below the updated low-volume threshold of 4,000 treatments per year. Of these 857 facilities, 351 meet the low-volume criteria specified in § 413.232 of this final rule. We continue to believe that the estimated administrative staff time burden of 5 minutes to develop the attestation and a negligible amount of time to submit it to the FI/MAC is appropriate. Therefore, we are finalizing our estimated administrative staff time burden of 5 minutes per facility. We estimate several dozen additional ESRD facilities may meet the criteria of a low-volume facility based on the 4,000 treatment threshold prior to implementation of the ESRD PPS and therefore, we rounded the total number of estimated low-volume facilities to 400. Therefore, we are finalizing the total initial ESRD facility burden to be 33.2 hours.

B. ICRs Regarding Transition Period (§ 413.239)

As discussed in section XIII.A. of the proposed rule, prior to January 1, 2011, an ESRD facility may make a one-time election to be excluded from the four-year transition to the ESRD PPS (74 FR 50003). That is, a facility may elect to be paid entirely based on the proposed ESRD PPS beginning January 1, 2011. Under proposed § 413.239(b), an ESRD facility may make a one-time election to be paid for items and services provided during transition based on 100 percent of the payment amount determined under § 413.215 of this part, rather than based on the payment amount determined under paragraph (a) of this section. The section specified that such election must be submitted to the facility's FI/MAC no later than November 1, 2010.

We estimated in the proposed rule that it would require an accountant or financial management staff member from each of the 4,921 ESRD facilities 1 hour to simulate average aggregate payments under the proposed ESRD PPS and compare them to average aggregate payments under the current basic case-mix adjusted composite payment system, for a total of 4,921 hours (74 FR 50016). In addition, for those facilities electing to be excluded from the four-year transition, we estimated that the burden associated with the requirement in proposed § 413.239(b) would be the time and effort necessary to develop an election and submit it to the FI/MAC (74 FR 50016). We estimated that it would require an administrative staff member from each facility 15 minutes to develop the notice and a negligible amount of time to submit it. We estimated that 36 percent of the estimated 4,921 ESRD facilities, or 1,794 ESRD facilities, would make the election no later than November 1, 2010. Therefore, we estimated that the total one-time ESRD facility burden would be 448.5 hours (74 FR 50017).

The comments pertaining to this information collection, the updated facility data included in the impact analysis and our responses are set forth below.

Comment: One commenter pointed out that we projected that it would take one hour per patient, per month for billing costs related to the proposed ESRD PPS. The commenter indicated that facilities should be compensated for the administrative costs associated with implementing the new payment system including the additional billing related ESRD PPS costs. The commenter further believed that one hour was an insufficient amount of time for this task.

Response: The one-hour timeframe to which the commenter referred pertained to the time that would be spent by ESRD facilities in making a determination to opt out of the 4-year ESRD PPS transition. Specifically, we estimated that each ESRD facility would spend one hour simulating average aggregate payments under the proposed ESRD PPS as compared to the average aggregate payments under the current basic case-mix adjusted composite payment system. With regard to the comment that ESRD facilities should be compensated for billing costs associated with the ESRD PPS and that the projected one-hour timeframe is insufficient to account for their per patient per month billing costs, we note that we computed the ESRD PPS base rate using ESRD facility 2007 costs updated to 2011 which include billing costs. As discussed in more detail in section II.K.2. of this final rule, we have not made significant changes to the current billing requirements. Under the ESRD PPS, facilities will continue to identify the renal dialysis items and services they furnish as well as other non-renal related services for each day of service. The only new additional reporting is related to the use of oral equivalents of injectable drugs. Thus, we believe that the ESRD PPS base rate adequately accounts for providers' billing costs.

Comment: One commenter indicated that they have exceeded the estimated 1-hour timeframe for deciding whether to opt out of the transition and stated that they have spent hundreds of hours attempting to assess the bundle's impact on their 14 facilities.

Response: We believe that the impact of the final ESRD PPS will be easier for ESRD facilities to assess than the proposed system because we are not implementing oral-only ESRD drugs effective January 1, 2011 and the final ESRD PPS has fewer adjustments. However, we disagree that the analysis will take ESRD facilities hundreds of hours to complete. We believe that ESRD facilities have been aware of and planning for the ESRD PPS for several years and have gained insight as to the factors that will go into their decisions regarding the transition. However, based on the public comments, we believe it is more appropriate to estimate two hours for an ESRD facility to complete an analysis of the significant changes made to the ESRD PPS in this final rule and determine whether to opt out of the ESRD PPS transition.

As reflected in section IV.B. of this final rule, there are 4,951 ESRD facilities. We have increased the number of hours necessary to simulate average aggregate payments under the current basic case-mix adjusted composite payment system from one hour to two hours, for a total of 9,902 hours. We are finalizing the estimated administrative staff member burden at 15 minutes per facility to develop and submit the election notice to elect to be excluded from the transition. We are finalizing that 43 percent of the estimated 4,951 ESRD facilities (or 2,120 ESRD facilities), will make the election no later than November 1, 2010. Therefore, we are finalizing the total one-time ESRD facility burden to be 530 hours. The final collection of information burden hours are indicated below in Table 34.

Table 34: ESRD Facility Burden

Regulation Section(s)	OMB Control Number	Respondents	Responses	Burden Per Response (hours)	Total Annual Burden (hours)
413.232	None	857	400	.083	33.2 hours
413.239(b)	None	4,951	2120	.25	530 hours

We have submitted a copy of this final rule to OMB for its review and approval of the aforementioned information collection requirements.

IV. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), 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 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule is an economically significant rule because we estimate that the requirement under section 1881(b)(14)(A)(ii) of the Act—that the estimated total payments for renal dialysis services in CY 2011 equal 98 percent of the estimated total payments that would have been made if the ESRD PPS were not implemented—equates to an approximate $200 million decrease in payments to ESRD facilities in CY 2011. In addition, given this estimated impact, this final rule also is a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the final rule. We requested comments on the economic analysis.

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, approximately 22 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's size standards, which considers small businesses those dialysis facilities having total Medicare

revenues of $34.5 million or less in any 1 year, and 19 percent of dialysis facilities are nonprofit organizations. For more information on SBA's size standards, *see* the Small Business Administration's Web site at *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf*

(Kidney Dialysis Centers are listed as 621492 with a size standard of $34.5 million). For purposes of the RFA, we estimate that approximately 22 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in the impact Table 35. Using the definitions in this ownership category, we consider the 614 facilities that are independent and the 470 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by large dialysis organizations (LDOs) and regional chains would have total revenues more than $34.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain). Overall, a hospital based ESRD facility (as defined by ownership type) is estimated to receive a 1.7 percent increase in payments under the new ESRD PPS for 2011. An independent facility (as defined by ownership type) is estimated to receive a −0.3 percent decrease in payments under the ESRD PPS for 2011. Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

The claims data we use to estimate payments to ESRD facilities in this RFA and RIA does not identify which dialysis facilities are part of an LDO, regional chain, or other type of ownership. As each individual dialysis facility has its own provider number and bills Medicare using this number. Therefore, in previous RFAs and RIAs presented in proposed and final rules that updated to the basic case-mix adjusted composite payment system, we considered each ESRD to be a small entity for purposes of the RFA. However, we conducted a special analysis for this final rule that enabled us to identify the ESRD facilities that are part of an LDO or regional chain. The results of this analysis are presented in the type of ownership category of impact Table 35.

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations 50,000 or less and therefore, they are not enumerated or included in this final RFA. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the 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. Any such regulatory impact analysis must conform to the provisions of section 604 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 do not believe this final rule has a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 187 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 187 rural hospital-based dialysis facilities will experience an estimated 4.4 percent increase in payments. As a result, this rule will not have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

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 $100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately $135 million. While dialysis facilities will be paid approximately $200 million less, we do not believe that this rule includes any mandates that would impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of $133 million.

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 requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not believe this final rule will have a substantial direct effect on State or local governments, preempt State law, or otherwise have Federalism implications.

Payment for ESRD Bad Debt

The changes to the ESRD bad debt payment in this final rule are not changes to the existing ESRD bad debt payment methodology and, therefore, there is no impact on ESRD payments from implementing the Rule of Construction described in Section 153(a)(4) of MIPPA and described elsewhere in this final rule.

B. Anticipated Effects

1. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2011 under the current basic case-mix adjusted composite payment system (current payments) to estimated payments in CY 2011 under the final ESRD PPS, including payments to ESRD facilities paid a blended rate under the transition (new payments). To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of current payments and new payments contain similar inputs. Therefore, we simulated payments only for those ESRD facilities that we are able to calculate both current payments and new payments.

ESRD providers were grouped into the categories based on characteristics provided in the Online Survey and Certification and Reporting (OSCAR) file and the most recent cost report data from the Healthcare Cost Report Information System (HCRIS). We also used the June 2008 update of CY 2007 National Claims History file as a basis for Medicare dialysis treatments and separately billable drugs and biologicals.

Table 35 shows the impact of the ESRD PPS compared to current payments to ESRD facilities under the basic case-mix composite payment system, including all separately billable items. Column A of impact Table 35 indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions).

Table 35 Impact of Final Changes in Payments to ESRD Facilities for CY 2011 ESRD

[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

Facility Type	Number of Facilities	Number of Treatments (in millions)	2011 Impact Assuming Blended and 100% PPS Payments[1]	2011 Impact Assuming All Facilities Paid Under 100% PPS Payments
All Facilities	4,951	36.7	-2.0%	-2.0%
Type				
Freestanding	4,361	32.9	-2.4%	-2.6%
Hospital based	590	3.8	1.8%	3.9%
Ownership Type				
Large dialysis organization	3,069	23.5	-3.0%	-3.7%
Regional chain	787	5.9	-0.9%	0.1%
Independent	614	4.1	-0.3%	0.7%
Unknown	11	0.1	-3.4%	-4.4%
Hospital based[2]	470	3.1	1.7%	3.7%
Geographic Location				
Urban	3,826	30.5	-2.1%	-2.0%
Rural	1,125	6.2	-1.6%	-2.1%
Census Region				
East North Central	785	5.8	-2.4%	-2.4%
East South Central	387	2.8	-3.0%	-4.2%
Middle Atlantic	582	4.6	-2.5%	-2.4%
Mountain	268	1.6	3.1%	6.0%
New England	156	1.2	-1.8%	-0.4%
Pacific	559	4.6	0.7%	3.1%
South Atlantic	1,119	8.4	-4.1%	-6.2%
West North Central	378	2.0	0.0%	1.3%
West South Central	683	5.2	-2.2%	-2.1%
Puerto Rico and Virgin Islands	34	0.4	2.8%	5.0%
Facility Size				
Less than 4,000 treatments[3]	857	1.8	5.4%	6.9%
4,000 to 9,999 treatments	1,949	10.3	-2.4%	-2.9%
10,000 or more treatments	2,084	24.4	-2.4%	-2.3%
Unknown	61	0.2	-1.5%	-2.3%
Percentage of Pediatric Patients				
Less than 2%	4,840	36.3	-2.0%	-2.1%
Between 2% and19%	55	0.4	1.0%	2.2%
Between 20% and 49%	13	0.0	7.5%	10.1%
More than 50%	43	0.0	2.3%	2.8%

[1] Assumed that 2120 out of 4951 Facilities choose to be excluded from the transition based on comparison of payments under current system to payments under the final ESRD PPS.

If payments under a 100% fully implemented ESRD PPS are higher than payments under current system, we assumed that the facility would elect to be excluded from the transition.

[2] Includes hospital based facilities not reported to have large dialysis organization or regional chain ownership.

[3] Of the 857 Facilities with less than 4,000 treatments, only 351 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these Low volume Facilities is a 15.2% increase in payments.

Section 1881(b)(14)(E)(ii) of the Act provides all ESRD facilities with the option to make a one-time election to be excluded from the transition from the current payment system to the ESRD PPS. Electing to be excluded from the 4-year transition means that the ESRD facility receives payments for renal dialysis services provided on or after January 1, 2011, based on 100 percent of the payment rate under the final ESRD PPS, rather than a blended rate based in part on the payment rate under the current payment system and in part on the payment rate under the ESRD PPS.

In order to estimate which ESRD facilities would and would not elect to opt out of the transition and receive payment based on 100 percent of the payment amount under the ESRD PPS, we estimated both the aggregate payments for each ESRD facility under the ESRD PPS (based on 100 percent of the payment amount under ESRD PPS) and payments in the first year of the transition (based on a blend of 25 percent of payments under the ESRD PPS and 75 percent of payments under the current basic case-mix adjusted composite payment system). We then assume that facilities that would receive higher aggregate payments under the ESRD PPS would elect to be paid based on 100 percent of the payment amount under the ESRD PPS, and facilities that would receive higher aggregate payments under the first year of the transition (based on a blend of 25 percent of payments under the ESRD PPS and 75 percent of payments under the current basic case-mix adjusted composite payment system) will elect to be paid under the transition. Based on these assumptions, we are estimating that 43 percent of ESRD facilities would choose to be excluded from the transition and we estimate that 57 percent of ESRD facilities would choose to be paid the blended rate under the transition.

Additionally, in accordance with section 1881(b)(14)(E)(iii) of the Act and as described in section VII.E of this final rule, we intend to apply a transition budget-neutrality adjustment factor to all payments. The purpose of this factor is to make the estimated total payments under the ESRD PPS equal the estimated total payments that would have been made if there had been no transition. We estimate this factor to be 0.969. Since the same factor would be applied to all payments, including the blended payment rates under the transition, the effect of the transition budget neutrality adjustment factor is the same for all impact categories.

The overall effect of the final ESRD PPS, in the first year of the transition, is shown in column C. This effect is determined by comparing total estimated payments under the ESRD PPS, which includes blended payments and payments that are computed using our assumption that 43 percent of ESRD facilities would elect to be paid 100 percent ESRD PPS and 57 percent of ESRD facilities would elect to go through the transition. These payments have also been adjusted to reflect the transition budget neutrality adjustment factor. Total payments are then compared to payments that would have been made to facilities for renal dialysis services provided during CY 2011 under the basic case-mix adjusted composite payment system plus items and services separately billable under Title XVIII, including ESRD-related Part D drugs.

In column C, the aggregate impact on all facilities is a 2.0 percent reduction in payments, which reflects the statutory 98 percent budget neutrality provision. Hospital-based ESRD providers of services show a 1.8 percent increase because as a group they receive higher payments under the ESRD PPS than they would receive under the current system. We believe that the model used to create the ESRD PPS adjustment factors more accurately predicts costs for this provider category. Facilities with less than 4,000 treatments show a 5.4 percent increase in payments under the ESRD PPS because many of these facilities are eligible to receive the low-volume adjustment, which is a 18.9 percent adjustment per treatment. As with hospital-based ESRD providers of services, we believe that the model more accurately predicts costs for this category. Facilities that chose to retain a composite rate exception in the current system will have an 11.3 percent increase in payments under the ESRD PPS. This may be explained by the fact that the current basic case-mix adjusted composite payment system does not completely account for their higher costs and that the ESRD PPS more accurately accounts for the higher costs of these facilities as a group. The largest decrease in payments under the ESRD PPS is for facilities in the South Atlantic census region which will experience a 4.1 percent decrease. We believe this decrease is a result of the current over usage of separately billable drugs.

Column D shows the effect if all ESRD facilities were paid 100 percent of the ESRD PPS. In this column, we are showing a hypothetical effect, as the statute provides for a 4-year transition to a fully implemented ESRD PPS. We show this column as a comparison to column C, in order to show how each impact category would have been effected if the ESRD PPS had been fully implemented in 2011. In column D, the overall effect for all facilities in aggregate is a 2.0 percent reduction, which reflects the statutory 98 percent budget neutrality provision. As with column C, we see the same categories of ESRD facilities most impacted by the ESRD PPS. However, in column D the changes are generally more pronounced as those providers do not have the mitigating effect of the transition. Since column D shows the hypothetical effect if all ESRD facilities were to be paid 100 percent of the ESRD PPS in the first year of the transition, there would be no need for a transition budget neutrality adjustment to account for the cost of the ESRD PPS transition. Therefore, we did not apply the transition budget neutrality factor to column D.

We believe that the comparison of columns C and D shows that the statutory option to transition does

provide a more gradual affect for provider categories that receive lower payments under the ESRD PPS, as well as the effect of the transition budget neutrality factor. Generally, providers that do well under the ESRD PPS show larger increases in column D compared to column C because column D does not reflect the transition budget neutrality adjustment. However, many provider categories include a combination of providers that are estimated to receive higher payments under the ESRD PPS and providers that are estimated to receive lower payments under the ESRD PPS. We believe the comparison of columns C and D also shows that application of the transition budget neutrality factor to all payments does not penalize any one group, but rather it evenly distributes the effect of this transition budget neutrality factor among all provider types.

2. Effects on Other Providers

Under the expanded bundle in the ESRD PPS, other provider types such as laboratories, DME suppliers, and pharmacies would have to seek payment from ESRD facilities rather than Medicare. This is because under the ESRD PPS, Medicare is paying ESRD facilities one combined payment for services that may have been separately paid by Medicare in the past. We noted that other provider types noted above may continue to provide certain ESRD-related serves; however, beginning January 1, 2011, they may no longer bill Medicare directly and instead must seek payment from ESRD facilities.

3. Effects on the Medicare and Medicaid Programs

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in 2011 will be approximately $8.0 billion. This estimate is based on various price update factors discussed in section II.E.2. of this final rule. In addition, we estimate that there will be an increase in fee-for-service Medicare beneficiary enrollment of 3.6 percent in CY 2011. Consistent with the requirement for 98 percent budget neutrality in the initial year of implementation, we intend for estimated aggregate payments under the ESRD PPS to equal 98 percent of the estimated aggregate payments that would have been made if the ESRD PPS were not implemented. Our methodology for estimating payment for purposes of the budget neutrality calculation uses the best available data.

4. Effects on Medicare Beneficiaries

The principal effect of the ESRD PPS on beneficiaries is that implementation of the system will change beneficiary financial liability for co-insurance. Under the current basic case-mix adjusted composite payment system, beneficiaries pay 20 percent of the basic case-mix adjusted payment amount plus 20 percent of ESRD-related separately billable drugs; however they do not pay co-insurance on separately billable laboratory tests. Under the ESRD PPS, beneficiaries will be responsible for paying 20 percent of the ESRD PPS payment amount or blended payment amount for patients treated in facilities that choose the ESRD PPS transition. As the beneficiary will be responsible for the co-insurance on the laboratory tests, we estimate they will have a 1.2 percent increase in their payments. Additional information regarding beneficiary co-insurance is in section II.K.1.b. of this final rule.

C. Alternatives Considered

In developing this final rule, we considered a number of alternatives. We considered other adjustments, including race, modality, and site of service. We considered alternative adjustments to explain variation in cost and resource usage among patients and ESRD facilities. For example, we considered alternatives in the outlier policy, such as outlier percentages of 1.5, 2, 2.5, to 3 percent, rather than the 1 percentage policy. We also considered a monthly payment, but instead are finalizing a per treatment payment.

The statute requires a low-volume adjustment of at least 10 percent and an outlier policy. However, the statute did provide the Secretary with discretion in defining low-volume facilities and establishing the details of the outlier policy. Throughout this final rule, we discuss our rationale for the policy decisions we have made for each adjustment that we are finalizing. Although we have discretion on some of the adjustments we are finalizing, there is no impact on the aggregate amount of spending in the first year of the ESRD PPS (CY 2011) because we have standardized the base rate. The base rate is standardized to account for the overall positive effect of the case-mix and other adjustments.

D. Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement showing the classification of the expenditures associated with the provisions of this final rule.

Table 36, below provides our best estimate of the decrease in CY 2011 Medicare payments under the ESRD PPS as a result of the changes presented in this final rule based on the best available data. The expenditures are classified as a transfer to the Federal Government of $230 million dollars (or as a savings to the Medicare Program) and as a transfer to provider from the beneficiaries of $30 million.

Table 36

Category	Primary Estimate
Transfers Annualized monetized transfers: "on budget"	-$200 million
From whom to whom?	Federal Government & Beneficiaries to ESRD Facilities

Note: In CY 2011, the -$200 million from the Federal Government and Beneficiaries to ESRD Providers is distributed as -$230 million from the Federal Government to the ESRD Provider, and +$30 million from the Beneficiaries to the ESRD Provider.

We received the following comments regarding the impact of the proposed rule on small dialysis organizations and independent dialysis facilities.

Comment: One commenter stated that CMS should include within the RFA, an analysis of the impact of the compliance requirements of the proposed rule on SDOs and an analysis of options for

regulatory relief. Other commenters expressed concern about the increase in administrative costs that will occur due to implementing the infrastructure to collect information to support the case-mix adjusters, specifically the co-morbidity adjustments.

Response: As discussed throughout this preamble, we have made numerous changes to the proposed ESRD PPS in response to public comments and further analysis. The principle change we have made that reduces the burden on ESRD facilities is to delay implementation of oral-only ESRD-related drugs currently paid under Part D. The inclusion of ESRD-related oral drugs is limited and should have minimal impact. We believe that many ESRD facilities already have contractual arrangements with a pharmacy to obtain Part B injectable drugs. Thus, we believe the inclusion of a limited number of oral drugs will not pose a significant burden on any ESRD facilities.

Many of the other adjustments reflect the adjustments in the current basic case-mix adjusted composite payment system (that is, age, BSA, and BMI) and therefore, should not pose new burden on ESRD facilities. In addition, we have not made significant changes in the information that ESRD facilities will be required to report on claims in order to be eligible for payment adjustments. The only new billing requirement is that facilities will be required to line item report ESRD-related oral drugs currently covered under Part D. Consistent with the policy under the current basic case-mix adjusted composite payment system, ESRD facilities will have to report non-ESRD-related services (that is, services that are not renal dialysis services) and the appropriate modifier on their claims in order to receive payment for these services outside the ESRD PPS payment. We have reduced the number of co-morbidity adjustment factors and limited the number of acute co-morbidity diagnostic categories which will minimize the effort needed to track and report co-morbid medical conditions that would be eligible for an adjustment.

Comment: Several commenters did not agree with the impacts provided in the proposed rule. One commenter conducted an independent analysis and asserted that LDOs were more likely than other dialysis providers to serve patients disadvantaged by poverty. While the commenter believes this finding would support a case-mix adjuster to better compensate LDOs for disproportionately servicing areas of high poverty, the commenter urged CMS to avoid implementing a case mix adjuster that is based on facility type. Other commenters indicated that CMS lacks the authority to adjust payments to facilities based on whether they are owned by a dialysis organization of a particular size. The commenters indicated that distinguishing facilities based on ownership status would be an unprecedented extension of CMS' authority to determine Medicare payments. One commenter stated that creating a tiered reimbursement on the basis of facility size or ownership type would create incentives for centers to pursue or retain a certain ownership status to receive higher reimbursement.

Other commenters advocated for an adjustment that would apply to small independent and hospital-based facilities, asserting that these providers have higher costs and lower margins than LDOs. One commenter disputed a finding by MedPAC that the spread in Medicare margin for LDOs compared to small dialysis organizations (SDOs) is about 6 percent and stated that SDOs are incurring even further losses from Medicare, maybe 3 percent more per treatment.

One commenter suggested that we revise the facility-level adjustments or develop a new case-mix adjustment to account for the administrative and financial burden for SDOs. Other commenters stated that the SDOs do not have the economies of scale and resources to implement the ESRD PPS and, therefore, will be forced to provide substandard care or close. The commenters expressed concern that competition allows patient choice and access to care and that we should support small businesses and work to "level the playing field for providers of all sizes."

Response: We have not provided a facility-level adjustment to reflect the size of the chain of dialysis facilities with which an ESRD facility is affiliated because our analysis does not indicate that such adjustments are warranted. In the final impact table (Table 35), facilities that are part of LDOs are projected to experience a −3.0 percent decrease in payment under the PPS compared to what they would have received in the absence of the PPS; medium-sized dialysis organizations (which are captured under the heading regional chains) are projected to experience a −0.9 percent decrease; SDOs are projected to experience a −0.3 percent decrease; and hospital-based facilities are projected to experience a 1.7 percent increase. Given that the impact percentages include the −2.0 percent decrease mandated by section 1881(b)(14)(A)(ii) of the Act, we do not believe these projected impacts indicate a need for adjustments based on the size of the facility or chain organization.

In addition, although there may currently be differences in the spread in Medicare margin for LDOs compared to small dialysis organizations (SDOs), the estimate indicated by the commenter is based upon the current basic case-mix adjusted composite payment system. As stated above, our analysis based on the payment adjustments in this final rule indicate that SDOs are projected do better under the ESRD PPS than larger organizations. We will be monitoring the effects of the ESRD PPS and will consider the commenters' suggestions as we refine the ESRD PPS.

With regard to the need for an adjustment for SDOs due to the administrative and financial burden of the ESRD PPS, we believe the decision to delay the implementation of oral-only Part D drugs under the ESRD PPS until after the transition as discussed in section II.A.3. of this final rule and the reduction in the number of co-morbidity adjustments described in section II.F.3. of this final rule will reduce substantially the administrative and financial burden on all ESRD facilities, including SDOs.

Comment: Many commenters stated that SDOs provide essential services to ESRD beneficiaries and requested that we take steps to ensure the survival of small ESRD facilities, thus preserving beneficiary choice. Commenters identified additional services such as dressing changes, staple removal and other basic nursing related tasks that small and independent ESRD facilities provide to patients who reside in remote areas to alleviate some of the burden associated with traveling to multiple healthcare providers for the provision of basic services. Commenters asserted that the calculations and adjusting of the base rate have reduced it to a value that will not allow SDOs and independents to survive. The commenters believed that the closure of these facilities would compromise beneficiary access to life sustaining dialysis and other basic services. The commenters stated that a higher base rate and fewer adjusters would be more beneficial to the SDOs and MDOs.

Response: We agree that ESRD facilities located in remote areas provide essential services to their patients and are interested in preserving beneficiary choice and access in these areas. As discussed further in sections II.F.3. and 4. of this final rule, we are finalizing a more targeted set of payment adjustments and reducing the standardization factor that is applied to the base rate. As a result, as discussed in section II.E.3. of this final rule, the

adjusted base rate has increased from $198.64 in the proposed rule to $229.63.

Comment: One commenter believed that section 150(d)(iv) of MIPPA provides CMS with the authority to make an annual update to account for the cost differential of ESRD facilities that do not qualify for the low-volume adjustment. This commenter further stated that such an adjustment would balance the incentives for efficiency and budget neutrality with the needs of patient care and a more competitive marketplace.

Response: We believe the commenter is referring to section 1881(b)(14)(D)(iv) of the Act which provides authority for other payment adjustments. Although we have the authority to establish other payment adjustments, we do not believe creating adjustments to create a more competitive marketplace is an appropriate use of this authority.

Comment: Several commenters did not believe that the market basket update would address the low margins for SDOs especially in the context of a two percent reduction in payments under the bundle. The commenters believed that at baseline, the SDO payments would be reduced while many of the cost inputs would continue to increase from inflation resulting in further reduction in SDOs' margins. The commenters asserted that SDOs have less room than other facilities to adjust under the PPS. These commenters concluded that even with new systems and processes in place, the adjustments that the SDOs will receive under the proposed ESRD PPS may not be sufficient to cover the additional costs and burdens of the ESRD PPS.

Response: As we indicated previously, the final impact analysis does not indicate that an adjustment for SDOs is warranted. In addition, to the extent facilities affiliated with SDOs expect to receive financial benefits from the ESRD PPS transition, that option is available to them.

Comment: Several commenters stated that they did not believe that the proposed facility adjustments and outlier policy adequately addresses the many needs of isolated essential facilities.

Response: We disagree with these commenters as the final impact analysis shows that all rural facilities (including those facilities that received IEF exceptions) would see only a slight decrease under the ESRD PPS in 2011 (−2.1 percent decrease). The impact on those few facilities that received a composite rate exception as isolated essential facilities is expected to be positive as those facilities are projected to receive an increase in payment over the current composite payment system.

Comment: One commenter stated that certain drugs used in the treatment of ESRD, particularly ESAs, have no competition within their drug class because they represent a manufacturer's monopoly. Because of the lack of competitive bidding, the commenter maintained that rural ESRD facilities would not be able to compete in price due to their smaller buying power compared to the larger chains. The commenter recommended an adjustment factor for small rural facilities to address this disadvantage.

Response: We do not believe that we should provide a special subsidy to facilities based on size or ownership because of a perceived disadvantage in buying power. We point out that facilities that believe that they are at a competitive disadvantage in purchasing required drugs or supplies due to size or location have the option of forming purchasing consortia in order to leverage their ability to buy products at discounted rates. In addition, in this final rule we have provided for a low-volume adjustment for qualifying ESRD facilities that furnish a small number of treatments and meet other requirements in order to preserve access to dialysis care, where operational costs due to economies of scale might otherwise jeopardize that access. Finally, we note that the impact analysis does not show that small or rural ESRD facilities are particularly disadvantaged under the new system.

E. Conclusion

The impact analysis shows an overall decrease in payments to all ESRD facilities for renal dialysis services of 2.0 percent. This is because of the statutory requirement that payments under the ESRD PPS in 2011 equal 98 percent of what ESRD facilities would have received were the ESRD PPS not implemented (or 98 percent of payments to ESRD facilities under the current payment system).

The analysis above, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis. The analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

■ For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart B—Medical and Other Health Services

■ 1. The authority citation for part 410 is revised to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd.

■ 2. Section 410.50 is amended by revising paragraph (a) to read as follows:

§ 410.50 Institutional dialysis services and supplies: Scope and conditions.

* * * * *

(a) All services, items, supplies, and equipment necessary to perform dialysis and drugs medically necessary and the treatment of the patient for ESRD and, as of January 1, 2011, renal dialysis services as defined in § 413.171 of this chapter.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 3. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395(g), 1395I(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–113 (133 stat. 1501A–332)

Subpart F—Specific Categories of Costs

■ 4. Section 413.89 is amended by adding a new paragraph (h)(3) to read as follows:

§ 413.89 Bad debts, charity, and courtesy allowances.

* * * * *

(h) * * *

(3) *ESRD facilities*—

(i) *Limitation on bad debt.* The amount of ESRD facility bad debts otherwise treated as allowable costs described in § 413.178.

(ii) *Exception.* Bad debts arising from covered services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the program. Additional exceptions for ESRD bad debt payments are described in § 413.178(d).

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services and Organ Procurement Costs

■ 5. Section 413.170 is amended by revising the introductory text, paragraph (a) and paragraph (b) to read as follows:

§ 413.170 Scope.

This subpart implements sections 1881(b)(2), (b)(4), (b)(7), and (b)(12) through (b)(14) of the Act by—

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis services in or under the supervision of an ESRD facility that meets the conditions of coverage in part 494 of this chapter and as defined in § 413.171(c).

(b) Providing procedures and criteria under which a pediatric ESRD facility (an ESRD facility with at least a 50 percent pediatric patient mix as specified in § 413.184 of this subpart) may receive an exception to its prospective payment rate prior to January 1, 2011; and

* * * * *

■ 6. Section 413.171 is added to read as follows:

§ 413.171 Definitions.

For purposes of this subpart, the following definitions apply:

Base rate. The average payment amount per-treatment, standardized to remove the effects of case-mix and area wage levels and further reduced for budget neutrality and the outlier percentage. The base rate is the amount to which the patient-specific case-mix adjustments and any ESRD facility adjustments, if applicable, are applied.

Composite Rate Services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.

ESRD facility. An ESRD facility is an independent facility or a hospital-based provider of services (as described in § 413.174(b) and (c) of this chapter), including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in § 494.10 of this chapter and meets the supervision requirements described in part 494 of this chapter, and that furnishes institutional dialysis services and supplies under § 410.50 and § 410.52 of this chapter.

New ESRD facility. A new ESRD facility is an ESRD facility (as defined above) that is certified for Medicare participation on or after January 1, 2011.

Pediatric ESRD Patient. A pediatric ESRD patient is defined as an individual less than 18 years of age who is receiving renal dialysis services.

Renal dialysis services. Effective January 1, 2011, the following items and services are considered "renal dialysis services," and paid under the ESRD prospective payment system under section 1881(b)(14) of the Act:

(1) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(2) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD;

(3) Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form),

(4) Diagnostic laboratory tests and other items and services not described in paragraph (1) of this definition that are furnished to individuals for the treatment of ESRD.

(5) Renal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis.

Separately billable items and services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of individuals with ESRD that were or would have been, prior to January 1, 2011, separately payable under Title XVIII of the Act and not included in the payment systems established under section 1881(b)(7) and section 1881(b)(12) of the Act.

■ 7. Section 413.172 is amended by revising paragraph (a), paragraph (b), and paragraph (b)(1) to read as follows:

§ 413.172 Principles of prospective payment.

(a) Payment for renal dialysis services as defined in § 413.171 and home dialysis services as defined in § 413.217 of this chapter are based on payment rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered renal dialysis services as defined in § 413.171 or home dialysis services. Approved ESRD facility means—

(1) Any independent ESRD facility or hospital-based provider of services (as defined in § 413.174(b) and § 413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

* * * * *

■ 8. Section 413.174 is amended as follows:

■ a. By revising paragraph (a).

■ b. By revising paragraphs (f) introductory text, (f)(3), and (f)(4).

■ c. By adding a new paragraphs (f)(5) and (f)(6). The revisions and additions read as follows:

§ 413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using a methodology that—

(1) Differentiates between hospital-based providers of services and independent ESRD facilities for items and services furnished prior to January 1, 2009;

(2) Does not differentiate between hospital-based providers of services and independent ESRD facilities for items and services furnished on or after January 1, 2009; and

(3) Requires the labor share be based on the labor share otherwise applied to independent ESRD facilities when applying the geographic index to hospital-based ESRD providers of services, on or after January 1, 2009.

* * * * *

(f) *Additional payment for separately billable drugs and biologicals.* Prior to January 1, 2011, CMS makes additional payment directly to an ESRD facility for certain ESRD-related drugs and biologicals furnished to ESRD patients.

* * * * *

(3) For drugs furnished prior to January 1, 2006, payment is made to hospital-based ESRD providers of services on a reasonable cost basis.

Effective January 1, 2006, and prior to January 1, 2011, payment for drugs furnished by a hospital-based ESRD provider of service is based on the methodology specified in § 414.904 of this chapter.

(4) For drugs furnished prior to January 1, 2006, payment is made to independent ESRD facilities based on the methodology specified in § 405.517 of this chapter. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs and biological furnished by independent ESRD facilities is based on the methodology specified in § 414.904 of this chapter.

(5) Effective January 1, 2011, except as provided below, payment to an ESRD facility for renal dialysis service drugs and biologicals as defined in § 413.171, furnished to ESRD patients on or after January 1, 2011 is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided.

(6) Effective January 1, 2014, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided.

■ 9. Section 413.176 is revised to read as follows:

§ 413.176 Amount of payments.

For items and services, for which payment is made under section 1881(b)(7), section 1881(b)(12), and section 1881(b)(14) of the Act:

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, Medicare pays the ESRD facility 80 percent of its prospective rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, CMS subtracts the amount applicable to the deductible from the ESRD facility's prospective rate and pays the facility 80 percent of the remainder, if any.

■ 10. Section 413.178 is amended by revising paragraph (d) to read as follows:

§ 413.178 Bad debts.

* * * * *

(d) *Exceptions.* (1) Bad debts arising from covered ESRD services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the program.

(2) For services furnished on or after January 1, 2011, bad debts arising from covered ESRD items or services that, prior to January 1, 2011 were paid under a reasonable charge-based methodology or a fee schedule, including but not limited to drugs, laboratory tests, and supplies are not reimbursable under the program.

■ 11. Section 413.180 is amended by adding a new paragraph (l) to read as follows.

§ 413.180 Procedures for requesting exceptions to payment rates.

* * * * *

(l) *Periods of exceptions.* (1) Prior to December 31, 2000, an ESRD facility may receive an exception to its composite payment rate for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities.

(2) Effective December 31, 2000, an ESRD facility not subject to paragraph (l)(3), is no longer granted any new exception to the composite payment rate as defined in § 413.180(1).

(3) Effective April 1, 2004 through September 27, 2004, and on an annual basis, an ESRD facility with at least 50 percent pediatric patient mix as specified in § 413.184 of this part, that did not have an exception rate in effect as of October 1, 2002, may apply for an exception to its composite payment rate.

(4) For ESRD facilities that are paid a blended rate for renal dialysis services provided during the transition described in § 413.239 of this part, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities are used as the payment amount in place of the composite rate, and will be terminated for ESRD services furnished on or after January 1, 2014.

(5) For ESRD facilities that, in accordance with § 413.239(b) of this part, elect to be paid for renal dialysis services provided during the transition based on 100 percent of the payment amount determined under § 413.220, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities are terminated for ESRD services furnished on or after January 1, 2011.

■ 12. Section 413.195 is added to read as follows:

§ 413.195 Limitation on Review.

Administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following is prohibited: The determination of payment amounts under section 1881(b)(14)(A) of the Act, the establishment of an appropriate unit of payment under section 1881(b)(14)(C) of the Act, the identification of renal dialysis services included in the bundled payment, the adjustments under section 1881(b)(14)(D) of the Act, the application of the phase-in under section 1881(b)(14)(E) of the Act, and the establishment of the market basket percentage increase factors under section 1881(b)(14)(F) of the Act.

■ 13. Section 413.196 is amended by adding new paragraphs (c) and (d) to read as follows:

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

* * * * *

(c) Effective for items and services furnished on or after January 1, 2011 and before January 1, 2012, CMS adjusts the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor.

(d) Effective for items and services furnished on or after January 1, 2012, CMS updates on an annual basis the following:

(1) The per-treatment base rate and the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor minus a productivity adjustment factor.

(2) The wage index using the most current hospital wage data.

(3) The fixed dollar loss amount as defined in § 413.237 of this part to ensure that outlier payments continue to be 1.0 percent of total payments to ESRD facilities.

■ 14. Section 413.210 is added to subpart H to read as follows:

§ 413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.

Except as noted in § 413.174(f), items and services furnished on or after January 1, 2011, under section 1881(b)(14)(A) of the Act and as identified in § 413.217 of this part, are paid under the ESRD prospective payment system described in § 413.215 through § 413.235 of this part.

(a) *Qualifications for payment.* To qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter.

(b) *Payment for items and services.* CMS will not pay any entity or supplier other than the ESRD facility for covered items and services furnished to a Medicare beneficiary. The ESRD facility must furnish all covered items and

services defined in § 413.217 of this part either directly or under arrangements.

■ 15. Section 413.215 is added to subpart H to read as follows:

§ 413.215 Basis of payment.

(a) Except as otherwise provided under § 413.235 or § 413.174(f) of this part, effective January 1, 2011, ESRD facilities receive a predetermined per treatment payment amount described in § 413.230 of this part, for renal dialysis services, specified under section 1881(b)(14) of the Act and as defined in § 413.217 of this part, furnished to Medicare Part B fee-for-service beneficiaries.

(b) In addition to the per-treatment payment amount, as described in § 413.215(a) of this part, the ESRD facility may receive payment for bad debts of Medicare beneficiaries as specified in § 413.178 of this part.

■ 16. Section 413.217 is added to subpart H to read as follows:

§ 413.217 Items and services included in the ESRD prospective payment system.

The following items and services are included in the ESRD prospective payment system effective January 1, 2011:

(a) Renal dialysis services as defined in § 413.171; and

(b) Home dialysis services, support, and equipment as identified in § 410.52 of this chapter.

■ 17. Section 413.220 is added to subpart H to read as follows:

§ 413.220 Methodology for calculating the per-treatment base rate under the ESRD prospective payment system effective January 1, 2011.

(a) *Data sources.* The methodology for determining the per treatment base rate under the ESRD prospective payment system utilized:

(1) Medicare data available to estimate the average cost and payments for renal dialysis services.

(2) ESRD facility cost report data capturing the average cost per treatment.

(3) The lowest per patient utilization calendar year as identified from Medicare claims is calendar year 2007.

(4) Wage index values used to adjust for geographic wage levels described in § 413.231 of this part.

(5) An adjustment factor to account for the most recent estimate of increases in the prices of an appropriate market basket of goods and services provided by ESRD facilities.

(b) *Determining the per treatment base rate for calendar year 2011.* Except as noted in § 413.174(f), the ESRD prospective payment system combines payments for the composite rate items and services as defined in § 413.171 of this part and the items and services that, prior to January 1, 2011, were separately billable items and services, as defined in § 413.171 of this part, into a single per treatment base rate developed from 2007 claims data. The steps to calculating the per-treatment base rate for 2011 are as follows:

(1) *Per patient utilization in CY 2007, 2008, or 2009.* CMS removes the effects of enrollment and price growth from total expenditures for 2007, 2008 or 2009 to determine the year with the lowest per patient utilization.

(2) *Update of per treatment base rate to 2011.* CMS updates the per-treatment base rate under the ESRD prospective payment system in order to reflect estimated per treatment costs in 2011.

(3) *Standardization.* CMS applies a reduction factor to the per treatment base rate to reflect estimated increases resulting from the facility-level and patient-level adjustments applicable to the case as described in § 413.231 through § 413.235 of this part.

(4) *Outlier percentage.* CMS reduces the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD prospective payment system that are outlier payments as described in § 413.237 of this part.

(5) *Budget neutrality.* CMS adjusts the per treatment base rate so that the aggregate payments in 2011 are estimated to be 98 percent of the amount that would have been made under title XVIII of the Social Security Act if the ESRD prospective payment system described in section 1881(b)(14) of the Act were not implemented.

(6) *First 4 Years of the ESRD prospective payment system.* During the first 4 years of ESRD prospective payment system (January 1, 2011 to December 31, 2013), CMS adjusts the per-treatment base rate in accordance with § 413.239(d).

■ 18. Section 413.230 is added to subpart H to read as follows:

§ 413.230 Determining the per treatment payment amount.

The per-treatment payment amount is the sum of:

(a) The per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in § 413.232 and § 413.235 of this part;

(b) Any outlier payment under § 413.237; and

(c) Any training adjustment add-on under § 414.335(b).

■ 19. Section 413.231 is added to subpart H to read as follows:

§ 413.231 Adjustment for wages.

(a) CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located.

(b) The application of the wage index is made on the basis of the location of the ESRD facility in an urban or rural area as defined in this paragraph (b).

(1) *Urban area* means a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB.

(2) *Rural area* means any area outside an urban area.

■ 20. Section 413.232 is added to subpart H to read as follows:

§ 413.232 Low-volume adjustment.

(a) CMS adjusts the base rate for low-volume ESRD facilities, as defined in paragraph (b) of this section.

(b) Definition of low-volume facility. A low-volume facility is an ESRD facility that:

(1) Furnished less than 4,000 treatments in each of the 3 years preceding the payment year; and

(2) Has not opened, closed, or had a change in ownership in the 3 years preceding the payment year.

(c) For the purpose of determining the number of treatments under paragraph (b)(1) of this section, the number of treatments considered furnished by the ESRD facility shall equal the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both:

(1) Under common ownership with, and

(2) 25 miles or less from the ESRD facility in question.

(d) The determination under paragraph (c) of this section does not apply to an ESRD facility that was in existence and certified for Medicare participation prior January 1, 2011.

(e) Common ownership means the same individual, individuals, entity, or entities, directly, or indirectly, own 5 percent or more of each ESRD facility.

(f) To receive the low-volume adjustment, an ESRD facility must provide an attestation statement to their Medicare administrative contractor that the facility has met all the criteria as established in paragraphs (a), (b), (c), and (d) of this section.

(g) The low-volume adjustment applies only for dialysis treatments provided to adults (18 years or older).

■ 21. Section 413.235 is added to subpart H to read as follows:

§ 413.235 Patient-level adjustments.

Adjustments to the per-treatment base rate may be made to account for variation in case-mix. These adjustments reflect patient characteristics that result in higher costs for ESRD facilities.

(a) CMS adjusts the per treatment base rate for adults to account for patient age, body surface area, low body mass index, onset of dialysis (new patient), and co-morbidities, as specified by CMS.

(b) CMS adjusts the per treatment base rate for pediatric patients in accordance with section 1881(b)(14) (D)(iv)(I) of the Act, to account for patient age and treatment modality.

(c) CMS provides a wage-adjusted add-on per treatment adjustment for home and self-dialysis training.

■ 22. Section 413.237 is added to subpart H to read as follows:

§ 413.237 Outliers.

(a) The following definitions apply to this section.

(1) *ESRD outlier services* are the following items and services that are included in the ESRD PPS bundle: (i) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(ii) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(iii) Medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and

(iv) Renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, excluding ESRD-related oral-only drugs effective January 1, 2014.

(2) *Adult predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to an adult beneficiary by an ESRD facility.

(3) *Pediatric predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to a pediatric beneficiary by an ESRD facility.

(4) *Adult fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to an adult beneficiary must exceed the adult predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(5) *Pediatric fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to a pediatric beneficiary must exceed the pediatric predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(6) *Outlier Percentage:* This term has the meaning set forth in § 413.220(b)(4).

(b) Eligibility for outlier payments.

(1) *Adult beneficiaries.* An ESRD facility will receive an outlier payment for a treatment furnished to an adult beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD outlier services exceeds the adult predicted ESRD outlier services MAP amount plus the adult fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for an adult beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the adult beneficiary by the number of dialysis treatments furnished to the adult beneficiary in the relevant month. A beneficiary is considered an adult beneficiary if the beneficiary is 18 years old or older.

(2) *Pediatric beneficiaries.* An ESRD facility will receive an outlier payment for a treatment furnished to a pediatric beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD outlier services exceeds the pediatric predicted ESRD outlier services MAP amount plus the pediatric fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for a pediatric beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the pediatric beneficiary by the number of dialysis treatments furnished to the pediatric beneficiary in the relevant month. A beneficiary is considered a pediatric beneficiary if the beneficiary is under 18 years old.

(c) *Outlier payment amount:* CMS pays 80 percent of the difference between:

(1) The ESRD facility's per-treatment imputed MAP amount for the ESRD outlier services, and

(2) The adult or pediatric predicted ESRD outlier services MAP amount plus the adult or pediatric fixed dollar loss amount, as applicable.

■ 23. Section 413.239 is added to subpart H to read as follows:

§ 413.239 Transition period.

(a) *Duration of transition period and composition of the blended transition payment.* ESRD facilities not electing under paragraph (b) of this section to be paid based on the payment amount determined under § 413.230 of this part, will be paid a per-treatment payment amount for renal dialysis services (as defined in § 413.171 of this part) and home dialysis, provided during the transition as follows—

(1) For services provided on and after January 1, 2011 through December 31, 2011, a blended rate equal to the sum of:

(i) 75 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 25 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(2) For services provided on and after January 1, 2012 through December 31, 2012, a blended rate equal to the sum of:

(i) 50 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 50 percent of the payment rate determined in accordance with section 1881(b)(14) of the Act;

(3) For services provided on and after January 1, 2013 through December 31, 2013, a blended rate equal to the sum of:

(i) 25 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 75 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(4) For services provided on and after January 1, 2014, 100 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act.

(b) *One-time election.* Except as provided in paragraph (b)(2) of this section, ESRD facilities may make a one-time election to be paid for renal dialysis services provided during the transition based on 100 percent of the payment amount determined under § 413.215 of this part, rather than based

on the payment amount determined under paragraph (a) of this section.

(1) Except as provided in paragraph (b)(3) of this section, the election must be received by each ESRD facility's Medicare administrative contractor (MAC) by November 1, 2010. Requests received by the MAC after November 1, 2010, will not be accepted regardless of postmarks, or delivered dates. MACs will establish the manner in which an ESRD facility will indicate their intention to be excluded from the transition and paid entirely based on payment under the ESRD PPS. Once the election is made, it may not be rescinded.

(2) If the ESRD facility fails to submit an election, or the ESRD facility's election is not received by their MAC by November 1, 2010, payments to the ESRD facility for items and services provided during the transition will be based on the payment amounts determined under paragraph (a) of this section.

(3) ESRD facilities that become certified for Medicare participation and begin to provide renal dialysis services, as defined in § 413.171 of this part, between November 1, 2010 and December 31, 2010, must notify their designated MAC of their election choice at the time of enrollment.

(c) *Treatment of new ESRD facilities.* For renal dialysis services as defined in § 413.171, furnished during the transition period, new ESRD facilities as defined in § 413.171, are paid based on the per-treatment payment amount determined under § 413.215 of this part.

(d) *Transition budget-neutrality adjustment.* During the transition, CMS adjusts all payments, including payments under this section, under the ESRD prospective payment system so that the estimated total amount of payment equals the estimated total amount of payments that would otherwise occur without such a transition.

■ 24. Section 413.241 is added to subpart H to read as follows:

§ 413.241 Pharmacy arrangements.

Effective January 1, 2011, an ESRD facility that enters into an arrangement with a pharmacy to furnish renal dialysis service drugs and biologicals must ensure that the pharmacy has the capability to provide all classes of renal dialysis service drugs and biologicals to patients in a timely manner.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 25. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l))

Subpart E—Determination of Reasonable Charges Under the ESRD Program

■ 26. Section 414.330 is amended by—

■ A. Removing "§ 413.170" and adding in its place "§ 413.210" in paragraph (a)(1) and paragraph (b)(1).

■ B. Revising the heading of paragraph (a)(2).

■ C. Revising the heading of paragraph (b)(2).

■ D. Removing the paragraph heading and adding in its place new introductory text in paragraph (c).

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) * * *

(2) *Exception for equipment and supplies furnished prior to January 1, 2011.* * * *

* * * * *

(b) * * *

(2) *Exception for home support services furnished prior to January 1, 2011.* * * *

* * * * *

(c) Payment limits for support services, equipment and supplies, and notification of changes to the payment limits apply prior to January 1, 2011 as follows:

* * * * *

■ 27. Revise § 414.335 to read as follows:

§ 414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Prior to January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies. Effective January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to a Medicare-approved ESRD facility in accordance with the per treatment payment as defined in § 413.230.

(b) After January 1, 2011, a home and self training amount is added to the per treatment base rate for adult and pediatric patients as defined in § 413.230

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 15, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: July 22, 2010.

Kathleen Sebelius,

Secretary.

Note: The following tables will not appear in the Code of Federal Regulations.

BILLING CODE P

Table A: Payment Multipliers for an Expanded Bundle of Services, ages 18 and older, 2006-08

Base Rate - $229.63

Variable	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment[3,4]
	Composite rate services[1]	Separately billable services[2]	
	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for patient characteristics			
Age			
18-44	1.254	0.996	1.171
45-59	1.023	0.992	1.013
60-69	1.000	1.000	1.000
70-79	1.033	0.963	1.011
80+	1.063	0.915	1.016
Body surface area (per 0.1 m^2)	1.023	1.014	1.020
Underweight (BMI <18.5)	1.000^	1.078	1.025
Time since onset of renal dialysis < 4 months	1.539	1.450	1.510
Pericarditis (acute*)	1.000^	1.354	1.114
Bacterial pneumonia (acute*)	1.000^	1.422	1.135
Gastro-intestinal tract bleeding (acute*)	1.000^	1.571	1.183
Hereditary hemolytic or sickle cell anemia (chronic*)	1.000^	1.225	1.072
Myelodysplastic syndrome (chronic*)	1.000^	1.309	1.099
Monoclonal gammopathy[5] (chronic*)	1.000^	1.074	1.024
Low volume facility adjustment Facility size < 4,000 treatments during each year from 2006-08	1.347	0.975	1.189

^A multiplier of 1.000 was used for factors that lacked statistical significance in models of resource use or lacked stability in the estimated multipliers.

[1]The CR payment multipliers ($PmtMult_{CR}$) are based on a facility level log-linear regression model of the average composite rate cost/session for 2006-08 (n=12,974 facility years). This model also included facility characteristics (an indicator of low volume facilities as a potential payment variable and control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate exception, % of patients in the facility with URR<65%, and % of home dialysis training treatments in the facility) and the percent of pediatric patients as additional covariates (R-sq=41.0%).

[2]Based on a patient-month level log-linear regression model of separately billable Medicare Allowable Payments/session for 2006-08 (n=8,603,325 patient months) that included facility characteristics (an indicator of low volume facilities as a potential payment variable as well as control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%) as additional covariates. An R-squared value of 5.1% was calculated at the patient level based on a regression model that used the average predicted SB MAP per treatment during each patient year (calculated by averaging the monthly predicted values for each patient from the patient-month SB model) to explain variation in the average observed MAP per treatment for the patient year (with a log transformation applied to both the average predicted and average observed SB values). The R-squared value for the patient-month level log-linear SB model was 3.3%.

[3]The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility level model of composite rate costs and $PmtMult_{SB}$ is the estimated multiplier from a patient level model of separately billable MAP. Based on total estimated costs of $177.72 per session for composite rate services, $83.97 per session for separately billable services, and $261.69 per session for composite rate and separately billable services ($177.72+$83.97), the relative weights are $Weight_{CR}$=0.6791 for composite rate services ($177.72/$261.69) and $Weight_{SB}$=0.3209 for separately billable services ($83.97/$261.69). The combined low volume multiplier was calculated relative to all other facilities.

[4]To determine the incremental payment for low volume facilities, the low volume facility payment multiplier was calculated relative to all other facilities combined. The estimated low volume coefficients from the regression models (which correspond to the CR and SB multipliers of 1.347 and 0.975, respectively, in the table above) were first divided by the weighted average of the other facility size coefficients in the models. A similar weighting procedure to that described above for the other payment multipliers was then used in calculating the resulting low volume adjustment of 1.189. The same payment adjustment is being used for both adult and pediatric patients in a low volume facility.

[5]Excludes multiple myeloma.

*Comorbidities referred to as "acute" were identified in the current month or previous 3 months of claims. Comorbidities referred to as "chronic" were identified in claims since 2000.

Table B: Payment Multipliers for Pediatric Patients Based on Adjustments for Age and Modality

Base Rate - $229.63

Cell	Patient characteristics		Separately billable (SB) payment multiplier[1]	Expanded bundle payment multiplier
	Age	Modality		
1	<13	PD	0.319	1.033
2	<13	Hemo	1.185	1.219
3	13-17	PD	0.476	1.067
4	13-17	Hemo	1.459	1.277

[1]Based on a pediatric patient month level regression model of SB MAP/session for 2006-08 (n=17,142 pediatric patient months) that included age (<13 vs. 13-17) and modality (PD vs. HD). An R-squared value calculated at the patient year level was 34.8%. This calculation was based on a regression model that used the average predicted SB MAP per treatment during each patient year (calculated by averaging the monthly predicted values for each patient from the patient-month SB model) to explain variation in the average observed SB MAP per treatment for the patient year. In estimating this R-squared value, a log transformation was applied to both the average predicted and average observed SB values. The R-squared value for the patient month regression model was 32.8%. Subgroup-specific smearing adjustments were applied to the estimated multipliers from the model. The SB payment multipliers presented above were calculated relative to the average SB multiplier among pediatric patients, such that the average pediatric SB payment multiplier is 1.000.

Table C: Part B Drugs Included in the Proposed and Final ESRD PPS Base Rate

Category	HCPCS	Title	Category Included in ESRD PPS Base Rate	
			Proposed Rule	Final Rule
Access management	J1642	INJ HEPARIN SODIUM PER 10 U	Yes	Yes
	J1644	INJ HEPARIN SODIUM PER 1000U		
	J1945	LEPIRIDUN		
	J2993	RETEPLASE INJECTION		
	J2997	ALTEPLASE RECOMBINANT		
	J3364	UROKINASE 5000 IU INJECTION		
	J3365	UROKINASE 250,000 IU INJ		
Anemia management	J0882	DARBEPOETIN	Yes	Yes
	J0886	EPO		
	J1751[1]	IRON DEXTRAN		
	J1752[1]	IRON DEXTRAN		
	J1756	IRON SUCROSE INJECTION		
	J2916	NA FERRIC GLUCONATE COMPLEX		
	J3420	VITAMIN B12 INJECTION		
	Q4055[1]	EPO		
Antiemetic	J0780	PROCHLORPERAZINE INJECTION	Yes	Yes
	J1260	DOLASETRON MESYLATE		
	J1626	GRANISETRON HCL INJECTION		
	J2405	ONDANSETRON HCL INJECTION		
	J2550	PROMETHAZINE HCL INJECTION		
	J2765	METOCLOPRAMIDE HCL INJECTION		
	J2950	PROMAZINE HCL INJECTION		
	J3230	CHLORPROMAZINE HCL INJECTION		
	J3250	TRIMETHOBENZAMIDE HCL INJ		
	J3310	PERPHENAZINE INJECITON		
Anxiolytic	J2060	LORAZEPAM INJECTION	Yes	Yes
	J2250	INJ MIDAZOLAM HYDROCHLORIDE		
	J3360	DIAZEPAM INJECTION		
Bone and mineral metabolism	J0610	CALCIUM GLUCONATE INJECTION	Yes	Yes
	J0630	CALCITONIN SALMON INJECTION		
	J0635	CALCITRIOL		
	J0636	INJ CALCITRIOL PER 0.1 MCG		
	J0895	DEFEROXAMINE MESYLATE INJ		
	J1270	INJECTION, DOXERCALCIFEROL		
	J1740	IBANDRONATE SODIUM		
	J2430	PAMIDRONATE DISODIUM /30 MG		
	J2500[1]	PARICALCITOL		
	J2501	PARICALCITOL		
Cellular management	J1955	INJ LEVOCARNITINE PER 1 GM	Yes	Yes
Pain management	J1170	HYDROMORPHONE INJECTION	Yes	Yes
	J1885	KETOROLAC TROMETHAMINE INJ		
	J2175	MEPERIDINE HYDROCHL /100 MG		
	J2270	MORPHINE SULFATE INJECTION		
	J2271	MORPHINE SO4 INJECTION 100MG		

Category	HCPCS	Title	Category Included in ESRD PPS Base Rate	
			Proposed Rule	Final Rule
	J2275	MORPHINE SULFATE INJECTION		
	J2300	INJ NALBUPHINE HYDROCHLORIDE		
	J2310	INJ NALOXONE HYDROCHLORIDE		
	J3010	FENTANYL CITRATE INJECITON		
	J3070	PENTAZOCINE INJECTION		
Anti-infective	J0278	AMIKACIN SULFATE	Yes	Yes
	J0285	AMPHOTERICIN B		
	J0290	AMPICILLIN 500 MG INJ		
	J0295	AMPICILLIN SODIUM PER 1.5 GM		
	J0456	AZITHROMYCIN		
	J0530	PENICILLIN G BENZATHINE INJ		
	J0560	PENICILLIN G BENZATHINE INJ		
	J0580	PENICILLIN G BENZATHINE INJ		
	J0637	CASPOFUNGIN ACETATE		
	J0690	CEFAZOLIN SODIUM INJECTION		
	J0692	CEFEPIME HCL FOR INJECTION		
	J0694	CEFOXITIN SODIUM INJECTION		
	J0696	CEFTRIAXONE SODIUM INJECTION		
	J0697	STERILE CEFUROXIME INJECTION		
	J0698	CEFOTAXIME SODIUM INJECTION		
	J0713	INJ CEFTAZIDIME PER 500 MG		
	J0715	CEFTIZOXIME SODIUM / 500 MG		
	J0743	CILASTATIN SODIUM INJECTION		
	J0744	CIPROFLOXACIN IV		
	J0878	DAPTOMYCIN		
	J1335	ERTAPENEM SODICUM		
	J1364	ERYTHRO LACTOBIONATE /500 MG		
	J1450	FLUCONAZOLE		
	J1580	GARAMYCIN GENTAMICIN INJ		
	J1590	GATIFLOXACIN INJECTION		
	J1840	KANAMYCIN SULFATE 500 MG INJ		
	J1890	CEPHALOTHIN SODIUM INJECTION		
	J1956	LEVOFLOXACIN INJECTION		
	J2020	LINEZOLID INJECTION		
	J2185	MEROPENEM		
	J2280	MOXIFLOXACIN		
	J2510	PENICILLIN G PROCAINE INJ		
	J2540	PENICILLIN G POTASSIUM INJ		
	J2543	PIPERACILLIN/TAZOBACTAM		
	J2700	OXACILLIN SODIUM INJECTION		
	J3000	STREPTOMYCIN INJECTION		
	J3260	TOBRAMYCIN SULFATE INJECTION		
	J3370	VANCOMYCIN HCL INJECTION		
Composite rate drugs that were billed separately	A4802	PROTAMINE SULFATE PER 50 MG	Yes	No
	J1200	DIPHENHYDRAMINE HCL INJECTIO		
	J1240	DIMENHYDRINATE INJECTION		
	J1940	FUROSEMIDE INJECTION		

Category	HCPCS	Title	Category Included in ESRD PPS Base Rate	
			Proposed Rule	Final Rule
	J2001	LIDOCAINE HCL 10MG		
	J2150	MANNITOL INJECTION		
	J2720	INJ PROTAMINE SULFATE/10 MG		
	J2795	ROPIVACAINE HCL INJECTION		
	J3410	HYDROXYZINE HCL INJECTION		
Hepatitis B vaccine	90371	HEP B IG, IM	No	No
	90740	HEPB VACC, ILL PAT 3 DOSE IM		
	90743	HEP B VACC, ADOL, 2 DOSE, IM		
	90744	HEPB VACC PED/ADOL 3 DOSE IM		
	90746	HEP B VACCINE, ADULT, IM		
	90747	HEPB VACC, ILL PAT 4 DOSE IM		
	90748	HEP B/HIB VACCINE, IM		
Flu vaccine	90655	FLU VACCINE	No	No
	90656	FLU VACCINE		
	90657	FLU VACCINE, 6-35 MO, IM		
	90658	FLU VACCINE, 3 YRS, IM		
	90660	FLU VACCINE, NASAL		
Pneumoccocal vaccine	90732	PNEUMOCOCCAL VACCINE	No	No
Other vaccine	90471	IMMUNIZATION ADMIN	Yes	No
	90585	BCG VACCINE, PERCUT		
	90632	HEP A VACCINE, ADULT IM		
	90633	HEP A VACC, PED/ADOL, 2 DOSE		
	90636	HEP A/HEP B VACC, ADULT IM		
	90648	HIB VACCINE, PRP-T, IM		
	90700	DTAP VACCINE, IM		
	90703	TETANUS VACCINE, IM		
	90707	MMR VACCINE, SC		
	90714	TETANUS AND DIPTHERIA TOXOIDS		
	90715	ACCELULLAR DPT		
	90716	CHICKEN POX VACCINE, SC		
	90717	YELLOW FEVER VACCINE, SC		
	90718	TD VACCINE > 7, IM		
	90723	DTAP-HEP B-IPV VACCINE, IM		
	90733	MENINGOCOCCAL VACCINE, SC		
	90734	MENINGOCOCCAL CONJUGATE VACCINE SEROGROUPS A,C,Y AND W-135 (TETRAVALENT), IM		
	90735	ENCEPHALITIS VACCINE, SC		
Immune system	J1440	FILGRASTIM 300 MCG INJECTION	Yes	No
	J1441	FILGRASTIM 480 MCG INJECTION		
	J1566	IMMUNE GLOBULIN		
	J1567	IMMUNE GLOBULIN		
	J2504	PEGADEMASE BOVINE		
	J7500	AZATHIOPRINE ORAL 50MG		
	J7502	CYCLOSPORINE ORAL 100 MG		
	J7506	PREDNISONE ORAL		

Category	HCPCS	Title	Category Included in ESRD PPS Base Rate	
			Proposed Rule	Final Rule
	J7507	TACROLIMUS ORAL PER 1 MG		
	J7515	CYCLOSPORINE ORAL 25 MG		
	J7517	MYCOPHENOLATE MOFETIL ORAL		
	J7518	MYCOPHENOLIC ACID ORAL		
	J7520	SIROLIMUS, ORAL		
	J9216	INTERFERON GAMMA 1-B INJ		
	Q4088	IMMUNE GLOBULIN		
	Q4092	IMMUNE GLOBULIN		
Non-ESRD drug	J0150	INJECTION ADENOSINE 6 MG	Yes	No
	J0152	ADENOSINE		
	J0170	ADRENALIN EPINEPHRIN INJECT		
	J0180	INJECTION, AGALSIDASE BETA, 1 MG		
	J0270	ALPROSTADIL FOR INJECTION		
	J0280	AMINOPHYLLIN 250 MG INJ		
	J0282	AMIODARONE HCL		
	J0330	SUCCINYCHOLINE CHLORIDE INJ		
	J0360	HYDRALAZINE HCL INJECTION		
	J0460	ATROPINE SULFATE INJECTION		
	J0475	BACLOFEN 10 MG INJECTION		
	J0583	BIVALIRUDIN		
	J0670	INJ MEPIVACAINE HCL/10 ML		
	J0702	BETAMETHASONE ACET&SOD PHOSP		
	J0706	CAFFEINE CITRATE INJECTION		
	J0735	CLONIDINE HYDROCHLORIDE		
	J0760	COLCHICINE INJECTION		
	J0835	INJ COSYNTROPIN PER 0.25 MG		
	J1040	METHYLPREDNISOLONE 80 MG INJ		
	J1070	TESTOSTERONE CYPIONAT 100 MG		
	J1080	TESTOSTERONE CYPIONAT 200 MG		
	J1100	DEXAMETHASONE SODIUM PHOS		
	J1160	DIGOXIN INJECTION		
	J1165	PHENYTOIN SODIUM INJECTION		
	J1245	DIPYRIDAMOLE INJECTION		
	J1250	INJ DOBUTAMINE HCL/250 MG		
	J1265	DOPAMINE HCL		
	J1410	INJ ESTROGEN CONJUGATE 25 MG		
	J1570	GANCICLOVIR SODIUM INJECTION		
	J1600	GOLD SODIUM THIOMALEATE INJ		
	J1610	GLUCAGON HYDROCHLORIDE/1 MG		
	J1630	HALOPERIDOL INJECTION		
	J1631	HALOPERIDOL DECANOATE INJ		
	J1645	DALTEPARIN SODIUM		
	J1650	INJ ENOXAPARIN SODIUM		
	J1670	TETANUS IMMUNE GLOBULIN INJ		
	J1700	HYDROCORTISONE ACETATE INJ		
	J1720	HYDROCORTISONE SODIUM SUCC I		
	J1730	DIAZOXIDE INJECTION		

Category	HCPCS	Title	Category Included in ESRD PPS Base Rate	
			Proposed Rule	Final Rule
	J1785	INJECTION IMIGLUCERASE /UNIT		
	J1790	DROPERIDOL INJECTION		
	J1815	INSULIN INJECTION		
	J1817	INSULIN FOR INSULIN PUMP USE		
	J1950	LEUPROLIDE ACETATE /3.75 MG		
	J2320	NANDROLONE DECANOATE 50 MG		
	J2321	NANDROLONE DECANOATE 100 MG		
	J2322	NANDROLONE DECANOATE 200 MG		
	J2360	ORPHENADRINE INJECTION		
	J2370	PHENYLEPHRINE HCL INJECTION		
	J2440	PAPAVERIN HCL INJECTION		
	J2515	PENTOBARBITAL SODIUM INJ		
	J2560	PHENOBARBITAL SODIUM INJ		
	J2597	INJ DESMOPRESSIN ACETATE		
	J2710	NEOSTIGMINE METHYLSLFTE INJ		
	J2780	RANITIDINE HYDROCHLORIDE INJ		
	J2794	RISPERIDONE		
	J2910	AUROTHIOGLUCOSE INJECITON		
	J2920	METHYLPREDNISOLONE INJECTION		
	J2930	METHYLPREDNISOLONE INJECTION		
	J3030	SUMATRIPTAN SUCCINATE / 6 MG		
	J3105	TERBUTALINE SULFATE INJ		
	J3120	TESTOSTERONE ENANTHATE INJ		
	J3130	TESTOSTERONE ENANTHATE INJ		
	J3240	THYROTROPIN INJECTION		
	J3301	TRIAMCINOLONE ACETONIDE INJ		
	J3430	VITAMIN K PHYTONADIONE INJ		
	J3487	ZOLEDRONIC ACID		
	J7192	FACTOR VIII RECOMBINANT		
	J7197	ANTITHROMBIN III INJECTION		
	J7611	ALBUTEROL, INHALATION SOLUTION		
	J7613	ALBUTEROL, INHALATION SOLUTION		
	J7614	LEVALBUTEROL, INHALATION SOLUTION		
	J9090	CYCLOPHOSPHAMIDE 500 MG INJ		
	J9310	RITUXIMAB CANCER TREATMENT		
	J9340	THIOTEPA INJECTION		
	Q4084	HYALURONAN OR DERIVATIVE SYNVISC, IA		
Unknown	J3490	DRUGS UNCLASSIFIED INJECTION	Yes	No

[1] Code terminated

Table D: List of Former Part D Drugs National Drug Codes Bundled in the ESRD PPS

Ingredient Name	NDC	Strength	Trade Name
Calcitriol	260530051	0.25 MCG	Calcitriol Capsules
	000540007	0.25 MCG	Calcitriol Capsules
	000930657	0.25MCG	Calcitriol Capsules
	000930658	0.5MCG	Calcitriol Capsules
	001791578	0.25MG	Calcitriol Capsules
	001791603	0.5MCG	Calcitriol Capsules
	004800657	0.25 MCG	Calcitriol Capsules
	004800658	0.5 MCG	Calcitriol Capsules
	110140011	0.25 MCG	Calcitriol Capsules
	142880007	0.25 MCG	Calcitriol Capsules
	178560007	0.25 MCG	Calcitriol Capsules
	548684584	0.25 MCG	Calcitriol Capsules
	551548251	0.25 MCG	Calcitriol Capsules
	647250048	0.25 MG	Calcitriol Capsules
	647250049	0.5 MG	Calcitriol Capsules
	000543120	1 MCG/ML	Calcitriol Oral Solution
	682589030	0.5 MCG	Calcitriol Capsules
	548683461	0.25 MCG	Rocaltrol Capsules
	604910562	0.5 MCG	Rocaltrol Capsules
	000049115	1 MCG/ML	Rocaltrol Oral Solution
	633040241	1 MCG/ML	Calcitriol Oral Solution
Paricalcitol	000744314	2 MCG	Zemplar Capsules
	000744315	4 MCG	
	000744317	1 MCG	
	110140056	2 MCG	
	110140057	4 MCG	
	242360664	1 MCG	
	511294272	1 MCG	
	551540001	1 MCG	
	551546971	1 MCG	
Doxercalciferol	110140017	0.5 MCG	Hectorol Capsules
	110140018	2.5 MCG	
	511293550	2.5 MCG	
	584680120	0.5 MCG	
	584680122	2.0 MCG	
	584680121	2.5 MCG	
Levocarnitine	544800145	1GM/10ML	Carnitor Solution Oral
	544800144	330MG	Carnitor Tablets
	586090144	330MG	Carnitor Tablets
	503830170	1GM/10ML	L Carnitine Solution Oral
	503830171	10%	Levocarnitine Oral Solution
	003745030	1G/10ML	Levocarnitine Oral Solution
	649800503	1G/10ML	Levocarnitine Oral Solution
	649800130	330MG	Levocarnitine Tablets
	647200160	330MG	Levocarnitine Tablets

Table E: ICD-9 CM Codes Recognized for a Co-morbidity Payment Adjustment

Bacterial Pneumonia	
ICD-9-CM	**Descriptor**
00322	Salmonella pneumonia
4820	Pneumonia due to Klebsiella pneumnoniae
4821	Pneumonia due to Pseudomonas
4822	Pneumonia due to Hemophilus influenzae
48230	Pneumonia due to Streptococcus, unspecified
48231	Pneumonia due to Streptococcus, Group A
48232	Pneumonia due to Streptococcus, Group B
48239	Pneumonia due to Streptococcus, other Streptococcus
48240	Pneumonia due to Staphylococcus, unspecified
48241	Methicillin susceptible pneumonia due to Staphylococcus aureus
48242	Methicillin resistant pneumonia due to Staphylococcus aureus
48249	Other Staphylococcus pneumonia
48281	Pneumonia due to Anaerobes
48282	Pneumonia due to Escherichia coli (E. coli)
48283	Pneumonia due to other gram-negative bacteria
48284	Pneumonia due to Legionnaires' disease
48289	Pneumonia due to other specified bacteria
5070	Pneumonitis due to inhalation of food or vomitus
5078	Pneumonitis due to other solids and liquids
5100	Empyema, with fistula
5109	Empyema. without mention of fistula
5130	Abscess of lung

Gastrointestinal Bleeding	
ICD-9-CM	**Descriptor**
53021	Ulcer of esophagus with bleeding
53100	Acute gastric ulcer with hemorrhage without mention of obstruction
53101	Acute gastric ulcer with hemorrhage with obstruction
53120	Acute gastric ulcer with hemorrhage and perforation without obstruction
53121	Acute gastric ulcer with hemorrhage and perforation with obstruction
53140	Chronic or unspecified gastric ulcer with hemorrhage without mention of obstruction
53141	Chronic or unspecified gastric ulcer with hemorrhage with obstruction
53160	Chronic or unspecified gastric ulcer with hemorrhage and perforation without mention of obstruction
53161	Chronic or unspecified gastric ulcer with hemorrhage and perforation with obstruction
53200	Acute duodenal ulcer with hemorrhage without mention of obstruction
53201	Acute duodenal ulcer with hemorrhage with obstruction
53220	Acute duodenal ulcer with hemorrhage and perforation without mention of obstruction
53221	Acute duodenal ulcer with hemorrhage and perforation with obstruction
53240	Chronic or unspecified duodenal ulcer with hemorrhage without mention of obstruction
53241	Chronic or unspecified duodenal ulcer with hemorrhage with obstruction
53260	Chronic or unspecified duodenal ulcer with hemorrhage and perforation without mention of obstruction
53261	Chronic or unspecified duodenal ulcer with hemorrhage and perforation with obstruction
53300	Acute peptic ulcer with hemorrhage without mention of obstruction
53301	Acute peptic ulcer with hemorrhage with obstruction
53320	Acute peptic ulcer with hemorrhage and perforation without mention of obstruction
53321	Acute peptic ulcer with hemorrhage and perforation with obstruction
53340	Chronic or unspecified peptic ulcer with hemorrhage without mention of obstruction
53341	Chronic or unspecified peptic ulcer with hemorrhage with obstruction
53360	Chronic or unspecified peptic ulcer with hemorrhage and perforation without mention of

	obstruction
53361	Chronic or unspecified peptic ulcer with hemorrhage and perforation with obstruction
53400	Acute gastrojejunal ulcer with hemorrhage without mention of obstruction
53401	Acute gastrojejunal ulcer with hemorrhage with obstruction
53420	Acute gastrojejunal ulcer with hemorrhage and perforation without mention of obstruction
53421	Acute gastrojejunal ulcer with hemorrhage and perforation with obstruction
53440	Chronic or unspecified gastrojejunal ulcer with hemorrhage without mention of obstruction
53441	Chronic or unspecified gastrojejunal ulcer with hemorrhage with obstruction
53460	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation without mention of obstruction
53461	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation with obstruction
53571	Eosinophilic gastritis, with hemorrhage
53783	Angiodysplasia of stomach and duodenum with hemorrhage
56202	Diverticulosis of small intestine with hemorrhage
56203	Diverticulitis of small intestine with hemorrhage
56212	Diverticulosis of colon with hemorrhage
56213	Diverticulitis if colon with hemorrhage
56985	Angiodysplasia of intestine with hemorrhage

Hereditary hemolytic and sickle cell anemia

ICD-9-CM	Descriptor
2820	Hereditary spherocytosis
2821	Hereditary elliptocytosis
2822	Anemias due to disorders of glutathione metabolism
2823	Other hemolytic anemias due to enzyme deficiency
28241	Sickle-cell thalassemia without crisis
28242	Sickle-cell thalassemia with crisis
28249	Other thalassemias
28261	Sickle-cell disease, Hb-SS disease without crisis
28262	Sickle-cell disease, Hb-SS disease with crisis
28263	Sickle-cell disease, Sickle-cell/Hb-C disease without crisis
28264	Sickle-cell disease, Sickle-cell/Hb-C disease with crisis
28268	Sickle-cell disease, Other sickle-cell disease without crisis
28269	Sickle-cell disease, Other sickle-cell disease with crisis

Monoclonal gammopathy (in the absence of multiple myeloma)

ICD-9-CM	Descriptor
2731	Monoclonal paraproteinemia [includes monoclonal gammopathy]

Myelodysplastic syndrome

ICD-9-CM	Descriptor
23871	Essential thrombocythemia
23872	Low grade myelodysplastic syndrome lesions
23873	High grade myelodysplastic syndrome lesions
23874	Myelodysplastic syndrome with 5q deletion
23875	Myelodysplastic syndrome, unspecified
23876	Myelofibrosis with myeloid metaplasia

Pericarditis

ICD-9-CM	Descriptor
4200	Acute pericarditis in diseases classified elsewhere
42090	Other and unspecified pericarditis, acute pericarditis, unspecified
42091	Other and unspecified pericarditis, acute idiopathic paricarditis
42099	Other acute pericarditis

Table F: ESRD-Related Laboratory Tests

CPT/ HCPCS	Short Description
82040	Assay of serum albumin
82108	Assay of aluminum
82306	Vitamin d, 25 hydroxy
82310	Assay of calcium
82330	Assay of calcium, Ionized
82374	Assay, blood carbon dioxide
82379	Assay of carnitine
82435	Assay of blood chloride
82565	Assay of creatinine
82570	Assay of urine creatinine
82575	Creatinine clearance test
82607	Vitamin B-12
82652	Vit d 1, 25-dihydroxy
82668	Assay of erythropoietin
82728	Assay of ferritin
82746	Blood folic acid serum
83540	Assay of iron
83550	Iron binding test
83735	Assay of magnesium
83970	Assay of parathormone
84075	Assay alkaline phosphatase
84100	Assay of phosphorus
84132	Assay of serum potassium
84134	Assay of prealbumin
84155	Assay of protein, serum
84295	Assay of serum sodium
84466	Assay of transferrin
84520	Assay of urea nitrogen
84540	Assay of urine/urea-n
84545	Urea-N clearance test
85014	Hematocrit
85018	Hemoglobin
85025	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count) and automated differential WBC count.
85027	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count)
85041	Automated rbc count

CPT/ HCPCS	Short Description
85044	Manual reticulocyte count
85045	Automated reticulocyte count
85046	Reticyte/hgb concentrate
85048	Automated leukocyte count
86704	Hep b core antibody, total
86705	Hep b core antibody, igm
86706	Hep b surface antibody
87040[1]	Blood culture for bacteria
87070[1]	Culture, bacteria, other
87071[1]	Culture bacteria aerobic othr
87073[1]	Culture bacteria anaerobic
87075[1]	Cultr bacteria, except blood
87076[1]	Culture anaerobe ident, each
87077[1]	Culture aerobic identify
87081[1]	Culture screen only
87340	Hepatitis b surface ag, eia
G0306	CBC/diff wbc w/o platelet
G0307	CBC without platelet

[1] Only ESRD-related when testing is related to the dialysis access site

[FR Doc. 2010–18466 Filed 7–26–10; 4:15 pm]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS–3206–P]

RIN 0938–AP91

Medicare Program; End-Stage Renal Disease Quality Incentive Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to implement a quality incentive program (QIP) for Medicare outpatient end-stage renal disease (ESRD) dialysis providers and facilities with payment consequences beginning January 1, 2012, in accordance with section 1881(h) of the Act (added on July 15, 2008 by section 153(c) of the Medicare Improvements for Patients and Providers Act (MIPPA)). The proposed ESRD QIP would reduce ESRD payments by up to 2.0 percent for dialysis providers and facilities that fail to meet or exceed a total performance score for performance standards established with respect to certain specified measures.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. eastern standard time (EST) on September 24, 2010.

ADDRESSES: In commenting, please refer to file code CMS–3206–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" 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–3206–P, P.O. Box 8010, Baltimore, MD 21244–8010.

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 to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–3206–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 telephone number (410) 786–9994 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. This document does not propose any paperwork requirements in the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lynn Riley, (410) 786–1286.

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 as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Table of Contents

Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

CIP Core Indicators Project
CMS Centers for Medicare & Medicaid Services
CPM Clinical performance measure
CROWNWeb Consolidated Renal Operations in a Web-Enabled Network
DFC Dialysis Facility Compare
DFR Dialysis Facility Report
ESA Erythropoiesis stimulating agent
ESRD End stage renal disease
FDA Food and Drug Administration
Kt/V A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
LDO Large dialysis organization
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
NQF National Quality Forum
PPS Prospective payment system
QIP Quality incentive program

REMIS Renal management information system
RFA Regulatory Flexibility Act
SIMS Standard information management system
SSA Social Security Administration
the Act Social Security Act
URR Urea reduction ratio

I. Background

A. Evolution of Quality Monitoring Initiative

Monitoring the quality of care provided to ESRD patients and provider/facility accountability are important components of the Medicare ESRD payment system and have been priorities for over 30 years. We will describe the evolution of our ESRD quality monitoring initiatives by category below.

1. ESRD Network Organization Program

In the End-Stage Renal Disease Amendments of 1978 (Pub. L. 95–292), Congress required the formation of ESRD Network Organizations to further support the ESRD program. CMS currently contracts with 18 ESRD Networks throughout the United States to perform oversight activities and to assist dialysis providers and facilities in providing appropriate care for their dialysis patients. The Networks' responsibilities include monitoring the quality of care provided to ESRD patients, providing technical assistance to patients who have ESRD and to providers/facilities that treat ESRD patients to assist them in improving care, addressing patient complaints and/or grievances, and emergency preparedness. In 1994, CMS and the ESRD Networks, with input from the renal community, established the ESRD Core Indicators Project (CIP). The ESRD CIP was CMS's first nationwide population-based study designed to assess and identify opportunities to improve the care of patients with ESRD. This project established the first consistent clinical ESRD database. Information in this database included clinical measures thought to be indicative of key components of care provided to individuals who required dialysis. The initial Core Indicators focused on adult hemodialysis patients who received care in dialysis facilities. The Core Indicators included measures related to anemia management, adequacy of hemodialysis, nutritional status and blood pressure control. On March 1, 1999, the ESRD CIP was merged with the ESRD Clinical Performance Measures (CPM) Project (described below).

2. Clinical Performance Measures (CPM) Project

Section 4558(b) of the Balanced Budget Act of 1997 required CMS to develop and implement, by January 1, 2000, a method to measure and report the quality of renal dialysis services furnished under the Medicare program. To implement this legislation, CMS developed the ESRD Clinical Performance Measures (CPM) Project based on the National Kidney Foundation's Dialysis Outcome Quality Initiative (NKF–DOQI) Clinical Practice Guidelines. The purpose of collecting and reporting the ESRD CPMs was to enable us to provide comparative data to ESRD providers/facilities to assist them in assessing and improving the care furnished to ESRD patients.

3. Dialysis Facility Compare (DFC)

Also in response to the Balanced Budget Act of 1997, CMS created Dialysis Facility Compare (DFC) as a new feature on *http://www.medicare.gov* that was modeled after Nursing Home Compare and continues to be used by CMS today. CMS worked with a contractor and a consumer workgroup to identify dialysis facility-specific measures that could be provided to the public for consumer choice and information purposes. This tool was launched in January 2001 on the *http://www.medicare.gov/Dialysis* Web site to provide information to the public for comparing the quality of dialysis facilities across the country, including specific information about services available and the quality of care furnished by a specific dialysis facility/provider. DFC captures administrative and quality related data submitted by dialysis facilities and providers.

The quality measures initially reported on DFC were measures of anemia control, adequacy of hemodialysis treatment and patient survival. Medicare claims data were used to calculate the anemia management and hemodialysis adequacy rates, and administrative data (non-clinically based data such as demographic data, and data acquired from the Social Security Administration (SSA) and obtained from the CMS forms 2728 and 2746) were used to determine patient survival rates. The anemia measure assessed the percentage of Medicare patients receiving an erythropoiesis-stimulating agent (ESA) at a given provider/facility whose anemia (low red blood cell count) was not controlled. More specifically, the anemia measure when DFC was launched in January 2001 assessed the percentage of Medicare patients whose hematocrit levels were at 33 percent (33 percent out of 100 percent) or more (or hemoglobin levels of 11 g/dL or more). Since that time, evidence about increased risk of certain adverse events associated with the use of ESAs, which are used to treat anemia, raised concerns about patients who have hemoglobin levels that are too high, as well as patients whose hemoglobin levels are too low. The Food and Drug Administration (FDA) responded by requiring manufacturers to develop a Medication Guide (*http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm054716.htm*) and to ensure that this information is provided to patients. The labeling guideline for ESAs states "The dosing recommendations for anemic patients with chronic renal failure have been revised to recommend maintaining hemoglobin levels within 10 g/dL to 12 g/dL". As a result of this guideline, in November 2008 DFC was revised to include two anemia measures: one measure shows the percentage of patients whose hemoglobin levels are considered too low (that is, below 10 g/dL), and a second measure shows the percentage of patients whose hemoglobin levels are too high (that is, above 12 g/dL). The dialysis adequacy measure assesses the percentage of in-center hemodialysis Medicare patients treated by the facility who had enough wastes removed from their blood during dialysis. More specifically, the measure is the percentage of Medicare patients with urea reduction ratio (URR) levels of 65 percent or more. The patient survival measure indicates general facility survival as better than expected, as expected, or worse than expected. These measures are updated annually on the DFC Web site, usually at the end of the year, using Medicare claims data from the previous year for the hemodialysis adequacy and anemia measures and Medicare administrative data from the past 4 years for the patient survival measure.

4. ESRD Quality Initiative

In 2004, the ESRD Quality Initiative was launched and continues today. The objective is to stimulate and support significant improvements in the quality of dialysis care. The initiative aims to refine and standardize dialysis care measures, ESRD data definitions, and data transmission to support the needs of the ESRD program; empower patients and consumers by providing access to facility service and quality information; provide quality improvement support to dialysis facilities and providers; assure compliance with conditions of coverage; and build strategic partnerships with

patients, providers/facilities, professionals, and other stakeholders. Components of this Quality Initiative include the DFC, and the CPM Project.

5. ESRD Conditions for Coverage

On April 15, 2008, we published in the **Federal Register**, the updated ESRD Conditions for Coverage final rule, which contains revised requirements that dialysis providers and facilities must meet in order to be approved by Medicare and receive payment (73 FR 20370 April 15, 2008). As part of the revised requirements, dialysis providers and facilities are each required to implement their own quality assessment and performance improvement program. In addition, providers and facilities are required to submit electronically the CPMs developed under the ESRD CPM Project for all Medicare patients on an annual basis. The CPMs were updated and expanded in April 2008. The current CPMs include 26 measures in the areas of anemia management; hemodialysis adequacy; peritoneal dialysis adequacy; mineral metabolism; vascular access; patient education/perception of care/quality of life; and patient survival.

6. CROWNWeb

CMS has developed a new web-based system, Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) for the purposes of electronically collecting information about patients, facilities, providers, and clinical data to support the CPM Project. CROWNWeb supports the mineral metabolism, anemia management, hemodialysis adequacy, peritoneal dialysis adequacy, survival, and type of vascular access CPMs. Use of the CROWNWeb system will increase the efficiency of data collection for both CMS and providers/facilities, improve data quality, and provide a more stable and accessible platform for continual improvements in functionality. In February 2009, for Phase one, we began implementing the CROWNWeb system with a number of providers/facilities testing the system and expanded reporting to additional providers/facilities in July 2009 for Phase two.

During these initial phases, nearly 200 dialysis providers/facilities (representing a cross section of small independent facilities and large dialysis organizations (LDOs)) were selected to enter data into CROWNWeb. These providers/facilities worked closely with CMS, their respective ESRD Networks, and CROWNWeb development and support contractors to understand the requirements of CROWNWeb, and to refine the internal business processes and procedures used to submit data effectively and efficiently into the system.

The successful launch of both Phase One and Phase Two and helpful feedback provided by users has enabled CMS to work on additional upgrades to CROWNWeb that address both the technical and usability elements of the system. We continue to further refine the system as an additional tool for quality improvement.

7. QIP Conceptual Model

On September 29, 2009, we published in the **Federal Register** (74 FR 49922), the ESRD Prospective Payment System (PPS) proposed rule, describing how the Agency proposes to implement the new ESRD PPS in 2011. As part of that proposed rule, we outlined a conceptual model of the initial ESRD QIP design and solicited public comments. We received and reviewed many helpful comments regarding the design of the QIP that contributed to the development of this proposed rule.

B. Statutory Authority for the ESRD QIP

Congress required in section 153 of MIPPA that the Secretary implement an ESRD quality incentive program (QIP). We believe that the QIP is the next step in the evolution of the ESRD quality program because it measures provider/facility performance rather than simply reporting outcomes data.

Specifically, section 1881(h) of the Social Security Act (the Act), as added by section 153(c) of MIPPA, requires the Secretary to develop a QIP that will result in payment reductions to providers of services and dialysis facilities that do not meet or exceed a total performance score with respect to performance standards established for certain specified measures. As provided under this section, the payment reductions, which will be up to 2.0 percent of payments otherwise made to providers and facilities under section 1881(b)(14) of the Act, will apply to payment for renal dialysis services furnished on or after January 1, 2012. The total performance score that providers and facilities must initially meet or exceed in order to receive their full payment in 2012 will be based on a specific performance period prior to this date. Under section 1881(h)(1)(C) of the Act, the payment reduction will only apply with respect to the year involved for a provider/facility and will not be taken into account when computing future payment rates for the impacted provider/facility.

For the ESRD quality incentive program, section 1881(h) of the Act generally requires the Secretary to: (1) Select measures; (2) establish the performance standards that apply to the individual measures; (3) specify a performance period with respect to a year; (4) develop a methodology for assessing the total performance of each provider and facility based on the performance standards with respect to the measures for a performance period; and (5) apply an appropriate payment reduction to providers and facilities that do not meet or exceed the established total performance score.

We view the ESRD QIP required by section 1881(h) of the Act as the next step in the evolution of the ESRD quality program that began more than 30 years ago. Our vision is to implement a robust, comprehensive ESRD QIP that builds on the foundation that has already been established.

C. Selection of the ESRD QIP Measures

As required by section 1881(h)(2)(A)(i) of the Act, we finalized the measures for the initial year of the QIP to include two-anemia management measures that reflect the labeling approved by the Food and Drug Administration (FDA) for the administration of erythropoesis stimulating agents (ESAs), and one-hemodialysis adequacy measure in the Medicare End-Stage Renal Disease Prospective Payment System Final Rule (CMS–1418–F) published on August 12, 2010. The following are the three finalized measures for the initial year of the ESRD QIP:

- Percentage of Medicare patients with an average Hemoglobin <10.0 g/dL
- Percentage of Medicare patients with an average Hemoglobin >12.0 g/dL
- Percentage of Medicare patients with an average Urea Reduction Ratio (URR) >65 percent.

Data for these measures are collected from ESRD claims submitted to CMS for payment purposes. We have publicly reported anemia and adequacy of hemodialysis data on DFC since January 2001. The quality measure selection is limited to these three measures for the first year of the QIP because they are measures for which we already have complete data available to us. We are working to develop additional quality measures that we can adopt for the ESRD QIP in subsequent years.

The ESRD QIP is the first Medicare program that links any provider or facility payments to performance based on outcomes as assessed through specific quality measures. The three measures that we adopted for the initial year of the ESRD QIP are important indicators of patient outcomes because poor management of anemia and inadequate dialysis can lead to

avoidable hospitalizations, decreased quality of life, and death. These measures are at the core of medical management of ESRD patients.

As noted previously, data for these three measures are collected through ESRD claims submitted to CMS. The process used to ensure accuracy of claims coding and measure calculation has been used and refined since our implementation of the DFC. A full description of the methodologies used for the calculation of the measures can be reviewed at: *http://www.dialysisreports.org/pdf/esrd/public/DFRGuide.pdf* under the "Facility Modality, Hemoglobin, and Urea Reduction Ratio" section.

As we have previously stated, we are committed to adding additional quality measures as soon as complete data sources become available to us. For example, we are considering the possibility of adopting measures such as Kt/V, vascular access rates, bone and mineral metabolism, and access infection rates to the ESRD QIP for future years. CMS is committed to further development of quality measures for future years of the QIP in order to better assess the quality of care provided by ESRD facilities.

II. Provisions of the Proposed Rule

A. Overview of the Proposed ESRD QIP

This proposed rule proposes to implement a quality incentive program for Medicare ESRD dialysis providers and facilities with payment reductions beginning January 1, 2012, in accordance with the statutory provisions set forth in section 1881(h) of the Act. This proposed rule was developed based on the conceptual model set forth in the September 29, 2009 proposed rule (74 FR 49922) and on comments received on this model. In general, we propose to calculate individual total performance scores ranging from 0–30 points for providers and facilities based on the three finalized measures. We propose to weigh the total performance score for each provider/facility such that the percentage of Medicare patients with an average Hemoglobin <10 g/dL measure makes up 50 percent of the score, and the other hemoglobin measure and the hemodialysis adequacy measure will each be 25 percent of the score. Providers/facilities that do not meet or exceed a certain total performance score would receive a payment reduction ranging from 0.5 percent to 2.0 percent. We also propose below how we plan to implement the public reporting requirements in section 1881(h)(6) of the Act.

B. Performance Standards for the ESRD QIP Measures

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the QIP for a performance period with respect to a year. Section 1881(h)(4)(B) of the Act provides that the performance standards shall include levels of achievement and improvement, as determined appropriate by the Secretary. However, for the first performance period, we propose to establish a performance standard for the two anemia management and one hemodialysis adequacy measures based on the special rule in section 1881(h)(4)(E) of the Act. This provision requires the Secretary to "initially" use as a performance standard for the anemia management and hemodialysis adequacy measures the lesser of a provider/facility-specific performance rate in the year selected by the Secretary under the second sentence of section 1881(b)(14)(A)(ii) of the Act, or a standard based on the national performance rate for such measures in a period determined by the Secretary. We are not proposing to include in this initial performance standard levels of achievement or improvement because we do not believe that section 1881(h)(4)(E) of the Act requires that we include such levels. In addition, we interpret the term "initially" to apply only to the performance period applicable for payment consequence calendar year 2012. For subsequent performance periods, we plan to propose performance standards under section 1881(h)(4)(A) of the Act. Such standards will include levels of achievement and improvement, as required under section 1881(h)(4)(B) of the Act, and are discussed below in section III.B QIP Changes and Updates.

As stated above, to implement the special rule for the anemia management and hemodialysis adequacy measures, we propose to select as the performance standard the lesser of the performance of a provider or facility on each measure during 2007 (the year selected by the Secretary under the second sentence of section 1881(b)(14)(A)(ii) of the Act, referred to as the base utilization year) or the national performance rates of all providers/facilities for each measure in 2008.

In terms of establishing a performance standard based on national performance rates, we propose to adopt a standard that is equal to the national performance rates of all dialysis providers and facilities based on 2008 data, as calculated and reported on the Dialysis Facility Compare Web site. We propose to use 2008 data because it is the most recent year for which data is publicly available prior to the beginning of the proposed performance period (discussed below). Specifically, the rates for the anemia management and hemodialysis adequacy measures were posted on DFC in November 2009, and are as follows:

- For the anemia management measure (referred to in this proposed rule as "Hemoglobin Less Than 10 g/dL")—the national performance percentage of Medicare patients who have an average hemoglobin value less than 10.0 g/dL: The national performance rate is 2 percent.
- For the anemia management measure (referred to in this NPRM as "Hemoglobin More Than 12 g/dL")—the national performance percentage of Medicare patients who have an average hemoglobin value greater than 12.0 g/dL: The national performance rate is 26 percent.
- For the proposed hemodialysis adequacy measure (referred to in this NPRM as "Hemodialysis Adequacy Measure")—the percentage of Medicare patients who have an average URR level above 65 percent: The national performance rate is 96 percent.

This means that, for the purpose of implementing the special rule for the anemia management and hemodialysis adequacy measures, we propose that the performance standard for each of the three measures for the initial performance period with respect to 2012 payment would be the lesser of (1) the provider/facility-specific rate for each of these measures in 2007, or (2) the 2008 national average rates for each of these measures.

C. Performance Period for the ESRD QIP Measures

Section 1881(h)(4)(D) of the Act requires the Secretary to establish a performance period with respect to a year, and for that performance period to occur prior to the beginning of such year. Because we are required under section 1881(h)(1)(A) of the Act to implement the payment reduction beginning with renal dialysis services furnished on or after January 1, 2012, the first performance period would need to occur prior to that date.

We propose to select all of CY 2010 as the initial performance period for the three finalized measures. We believe that this is the performance period that best balances the need to collect sufficient data, analyze the data, allows us sufficient time to calculate the provider/facility-specific total performance scores, determine whether providers and facilities meet the

performance standards, prepare the pricing files needed to implement applicable payment reductions beginning on January 1, 2012, and allow providers and facilities time to preview their performance scores and inquire about their scores prior to finalizing their scores and making performance data public (discussed in section II.D. of this proposed rule). We emphasize that providers/facilities are already required to submit all the necessary data needed to calculate the measures as part of their Medicare claims, so this proposal will not create any new requirements. We seek public comments about the selection of CY 2010 as the initial performance period.

D. Methodology for Calculating the Total Performance Score for the ESRD QIP Measures

Section 1881(h)(3)(A)(i) of the Act requires the Secretary to develop a methodology for assessing the total performance of each provider and facility based on the performance standards with respect to the measures selected for a performance period. Section 1881(h)(3)(A)(iii) of the Act states that the methodology must also include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement, such as weighting scores to ensure that providers/facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary. In addition, section 1881(h)(3)(B) of the Act requires the Secretary to calculate separate performance scores for each measure. Finally, under section 1881(h)(3)(A)(ii) of the Act, for those providers and facilities that do not meet (or exceed) the total performance score, the Secretary is directed to ensure that the application of the scoring methodology results in an appropriate distribution of reductions in payments to providers and facilities, with providers and facilities achieving the lowest total performance scores receiving the largest reductions.

We propose to calculate the total performance of each provider and facility with respect to the measures we have adopted for the initial performance period by assigning 10 points to each of the three measures. That is, if a provider or facility meets or exceeds the performance standard for one measure, then it would receive 10 points for that measure. We propose to award points on a 0 to 10 point scale because this scale is commonly used in a variety of settings and we believe it can be easily understood by stakeholders. We also believe that the scale provides sufficient variation to show meaningful differences in performance between providers/facilities.

We propose that a provider or facility that does not meet or exceed the initial performance standard for a measure based on its 2010 data would receive fewer than 10 points for that measure, with the exact number of points corresponding to how far below the initial performance standard the provider/facility's actual performance falls. Specifically, we propose to implement a scoring methodology that subtracts 2 points for every 1 percentage point the provider or facility's performance falls below the initial performance standard. For example, if under the special rule, the initial performance standard for a particular provider or facility for the Hemoglobin More Than 12 g/dL is set under section 1881(h)(4)(E)(ii) as the 2008 national average rate (26 percent), then if that provider/facility had 28 percent of Medicare patients with hemoglobin levels greater than 12 g/dL during 2010 (the initial performance period), the provider/facility would receive 6 points for its performance on the measure because 28 percent is 2 percentage points below the performance standard (see Table 1, which also illustrates how the scoring would work if the Hemoglobin Less Than 10 g/dL was set under section 1881(h)(4)(E)(ii) as the 2008 national average rate (2 percent)). However, if the initial performance standard for the provider/facility is set under section 1881(h)(4)(E)(i) as the provider or facility's actual performance during 2007 (for purposes of this example, 30 percent), the provider/facility would receive 10 points for this measure so long as its performance during 2010 (the initial performance period) was not worse than 30 percent (see Table 2, which also illustrates how the scoring would work if the Hemoglobin Less Than 10 g/dL was set under section 1881(h)(4)(E)(i) as the facility's actual performance during 2007 (for purposes of the example, 4 percent)). Tables 3 and 4 illustrate how scores would be assigned for the Hemodialysis Adequacy Measure.

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Table 1. Proposed Scoring Methodology for Anemia Management Measures using National Average Performance Rates in 2008 as the Performance Standard for 2010 Facility-Specific Comparison

	Anemia Management Measures		
	Percentage of Medicare patients whose average hemoglobin levels are less than 10 g/dL		Percentage of Medicare patients whose average hemoglobin levels are greater than 12 g/dL
POINTS	**Percentage**		**Percentage**
10 points	**2 percent or less**		**26 percent or less**
8 points	3 percent		27 percent
6 points	4 percent		28 percent
4 points	5 percent		29 percent
2 points	6 percent		30 percent
0 point	7 percent or more		31 percent or more

Note that the bolded rows show the performance standard for the applicable measure.

Table 2. Proposed Scoring Methodology for Anemia Management Measures using Facility-Specific Rates in 2007 as the Performance Standard and 2010 Facility-Specific Rate for Comparison

	Anemia Management Measures		
	Percentage of Medicare patients whose average hemoglobin levels are less than 10 g/dL		Percentage of Medicare patients whose average hemoglobin levels are greater than 12 g/dL
POINTS	**Percentage**		**Percentage**
	4 percent (Example of a 2007 facility-specific score)		**30 percent (Example of a 2007 facility-specific score)**
10 points	4 percent or less		30 percent or less
8 points	5 percent		31 percent
6 points	6 percent		32 percent
4 points	7 percent		33 percent
2 points	8 percent		34 percent
0 points	9 percent or more		35 percent or more

Table 3. Proposed Scoring Methodology for Hemodialysis Adequacy Measure using National Average Performance Rates in 2008 as the Performance Standard for 2010 Facility-Specific Comparison

POINTS	Hemodialysis Adequacy Measure
	Percentage of Medicare patients whose average URR levels are greater than 65 percent
10 points	**96 percent or more**
8 points	95 percent
6 points	94 percent
4 points	93 percent
2 points	92 percent
0 points	91 percent or less

Table 4. Proposed Scoring Methodology for Hemodialysis Adequacy Measure using Facility-Specific Rates in 2007 as the Performance Standard and 2010 Facility-Specific Rate for Comparison

POINTS	Hemodialysis Adequacy Measure
	Percentage of Medicare patients whose URR levels are greater than 65 percent
	92 Percent (Example of a 2007 facility-specific score)
10 points	92 percent or more
8 points	91 percent
6 points	90 percent
4 points	89 percent
2 points	88 percent
0 points	87 percent or less

We note that our proposed methodology—that is, subtracting 2 points for every 1 percentage point the provider or facility's performance falls below the performance standard—does not take into account the relative variability in performance associated with each measure. For example, based on 2008 data, a 1 percentage point difference under the Hemoglobin Less Than 10 g/dL measure would affect a greater proportion of facilities and providers than a 1 percentage point difference under the Hemoglobin More Than 12 g/dL measure. The table below highlights the variability in performance associated with each measure. (We note that lower scores on the anemia measures reflect better performance.)

Table 5: Variation among finalized ESRD QIP measures in 2008

	Nat'l Average	Median	Mode	Low Range	High Range	1 SD	2 SD	3 SD	25th percentile	50th percentile	75th percentile
Hgb<10	2%	2%	0%	0%	31%	95%	99%	100%	0%	2%	3%
Hgb>12	26%	25%	13%	0%	93%	72%	97%	100%	15%	25%	38%
URR>65	96%	97%	100%	0%	100%	96%	99%	100%	94%	97%	100%

Despite this difference in variability in performance among the measures, we are proposing to apply the straightforward methodology we have described above in a manner that is consistent across all three measures adopted in this rule. In designing the scoring methodology for the first year, CMS wanted to adopt a clear-cut approach (that is, subtracting two points for each percentage point providers and facilities fell below their performance standard) consistent with the conceptual model published in the End-Stage Renal Disease Prospective Payment System Final Rule (CMS–1418–F) on August 12, 2010 in the **Federal Register**. We seek public comment on our proposal to apply the score reductions in this manner, as opposed to a methodology which takes into account the relative variation in performance that exists for each measure.

We recognize that this straightforward approach may not be appropriate in future years of the QIP as we adopt new measures for inclusion in the program that may have a wider variability in performance. Moreover, we may need to reevaluate this approach for the three measures adopted in this rule, depending on how providers and facilities perform in future years on these measures. If this approach is finalized, we will continue to evaluate the applicability and appropriateness of such an approach in future years of the QIP. As we have stated, we want to ensure that the performance measures included in the QIP will result in meaningful quality improvement for patients at both the national and individual facility/provider level. Therefore, we seek comment on potential methodologies that would take into account variation in performance amongst all measures included in the QIP. For example, under one possible methodology, a provider or facility's performance could be awarded 10 points for achieving a higher level of performance (for example, the 90th percentile). The remaining points could then be assigned according to a linear distribution, where a provider/facility might receive 0 points for a lower level of performance (for example, 1 standard deviation below the mean).

In calculating the total performance score, section 1881(h)(3)(A)(iii) of the Act requires the agency to weight the performance scores with respect to individual measures to reflect priorities for quality improvement, such as weighting scores to ensure that providers/facilities have strong incentives to meet or exceed the performance standards. In the development of our conceptual model, we initially considered that the initial scoring method would weight each of the three proposed measures equally. After further examination and based on the public comments received, we propose to give greater weight to the Hemoglobin Less Than 10 g/dL measure. Low hemoglobin levels below 10 g/dL can lead to serious adverse health outcomes for ESRD patients such as increased hospitalizations, need for transfusions, and mortality. Giving more weight to the Hemoglobin Less Than 10 g/dL measure ensures that providers/facilities are incentivized to continue to properly manage and treat anemia. We believe that this is important in light of concerns that have been raised that the new bundled ESRD payment system could improperly incentivize providers/facilities to undertreat patients with anemia by underutilizing ESAs.

Specifically, we propose to weight the Hemoglobin Less Than 10 g/dL measure as 50 percent of the total performance score. The remaining 50 percent of the total performance score would be divided equally between the Hemoglobin More Than 12 g/dL measure and the Hemodialysis Adequacy Measure. When calculating the total performance score for a provider/facility, we would first multiply the score achieved by that provider/facility on each measure (0–10 points) by that measure's assigned weight (.50 or .25). Then we would add each of the three numbers together, resulting in a number (although not necessarily an integer) between 0–10. Lastly, this number would be multiplied by the number of measures (three) and rounded to the nearest integer (if necessary). In rounding, any fractional portion 0.5 or greater would be rounded up to the next integer, while fractional portions less than 0.5 are rounded down. Thus, a score of 27.4 would round to 27, while 27.6 would round to 28.

An example of how the proposed scoring methodology would work follows below. The example assumes that the performance standard for Facility A during the initial performance period is based on the 2008 national average rates under section 1881(h)(4)(E)(ii) of the Act (which are set forth above) (because Facility A's base utilization year results were higher than the 2008 national average) and that Facility A achieves the following results in 2010:

1. Hemoglobin Less Than 10 g/dL: 2 percent.

2. Hemoglobin More Than 12 g/dL: 26 percent.

3. Hemodialysis Adequacy: 93 percent.

The total performance score for Facility A would be 26 points. Facility A would receive 10 points for achieving the 2008 national average rate for the Hemoglobin Less Than 10 g/dL measure (*see* Table 1); 10 points for achieving the 2008 national average rate for the Hemoglobin More Than 12 g/dL measure (*see* Table 1); and 4 points for performing 3 percentage points below the 2008 national average rate for the Hemodialysis Adequacy Measure in 2010. Next, we would multiply each individual measure's score by its assigned weight: $10 \times .5 = 5$; $10 \times .25 = 2.5$; $4 \times .25 = 1$. Then, all three scores would be added together and multiplied by three: $(5 + 2.5 + 1) \times 3 = 25.5$. Finally, we would round Facility A's score to the nearest whole number, resulting in a total performance score of 26 points (see Table 6 below).

Table 6. Proposed Methodology for Calculating the Total Performance Score; Example showing National Performance Rate as the Performance Standard

Measure	2008 National Average Rates	2010 Performance	Score	Weight	Weighted Score
Hemoglobin Less Than 10g/dL	2%	2%	10	0.5	5.0
Hemoglobin More Than 12g/dL	26%	26%	10	0.25	2.5
Hemodialysis Adequacy Measure	96%	93%	4	0.25	1.0
				Subtotal	8.5
				x 3	25.5
	Total Performance Score				**26**

It is important to note that this example assumes that Facility A's facility specific performance in 2007 (the base utilization year) on each of the three measures was better than or equal to the national performance average in 2008. If however, Facility A's performance in 2007 on the Hemodialysis Adequacy Measure had been 92 percent, then its performance standard for that measure would have been set according to section 1881(h)(4)(E)(i), therefore setting a lower performance standard for Facility A (*see* Table 4). In that case, Facility A's score of 93 percent during the performance period would have earned it a score of 10 points, resulting in a total performance score of 30 points (*see* Table 7 below).

Table 7. Proposed Methodology for Calculating the Total Performance Score; Example showing Facility-Specific Performance during 2007 as a Performance Standard

Measure	2007 Performance (Facility-Specific)	2008 National Average Rates	2010 Performance	Score	Weight	Weighted Score
Hemoglobin Less Than 10g/dL	1%	2%	2%	10	0.5	5.0
Hemoglobin More Than 12g/dL	25%	26%	26%	10	0.25	2.5
Hemodialysis Adequacy Measure	92%	96%	93%	10	0.25	2.5
					Subtotal	10.0
					x 3	30.0
	Total Performance Score					**30**

As we stated above, we believe that this proposed weighting methodology will ensure that providers/facilities have the incentive to adequately maintain patients' hemoglobin levels, particularly considering concerns about appropriate ESA use that could arise when the new bundled ESRD payment system is implemented. We believe this proposed weighting methodology is appropriate for the initial year of the QIP. However, consistent with our desire to improve the quality of care provided to ESRD patients, we solicit comments on potential weighting methodologies that could be incorporated to the QIP in future years as new measures are introduced.

As previously discussed, we believe this proposed total performance score methodology is appropriate for the initial performance period in the new ESRD QIP, but recognize that it will be important to monitor and potentially reevaluate this methodology as provider and facility performance changes and as new measures are added in future years of the ESRD QIP. We seek public comments about the proposed scoring methodology for the ESRD QIP.

E. Payment Reductions Using the Total Performance Score

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of reductions in payments among providers and facilities achieving different levels of total performance scores, with providers and facilities achieving the lowest total performance scores receiving the largest reductions.

We propose to implement a sliding scale of payment reductions for payment consequence year 2012, where the minimum total performance score that providers/facilities would need to achieve in order to avoid a payment reduction would be 26 points. Providers/facilities that score between 21–25 points would receive a 0.5 percent payment reduction, between 16–20 points a 1.0 percent payment reduction, between 11–15 points a 1.5 percent payment reduction, and between 0–10 points the full 2.0 percent payment reduction (*see* Table 8). Applying this payment reduction scale to the example of Facility A above, Facility A's total performance score of 26 would result in it receiving no payment reduction.

Table 8. Proposed Payment Reduction Scale

Total Performance Score	Percent of Payment Reduction
26 to 30 Points	0.0 Percent
21 to 25 Points	0.5 Percent
16 to 20 Points	1.0 Percent
11 to 15 Points	1.5 Percent
0 to 10 Points	2.0 Percent

In developing the proposed payment reduction scale, we carefully considered the size of the incentive to providers/facilities to provide high quality care and range of total performance scores to which the payment incentive applies, recognizing that this would be the first year of a new program. Our goal is to avoid situations where small deficiencies in a provider/facility's performance results in a large payment reduction. For example, we want to avoid imposing a large payment reduction on providers/facilities whose performance on one or more measures falls just slightly below the performance standard. At the same time, we want poorly performing providers/facilities to receive a more significant payment reduction. Our analysis suggests that use of payment differentials of 0.5 percent for the total performance score ranges we are proposing differentiates between providers/facilities with fair to good performance and providers/facilities with poor performance. We will consider smaller differentials between payment levels for future years of the QIP, which we believe will further differentiate providers/facilities based on their performance. Additionally, section 1881(h)(1)(A) of the Act requires that the Secretary implement payment reductions of up to 2.0 percent, and section 1881(h)(3)(A)(ii) requires that the application of the total performance score methodology result in an appropriate distribution of reductions in payment among providers/facilities. Consistent with these requirements, we believe that Medicare beneficiaries will be best served if the full 2.0 percent payment reduction is initially applied only to those providers/facilities whose performance falls well below the performance standards. We believe that applying a payment reduction of 2.0 percent to providers/facilities whose performance falls significantly below the performance standards, coupled with applying 0.5 payment differential reductions to providers/facilities based on lesser degrees of performance deficiencies, will incentivize all providers/facilities to improve the quality of their care and avoid a payment reduction the following year. We seek public comments about how the proposed payment reduction scale will incentivize providers/facilities to meet or exceed the performance standards for the first year of the QIP, and whether it is an appropriate standard to use in future years.

In general, ESRD facilities are paid monthly by Medicare for the ESRD services they furnish to a beneficiary even though payment is on a per treatment basis. In finalizing the new bundled payment system starting on January 1, 2011, we elected to continue the practice of paying ESRD facilities monthly for services furnished to a beneficiary in the End-Stage Renal Disease Prospective Payment System Final Rule (CMS–1418–F) published on August 12, 2010.

In keeping with this practice, we propose to apply any payment reduction under the QIP for payment consequence year 2012 to the monthly payment amount received by ESRD facilities and providers. The payment reduction would be applied after any other applicable adjustments to an ESRD facility's payment, including case-mix, wage index, outlier, etc, were made. (This includes providers/facilities being paid a blended amount under the transition and those that had elected to be excluded from the transition and receive its payment amount based entirely on the payment amount under the ESRD PPS.)

Section 1833 of the Act governs payments of benefits for Part B services and the cost sharing amounts for services that are considered medical and other health services. In general, many Part B services are subject to a payment structure that requires beneficiaries to be responsible for a 20 percent co-insurance after the deductible (and Medicare pays 80 percent). With respect

to dialysis services furnished by ESRD facilities to individuals with ESRD, under section 1881(b)(2)(a) of the Act, payment amounts are 80 percent (and 20 percent by the individual).

Under the proposed approach for implementing the QIP payment reductions, the beneficiary co-insurance amount would be 20 percent of the total Medicare ESRD payment, after any payment reductions are applied. To the extent a payment reduction applies, we note that the beneficiary's co-insurance amount would be calculated after applying the proposed payment reduction and would thus lower the co-insurance amount. We seek public comment on the impact of this effect.

We propose to incorporate the statutory requirements of the QIP payment reduction set forth in proposed § 413.177.

F. Public Reporting Requirements

1. Introduction

Section 1881(h)(6)(A) of the Act requires the Secretary to establish procedures for making information regarding performance under the ESRD QIP available to the public, including information on the total performance score (as well as appropriate comparisons of providers and facilities to the national average with respect to such scores) and performance scores for individual measures achieved by each provider and facility. Section 1881(h)(6)(B) further requires that a provider or facility has an opportunity to review the information to be made public with respect to it prior to its publication.

In addition, section 1881(h)(6)(C) of the Act requires the Secretary to provide each provider and facility with a certificate containing its total performance score to post in patient areas within their facility. Finally, section 1881(h)(6)(D) of the Act requires the Secretary to post a list of providers/facilities and performance-score data on a CMS-maintained Web site.

2. Notifying Providers/Facilities of Their QIP Scores

Section 1881(h)(6)(B) of the Act requires CMS to establish procedures that include giving providers/facilities an opportunity to review the information that is to be made public with respect to the provider or facility prior to such data being made public.

CMS currently uses a secure, web-based tool to share confidential, facility-specific quality data with providers, facilities, and select others. Specifically, we provide annual Dialysis Facility Reports (DFRs) to dialysis providers/facilities, ESRD Network Organizations, and State Survey Agencies. The DFRs provide valuable facility-specific and comparative information on patient characteristics, treatment patterns, hospitalizations, mortality, and transplantation patterns. In addition, the DFRs contain actionable practice patterns such as dose of dialysis, vascular access and anemia management. We expect providers and facilities to use the data included in the DFRs as part of their ongoing clinical quality improvement projects.

The information contained in DFRs is sensitive and as such, most of that information is made available through a secure Web site only to that provider/facility and its ESRD Network Organization, State Survey Agency, and the applicable CMS Regional Office. However, select measures based on DFR data are made available to the public through the DFC Web site, which allows Medicare beneficiaries and others to review and compare characteristics and quality information on dialysis providers and facilities in the United States. To allow dialysis providers/facilities a chance to "preview" these data before they are released publicly, we supply draft DFRs to providers/facilities in advance of every annual DFC update. Dialysis providers and facilities are generally provided 30 days to review their facility-specific data and submit comments if the provider/facility has any questions or concerns regarding the report. A provider/facility's comment is evaluated and researched. If a provider/facility makes us aware of an error in any DFR information, a recalculation of the quality measurement results for that provider/facility is conducted, and the revised results are displayed in the DFC Web site.

We propose to use the above-described procedures, including the DFRs framework, to allow dialysis providers/facilities to preview their quality data under the QIP before they are reported publicly. Specifically, the quality data available for preview through the web system will include a provider/facility's performance score (both in total and by individual quality measure) as well as a comparison of how well the provider/facility's performance scores compare to national averages for total performance and individual quality measure performance. We believe that adapting these existing procedures for purposes of the ESRD QIP will create minimum expense and burden for providers/facilities because they will not need to familiarize themselves with a new system or process for obtaining and commenting upon their preview reports. We also note that under these procedures, dialysis providers and facilities would have an opportunity to submit performance score inquiries and to ask questions of CMS data experts about how their performance scores were calculated on a facility-level basis. This performance score inquiry process would also give providers/facilities the opportunity to submit inquiries, including what they believe to be errors in their performance score calculations, prior to the public release of the performance scores. Any provider/facility that submits an inquiry will receive a response.

While we believe that the DFR process is the most logical solution for meeting the data preview requirement at this time, we may decide to revise this approach in the future. Should we decide to make changes, or should we find a more administratively feasible or cost-effective solution, we propose to use sub-regulatory processes to revise our approach for administering the QIP performance score preview process in a way that maintains our compliance with section 1881(h)(6)(B) of the Act. We also propose to use sub-regulatory processes to determine issues such as the length of the preview period and the process we will use to address inquiries received from dialysis providers/facilities during the preview period.

We seek public comments on our proposal to use the DFR process and suggestions for other options that will allow dialysis providers/facilities to preview the information that is to be made public with respect to the provider or facility in advance of such information being made public.

3. Informing the Public Through Facility-Posted Certificates

Section 1881(h)(6)(C) of the Act requires the Secretary to provide certificates to dialysis providers and facilities about their total performance scores under the QIP. This section also requires each provider/facility that receives a QIP certificate to display it prominently in patient areas.

We propose to meet this requirement by providing providers and facilities with an electronic file in a generally accessible format (for example, Microsoft Word and/or Adobe Acrobat). We propose to disseminate these certificates to providers and facilities once per year after the preview period for the QIP performance scores has been completed. We would use a secure, web-based system, similar to the system used to allow facilities to preview their QIP performance scores, to disseminate certificates. The secure web-based

system would allow CMS to transmit performance score certificates to providers/facilities in a secure manner. CMS will make every effort to synchronize the release of the certificates for provider/facility display with the release of performance score information on the Internet.

Under our proposal, each provider/facility would be required to display the certificate no later than 5 business days after CMS sends it. We expect that dialysis providers/facilities would have the capability to download and print their certificates from the secure Web site. We propose that providers/facilities would be prohibited from altering the content of the certificates and that they must print the certificates on plain, blank, white or light-colored paper, no smaller than 8½ inches by 11 inches (a standard-sized document). In addition, providers/facilities may not reduce or otherwise change the font size on the certificate.

Once printed, we propose that each provider/facility must post at least one copy of the certificate prominently in a patient area of the dialysis provider/facility. Specifically, we propose that providers/facilities must post the certificate in a conspicuous place where they post other patient-directed materials so that it is in plain view for all patients (or their parents/guardians or representatives) to inspect. We will update the certificates annually with new performance information, and providers/facilities must post the updated certificate within 5 business days of the day that we transmit it. We expect that providers/facilities will take steps to prevent certificates from being altered, defaced, stolen, marred, or covered by other material. In the event that a certificate is stolen or destroyed while it is posted, providers/facilities would be responsible for replacing the stolen or destroyed certificate with a fresh copy by re-printing the certificate file they have received from CMS. The provider/facility would also be responsible for answering patient questions about the certificate in an understandable manner, taking into account that some patients might have limited English proficiency.

We propose to include on the certificate of each provider/facility all of the information that we are also making available to the public under sections 1881(h)(6)(A) and 1881(h)(6)(D) with respect to the provider/facility. These data elements are:

- The total performance score achieved by the provider/facility under the QIP with respect to the year involved;
- Comparative data that shows how well the provider/facility's total performance score compares to the national total performance score average;
- The performance score that the provider/facility achieved on each individual measure with respect to the year involved; and
- Comparative data that shows how well the provider/facility's individual quality measure performance scores compare to the national performance score average for each quality measure.

We considered several options for making QIP performance score data available via certificates. Regarding the content of the certificates, we considered including not just information for the ESRD QIP-related quality measures, but additional quality measure information that CMS has at its disposal from the DFC Web site that is not related to the QIP, such as risk-adjusted survival information. Ultimately, we determined that an electronic method of disseminating certificates was the easiest way for CMS to deliver certificates directly to providers/facilities because it is the least burdensome and most cost effective way of providing the certificates. We also determined that the information posted on the certificates should be restricted only to QIP information. We believe that limiting the information on the certificate to QIP-specific data will make the certificate easier for Medicare beneficiaries to read and understand.

We seek public comments on how to make the information contained on the certificate as user friendly and easy to understand as possible, and how to make the information available to Medicare beneficiaries who may be unable to read the certificates due to a physical disability or because of limited or no reading proficiency in the English language. We are particularly interested in comments on how we can educate Medicare beneficiaries and their families about the presence of certificates in dialysis providers/facilities and how the information can be used to engage in meaningful conversations with their dialysis caregivers and the clinical community about the quality of America's kidney dialysis care.

Furthermore, we seek public comments on the proposal to use the DFR distribution process to provide the certificates to providers/facilities under section 1881(h)(6)(C) of the Act. Specifically, we seek comments on the feasibility and advisability of using the DFR system to provide the certificates to providers/facilities in a generally available format such as Microsoft Word or Adobe Acrobat.

4. Informing the Public Through Medicare's Web Site

Section 1881(h)(6)(D) of the Act requires the Secretary to use a CMS-maintained Web site for the purpose of establishing a list of dialysis providers/facilities that furnish renal dialysis services to Medicare beneficiaries and that indicates the total performance score and the performance score for individual measures achieved by the provider or facility.

We currently use the DFC Web site (a CMS-maintained Web site) to publish information about the availability of dialysis providers/facilities across the United States, as well as data about how well each of these providers/facilities has performed on existing dialysis-related quality of care measures. DFC is part of a larger suite of "Compare" tools, all of which are available online at *http://www.medicare.gov.* In addition to DFC, CMS hosts Nursing Home Compare, Home Health Compare, and Hospital Compare, as well as tools that allow users to compare prescription drug plans, health plans, and Medigap policies.

DFC links Medicare beneficiaries with detailed information about each of the over 4,700 dialysis providers/facilities approved by Medicare, and allows them to compare providers/facilities in a geographic region. Users can review information about the size of the provider/facility, the types of dialysis offered, the provider/facility's ownership, and whether the provider/facility offers evening treatment shifts. Beneficiaries can also compare dialysis providers/facilities based on three key quality measures—how well patients at a provider/facility have their anemia managed, and how well patients at a provider/facility have waste removed from their blood during dialysis, and whether the patients treated at a provider/facility generally live as long as expected. DFC aims to help beneficiaries decide which dialysis provider/facility would best serve their care needs, as well as to encourage conversations among beneficiaries and their caregivers about the quality of care at dialysis providers/facilities, thus providing an additional incentive for dialysis providers/facilities to improve the quality of care they furnish. Lastly, DFC links beneficiaries to resources that support family members, as well as beneficiary advocacy groups.

Because DFC is a current component of the Medicare suite of Compare tools, we propose to use DFC as the mechanism for meeting the Web-based

public information requirement under section 1881(h)(6)(D) of the Act. DFC is a consumer-focused tool, and the implementation of the QIP will not change this focus. We recognize that sharing information with the public about the QIP is not only a statutory requirement: It is also a function of open and transparent government. Ultimately, the intent of DFC is to provide beneficiaries with the information they need to be able to make proper care choices.

We believe that DFC already provides accurate and trusted information about the characteristics of all Medicare-approved dialysis providers/facilities, as well as information about the quality of care furnished by these providers/facilities. Furthermore, CMS already has the information technology infrastructure in place to support DFC and its public reporting functions; therefore, adding new QIP-related data to the DFC Web site would not create additional significant expenditures or overly burden agency resources.

We propose to update the DFC Web site once per year at a minimum with the following data elements for every provider/facility listed on DFC (that is, every Medicare-approved provider/facility):

- The total performance score achieved by each provider/facility under the QIP with respect to the year involved;
- Comparative data that shows how well the provider/facility's total performance score compares to the national total performance score average;
- Scores for each of the individual measures that comprise the overall QIP performance score for the provider/facility with respect to the year involved; and
- Comparative data that shows how well the provider/facility's individual quality measure performance scores compare to the national performance score average for each quality measure.

We note that this is the same information that we are proposing to include on the certificates that we will provide to providers/facilities. We seek public comments about whether the total performance score and the individual measure performance scores should be integrated into the design of the DFC tool itself or whether we should alternatively implement section 1881(h)(6)(D) by making a file available to the public on the CMS Web site (at *http://www.cms.hhs.gov*). We are sensitive to the need to balance our interest in making QIP performance score information public with our need to provide beneficiaries with easy-to-understand, non-technical information about providers/facilities that they can use to make decisions about where to receive dialysis care.

We also seek public comment on the advisability of using DFC as our mechanism for making QIP information available over the Internet. We also seek comment on the presentation of QIP information on the Web site and the breadth of detail that we should make publicly available regarding QIP performance scores. Lastly, we seek comment on how DFC could be redesigned to make QIP information useful to Medicare beneficiaries as they compare the quality of care available at the nation's Medicare-approved dialysis providers/facilities.

III. Future QIP Considerations

A. Program Monitoring and Evaluation

CMS plans to monitor and evaluate the new ESRD Prospective Payment System (PPS) and QIP as part of our ongoing effort to ensure that Medicare beneficiaries with ESRD receive high quality care. The monitoring will focus on whether, following implementation of the new PPS and the QIP, we observe changes in access to and quality of care, especially within the vulnerable populations. We will be evaluating the effects of the new PPS and the QIP in areas such as:

- Access to care for beneficiaries including categories or subgroups of beneficiaries.
- Changes in care practices that could adversely impact on the quality of care for beneficiaries.
- Patterns of care suggesting particular effects of the new PPS, for example, whether there are increases/decreases in utilization of injectable ESRD drugs and the use of home modalities for certain groups of ESRD beneficiaries.
- Best practices of high-performing providers/facilities that might be adopted by other providers/facilities.

CMS currently collects detailed claims data on patients' hemoglobin levels and adequacy of dialysis, and also collects information on other facets of ESRD care, including treatments provided, drugs, hospitalizations, and deaths. In addition, we collect beneficiary enrollment data which provide important demographic and other information related to Medicare ESRD beneficiaries. These data and other data sources will provide the basis for early examination of overall trends in care delivery, access, and quality. We also will use the data to assess more fully the quality of care furnished to Medicare beneficiaries under the new PPS, and to help inform possible refinements to the PPS and QIP moving forward. We welcome public comments about an approach to monitoring and evaluating the PPS and the QIP.

B. Potential QIP Changes and Updates

As noted above, section 1881(h)(4)(B) of the Act provides that the performance standards established under section 1881(h)(4)(A) shall include levels of achievement and improvement, as determined appropriate by the Secretary. We anticipate that we will propose to adopt performance standards under section 1881(h)(4)(A) of the Act that include levels of achievement and improvement for the 2013 QIP.

In addition, we anticipate strengthening the performance standard for each measure in future years of the QIP, including potentially moving away from using the national performance rate as the performance standard and instead identifying absolute standards that reflect performance goals widely recognized by the ESRD medical community as demonstrating high quality care for ESRD patients. For instance, we may seek to raise the performance standard for each of the three measures finalized for the 2012 QIP above the proposed or finalized level (that is, Hemoglobin Less Than 10 g/dL—2 percent; Hemoglobin More Than 12 g/dL—26 percent; and Hemodialysis Adequacy Measure—96 percent).

Additionally, for these initial three finalized measures, we intend to establish the national performance rates of each of these measures as "floors" such that the performance standards will never be lower than those set for the previous year; even if provider/facility performance—and therefore the national performance rate—fails to improve, or even declines, over time, the performance standard to which facilities and providers will be held for these measures will not be reduced from one year to the next. This will better ensure that the quality of ESRD patient care will continue to improve over time. Establishing such floors for performance standards, however, will in no way prohibit the Secretary from establishing performance standards that are higher than the floors if the Secretary determines that higher performance standards are appropriate.

In establishing new measures for the QIP in future years, we intend that the concept of "floors" described above would be established for each new measure and applied to these new measures in order to better ensure improvement in quality of care, once we have a historical perspective on how the

measure performs. While we will consider use of national performance rates, we also will take into consideration future performance measures that reflect performance goals widely recognized by the ESRD medical community as demonstrating high quality care for ESRD patients, should such a consensus be reached.

As noted above, section 1881(h)(2)(A) of the Act also requires that the measures include, to the extent feasible, measures on patient satisfaction, as well as such other measures that the Secretary specifies, including iron management, bone mineral metabolism (i.e. for calcium and phosphorus), and vascular access. CMS is currently developing measures in each of the areas specified in section 1881(h)(2)(A) of the Act and is also developing additional measures such as Kt/V, access infection rate, fluid weight management, and pediatric measures. As part of the process of developing these new measures, where necessary data are not currently being collected, we intend to require providers to submit data needed to establish a baseline for each of the measures under consideration, as listed above, as soon as is practicable. For most measures, CMS will use a collection process that has been determined appropriate by the Secretary to obtain this data. For collection of calcium and phosphorus levels, however, we intend to collect information on facility and provider ESRD claims as soon as practicable. Additional detail on submission of the calcium and phosphorus levels will be provided as soon as it is available. We anticipate proposing additional measures, such as those listed above under section 1881(h)(2)(A) of the Act, in future rulemaking for the QIP.

We seek public comments on how we might best incorporate both improvement and achievement standards as specified by the Act. We also seek comments on performance standards for future years of the QIP. We are committed to adopting additional quality measures for the QIP as soon is practicable. While we are evaluating measures for inclusion in future years of the QIP, we also seek public comment on setting performance standards for the first year a new measure is included in the QIP.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Section VIII.C. of the preamble of this proposed rule discusses a disclosure requirement. As stated earlier in the preamble, section 1881(h)(6)(C) of the Act requires the Secretary to provide certificates to dialysis care providers and facilities about their total performance scores under the QIP. This section also requires each provider and facility that receives a QIP certificate to display it prominently in patient areas.

To comply with this requirement, CMS will be issuing QIP certificates to providers and facilities via a generally accessible electronic file format. We propose that each provider and facility would prominently display the QIP certificate in patient areas. In addition, we propose that each provider and facility will take the necessary measures to ensure the security of the certificate in the patient areas. Finally, we propose that each provider/facility would have staff available to answer questions about the certificate in an understandable manner, taking into account that some patients might have limited English proficiency.

The burden associated with the aforementioned requirements is the time and effort necessary for providers and facilities to print the QIP certificates, display the certificate prominently in patient areas, ensure the safety of the certificate, and respond to patient inquiries in reference to the certificates. We estimate that 4,311 providers and facilities will receive QIP certificates and will be required to display them. We also estimate that it will take each provider or facility 10 minutes to print, prominently display and secure the QIP certificate, for a total estimated annual burden of 719 hours. We estimate that approximately one-third of ESRD patients will ask a question about the QIP certificate. We further estimate that it will take each provider/facility 5 minutes to answer each patient question about the QIP certificate, or 1.65 hours per provider or facility each year. The total estimated annual burden associated with this requirement is 7,121 hours. The total estimated annual burden for both displaying the QIP certificates and answering patient questions about the certificates is 7,839 hours. While the total estimated annual burden associated with both of these requirements as discussed is 7,839 hours, we do not believe that there will be a significant cost associated with these requirements because we are not requiring facilities to complete new forms. As discussed in Section VI. of the preamble of this proposed rule, we estimate that the total cost for all ESRD facilities to comply with the collection of information requirements would be less than $200,000.

If you wish to 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–3206–P].

Fax: (202) 395–6974; or

E-mail: *OIRA_submission@omb.eop.gov.*

V. 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 preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review, 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 (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 Order 12866 directs 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). As explained in the analysis that follows, we have determined that this proposed rule is not economically significant since it does not have effects of $100 million or more. Furthermore, it is not considered a major rule under the Congressional Review Act.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers or facilities are small entities, either by nature of their nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. Based on our review of 2007–2008 DFC quality performance data, we estimate that approximately 19 percent of ESRD facilities are small entities according to the Small Business Administration's (SBA) size standard of those dialysis facilities having total revenues of $34.5 million or less in any one year, and that 19 percent of dialysis facilities are nonprofit organizations. For more information on SBA's size standards, see the SBA Web site at *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf.* (Kidney Dialysis Centers are listed as North American Industry Classification System (NAICS) Code 621492 with a size standard of $34.5 million.)

Using DFC performance data based on Medicare claims from 2007 and 2008, we consider the 802 independent facilities and hospital-based facilities to be small entities. The ESRD facilities that are owned and operated by a Large Dialysis Organization (LDO) and/or regional chain, comprising approximately 3,509 facilities, would have total revenues in excess of $34.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain). Table 9 below shows the estimated impact of the QIP on small entities for payment consequence year 2012. The distribution of ESRD providers/facilities by facility size (both among facilities considered to be small entities for purposes of this analysis and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities).

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Table 9. Impact of Proposed QIP Payment Reductions to ESRD Facilities for CY 2012 Includes estimated impact on small entities for Regulatory Flexibility Act (RFA) analysis)

Facility type	Number of facilities	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	4,311	1,106	-0.19%
Type:			
Freestanding	3,916	977	-0.18%
Hospital Based	167	47	-0.25%
Unknown[1]	228	82	-0.30%
Facility Size:[2]			
Small entities	802	252	-0.27%
Large entities	3,509	854	-0.17%
Urban/Rural status:			
Urban	3,159	788	-0.19%
Rural	924	236	-0.18%
Unknown[3]	228	82	-0.30%
Geographic Region:			
Northeast	652	182	-0.22%
South	2,048	521	-0.18%
Midwest	871	237	-0.22%
West	705	158	-0.16%
Other[4]	35	8	-0.23%
Facility Size (# of treatments):			
Less than 3,000 treatments	261	77	-0.28%
3,000-9,999 treatments	2,566	675	-0.20%
Over 10,000 treatments	1,484	354	-0.18%

[1] Based on DFC self-reported status.
[2] "Small entities" include hospital-based facilities and non-chain facilities based on DFC self-reported status.
[3] Based on DFC self-reported status.
[4] Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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SOURCE: Analysis of DFC/Medicare claims data (2007–2008) for ESRD providers/facilities reporting data on all three measures.

We note that guidance issued by the Department of Health and Human Services interpreting the RFA considers effects to be economically significant if they reach a threshold of 3 to 5 percent or more of total revenue or total costs.

Under the proposed rule, the maximum payment reduction applied to providers/facilities, regardless of its size, is 2.0 percent of aggregate Medicare payments for dialysis services. This falls below the 3.0 percent threshold for economic significance established by HHS. To further ascertain the impact on small entities for purposes of the RFA, we projected provider/facility performance based on DFC performance data from 2007 and 2008. For the 2012 QIP, of the 1,106 ESRD facilities expected to receive a payment reduction, 252 small entities would be expected to receive a payment reduction (ranging from 0.5 percent up to 2.0 of total payments). We expect payment reductions received would average approximately $18,000 per facility, regardless of facility size. Using our projections of provider/facility performance, we next estimated the impact of expected payment reductions on small entities by comparing the total payment reduction for the 252 small entities expected to receive a payment reduction with aggregate ESRD payments to all small entities. For the entire group of 802 small entities, a minor decrease of 0.27 percent in aggregate ESRD payments is observed.

Therefore, we are not preparing an initial analysis for the RFA because the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the 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 for Medicare payment regulations and has fewer than 100 beds. We do not believe this proposed rule has a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. Therefore, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 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. In 2010, that threshold is approximately $135 million. This rule will not have a consequential effect on State, local, or tribal governments in the aggregate, or by the private sector of $135 million.

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 requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

B. Anticipated Effects

This proposed rule is intended to mitigate possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries as a result of payment changes under the ESRD PPS by implementing a quality incentive program (QIP) that would reduce ESRD payments by up to 2 percent to dialysis providers/facilities that fail to meet or exceed a total performance score with respect to performance standards established by the Secretary with respect to certain specified measures. The methodology that we are proposing to determine a provider/facility's performance score is described in section VI (Methodology for Calculating the Total Performance Score for the ESRD QIP Measures). Any reductions in ESRD payment would begin on January 1, 2012 for services furnished on or after January 1, 2012.

The End-Stage Renal Disease Prospective Payment System Final Rule (CMS–1418–F) published on August 12, 2010 estimates payments to ESRD facilities in 2012 to be $8.5 billion. The calculations used to determine the impact of this proposed rule reveal that approximately 27 percent or 1,106 ESRD dialysis facilities would likely receive some kind of payment reduction for 2012. Again using DFC/Medicare claims data from 2007–2008, Table 10 shows the overall estimated distribution of payment reductions resulting from the 2012 QIP.

Table 10. Estimated Distribution of CY 2012 ESRD QIP Payment Reductions.

Payment Reduction	Number of ESRD Facilities
No Payment Reduction	3,205
0.5% Payment Reduction	709
1.0% Payment Reduction	183
1.5% Payment Reduction	184
2.0% Payment Reduction	30

To estimate the total payment reductions in 2012 resulting from the proposed rule for each facility, we multiplied the number of patients treated at each facility receiving a reduction times an average of three treatments per week. We then multiplied this product by a base rate of $229.63 per dialysis treatment (before an adjustor is applied) to arrive at a total ESRD payment for each facility:

((Number of patients treated at each facility × 3 treatments per week) × base rate)

Finally, we applied the estimated payment reduction percentage expected under the QIP, yielding a total payment reduction amount for each facility:

(Total ESRD payment estimated payment reduction percentage)

Totaling all of the payment reductions for each of the 1,106 facilities expected to receive a reduction leads to a total payment reduction of approximately $17.3 million for payment consequence year 2012. Further, we estimate that the total costs associated with the collection

of information requirements described in Section IV. of the preamble of this proposed rule would be less than $200,000 for all ESRD facilities. As a result, the estimated aggregate $17.5 million impact for 2012 does not reach the $100 million threshold for an economically significant rule.

C. Alternatives Considered

As stated above, this proposed rule proposes to implement a QIP for Medicare ESRD dialysis providers and facilities with payment reductions beginning January 1, 2012. Under section 1881(h) of the Act, after selecting measures, establishing performance standards that apply to each of the measures, specifying a performance period, and developing a methodology for assessing the total performance of each provider and facility based on the specified performance standards, the Secretary is required to apply an appropriate reduction to ESRD providers and facilities that do not meet or exceed the established total performance score. In developing the proposed QIP, we carefully considered the size of the incentive to providers and facilities to provide high-quality care. We also selected the measures adopted for the 2012 ESRD QIP because these measures are important indicators of patient outcomes and quality of care. Poor management of anemia and inadequate dialysis, for example, can lead to avoidable hospitalizations, decreased quality of life, and death. Thus, we believe the measures selected will allow CMS to continue focusing on improving the quality of care that Medicare beneficiaries receive from ESRD dialysis providers and facilities.

We considered alternatives for identifying the performance standard, including the mean, median, and mode. However, we determined that the national average would be appropriate for the first payment year for the reasons listed below:

- CMS believes that the legislative intent was to set the performance standard at the "average", as this is the performance standard that has been publicly reported on the Dialysis Facility Compare Web site (DFC) for the past ten years and was the standard in effect when the language was crafted;
- Recognizing however that there was some flexibility, CMS reviewed other possible standards and noted that there was little difference in the range of performance, with the exception of performance for Hemoglobin More Than 12 (Hgb <10–0%–3%; Hgb >12–8%–38%; URR 94%–100%). As the bundled payment will likely reverse the incentive that may be leading to the wider range for the Hgb>12, the differences in the performance did not warrant moving from the use of a national average for performance.
- CMS has seen great improvement in the rates for these measures over the past several years in part due to public reporting and continuous oversight and monitoring. The rate for Hemoglobin Less Than 10 has improved and maintained improvement, while Hemoglobin More Than 12 improved from 44% in 2007 to 26% in 2008 as demonstrated below. Should it become evident that the rates begin to move in the wrong direction due to the bundled payment, different performance standards can be proposed through future rulemaking. For example, if the national average for Hemoglobin Less Than 10 began to drop, CMS could propose to require a rate of 2% or less regardless of the national average;
- The national average was also selected because of the rapid implementation date for the first year and because the period of performance for the first payment year has already begun. We anticipate the final rule will be published near the end of the performance period. Therefore, introduction of a new performance standard after the period of performance has nearly ended was not appropriate.

We also considered alternatives for applying payment reductions. Our main alternatives considered varying point reductions based on each 1 percentage point a facility or provider was below the performance standard. We did not propose alternatives that applied payment reductions that accounted for the variability seen within each measure, and as noted above, we ask for public comment on such alternatives.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services propose to amend 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395(g), 1395I(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–113 (133 stat. 1501A–332).

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services and Organ Procurement Costs

2. Section 413.177 is added to subpart H to read as follows:

§ 413.177 Quality Incentive Program Payment.

(a) With respect to renal dialysis services as defined under § 413.171 of this part, in the case of a provider of services or a renal dialysis facility that does not meet the performance requirements described in section 1881(h)(1)(B) of the Act for the performance year, payments otherwise made to the provider or facility under this subpart for renal dialysis services will be reduced by up to 2.0 percent, as determined appropriate by the Secretary.

(b) Any payment reduction will apply only to services provided in the payment year involved and will not be taken into account in computing the single payment amount under this subpart for services provided in a subsequent payment year.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 18, 2010.

Marilyn Tavenner,

Acting Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

Approved: July 19, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–18465 Filed 7–26–10; 4:15 pm]

BILLING CODE 4120–01–P

Federal Register

Thursday,
August 12, 2010

Part III

Securities and Exchange Commission

17 CFR Parts 275 and 279
Amendments to Form ADV; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 275 and 279

[Release No. IA–3060; File No. S7–10–00]

RIN 3235–AI17

Amendments to Form ADV

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission is adopting amendments to Part 2 of Form ADV, and related rules under the Investment Advisers Act, to require investment advisers registered with us to provide new and prospective clients with a brochure and brochure supplements written in plain English. These amendments are designed to provide new and prospective advisory clients with clearly written, meaningful, current disclosure of the business practices, conflicts of interest and background of the investment adviser and its advisory personnel. Advisers must file their brochures with us electronically and we will make them available to the public through our Web site. The Commission also is withdrawing the Advisers Act rule requiring advisers to disclose certain disciplinary and financial information.

DATES: *Effective Date:* October 12, 2010. *Compliance Dates:* See Section V of this release.

FOR FURTHER INFORMATION CONTACT: Vivien Liu, Senior Counsel, Don L. Evans, Senior Counsel, Daniel S. Kahl, Branch Chief, or Sarah A. Bessin, Assistant Director, at (202) 551–6787 or *IArules@sec.gov,* Office of Investment Adviser Regulation, Division of Investment Management, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–8549.

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission ("Commission" or "SEC") is adopting amendments to rules 203–1, 204–1, 204–2, and 204–3 [17 CFR 275.203–1, 275.204–1, 275.204–2, and 275.204–3] under the Investment Advisers Act of 1940 [15 U.S.C. 80b] ("Advisers Act" or "Act");[1] and amendments to Form ADV [17 CFR 279.1] under the Advisers Act. The Commission also is withdrawing rule 206(4)–4 [17 CFR 275.206(4)–4] under the Advisers Act.

Table of Contents

I. Introduction

Investment advisers provide a wide range of advisory services and play an important role in helping individuals and institutions make significant financial decisions. From individuals and families seeking to plan for retirement or save for college to large institutions managing billions of dollars, clients seek the services of investment advisers to help them evaluate their investment needs, plan for their future, develop and implement investment strategies, and cope with the ever-growing complexities of the financial markets. Today, the more than 11,000 advisers registered with us manage more than $38 trillion for more than 14 million clients.[2]

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 subrogate clients' interests to its own.[3] 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.[4] A client may use this disclosure to select his or her own adviser and evaluate the adviser's business practices and conflicts on an ongoing basis. As a result, the disclosure clients and prospective clients receive is critical to their ability to make an informed decision about whether to engage an adviser and, having engaged the adviser, to manage that relationship.

To allow clients and prospective clients to evaluate the risks associated with a particular investment adviser, its business practices, and its investment strategies, it is essential that clients and prospective clients have clear disclosure that they are likely to read and understand. For example, such disclosure could enable a prospective client to screen advisers based on disciplinary history, financial industry affiliations or compensation methods. Such screening would allow clients to avoid advisers with a disciplinary history, should they wish to do so. Clients also would be able to choose advisers based on affiliations and compensation methods; in some cases, the client may not be comfortable with the conflicts of interest that those affiliations and compensation methods create, while other clients may value an advisory relationship that allows for broader access to other financial services and may seek an adviser with financial industry affiliates. A prospective client may seek modifications to an investment advisory agreement to better protect the client against an investment adviser's potential conflict of interest, either by better aligning the adviser's interest with that of the client or by prohibiting a particular practice in the client's account. If an adviser is unwilling to make such modifications, a prospective client may select a different adviser.

Since 1979, the Commission has required each adviser registered with us to deliver a written disclosure statement to clients pursuant to rule 204–3 under the Advisers Act.[5] An investment adviser may use this client disclosure statement to satisfy its disclosure

[1] Unless otherwise noted, when we refer to rule 203–1, 204–1, 204–2, or 204–3, or any paragraph of these rules, we are referring to 17 CFR 275.203–1, 275.204–1, 275.204–2, or 275.204–3, respectively, of the Code of Federal Regulations in which these rules are published.

[2] These figures are based on data derived from investment advisers' responses to questions on Part 1A of Form ADV reported through the Investment Adviser Registration Depository ("IARD") as of May 3, 2010. We note that these figures will change due to the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[3] Proxy Voting by Investment Advisers, Investment Advisers Act Release No. IA–2106 (Jan. 31, 2003) [68 FR 6585 (Feb. 7, 2003)] ("Proxy Voting Release").

[4] See *SEC* v. *Capital Gains Research Bureau, Inc.,* 375 U.S. 180 (1963); In the Matter of Arleen W. Hughes, Exchange Act Release No. 4048 (Feb. 18, 1948).

[5] Advisers use Form ADV to apply for registration with us (Part 1A) or with state securities authorities (Part 1B), and must keep it current by filing periodic amendments as long as they are registered. See rules 203–1 and 204–1. Form ADV has two parts. Part 1(A and B) of Form ADV provides regulators with information to process registrations and to manage their regulatory and examination programs. Part 2A contains the requirements for the disclosure "brochure" that advisers must provide to prospective clients initially and to existing clients annually, and Part 2B contains information about the advisory personnel providing clients with investment advice. Prior to the amendments we are adopting today, Part 2 was designated as "Part II."

obligations as a fiduciary.[6] Part 2 of Form ADV sets out minimum requirements for this disclosure statement to clients, which is commonly referred to as the "brochure."[7]

In the past, Part 2 has required advisers to respond to a series of multiple-choice and fill-in-the-blank questions organized in a "check-the-box" format, supplemented in some cases with brief narrative responses. Advisers have had the option of providing information required by Part 2 in an entirely narrative format, but few have done so.

In 2008, we proposed a different approach to enhance the disclosure statement advisers provide to their clients.[8] Instead of the check-the-box format, each adviser registered with us would provide clients with a narrative plain English brochure that describes the adviser's business, conflicts of interest, disciplinary history, and other important information that would help clients make an informed decision about whether to hire or retain that adviser. Our proposal was designed to require advisers to disclose meaningful information in a clearer format.[9] In addition, we proposed that advisers be required to file their brochures with us electronically so that we could make them available to the public on our Web site.[10]

We received 81 letters commenting on the Proposing Release.[11] Commenters agreed with our proposal to move to a narrative brochure,[12] although many suggested modifications to certain requirements.[13] After careful consideration of these comment letters, we are adopting amendments to Part 2 of Form ADV and related rules under the Advisers Act. In light of our adoption of Part 2, we also are withdrawing rule 206(4)–4, which separately required advisers to disclose to clients certain financial and disciplinary information, because our amendments render that rule largely duplicative.

II. Discussion of Form ADV, Part 2

The revised Part 2 requirements that we are adopting today include two sub-parts, Part 2A and Part 2B.[14] Part 2A contains 18 disclosure items about the advisory firm that must be included in an adviser's brochure. We refer to Part 2B as the "brochure supplement," which includes information about certain advisory personnel on whom clients rely for investment advice. In this section, we discuss our amendments relating to each of these sub-parts, which are addressed separately because they are subject to differing content, updating and delivery requirements.

A. Part 2A: Brochure Format and Content

1. Format

We are adopting a requirement that investment advisers registered with us provide prospective and existing clients with a narrative brochure written in plain English.[15] Commenters supported use of a narrative format.[16] For example, one commenter stated that "the current check-the-box format does not always result in clear and meaningful client disclosure and it presents challenges for advisers in identifying and presenting all of the types of information that should be addressed in Part 2."[17] Another commenter expressed the view that "the flexibility of a narrative format should result in clearer and more meaningful disclosures that make relevant information readily accessible to prospects and clients."[18] We believe these amendments will greatly improve the ability of clients and prospective clients to evaluate firms offering advisory services and the firms' personnel, and to understand relevant conflicts of interest that the firms and their personnel face and their potential effect on the firms' services.

We have added an instruction to Part 2 of Form ADV to require that an adviser provide the information in a specified format.[19] We are persuaded by commenters that this format for items in the brochure will facilitate investors' comparison of multiple advisers and are adopting this requirement.[20] An adviser

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[6] See Investment Adviser Requirements Concerning Disclosure, Recordkeeping, Applications for Registration and Annual Filings, Investment Advisers Act Release No. 664 (Jan. 30, 1979) [44 FR 7870 (Feb. 7, 1979)] ("1979 Adopting Release").

[7] Items in Part 2 of Form ADV may not address all conflicts an adviser may have, and may not identify all material disclosure that an adviser may be required to provide clients. As a result, delivering a brochure prepared under Form ADV's requirements may not fully satisfy an adviser's disclosure obligations under the Advisers Act. See Instruction 3 of General Instructions for Part 2 of Form ADV; rule 204–3(f).

[8] Amendments to Form ADV, Investment Advisers Act Release No. 2711 (Mar. 3, 2008) [73 FR 13958 (Mar. 14, 2008)] ("Proposing Release").

[9] See Proposing Release, supra note 8 at n.6 and accompanying text.

[10] Id. at Section II.A.3.

[11] Comment letters submitted in File No. S7–10–00 are available on the Commission's Web site at: *http://www.sec.gov/rules/proposed/s71000.shtml*.

[12] See, e.g., comment letter of the American Bar Association, Section of Business Law, Committee on Federal Regulation of Securities and Committee on State Regulation of Securities (June 18, 2008) ("ABA Committees Letter"); comment letter of the Consumer Federation of America (July 2, 2008) ("Consumer Federation Letter"); comment letter of Citigroup Global Markets Inc. (May 16, 2008) ("CGMI Letter"); comment letter of Fried, Frank, Harris, Shriver & Jacobson LLP (May 2, 2008) ("Fried Frank Letter"); comment letter of the Investment Adviser Association (May 16, 2008) ("IAA Letter"); comment letter of the Investment Company Institute (May 16, 2008) ("ICI Letter").

[13] See, e.g., comment letter of Alternative Investment Compliance Association (May 16, 2008) ("AICA Letter"); comment letter of Capital Institutional Services, Inc. (May 16, 2008) ("CAPIS Letter"); comment letter of Shaun Eddy (May 9, 2008) ("Eddy Letter"); comment letter of the Financial Planning Association (May 16, 2008) ("FPA Letter"); Fried Frank Letter; IAA Letter; ICI Letter; comment letter of Janus Capital Management LLC (May 16, 2008) ("Janus Letter"); comment letter of Nancy Lininger (May 18, 2008) ("Lininger Letter"); comment letter of the National Association of Personal Financial Advisers (June 4, 2008) ("NAPFA Letter"); comment letter of National Compliance Services, Inc. (May 9, 2008) ("NCS Letter"); comment letter of National Regulatory Services (May 16, 2008) ("NRS Letter"); comment letter of L. A. Schnase (May 9, 2008) ("Schnase Letter"); comment letter of Sidley Austin LLP (May 23, 2008) ("Sidley Letter"); comment letter of USAA Investment Management Company/USAA Financial Planning Services Insurance Agency, Inc. (May 16, 2008) ("USAA Letter"); comment letter of Wellington Management Company, LLP (May 15, 2008) ("Wellington Letter").

[14] Part 2 is a uniform form used by investment advisers registered with both the Commission and the state securities authorities. See Instruction 5 of General Instructions for Form ADV. This Release discusses the Commission's adoption of Form ADV and related rules applicable to advisers registered with the Commission. Form ADV is also used by state securities regulators to register investment advisers. It includes certain items and instructions to Part 2 (e.g., Item 19 of Part 2A, Item 10 of Appendix 1 to Part 2A, and Item 7 of Part 2B) that apply only to state-registered advisers. State-registered advisers are required by state, rather than federal, law to respond to these items. Completion of these items, therefore, is not an SEC requirement, and these items are not included in this Release as an SEC rule.

[15] See Instructions 1 and 2 of General Instructions for Part 2 of Form ADV. In many instances where we refer to "client" in this release we are referring to both an existing and prospective client.

[16] See ABA Committees Letter; comment letter of the American Institute of Certified Public Accountants (May 20, 2008) ("AICPA Letter"); CAPIS Letter; Consumer Federation Letter; CGMI Letter; Fried Frank Letter; IAA Letter; ICI Letter; Janus Letter; comment letter of Merrill Lynch, Pierce, Fenner & Smith, Incorporated (May 16, 2008) ("Merrill Lynch Letter"); comment letter of the Money Management Institute (May 16, 2008) ("MMI Letter"); comment letter of Morgan Stanley & Co. Incorporated (May 16, 2008) ("Morgan Stanley Letter"); NAPFA Letter; comment letter of the North American Securities Administrators Association, Inc. (May 16, 2008) ("NASAA Letter"); NRS Letter; comment letter of the National Society of Compliance Professionals Inc. (May 16, 2008) ("NSCP Letter"); comment letter of Charles Schwab & Co. and Charles Schwab Investment Management, Inc. (May 16, 2008) ("Schwab Letter"); Wellington Letter.

[17] NAPFA Letter.

[18] Wellington Letter.

[19] Instruction 1 of General Instructions for Part 2 of Form ADV.

[20] See ABA Committees Letter; comment letter of First Allied Securities, Inc. (May 16, 2008) ("First Allied Letter"); comment letter of Mercer Advisors (May 2, 2008) ("Mercer Letter"); NCS Letter; NRS Letter; comment letter of Reed Smith on behalf of Federated Investors, Inc. (May 16, 2008) ("Federated Letter").

must respond to each item in the brochure, and must present the information in order of the items in the form, using the headings provided by the form. If an item is inapplicable to an adviser, the adviser must include the heading and an explanation that the information is inapplicable.[21] If information an adviser provides in response to one item is also responsive to another item, the adviser may cross-reference the information in the other item.[22]

Also, it is critical that advisers communicate clearly to their clients and prospective clients in the brochure. Thus, instructions to Part 2 provide that, in drafting the brochure, advisers, among other things, should use short sentences; definite, concrete, everyday words; and the active voice. In addition, the brochure should discuss only conflicts the adviser has or is reasonably likely to have, and practices in which it engages in or is reasonably likely to engage.[23] If a conflict arises or the adviser decides to engage in a practice that it has not disclosed, supplemental information must be provided to the client.

2. Brochure Items

Part 2A, as adopted, contains 18 separate items, each covering a different disclosure topic.[24] We have drawn the items in Part 2A largely from disclosure advisers have long been required to make in response to the previous Part 2, and have added items to address new concerns or developments. Much of the disclosure required in Part 2A addresses an adviser's conflicts of interest with its clients, and is disclosure that the adviser, as a fiduciary, must make to clients in some manner regardless of the form requirements.

Some commenters urged us to require fewer items and require advisers to provide less detailed information.[25] We have reviewed carefully these suggestions and have modified some of our items in response. In some cases, however, commenters urged us to eliminate particular proposed disclosures, such as the fee schedule, that have long been required in Part 2 and provide investors essential information. Elimination of such proposed disclosures would result in clients not receiving important information they currently receive from their advisers and on which they may rely. In many other cases, further cuts would not have reduced the amount of disclosure an adviser would have to make to clients, but rather would have permitted the disclosure to be made in a different document or manner. Thus, elimination of disclosure requirements in Part 2A suggested by some commenters would be unlikely to reduce burdens or eliminate the amount of information required to be provided to clients to satisfy an adviser's fiduciary obligations.[26]

We agree that disclosure to clients should be succinct and readable. We note that advisers, because of how they choose to present their programs or services to clients or the complexity of their disclosures, have the ability to take steps that would limit the length of their brochures. For example, advisers may create separate brochures for different types of advisory clients, each of which may be shorter, clearer, and contain less extraneous information than would a combined brochure.[27] Advisers that choose to disclose more than is required by the form (and their fiduciary obligations) will create lengthier brochures than those that take a more focused approach. Advisers with a more complicated offering of advisory services (or business arrangements) might consider including a summary in the beginning of their brochure, followed by a more detailed discussion of each item in the brochure. We have amended the instructions to clarify that including a summary is permissible.[28]

Below, we discuss each of the items in the form and the modifications we have made from our proposal.

Item 1. Cover Page. Item 1 requires that an adviser disclose on the cover page of its brochure the name of the firm, its business address, contact information, Web site (if it has one), and the date of the brochure. The cover page also must include a statement that the brochure has not been approved by the Commission or any state securities authority. If an adviser refers to itself as a "registered investment adviser," it also must include a disclaimer that registration does not imply a certain level of skill or training.[29]

The item reflects one change from our proposal. Item 1 requires an adviser to disclose on the cover page of the brochure only a general telephone number and/or e-mail address that clients can use to contact the adviser if they have questions about the brochure. Commenters asserted that some larger advisers would find it cumbersome to comply with our proposal, which would have required the name and phone number of a specific individual or service center.[30]

Item 2. Material Changes. Item 2 requires that an adviser amending its brochure identify and discuss the material changes since the last annual update on the cover page or the following page or as a separate document accompanying the brochure.[31] This item is designed to make clients aware of information that has changed since the prior year's brochure and that may be important to them.

[21] Instruction 1 of General Instructions for Part 2 of Form ADV.

[22] Id.

[23] Instruction 2 of General Instructions for Part 2 of Form ADV.

[24] Part 2A consists of a main body and an appendix, Appendix 1. Appendix 1 contains the requirements for a specialized type of firm brochure—a wrap fee program brochure—and requires disclosure similar to current Schedule H of Part 2 of Form ADV. See rule 204–3(d); Appendix 1 to Part 2A; infra note 182 and accompanying text.

[25] See, e.g., comment letter of the Financial Service Institute (May 16, 2008) ("FSI Letter"); Schwab Letter; comment letter of the Securities Industry and Financial Markets Association (May 16, 2008) ("SIFMA Letter"); comment letter of Sutherland Asbill & Brennan LLP (May 16, 2008) ("Sutherland Letter").

[26] Advisers with fewer conflicts and simpler business arrangements will be able to prepare shorter brochures.

[27] See rule 204–3(e) (allowing advisers that provide substantially different advisory services to different clients to provide clients with different brochures as long as each client receives all information about the services and fees that are applicable to that client). Note that an adviser may not omit any information required by Item 9 of Part 2A (Disciplinary Information) in any brochure provided to any client, and that each brochure must be filed through IARD. See rule 204–3(a); see also Instruction 2 for Part 2A of Form ADV. An adviser that creates separate brochures must file each brochure through the IARD system. See Instruction 9 for Part 2A of Form ADV.

[28] See Instruction 8 of Instructions for Part 2A of Form ADV. We have also added an instruction to Part 2 explaining that advisers must provide the client with sufficiently specific facts so that the client is able to understand the conflicts of interest the adviser has and the business practices in which it engages, and can give his or her informed consent to the transaction or practice that gives rise to the conflict or to reject the transaction or practice. See Instruction 3 of General Instructions for Part 2 of Form ADV.

[29] We have observed that the emphasis on SEC registration, in some advisers' marketing materials, appears to suggest that registration either carries some official imprimatur or indicates that the adviser has attained a particular level of skill or ability. Section 208(a) of the Advisers Act [15 U.S.C. 80b–8(a)] makes such suggestions unlawful.

[30] See First Allied Letter; IAA Letter; SIFMA Letter.

[31] Advisers may include the summary in their brochure or in a separate document. Item 2 of Part 2A. A summary prepared as a separate document can be used to satisfy an adviser's annual client delivery obligations. See rule 204–3(b)(2), discussed in Section II.A.3 below. Summaries provided as a separate document must be filed with the Commission as an exhibit to Part 2. See Note to paragraphs (a) and (b) of rule 204–1; Instruction 6 for Part 2A of Form ADV. If an adviser includes the summary of material changes in its brochure, and amends its brochure on an interim basis between annual updating amendments, the adviser should consider whether it should update its summary of material changes to avoid confusing or misleading clients reading the updated brochure. See Note to Instruction 6 for Part 2A of Form ADV.

Several commenters supported this requirement, agreeing that advisers can achieve meaningful disclosure with an annual disclosure highlighting changes to the brochure.[32] Others expressed concern that advisers would write lengthy summaries to avoid liability.[33] We emphasize that we intend this document to be a summary that identifies and broadly discusses the material changes,[34] and that it should not be a lengthy discussion that replicates the brochure itself.[35] Instead, the summary need contain no more than necessary to inform clients of the substance of the changes to the adviser's policies, practices or conflicts of interests so that they can determine whether to review the brochure in its entirety or to contact the adviser with questions about the changes.

Item 3. Table of Contents. Item 3 requires each adviser to include in its brochure a table of contents detailed enough to permit clients and prospective clients to locate topics easily. Some commenters supported the use of a table of contents but urged the Commission to mandate a uniform format so that investors can compare brochures of multiple advisers more easily.[36] Others opposed a uniform format, arguing that flexibility would enable an adviser to best convey information about its firm to clients.[37] As discussed above, we are persuaded by commenters that a uniform format for items in the brochure will facilitate investors' comparison of multiple advisers and are adopting this requirement. We therefore added an instruction to Part 2 of Form ADV to require advisers to present the information in the order of the items in the form, using the headings provided by the form.[38]

Item 4. Advisory Business. Item 4 requires each adviser to describe its advisory business, including the types of advisory services offered, whether it holds itself out as specializing in a particular type of advisory service, and the amount of client assets that it manages. In computing the amount of client assets that it manages, an adviser may use a method that differs from the method used in Part 1A of Form ADV to report "assets under management."[39] An adviser opting to use a different method must keep documentation describing the method used.[40]

Two commenters urged the Commission not to require that advisers make additional disclosure if they hold themselves out as specializing in a particular type of advisory service. One was concerned that advisers would have interpretive problems in defining specialized advisory services and that disclosure describing specialized services would not provide meaningful information to clients.[41] The other argued that Item 8 (Strategies and Risks) covers similar information.[42] As we explained in the Proposing Release, we require that advisers identify a specialized advisory service because we believe that clients likely will want to understand this before engaging that adviser.[43] Accordingly, we are adopting this item as proposed.

Commenters were divided on whether we should require investment advisers to calculate the amount of their assets in a manner consistent with the instructions for Part 1A in order to avoid confusion.[44] The methodology for calculating assets required under Part 1A is designed for a particular purpose (i.e., for making a determination as to whether an adviser should register with the Commission or with the states), rather than to convey meaningful information about the scope of the adviser's business. Thus, we are permitting advisers to use a different methodology for Part 2A disclosure.[45]

Finally, several commenters urged that we permit an adviser to update the amount of assets under management only in its annual updating amendment rather than (as we proposed) at the time an adviser makes an interim update to its brochure if the amount had become materially inaccurate.[46] We believe that our proposal appropriately balanced the burdens that would be imposed on advisers by having to amend their brochures repeatedly with the need to provide clients with reasonably current information. Therefore, we are adopting this instruction as proposed.[47] Advisers must update the amount of their assets under management annually (as part of their annual updating amendment) and make interim amendments only for material changes in assets under management when they are filing an "other than annual amendment" for a separate reason. As we have noted, as a fiduciary, an adviser has an ongoing obligation to inform its clients of any material information that could affect the advisory relationship, which could include a material change to assets under management.[48]

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[32] See ASG Letter; comment letter of the CFA Institute Centre for Financial Market Integrity (May 22, 2008) ("CFA Institute Letter"); Consumer Federation Letter; FPA Letter; IAA Letter; Janus Letter; NASAA Letter.

[33] See AICA Letter; FSI Letter; ICI Letter; comment letter of Jackson, Grant Investment Advisers, Inc. (May 26, 2008) ("Jackson Letter"); comment letter of Katten Muchin Rosenman LLP (May 16, 2008) ("Katten Letter"); Mercer Letter; Morgan Stanley Letter; NSCP Letter; comment letter of the Financial Service Roundtable (May 16, 2008) ("Roundtable Letter"); SIFMA Letter; Sutherland Letter.

[34] We have revised Item 2 to require advisers not only to identify, but also to "discuss" material changes to clarify our intent.

[35] A few commenters also sought clarification of the term "material changes." See comment letter of the American Council of Life Insurance (May 16, 2008) ("ACLI Letter"); Fried Frank Letter; FSI Letter; IAA Letter; Roundtable Letter; comment letter of T. Rowe Price Associates, Inc. (May 16, 2008) ("T. Rowe Letter"). The standard of materiality under the Advisers Act is whether there is a substantial likelihood that a reasonable investor (here, client) would have considered the information important. See *S.E.C.* v. *Steadman,* 967 F.2d 636, 643 (D.C. Cir. 1992). *Cf. Basic Inc.* v. *Levinson*, 485 U.S. 224, 231–232 (1988); *TSC Industries* v. *Northway, Inc.,* 426 U.S. 438, 445, 449 (1976). This is a facts and circumstances test, requiring an assessment of the "total mix of information," in the characterization of the Supreme Court. *TSC Industries,* 426 U.S. at 449. Given that materiality depends on the factual situation, which may vary with each situation, we do not believe that it is appropriate to specifically define or provide any bright line tests for what is and is not material.

[36] See supra note 20.

[37] See Fried Frank Letter; Janus Letter; Lininger Letter.

[38] Instruction 1 of General Instructions for Part 2 of Form ADV.

[39] For an explanation of Part 1A's requirements for computing "assets under management," see Instruction 5.B for Part 1A of Form ADV.

[40] See rule 204–2(a)(14)(ii) and Note to Item 4.E of Part 2A.

[41] See NAPFA letter.

[42] See Sutherland Letter.

[43] See Proposing Release at Section II.A.2.

[44] The CFA Institute Letter, IAA Letter, Janus Letter, Mercer Letter, and NRS Letter argued that the calculation requirements should be the same. Others supported our proposal that would permit advisers to use a different calculation of assets under management than the one required for Part 1A, with most of these commenters arguing that this flexibility would allow advisers to more accurately portray the business of the firm and total assets managed. See comment letter of Ashland Compliance Group LLC (May 16, 2008) ("Ashland Letter"); Lininger Letter; MMI Letter; Morgan Stanley Letter.

[45] For example, in calculating "assets under management," for purposes of Part 1A, an adviser may include the entire value of a managed portfolio, but only if at least 50% of the portfolio's total value consists of securities. See current Form ADV: Instructions for Part 1A of Form ADV. Thus, for Part 1A purposes, an adviser will not include other assets (including securities) that it manages in a "non-securities" portfolio. The Part 1A formula for calculating assets under management was designed based on considerations related to the National Securities Markets Improvement Act of 1996 division of responsibility for regulation of advisers between the Commission and state securities regulatory authorities. Public Law 104–290, 110 Stat. 3416 (1996).

[46] See Morgan Stanley Letter; MMI Letter.

[47] See Note to Instruction 4 of General Instructions for Form ADV.

[48] Note to Instruction 2 of Instructions for Part 2A of Form ADV. Disclosure updating the adviser's assets under management could be provided to clients by means other than the brochure. We have brought enforcement actions charging advisers with engaging in fraud by misrepresenting their assets under management to advisory clients and

Continued

Item 5. Fees and Compensation. Item 5 requires that an adviser describe in its brochure how it is compensated for its advisory services, provide a fee schedule, and disclose whether fees are negotiable.[49] An adviser must disclose whether it bills clients or deducts fees directly from clients' accounts, and how often it assesses fees (or bills clients).[50] The item also requires each adviser to describe the types of other costs, such as brokerage, custody fees and fund expenses that clients may pay in connection with the advisory services provided to them by the adviser.[51] An adviser charging fees in advance must explain how it calculates and refunds prepaid fees when a client contract terminates.[52]

Item 5 also requires an adviser that receives compensation attributable to the sale of a security or other investment product (e.g., brokerage commissions), or whose personnel receive such compensation, to disclose this practice and the conflict of interest it creates, and to describe how the adviser addresses this conflict.[53] Such an adviser also must disclose that the client may purchase the same security or investment product from a broker that is not affiliated with the adviser.[54]

Some commenters expressed strong support for these disclosure requirements, with one commenter stating that such disclosure is "essential to a healthy adviser-client relationship."[55] Others argued generally that most of the information is not relevant for many clients, and specifically that providing a complete set of fee schedules would impose an undue burden on advisers.[56] We disagree with commenters who favored a broad elimination of fee information from the brochure. Information about fees is important to clients and can be used to compare fees of different advisers.[57] More persuasive, however, were arguments that brochure fee information is likely not useful to institutional and large, sophisticated clients who are often in a position to negotiate fee arrangements with their adviser and for whom, therefore, a fee table would have little utility.[58] These arguments have persuaded us to provide an exception which permits an adviser to omit disclosure of its fee schedule and the other information in Item 5.A in any brochure provided only to clients who are "qualified purchasers."[59]

A few commenters urged us to not require description of other types of fees or expenses because, among other things, such fees may vary significantly among clients and disclosure regarding them may confuse clients.[60] However, this simple and brief disclosure (which is not required to include the amount or range of the fees) may be helpful to investors unacquainted with the practices of an adviser or the ancillary costs of actively managed investing. Therefore, we are adopting this disclosure requirement, as proposed.

As noted above, Item 5 also requires an adviser that receives transaction-based compensation, or whose personnel receive such compensation, to disclose this practice and the conflict of interest it creates and to describe how the adviser addresses this conflict. Some commenters argued that this item inappropriately implies endorsement of a "fee-based" compensation structure over a "commission-based" structure.[61] That is not our intent. The item simply recognizes that an adviser that accepts compensation from the sale to a client of securities has an incentive to base investment recommendations on the amount of compensation it will receive, rather than on the client's best interests, and thus involves a significant conflict of interest.[62] As a result, we are adopting the requirement as proposed.[63]

Item 6. Performance-Based Fees and Side-By-Side Management. Item 6 requires an adviser that charges performance-based fees or that has a supervised person who manages an account that pays such fees to disclose this fact. If such an adviser also manages accounts that are not charged a performance fee, the item also requires the adviser to discuss the conflicts of interest that arise from its (or its supervised person's) simultaneous management of these accounts, and to describe generally how the adviser addresses those conflicts.[64]

prospective clients, including in advisory brochures. See, e.g., *SEC* v. *Locke Capital Management, Inc. and Leila C. Jenkins,* Litigation Release No. 20936 (Mar. 9, 2009) (settled order).

[49] See Item 5.A of Part 2A.

[50] See Item 5.B of Part 2A.

[51] See Item 5.C of Part 2A.

[52] See Item 5.D of Part 2A. Item 18 of Part 2A also requires the disclosure of certain financial information about an adviser that requires prepayment of fees.

[53] See Item 5.E of Part 2A. Because of this conflict of interest, advisers are required by the antifraud provisions of the Advisers Act to disclose their receipt of transaction-based compensation to clients. We have brought enforcement actions charging advisers with failures to make such disclosures. See, e.g., In the Matter of Financial Design Associates, Inc. and Albert L. Coles, Jr., Investment Advisers Act Release No. 2654 (Sept. 25, 2007) (settled order); In the Matter of IMS, CPAs & Associates, Vernon T. Hall, Stanley E. Hargrave, and Jerome B. Vernazza, Investment Advisers Act Release No. 1994 (Nov. 5, 2001) (settled order) (petitioners' appeal denied in *Vernazza* v. *SEC,* 327 F.3d 851 (9th Cir. 2003)).

[54] See Item 5.E.2 of Part 2A. In addition to the requirement in Item 5.E.2 of Part 2A, an adviser that receives more than half of its revenue from commissions and other sales-based compensation must explain that commissions are the firm's primary (or, if applicable, exclusive) form of compensation. See Item 5.E.3 of Part 2A. An adviser that charges advisory fees in addition to commissions or markups to an individual client must disclose whether it reduces its fees to offset the commissions or markups. See Item 5.E.4 of Part 2A.

[55] See comment letter of the Certified Financial Planner Board of Standards, Inc. (May 29, 2008) ("CFP Board Letter"). The ASG Letter, the CFA Institute Letter, the Lininger Letter, and the NRS Letter also expressed strong support for most of these requirements.

[56] See comment letter of Eric A. Brill (Apr. 26, 2008) ("Brill Letter"); IAA Letter. The IAA Letter stated that larger firms may have to prepare extremely long fee schedules. They urged the Commission to provide flexibility regarding fee schedule disclosure as long as the fee is fully disclosed in the advisory contract. One commenter suggested that we amend General Instruction 4, which permits advisers to update any change to its fee schedules only annually, reasoning that potential clients would need this updated information in selecting advisers. See NASAA Letter. The exception contained in the instruction is designed to prevent an adviser from having to make multiple interim amendments as a result of small changes in a fee schedule each of which may be material only to certain affected clients or prospective clients who would learn of them when considering whether to enter into an advisory agreement that would reflect a revised fee. On balance, we believe that an annual update may be sufficient.

[57] This information may be particularly useful to clients searching for an adviser by comparing information on brochures that will be available on the Internet.

[58] See IAA letter; Wellington Letter.

[59] "Qualified purchasers," as defined under section 2(a)(51)(A) of the Company Act [15 USC 80a–2(a)(51)(A)], include, among others, natural persons who own $5 million or more in investments and persons who manage $25 million or more in investments for their account or other accounts of other qualified purchasers.

[60] See NAPFA Letter; NRS Letter; NSCP Letter.

[61] See FSI Letter; Sutherland Letter.

[62] Moreover, the item is not, in substance, different from the previous Item 9 of Part 2, which, in recognition of this conflict, required an adviser to disclose whether the adviser effects securities transactions for clients. See also supra note 53; Applicability of the Investment Advisers Act to Financial Planners, Pension Consultants, and Other Persons Who Provide Investment Advisory Services as a Component of Other Financial Services, Investment Advisers Act Release No. 1092 (Oct. 16, 1987) [52 FR 38400 (Oct. 16, 1987)] ("Release 1092").

[63] We note that nothing in the Advisers Act precludes an adviser from accepting transaction-based compensation. However, an adviser that receives compensation in connection with the purchase or sale of securities should carefully consider the applicability of the broker-dealer registration requirements of the Securities Exchange Act of 1934.

[64] As fiduciaries, advisers must disclose all material information regarding any proposed performance fee arrangements as well as any material conflicts posed by the arrangements. See Exemption To Allow Investment Advisers To Charge Fees Based Upon a Share of Capital Gains Upon or Capital Appreciation of a Client's Account, Investment Advisers Act Release No. 1731, at nn.13–14 and accompanying text (July 15, 1998) [63 FR 39022 (July 21, 1998)].

Two commenters explicitly supported this requirement.[65] Two other commenters urged us to eliminate it, arguing that the required disclosure already should be in Item 5 (Fees and Compensation) or is required by other items.[66] As discussed in the Proposing Release, an adviser charging performance fees to some accounts but not others faces a variety of conflicts of interest.[67] The number of advisers with these arrangements has grown, and we believe that it is important that clients and prospective clients receive disclosure regarding these conflicts and how the adviser addresses them.[68] While Item 5 requires disclosure of an adviser's fee arrangements, it does not specifically require disclosure of the conflicts any particular fee arrangement may create other than with respect to transaction-based compensation.

Item 7. Types of Clients. Item 7 requires that the brochure describe the types of advisory clients the firm generally has, as well as the firm's requirements for opening or maintaining an account, such as minimum account size. One commenter recommended that we eliminate this proposed disclosure requirement, arguing that the information is not material to the decision of whether to hire or retain an investment adviser.[69] We disagree. We believe that many prospective clients would consider the type of clients to be an important factor in determining whether an adviser's business model is a good fit for them.[70] As a result, we are adopting Item 7 as proposed.

Item 8. Methods of Analysis, Investment Strategies and Risk of Loss. Item 8 requires that advisers describe their methods of analysis and investment strategies and disclose that investing in securities involves risk of loss which clients should be prepared to bear.[71] Item 8 also requires specific disclosure of how strategies involving frequent trading can affect investment performance. Finally, this item requires that advisers explain the material risks involved for each significant investment strategy or method of analysis they use and particular type of security they recommend, with more detail if those risks are unusual.

Several commenters supported this proposed disclosure requirement as central to the adviser's fiduciary relationship with its client.[72] One objected, stating that the item creates a different disclosure obligation for multi-strategy firms because, as proposed, it only required advisers primarily using a particular strategy to discuss the risks involved in their strategy.[73] We agree that advisers should disclose material risks associated with their strategies that will be relevant to most clients, regardless of whether they use one strategy or many strategies. We have, therefore, modified the item to require that advisers explain the material risks involved for each significant investment strategy or method of analysis they use, rather than those they primarily use, as we believe this threshold for disclosure better captures those methods of analysis or strategies that will be relevant to most clients.[74] However, as we noted in the proposal, the brochure may not always be the best place for a multi-strategy adviser to disclose risks associated with all of its methods of analysis or strategies.[75] Disclosure of that information likely would lengthen the brochure unnecessarily given that different clients will be pursuing different strategies, each of which poses specific and different risks.

Some commenters urged us to define the term "frequent trading of securities," which is used in Item 8.B, but did not suggest a definition in response to our request.[76] As commenters implicitly acknowledged, the phrase "frequent trading" is hard to define. We would expect advisers to respond to this item only if their intended investment strategies involve frequent trading of securities that a reasonable client would otherwise not expect in light of the other disclosures contained in the brochure.

Several commenters urged us to not require disclosure in the brochure of cash balance practices, arguing that such practices vary widely depending on the client, are typically addressed in the client's investment advisory agreement, and typically do not involve conflicts of interest.[77] We acknowledge that in many instances such practices do not involve conflicts of interest and have omitted the requirement from Part 2A. We note, however, that an adviser may have an obligation (independent of Part 2A) to disclose material information about its policies regarding the management of cash balances where the omission of such information would constitute a breach of the adviser's fiduciary duty (e.g., where the cash is not managed in the best interest of the client).[78]

One commenter noted that, as proposed, Items 8.B and 8.C would require disclosure of all risks associated with using a particular investment strategy or primarily recommending a particular type of security, and not just material risks.[79] We intended these items to require disclosure only of material risks, and have amended these items accordingly.[80]

This commenter also noted that Items 8.B and 8.C call for detailed discussions of "significant or unusual" risks, inquired whether this differed from "material" risks, and asked for clarification of this terminology. This requirement is intended to elicit from the adviser disclosure of significant risks associated with using a particular investment strategy or recommending a particular type of security that otherwise would not be apparent to the client from reading the adviser's

[65] See CFA Institute Letter; Lininger Letter.

[66] See IAA Letter; Schnase Letter.

[67] See Proposing Release, at nn.51–53 and accompanying text. An adviser charging performance fees to some accounts faces a variety of conflicts because the adviser can potentially receive greater fees from its accounts having a performance-based compensation structure than from those accounts it charges a fee unrelated to performance (e.g., an asset-based fee). As a result, the adviser may have an incentive to direct the best investment ideas to, or to allocate or sequence trades in favor of, the account that pays a performance fee. We have brought enforcement actions charging advisers with undisclosed conflicts in regard to accounts that pay performance fees. See, e.g., In the Matter of Nevis Capital Management, LLC, et al., Investment Advisers Act Release No. 2214 (Feb. 9, 2004) (settled order). See also In the Matter of Alliance Capital Management, L.P., Investment Advisers Act Release No. 2205 (Dec. 18, 2003) (settled order).

[68] According to data derived from investment advisers' responses to Item 5.E of Part 1A of Form ADV reported through IARD as of May 3, 2010, approximately 28% of SEC-registered investment advisers reported charging performance-based fees to some accounts but not others.

[69] See Sutherland Letter.

[70] We note that disclosure of this information is already required in the previous Item 2 of Part 2 of Form ADV.

[71] We have brought enforcement actions charging advisers with omissions and misrepresentations regarding investment strategies. See, e.g., In the Matter of George F. Fahey, Investment Advisers Act Release No. 2196 (Nov. 24, 2003) (settled order); In the Matter of Gary L. Hamby and Gary B. Ross, Investment Advisers Act Release No. 1668 (Sept. 22, 1997) (settled order).

[72] See CFA Institute Letter; Lininger Letter; NAPFA Letter; NRS Letter.

[73] See NAPFA Letter.

[74] For these purposes, we would view a method of analysis or strategy as significant if more than a small portion of the adviser's clients' assets are advised using the method or strategy.

[75] See Proposing Release at Section II.A.2.

[76] See comment letter of Gary D. Case (May 12, 2008) ("Case Letter"); FSI Letter; IAA Letter; comment letter of ProEquities, Inc. (May 21, 2008) ("ProEquities Letter"); comment letter of the Trust Advisory Group (May 12, 2008) ("TAG Letter"); T. Rowe Price Letter.

[77] See ASG Letter; IAA Letter; T. Rowe Letter.

[78] An adviser that is also registered as a broker-dealer may also have disclosure obligations relating to its cash balance practices arising under Commission and self-regulatory organization requirements. See NYSE information Memo No. 05–11 (Customer Account Sweeps to Banks) (Feb. 2005).

[79] See Schnase Letter.

[80] See Items 8.B and 8.C of Part 2A (requiring disclosure of "material risks").

brochure. An adviser that describes a wide range of investment advisory activities in its brochure but, in fact, specializes, for example, in investing in leveraged exchange-traded funds should disclose such information in response to this item.

Item 9. Disciplinary Information. Item 9 requires that an adviser disclose in its brochure material facts about any legal or disciplinary event that is material to a client's (or prospective client's) evaluation of the integrity of the adviser or its management personnel. These requirements incorporate into the brochure the client disclosure regarding disciplinary information required by rule 206(4)-4 under the Advisers Act.

Items 9.A, B, and C provide a list of disciplinary events that are presumptively material if they occurred in the previous 10 years. Item 9 cautions advisers, however, that the events listed in that item are those that are presumed to be material and do not constitute an exhaustive list of material disciplinary events. The list includes any convictions for theft, fraud, bribery, perjury, forgery, counterfeiting, extortion and violations of securities laws by the adviser or one of its executives. Events such as these reflect on the integrity of the adviser and its management personnel and, therefore, are presumptively material to clients. The adviser may rebut this presumption, in which case no disclosure to clients is required.[81] An adviser rebutting this presumption must document its determination in a memorandum and retain that record to enable our staff to monitor compliance with this important disclosure requirement.[82]

As required by rule 206(4)–4, Item 9 requires that disciplinary events more than 10 years old be disclosed if the event is so serious that it remains material to a client's or prospective client's evaluation of the adviser and the integrity of its management. Three commenters requested that the Commission further define and clarify what disciplinary information is material in these circumstances.[83] We have determined not to do so, however, as advisers should evaluate their obligations to disclose information to clients under existing materiality standards adopted by the courts and the Commission.[84] We note that a prior disciplinary event involving an adviser would be important to clients for many reasons, including how it may reflect upon the adviser's integrity, the effect it may have on the degree of trust and confidence a client would place in the adviser, or if it imposed limitations on an adviser's activities.[85]

Two other commenters addressed the rebuttable presumption of materiality under Item 9.[86] One commenter supported the flexibility of allowing advisers to rebut the presumption of materiality.[87] Other commenters suggested, however, that an adviser should not be permitted to rebut this presumption, stating that this would give advisers little incentive to disclose disciplinary information that may be considered material.[88] We note that an adviser, as a fiduciary, has an obligation to disclose material information to clients.[89] We believe that the legal consequences that flow from its failure to meet this obligation provide an incentive for an adviser to disclose material disciplinary information. Moreover, advisers that seek to exclude information from their brochures because they believe that they can rebut the presumption of materiality must memorialize the basis for that determination, which is subject to review by our staff.[90]

In the Proposing Release, we requested comment on whether we should require disclosure about arbitration awards and claims.[91] A few commenters supported arbitration disclosure, arguing that investors deserve the most complete information available to build a picture of an adviser's integrity.[92] Others objected, with some reasoning that arbitration claims are easy to make and that arbitration settlements and awards may not necessarily include findings of wrongdoing (i.e., parties may settle arbitration proceedings and/or arbitration awards may be granted even in the absence of legal violations).[93] For this reason, we have determined not to require disclosure of arbitration awards in the client brochure. Advisers should, however, carefully consider whether particular arbitration awards or settlements do, in fact, involve or implicate wrongdoing and/or reflect on the integrity of the adviser, and should be disclosed to clients in the brochure or through other means.[94] Because many disputes involving securities firms (including investment advisers) are resolved through arbitration or other methods of alternative dispute resolution, we will continue to assess whether we should require that these events be reported by firms registered with us.

Item 9 requires that an adviser must disclose if it (or any of its management persons) has been involved in one of the events listed in that item. "Involved" is defined as "[e]ngaging in any act or omission, aiding, abetting, counseling, commanding, inducing, conspiring with or failing reasonably to supervise another in doing an act."[95] Three commenters requested that we narrow the definition of "involved," arguing that the proposed definition is both overbroad and vague.[96] Other commenters supported using the term

[81] Note to Item 9 of Part 2A (explaining four factors an adviser should consider when assessing whether the presumption can be rebutted).

[82] Rule 204–2(a)(14)(iii).

[83] See AICPA Letter; Sutherland Letter; Jackson Letter.

[84] See supra note 35 for a discussion of materiality under the Advisers Act. See also the note at the end of Item 9 of Part 2A and Financial and Disciplinary Information that Investment Advisers Must Disclose to Clients, Investment Advisers Act Release No. 1035 (Sept. 19, 1986) [51 FR 34229 (Sept. 26, 1986)] (" Rule 206(4)–4 Proposing Release"), at nn.12–13 and accompanying text. One commenter noted the use of the term "currently material" in Item 9 and asked if this phrase differed in meaning from "material." See ABA Committees Letter. We did not intend this phrase to have a different meaning than "material" and, therefore, we have deleted the word "currently" in the Item 9 as adopted.

[85] See Rule 206(4)–4 Proposing Release, at nn. 12–13 and accompanying text. The Commission has long viewed information about a prior disciplinary proceeding involving an adviser as important to clients and that failure to disclose such a proceeding may violate the antifraud provisions of sections 206(1) and 206(2) of the Advisers Act. See e.g., In the Matter of Jesse Rosenblum, Investment Advisers Act Release No. 913 (May 17, 1984).

[86] See Morgan Stanley Letter; Sutherland Letter.

[87] See IAA Letter.

[88] See NASAA Letter; NCS Letter.

[89] We note that failure to disclose material information to clients constitutes a violation of section 206 of the Advisers Act. We have brought enforcement actions charging advisers with failures to make such disclosures. See, e.g., Colley Asset Management, Inc., and John E. Colley, Investment Advisers Act Release No. 2363 (Feb. 25, 2005) (settled order).

[90] We also note that an adviser is required in Part 1A of Form ADV to disclose disciplinary events regardless of whether they are material. Part 1A is filed electronically with the Commission and is publicly available on our website.

[91] See Proposing Release at Section II.A.2. We also requested comment in the Proposing Release on whether we should require that advisers subject to a Commission administrative order provide clients with a copy of that order. Commenters did not support such a requirement and stated that, when appropriate, we should require delivery of orders in individual proceedings. See Federated Letter; Fried Frank Letter; Morgan Stanley Letter; Sutherland Letter. We agree with commenters and Part 2A does not require that such orders be provided to advisory clients.

[92] See Consumer Federation Letter; CFA Institute Letter; CFP Board Letter; NASAA Letter.

[93] See comment letter from Michael Berlin (Apr. 28, 2008) ("Berlin Letter"); Federated Letter; First Allied Letter; Fried Frank Letter; IAA Letter; ICI Letter; Janus Letter; Mercer Letter; Morgan Stanley Letter; NRS Letter; SIFMA Letter; comment letter of R.C. Verbeck (May 12, 2008) ("Verbeck Letter").

[94] We note that failure to disclose material information to clients constitutes a violation of section 206 of the Advisers Act.

[95] See the Glossary to Form ADV.

[96] See Federated Letter; IAA Letter; Morgan Stanley Letter.

"involved," as defined.[97] One of these commenters noted that this term also is used in Form BD and in Form U4 and, as such, changing the meaning of the term (or eliminating it from Part 2A) would undermine uniformity and create disparate reporting between broker-dealers and advisers.[98] We believe that, for purposes of consistency, it is appropriate to continue to define the term "involved" as currently defined in Form ADV. This term and definition has been used in Form ADV for over 9 years and on Form BD for over 14 years, and we believe its meaning should be well understood.[99]

Some commenters recommended that advisers be permitted to satisfy the obligation to disclose and update disciplinary events by referring clients to the Investment Adviser Public Disclosure system (IAPD) to obtain the firm's disclosures from Part 1A of Form ADV and providing a copy of the disciplinary disclosures to clients who do not have Internet access.[100] One commenter strongly opposed this recommendation, however, stating that "[a]rming investors with this information is one of the best tools we have to put investors on their guard so that they can protect their own interests."[101]

The disciplinary information provided in Part 1A is provided to the Commission primarily for registration purposes and not with an eye towards client disclosure. Part 1A, therefore, requires disclosure not just about the advisory firm and its management personnel, but also about all of its "advisory affiliates." A firm's advisory affiliates include all of the firm's employees, officers, partners, or directors and all persons directly or indirectly controlling or controlled by the firm.[102] Having disciplinary information about this broad group is important to the Commission for regulatory purposes. However, many of the largest investment advisers may have a large number of advisory affiliates and voluminous disciplinary disclosure, much of which may be regarding advisory affiliates with no relationship to particular clients. Accordingly, we believe that requiring clients to sift through an advisory firm's Part 1A disciplinary disclosure is not the most effective client disclosure. Therefore, we are adopting the proposed requirement that the brochure affirmatively disclose disciplinary information about the adviser and its management personnel.

Because Part 2A, as amended, incorporates disciplinary disclosures formerly required by rule 206(4)–4 directly in the advisory brochure requirements, we are rescinding rule 206(4)–4.[103] The rescission of rule 206(4)–4 will be effective, with respect to any particular investment adviser, on the date by which that adviser must deliver its narrative brochure to existing clients and begin delivering its brochure to prospective clients under the rule and form amendments we are adopting today.[104] Some advisers, however, may have clients to whom they are not required to deliver a brochure, such as certain clients receiving only impersonal investment advice or those that are registered investment companies and business development companies.[105] For these advisers, their fiduciary duty of full and fair disclosure requires them to continue to disclose to all their clients material disciplinary and legal events and their inability to meet contractual commitments to their clients.[106]

Item 10. Other Financial Industry Activities and Affiliations. Item 10 requires each adviser to describe in its brochure material relationships or arrangements the adviser (or any of its management persons) has with related financial industry participants, any material conflicts of interest that these relationships or arrangements create, and how the adviser addresses the conflicts.[107] In addition, if an adviser selects or recommends other advisers for clients, Item 10 requires that it disclose any compensation arrangements or other business relationships between the advisory firms, along with the conflicts created, and explain how it addresses these conflicts.[108] The disclosure that Item 10 requires highlights for clients their adviser's other financial industry activities and affiliations that can create conflicts of interest and may impair the objectivity of the adviser's investment advice.

Two commenters explicitly stated that they supported the disclosure required by this item.[109] At the suggestion of one commenter,[110] we have modified Item 10.D to require advisers that recommend other advisers to disclose, in particular, payments or business relationships that create material conflicts of interest with clients, so as not to capture all relationships.

Item 11. Code of Ethics, Participation or Interest in Client Transactions and Personal Trading.

Code of Ethics. Item 11 requires each adviser to describe briefly its code of ethics and state that a copy is available upon request.[111] Two commenters strongly supported the proposed item, believing the required disclosure is

[97] See CFA Institute Letter; NASAA Letter.

[98] See NASAA Letter.

[99] See Amendments to Form ADV, Investment Advisers Act Release No. 1897 (Sept. 12, 2000) [65 FR 57438 (Sept. 22, 2000)]; Form BD Amendments, Securities Exchange Act Release No. 37431 (July 12, 1996) [61 FR 37357 (July 18, 1996)].

[100] See comment letter of the Alternative Investment Management Association (May 16, 2008) ("AIMA Letter"); ASG Letter; Janus Letter; Morgan Stanley Letter; NRS Letter; SIFMA Letter; Sutherland Letter.

[101] Consumer Federation Letter.

[102] See Form ADV: Glossary. Firm employees that perform only clerical, administrative, support, or similar functions are excluded from the definition.

[103] In addition to requiring disclosure of certain disciplinary information, rule 206(4)–4 requires an adviser to disclose certain financial information to clients. As with the disciplinary disclosure, we have incorporated this requirement into the new brochure. Similar to rule 206(4)–4(a)(1), Item 18.B of Part 2A requires certain advisers to disclose any financial condition that is reasonably likely to impair their ability to meet contractual commitments to clients. See infra note 177 and accompanying text.

[104] See infra Section V.

[105] Our requirements regarding to which clients an adviser must deliver a brochure are discussed in Section II.A.3 below. One commenter suggested that we retain rule 206(4)–4 to require only the delivery of disciplinary information to clients for whom the brochure delivery requirement does not apply. See ABA Committees Letter.

[106] See Financial and Disciplinary Information that Investment Advisers Must Disclose to Clients, Investment Advisers Act Release No. 1035 (Sept. 19, 1986) ("Rule 206(4)–4 Adopting Release") ("explaining that rule 206(4)–4 was designed to codify an investment adviser's fiduciary obligation to disclose material financial and disciplinary information to clients."). We have brought enforcement actions charging advisers with failures to make such disclosures. See, e.g., In the Matter of Veritas Financial Advisors LLC, Veritas Advisors, Inc., Patrick J. Cox and Rita A. White, Investment Advisers Act Release No. 2577 (Dec. 29, 2006) (settled order); In the Matter of Harry Michael Schwartz, Investment Advisers Act Release No. 1833 (Sept. 27, 1999) (settled order); In the Matter of Renaissance Capital Advisors, Inc., and Richard N. Fine, Investment Advisers Act Release No. 1688 (Dec. 22, 1997) (settled order). In addition, under section 9(a) of the Company Act [15 USC 80a–9(a)] an investment adviser to a registered investment company may be prohibited from serving in certain capacities with the fund as a result of a disciplinary event.

[107] This item is similar to Item 8 of the previous Part 2. Two commenters requested that we clarify or provide guidance regarding "materiality" in describing relations and arrangements with related persons, and conflicts of interest arising from these relations or arrangements. See IAA Letter; NRS Letter. We address this comment earlier in this Release. See supra note 35 for a further discussion of materiality under the Advisers Act.

[108] We have brought enforcement actions charging advisers with failures to make such disclosures. See, e.g., In the Matter of Morgan Stanley & Co., Incorporated, Investment Advisers Act Release No. 2904 (July 20, 2009) (settled order); In the Matter of Yanni Partners, Inc. and Theresa A. Scotti, Investment Advisers Act Release No. 2642 (Sept. 5, 2007) (settled order).

[109] See CFA Institute Letter; Lininger Letter.

[110] See Sutherland Letter.

[111] This requirement is almost identical to the previous disclosure requirement in Item 9 of the previous Part 2.

indicative of an adviser's commitment to its fiduciary duties.[112] One recommended that we instead simply require an adviser to note in the brochure that a copy of its code of ethics is available upon request.[113] We believe that a brief, concise summary of the code of ethics (as the item requires) will be helpful to prospective clients who may not wish or feel the need to request the entire code of ethics and will assist those clients in determining whether they would like to read the entire code of ethics.[114]

Participation or Interest in Client Transactions. If the adviser or a related person recommends to clients, or buys or sells for client accounts, securities in which the adviser or a related person has a material financial interest, Item 11.B requires the brochure to discuss this practice and the conflicts of interest presented.[115] Conflicts could arise, for example, when an adviser recommends that clients invest in a pooled investment vehicle that the firm advises or for which it serves as the general partner,[116] or when an adviser with a material financial interest in a company recommends that a client buy shares of that company.[117] The item requires advisers to disclose any practices giving rise to these conflicts, the nature of the conflicts presented, and how the adviser addresses the conflicts. Two commenters expressed support for this requirement.[118] We are adopting Item 11.B. substantially as proposed, except that at the suggestion of three commenters, we have omitted the portion of the proposed item that required advisers to disclose "procedures" for making the disclosures to clients.[119] We agree with these commenters that the requirement was inconsistent with the Commission's general approach throughout the brochure of requiring disclosure about conflicts and how they are addressed, but not about "procedures."

Personal Trading. Items 11.C and 11.D require disclosure of personal trading by the adviser and its personnel.[120] Item 11.C requires an adviser to disclose whether it or a related person (e.g., advisory personnel) invests (or is permitted to invest) in the same securities that it recommends to clients, or in related securities (such as options or other derivatives). If so, the brochure must discuss the conflicts presented and describe how the firm addresses the conflicts. Item 11.D requires a similar discussion, but focuses on the specific conflicts an adviser has when it or a related person trades in the same securities at or about the same time as a client.[121] In response to this item, an adviser should explain how its internal controls, including its code of ethics, prevent the firm and its staff from buying or selling securities contemporaneously with client transactions.

One commenter suggested that we specify a minimum amount of assets that must be managed by an adviser in order for that adviser to be required to disclose personal securities transactions, arguing that small firms' securities transactions are not large enough to generate a market impact and thus should not require disclosure.[122] We disagree. A small firm could still place a trade large enough to have a market impact, especially in a thinly traded security. In addition, given that an adviser's ability to place its own trades before or after client trades in the same security may affect the objectivity of the adviser's recommendations, we believe disclosure of this practice is warranted. As a result, we are adopting Items 11.C and 11.D as proposed.

Finally, we note that we have modified the note to Item 11 to clarify that Items 11.B, 11.C, and 11.D would not require disclosure with respect to securities that are not "reportable securities" under Advisers Act rule 204A–1(e)(10), such as shares in unaffiliated mutual funds.[123] As we indicated in the Proposing Release, such securities are not reportable under Advisers Act Rule 204A–1 because they appear to present little opportunity for front-running.[124]

Item 12. Brokerage Practices. Item 12 requires that advisers describe how they select brokers for client transactions and determine the reasonableness of brokers' compensation. This item also requires advisers to disclose how they address conflicts of interest arising from their receipt of soft dollar benefits (i.e., research or other products or services they receive in connection with client brokerage).[125]

Soft Dollar Practices. Many advisers receive brokerage and research services in reliance on section 28(e) of the Securities Exchange Act of 1934 ("Exchange Act"),[126] as well as other soft dollar products and services provided by brokers in connection with client transactions.[127] Use of client securities transactions to obtain research and other benefits creates incentives that result in conflicts of interest between advisers and their clients.[128] Because of these

[112] See CFA Institute Letter; CFP Board Letter.

[113] See Morgan Stanley Letter.

[114] This summary should not be a reiteration of the entire code of ethics, but rather should provide enough information for the client to determine if it would like to read the full code of ethics and to understand generally the adviser's ethical culture and standards, how the adviser controls sensitive information, and what steps it has taken to prevent employees from misusing their inside positions at clients' expense. See Investment Adviser Code of Ethics, Investment Advisers Act Release No. 2256 (July 2, 2004), at text accompanying notes nn.66–67 [69 FR 41696 (July 9, 2004)].

[115] An adviser's related persons are: (1) The adviser's officers, partners, or directors (or any person performing similar functions); (2) all persons directly or indirectly controlling, controlled by, or under common control with the adviser; (3) all of the adviser's current employees; and (4) any person providing investment advice on the adviser's behalf. See Form ADV: Glossary. Items 11.B, 11.C, and 11.D are similar to Item 9 of the previous Part 2.

[116] We have brought enforcement actions charging advisers with failures to make such disclosures. See, e.g., In the Matter of Thomson McKinnon Asset Management, L.P., Investment Advisers Act Release No. 1243 (July 26, 1990) (settled order).

[117] We have brought enforcement actions charging advisers with failures to make such disclosures. See, e.g., In the Matter of Chancellor Capital Management, Inc., et al., Investment Advisers Act Release No. 1447 (Oct. 18, 1994) (settled order).

[118] See CFA Institute Letter; CFP Board Letter.

[119] See IAA Letter; ICI Letter; T. Rowe Letter.

[120] We have brought enforcement actions charging advisers with fraudulent personal trading. See In the Matter of Roger W. Honour, Investment Advisers Act Release No. 1527 (Sept. 29, 1995) (settled order).

[121] We have brought enforcement actions charging advisers with inaccurate disclosure in this context. See, e.g., In the Matter of Hutchens Investment Management and William Hutchens, Investment Advisers Act Release No. 2514 (May 9, 2006) (settled order).

[122] See comment letter of Thaddeus Borek, Jr. (May 16, 2008).

[123] See Code of Ethics Adopting Release, supra note 114 at n.42 and accompanying text.

[124] See Proposing Release, supra note 2, at n.85.

[125] Item 12 is similar to Item 12.B in the previous Part 2.

[126] Section 28(e) of the Exchange Act provides a limited "safe harbor" for advisers with discretionary authority in connection with their receipt of soft dollar benefits. Under section 28(e), a person who exercises investment discretion over a client account has not acted unlawfully or breached a fiduciary duty solely by causing the account to pay more than the lowest commission rate available, so long as that person determines in good faith that the commission amount is reasonable in relation to the value of the brokerage and research services provided. Advisers must disclose their receipt of soft dollar benefits to clients, regardless of whether the benefits fall inside or outside of the safe harbor. See Interpretive Release Concerning the Scope of Section 28(e) of the Securities Exchange Act of 1934 and Related Matters, Exchange Act Release No. 23170 (Apr. 23, 1986) [51 FR 16004 (Apr. 30, 1986)], at n.33 and accompanying text.

[127] According to IARD data as of May 3, 2010, approximately 61% of advisers registered with the Commission report on Form ADV, Part 1A, Item 8.E that they or related persons receive soft dollar benefits in connection with client transactions.

[128] Commission Guidance Regarding Client Commission Practices Under Section 28(e) of the Securities Exchange Act of 1934, Exchange Act Release No. 54165 (July 18, 2006) [71 FR 41978 (July 24, 2006)] ("2006 Soft Dollar Release") ("[u]se of client commissions to pay for research and brokerage services presents money managers with significant conflicts of interest, and may give incentives for managers to disregard their best execution obligations when directing orders to

conflicts, we have long required advisers to disclose their policies and practices with respect to their receipt of soft dollar benefits in connection with client securities transactions.[129]

Item 12 requires an adviser that receives soft dollar benefits in connection with client securities transactions to disclose its practices.[130] The description must be specific enough for clients and prospective clients to understand the types of products or services the adviser is acquiring and permit them to evaluate associated conflicts of interest. Disclosure must be more detailed for products or services that do not qualify for the safe harbor in section 28(e) of the Exchange Act, such as services that do not aid in the adviser's investment decision-making process.[131]

Item 12 also requires that an adviser discuss in its brochure the types of conflicts it has when it accepts soft dollar benefits and explain how it addresses those conflicts.[132] The item requires the adviser to explain whether it uses soft dollars to benefit all client accounts or only those accounts whose brokerage "pays" for the benefits, and whether the adviser seeks to allocate the benefits to client accounts proportionately to the soft dollar credits those accounts generate. The item also requires the adviser to explain whether it "pays up" for soft dollar benefits.[133]

Some commenters, including one association representing more than 130 pension funds, expressed their strong support for the soft dollar disclosure requirement.[134] Other commenters objected to various portions of this item.[135] Some of these commenters recommended elimination of the proposed requirements to disclose whether an adviser allocates soft dollar benefits to client accounts proportionately to the brokerage credits those accounts generate,[136] and to disclose the "procedures" it uses to direct client transactions to a particular broker-dealer.[137] Some of these commenters also questioned the conflicts we identified and expressed concern that the item will tend to create a misleading impression that the use of soft dollar arrangements is harmful.[138]

There are significant conflicts associated with soft dollar arrangements. Section 28(e) was enacted, in part, to address them.[139] We are not taking a view on the propriety of soft dollar arrangements, but rather are requiring full disclosure of arrangements that involve significant conflicts of interest.[140] Moreover, disclosure required by Item 12 is similar to disclosure requirements previously required in Part 2 of Form ADV.[141] We are adopting this requirement as proposed.

Client Referrals. If an adviser uses client brokerage to compensate or otherwise reward brokers for client referrals, it also must disclose this practice, the conflicts of interest it creates, and any procedures the adviser used to direct client brokerage to referring brokers during the last fiscal year (i.e., the system of controls used by the adviser when allocating brokerage).[142] Part 2 previously required that advisers disclose these arrangements, but did not specifically require that the description discuss the conflicts of interest created.[143] We did not receive any comments relating to this item and are adopting the requirement as it was proposed so that clients are aware that their adviser may have a bias toward referring brokers, a significant conflict of interest.[144]

Directed Brokerage. Item 12 requires an adviser that permits clients to direct brokerage to describe its practices in this area. Item 12 also requires that such an adviser explain that it may be unable to obtain the most favorable execution of client transactions if the client directs brokerage and that directing brokerage may be more costly for clients.[145] If, however, an adviser routinely recommends, requests or requires clients to direct brokerage, Item 12 also requires the adviser to describe this practice in its brochure, to disclose that not all advisers require directed brokerage, and to describe any relationship with a broker-dealer to which the brokerage may be directed that creates a material conflict of interest.[146] An adviser may omit disclosure regarding its inability to obtain best execution if directed brokerage arrangements are only conducted subject to the adviser's ability to obtain best execution.[147]

Two commenters addressed this requirement. One, representing pension funds, endorsed our proposal as supporting transparency in brokerage arrangements.[148] The other urged that we broaden the proposed exception in the item to all directed brokerage subject to best execution, whether recommended by the adviser or directed by the client. The commenter pointed out that such client-imposed limitations on direction of brokerage should

obtain client commission services as well as to trade client securities inappropriately in order to earn credits for client commission services").

[129] See Item 12 of the previous Part 2.

[130] See Item 12.A.1 of Part 2A.

[131] See note to Item 12.A.1.e of Part 2A.

[132] See Item 12.A.1. An adviser accepting soft dollar benefits must explain that (a) the adviser benefits because it does not have to produce or pay for the research or other products or services acquired with soft dollars, and (b) the adviser therefore has an incentive to select or recommend brokers based on the adviser's interest in receiving these benefits, rather than on the client's interest in getting the most favorable execution. See Item 12.A.1.a and b of Part 2A.

[133] "Paying up" refers to an adviser causing a client account to pay more than the lowest available commission rate in exchange for soft dollar products or services.

[134] See comment letter of the Council of Institutional Investors (May 16, 2008) ("CII Letter"); CFA Institute Letter; NRS Letter; comment letter of Carolina Capital Markets, Inc. (Aug. 8, 2008).

[135] See, e.g., comment letter of the Alliance in Support of Independent Research (May 16, 2008) ("Alliance Letter"); CAPIS Letter; IAA Letter; ICI Letter; comment letter of Pickard and Djinis LLP (May 14, 2008) ("Pickard Letter"); SIFMA Letter; T. Rowe Letter.

[136] See Alliance Letter; CAPIS Letter; IAA Letter; ICI Letter; Pickard Letter.

[137] See Alliance Letter; CAPIS Letter; IAA Letter; ICI Letter.

[138] See Alliance Letter; IAA Letter; ICI Letter; SIFMA Letter.

[139] See 2006 Soft Dollar Release, supra note 128, at nn.4–6 and accompanying text.

[140] We have brought enforcement actions charging advisers with not adequately disclosing soft dollar arrangements and related conflicts. See, e.g., In the Matter of Schultze Asset Management LLC and George J. Schultze, Investment Advisers Act Release No. 2633 (Aug. 15, 2007) (settled order); In the Matter of Rudney Associates, Inc. et al., Investment Advisers Act Release No. 2300 (Sept. 21, 2004) (settled order).

[141] Item 12.B. of the previous Part 2 required, for example, that the adviser describe the factors considered in selecting brokers and determining the reasonableness of their commissions. In addition, if the value of products, research and services given to the adviser is a factor in selecting brokers, the adviser was required to, among other things, describe whether clients may pay commissions higher than those obtainable from other brokers in return for those products and services.

[142] Item 12.A.2 of Part 2A.

[143] See Item 13.B. of the previous Part 2.

[144] We have brought enforcement actions charging advisers with failing to disclose to clients that they directed their brokerage commissions in return for client referrals. See, e.g., In the Matter of Fleet Investment Advisors, Inc., Investment Advisers Act Release No. 1821 (Sept. 9, 1999) (settled order).

[145] See Item 12.A.3.b of Part 2A. As we discussed in the Proposing Release, clients sometimes instruct their adviser to send transactions to a specific broker-dealer for execution. Clients may initiate this type of arrangement for a variety of reasons, such as favoring a family member or friend or compensating the broker-dealer indirectly for services it provides to the client. But the arrangement also may be initiated by the adviser, who may benefit, for example, when brokerage is directed to its affiliated broker-dealer. In either case, clients directing (or agreeing to direct) brokerage need to understand the consequences of directing brokerage, including the possibility that their accounts will pay higher commissions and receive less favorable execution.

[146] See Item 12.A.3.a of Part 2A. We have brought enforcement actions charging advisers with failures to make such disclosures. See also In the Matter of Callan Associates, Investment Advisers Act Release No. 2650 (Sept. 19, 2007) (settled order); In the Matter of Jamison, Eaton & Wood, Inc., Investment Advisers Act Release No. 2129 (May 15, 2003) (settled order).

[147] See note to Item 12.A.2 of Part 2A.

[148] See CII Letter.

address the Commission's concerns in proposing the item.[149] We agree, and have revised the note following the item accordingly.

Trade Aggregation. Clients engaging an adviser can benefit when the adviser aggregates trades to obtain volume discounts on execution costs. Item 12 requires the adviser to describe whether and under what conditions it aggregates trades. If the adviser does not aggregate trades when it has the opportunity to do so, the adviser must explain in the brochure that clients may therefore pay higher brokerage costs. One commenter supported this disclosure, stating that it is helpful and meaningful to clients.[150] However, another commenter expressed concern that such disclosure would suggest that advisers should always aggregate orders, and noted that there are circumstances where an adviser may decide that it is better for the client not to do so, such as with multiple large trades that may create a market impact.[151] Other commenters argued that trade aggregation practices are not material to clients.[152] But aggregation practices may have a material effect on the quality of execution. Thus, we believe that such practices should be disclosed in the brochure.

Finally, one commenter suggested deleting the words "in quantities sufficient to obtain reduced transaction costs" from the first sentence of Item 12.B since there may be other circumstances in which advisers may aggregate client trades that should be disclosed to clients.[153] As this item was intended to require advisers to explain their aggregation practices along with the reasons for and consequences of those practices more generally, we have removed this limiting phrase.

Item 13. Review of Accounts. Item 13 requires that an adviser disclose whether, and how often, it reviews clients' accounts or financial plans, and identify who conducts the review.[154] An adviser that reviews accounts other than regularly must explain what circumstances trigger an account review.

Three commenters addressed this item. One supported it as being helpful to clients.[155] Two thought that this item provided non-critical information that could be eliminated in the interest of providing a shorter brochure to clients.[156] We believe the disclosure, which can be brief, provides very useful information to clients about their advisers' management of their accounts. As a result, we are adopting this item substantially as it was proposed.[157]

Item 14. Client Referrals and Other Compensation. Item 14 requires an adviser to describe in its brochure any arrangement under which it or its related person compensates another for client referrals and describe the compensation. The brochure also must disclose any arrangement under which the adviser receives any economic benefit, including sales awards or prizes, from a person who is not a client for providing advisory services to clients.[158]

We received three comments on this item. One supported the proposed item, stating that these areas involve practices that raise conflicts of interest.[159] Another suggested that it be omitted because certain disclosure required under this item is already required by rule 206(4)–3 under the Advisers Act (the "cash solicitation rule").[160] The cash solicitation rule, however, applies only to certain types of payments and requires disclosure by the solicitor rather than the adviser.[161] Finally, one commenter urged that we amend the Item to disclose the conflicts of interest associated with these arrangements.[162] We agree. There are significant conflicts of interest when an adviser receives benefits from a third party for providing advisory services to a client, or when an adviser pays a third party for client referrals. We are revising Item 14.A from our proposal to require an adviser that accepts benefits from a non-client for providing advisory services to clients describe the arrangement, any conflicts of interests that arise from the arrangement, and how the adviser addresses those conflicts.

Item 15. Custody. Item 15 requires an adviser with custody of client funds or securities to explain in its brochure that clients will receive account statements directly from the qualified custodian, such as a bank or broker-dealer that maintains those assets. Advisers must also explain to clients that they should carefully review the account statements they receive from the qualified custodian. In addition, if an adviser also sends clients account statements, the adviser's explanation must include a statement urging clients to compare the account statements they receive from the qualified custodian with those they receive from the adviser. Comparing statements will allow clients to determine whether account transactions, including deductions to pay advisory fees, are proper. This disclosure is very similar to the statement required to be made by advisers under our recently amended custody rule.[163]

We proposed an alternative disclosure requirement in Item 15 that we are not adopting today. Proposed Item 15.A. would have required that, if clients did not receive account statements from qualified custodians, the adviser must disclose the risks that clients would face as a result.[164] This alternative is no longer relevant because the amendments to the custody rule eliminated the option that permitted advisers to substitute their own account statements for those from a qualified custodian.[165]

Item 16. Investment Discretion. Item 16 requires an adviser with discretionary authority over client accounts to disclose this fact in its brochure,[166] and any limitations clients may (or customarily do) place on this

[149] See Alliance Letter.

[150] See NRS Letter.

[151] See IAA Letter.

[152] See Fried Frank Letter.

[153] See Schnase Letter.

[154] Item 13 is similar to Item 11 in the previous Part 2.

[155] See CFA Institute Letter.

[156] See SIFMA Letter; Sutherland Letter.

[157] The Schnase Letter suggested changing the word "employee" in Item 13.A to "supervised person." As defined in the Form ADV Glossary, "supervised person" means "any of your officers, partners, directors (or other persons occupying a similar status or performing similar functions), or employees, or any other person who provides investment advice on your behalf and is subject to your supervision or control." For purposes of consistency throughout Part 2A, we are making the change suggested by the commenter. We also are substituting the word "supervised person" for the word "employee" in Item 14.B, Instruction 6 for Part 2A, Appendix 1 (the wrap fee program brochure), and Item 6.C of Part 2A, Appendix 1.

[158] Similar disclosure was previously required by Item 13 of Part 2.

[159] See CFA Institute Letter.

[160] See Sutherland Letter.

[161] Rule 206(4)–3 applies to advisers paying cash referral fees to solicitors, and thus does not require disclosure of non-cash benefits. The rule requires, among other things, that an unaffiliated solicitor provide the adviser's brochure and a separate disclosure document described in the rule to clients or prospective clients at the time of any solicitation activities. See rule 206(4)–3(a)(2)(iii).

[162] See Schnase Letter. This commenter also suggested that we rename this item since Item 14.B relates only to payment for client referrals. In light of this comment, we are renaming this item "Client Referrals and Other Compensation."

[163] See Custody of Funds or Securities of Clients by Investment Advisers, Investment Advisers Act Release No. 2968 (Dec. 30, 2009) [75 FR 1456 (Jan. 11, 2010)] ("Custody Rule Adopting Release") at section II.A.

[164] Id. We received two comments on proposed Item 15.A. See ICI Letter; ABA Committee Letter.

[165] Custody Rule Adopting Release, see supra note 163.

[166] An adviser has "discretionary authority" if it is authorized to make purchase and sale decisions for client accounts. See Form ADV Glossary. This definition of discretionary authority is derived from section 3(a)(35) of the Exchange Act [15 U.S.C. 78c(a)(35)]. An adviser also has discretionary authority if it is authorized to select other advisers for the client. This Item is similar to Item 12.A of the previous Part 2.

authority.[167] Two commenters suggested that the Commission not require advisers to provide duplicative disclosure regarding discretionary authority as it likely would be incorporated into the description of the advisory business in Item 4.[168] We note that if the information is provided in response to Item 4, the adviser may cross-reference the information. We therefore are adopting this item as proposed.

Item 17. Voting Client Securities. Item 17 requires advisers to disclose their proxy voting practices. This item parallels rule 206(4)–6 under the Advisers Act, which, among other things, requires advisers registered with the Commission to disclose certain information about their proxy voting practices.[169] Item 17 also requires advisers to disclose whether they have or will accept authority to vote client securities and, if so, to describe briefly the voting policies they adopted under rule 206(4)–6. Each adviser must describe whether (and how) clients can direct it to vote in a particular solicitation, how the adviser addresses conflicts of interest when it votes securities, and how clients can obtain information from the adviser on how the adviser voted their securities. Item 17 also requires an adviser to explain that clients may obtain a copy of the adviser's proxy voting policies and procedures upon request. Advisers that do not accept authority to vote securities must disclose how clients receive their proxies and other solicitations.[170]

Some commenters suggested that we eliminate Item 17 in its entirety, arguing either that the required disclosure is not important to clients or that most of the information already is available in advisory contracts.[171] Others supported this disclosure requirement, noting that clients are interested in understanding the potential conflicts of interest that may arise from an adviser's proxy voting.[172] We agree that proxy voting practices and the conflicts arising from such practices are important information that should be disclosed, and note that rule 206(4)–6 independently would require the same disclosure even if we were to eliminate it from the brochure.[173] Accordingly, we are adopting Item 17, but with one modification.

We had proposed to require detailed information about an adviser's use of third-party proxy voting services and how the adviser pays for proxy voting services. Most of the commenters addressing this proposed requirement argued that the information is not relevant for most clients.[174] In light of the Commission's Concept Release on the U.S. proxy system issued on July 14, 2010, which requests comment on a wide range of questions and issues relating to proxy advisory firms,[175] we are adopting Item 17 without this requirement. Clients interested in this information may obtain it from their advisers upon request.

Item 18. Financial Information. This item requires disclosure of certain financial information about an adviser when material to clients. Specifically, an adviser that requires prepayment of fees must give clients an audited balance sheet showing the adviser's assets and liabilities at the end of its most recent fiscal year.[176] The item also requires an adviser to disclose any financial condition reasonably likely to impair the adviser's ability to meet contractual commitments to clients if the adviser has discretionary authority over client assets, has custody of client funds or securities, or requires or solicits prepayment of more than $1,200 in fees per client and six months or more in advance.[177] For instance, disclosure may be required where a judgment or arbitration award was sufficiently large that payment of it would create such a financial condition. Under these circumstances, clients are exposed to the risk that their assets may not be properly managed—and prepaid fees may not be returned—if, for example, the adviser becomes insolvent and ceases to do business. Finally, Item 18 requires an adviser that has been the subject of a bankruptcy petition during the past ten years to disclose that fact to clients.[178] As discussed above, although we are rescinding rule 206(4)–4 we caution advisers that their fiduciary duty of full and fair disclosure may require them to continue to disclose any precarious financial condition promptly to all clients, even clients to whom they may not be required to deliver a brochure or amended brochure.[179]

One commenter recommended elimination of the balance sheet requirement, stating that the balance sheet gives an imperfect picture of the financial health of an adviser,[180] and another was concerned that disclosure of financial information would unduly discriminate against smaller advisers.[181] We believe that a client that becomes a creditor of an adviser because it prepays fees would want information about the adviser's condition. This information is currently required to be disclosed to clients, and commenters have not persuaded us that it should be omitted. As a result, we are adopting Item 18 as proposed.

Item 19. Index. We proposed to require that the brochure filed with us include an index of the items required by Part 2A indicating where in the brochure the adviser addresses each item. This index was intended to facilitate review by our staff for compliance with the requirements of Part 2A. As discussed above, we are now requiring advisers to provide their

[167] For example, clients may not understand that they may ask the adviser not to invest in securities of particular issuers.

[168] See IAA Letter; Sutherland Letter. They argued that such information would already be disclosed under Items 4.B, 4.C and 4.E (advisory business) or Item 8 (strategies and risks).

[169] Proxy Voting Release, see supra note 3. Rule 206(4)–6 requires advisers to adopt and implement written voting policies and procedures. Advisers also are required to keep certain records relating to their voting. Advisers that exercise voting authority over client securities must describe their voting policies and procedures to clients and furnish clients with a complete copy upon request.

[170] If an adviser accepts proxy voting authority for some accounts but not others, the adviser should disclose the relevant information required by this Item for each type of account unless the adviser has prepared separate brochures for the other accounts.

[171] See NAPFA Letter; Morgan Stanley Letter.

[172] See CFA Institute Letter; CII Letter.

[173] We have brought enforcement actions relating to advisers' proxy voting policies and procedures. See, e.g., In the Matter of INTECH Investment Management LLC and David E. Hurley, Investment Advisers Act Release No. 2872 (May 7, 2009) (settled order).

[174] See ASG Letter; Fried Frank Letter; IAA Letter; ICI Letter; Janus Letter; Lininger Letter. A few commenters supported this disclosure. See CFA Institute Letter; CII Letter.

[175] Concept Release On The U.S. Proxy System, Investment Advisers Act Release No. IA–3052 (July 14, 2010) [75 FR 42982 (July 22, 2010)].

[176] As proposed, we are increasing the threshold amount from the existing threshold, $500, to $1,200 to reflect the effects of inflation, based upon the Personal Consumption Expenditures Chain-Type Price Index as published by the U.S. Department of Commerce, since we adopted Form ADV in 1979. We also are requiring, as proposed, an audited balance sheet from advisers that solicit clients to prepay fees over $1,200. This portion of Item 18 is similar to Item 14 in the previous Part 2.

[177] This disclosure was previously required by rule 206(4)–4. In the release adopting rule 206(4)–4, we noted that a determination about what constitutes financial condition reasonably likely to impair an adviser's ability to meet contractual commitments is inherently factual in nature but will generally include insolvency or bankruptcy. See Rule 206(4)–4 Adopting Release, supra note 106 at n.6.

[178] This includes the obligation of an adviser that is organized as a sole proprietorship to disclose a personal bankruptcy. This requirement conforms to our view that bankruptcy generally constitutes a "financial condition of the adviser that is reasonably likely to impair the ability of the adviser to meet contractual commitments to clients" requiring disclosure under rule 206(4)–4. See Rule 206(4)–4 Adopting Release, supra note 106.

[179] See supra note 106 and accompanying text.

[180] See Fried Frank Letter.

[181] See Verbeck Letter.

responses to the items in Part 2 in the same order as the items appear in the form. As a result, the index would be duplicative of the table of contents and is no longer necessary. We therefore are not adopting this requirement.

Part 2A Appendix 1: The Wrap Fee Program Brochure. Advisers that sponsor wrap fee programs[182] continue to be required to prepare a separate, specialized firm brochure (a "wrap fee program brochure" or "wrap brochure") for clients of the wrap fee program in lieu of the sponsor's standard brochure.[183] The items in Appendix 1 to Part 2A contain the requirements for a wrap fee program brochure, and are substantially similar to those previously in Schedule H, the separate wrap fee program brochure in previous Part 2.[184] However, we are revising the requirements of Schedule H to incorporate many of our amendments to the Part 2A firm brochure.

We also are adopting an additional disclosure requirement to the wrap fee program brochure. It requires an adviser to identify whether any of its related persons is a portfolio manager in the wrap fee program and, if so, to describe the associated conflicts. For example, an adviser may have an incentive to select a related person to participate as a portfolio manager based on the person's affiliation with the adviser, rather than based on expertise or performance. This item requires advisers to disclose whether related person portfolio managers are subject to the same selection and review criteria as the other portfolio managers who participate in the wrap fee program and, if they are not, how they are selected and reviewed.

Two commenters requested clarification that an adviser can delegate its brochure delivery requirement to the sponsor of the wrap fee program,[185] and one of these commenters also requested clarification that the adviser could satisfy its recordkeeping obligations that evidence delivery of the brochure by such records being retained in the offices of the sponsor and not the adviser, as long as the adviser was able to provide the records to Commission staff upon request.[186] We confirm that a sponsor may deliver the adviser's brochures and maintain certain records as long as the sponsor, upon request of the Commission's staff, will produce promptly the records for the staff at the appropriate office of the adviser or the sponsor. This delegation does not relieve the adviser of its legal delivery obligation, however, and thus the adviser should take steps to assure itself that the sponsor is performing the tasks the adviser has delegated.

3. Delivery and Updating of Brochures

The Commission also is adopting amendments to rule 204–3; our rule under the Advisers Act that requires registered advisers to deliver their brochures and certain updates to clients and prospective clients.[187]

a. Delivery to Clients

Initial Delivery. Rule 204–3, as amended, requires an adviser to deliver a current brochure before or at the time it enters into an advisory contract with the client.[188] The rule does not require advisers to deliver brochures to certain advisory clients receiving only impersonal investment advice[189] or to clients that are investment companies registered under the Investment Company Act of 1940 ("Company Act").[190] As proposed, we have expanded the latter exception to cover advisers to business development companies ("BDCs") that are subject to section 15(c) of the Company Act, which requires a board of directors to request, and the adviser to furnish, information to enable the board to evaluate the terms of the proposed advisory contract.[191] Because of this safeguard, we believe that adopting an obligation for these advisers to deliver a brochure to these BDC clients is not necessary.[192] An adviser does not have to prepare (or file with us) a brochure if it does not have any clients to whom a brochure must be delivered.[193]

Annual Delivery. Advisers must annually provide to each client to whom they must deliver a brochure either: (i) A copy of the current (updated) brochure that includes or is accompanied by the summary of material changes; or (ii) a summary of material changes that includes an offer to provide a copy of the current brochure.[194] As proposed, each adviser

[182] Under wrap fee programs, which also are sometimes referred to as "separately managed accounts," advisory clients pay a specified fee for investment advisory services and the execution of transactions. The advisory services may include portfolio management and/or advice concerning selection of other advisers, and the fee is not based directly upon transactions in the client's account.

[183] We adopted the requirement for a separate brochure for wrap fee clients in 1994. See Disclosure by Investment Advisers Regarding Wrap Fee Programs, Investment Advisers Act Release No. 1411 (Apr. 19, 1994) [59 FR 21657 (Apr. 26, 1994)]. Advisers whose entire advisory business is sponsoring wrap fee programs will prepare a wrap brochure but will not be required to prepare a standard advisory firm brochure. See Instruction 10 of Instructions for Part 2A of Form ADV. An adviser will have to prepare both a standard firm brochure and a wrap fee program brochure if it both sponsors a wrap fee program and provides other types of advisory services, and will deliver both a standard and a wrap brochure to a client who receives both types of services. Wrap fee sponsors would, like other advisers, be required to provide brochure supplements to their wrap fee clients.

[184] We have brought enforcement actions regarding wrap fee program disclosure. See, e.g., In re Banc of America Investment Services, Inc. and Columbia Management Advisors, LLC (as successor in interest to Banc of America Capital Management, LLC), Investment Advisers Act Release No. 2733 (May 1, 2008) (settled order).

[185] See Federated Letter; MMI Letter.

[186] See MMI Letter. Rules 204–2(a)(14) and 204–2(e)(1) under the Advisers Act describe advisers' recordkeeping obligations relating to brochure delivery.

[187] The brochure delivery and updating obligations are the same for both a standard brochure and a wrap fee program brochure. See rule 204–3.

[188] See rule 204–3(b). Rule 204–3 requires a registered adviser to furnish each client and prospective client with a written disclosure statement which may be either a copy of the adviser's completed Part 2A or a written document containing the information required by Part 2A. Previously, such delivery had to occur at least 48 hours before entering into the advisory agreement, or at the time of entering into the agreement if the client has the right to terminate the agreement without penalty within five business days thereafter. We received two comments on this proposed change to the timing of the required initial brochure delivery, both in support. See Pickard Letter; T. Rowe Letter.

[189] See rule 204–3(c)(2) and Instruction 1 for Part 2A of Form ADV. Advisers are not required to deliver brochures to advisory clients receiving only impersonal investment advice for which the adviser charges less than $500 per year. As proposed, we increased the dollar threshold triggering this exception from $200 to $500 to reflect the effects of inflation, based upon the Personal Consumption Expenditures Chain-Type Price Index, as published by the U.S. Department of Commerce, since rule 204–3 was adopted in 1979. We did not receive comments on this change.

[190] See rule 204–3(c)(1) and Instruction 1 for Part 2A of Form ADV.

[191] See supra note 190. As discussed above, an adviser's fiduciary duty of full and fair disclosure, however, may require it to continue to disclose any material legal event or precarious financial condition promptly to all clients, even clients to whom it may not be required to deliver a brochure or amended brochure. See supra note 106 and accompanying text.

[192] Two commenters urged us to adopt an exception for "hedge funds," or clarify that advisers to hedge funds are not required to deliver copies of brochures to their investors. See ABA Committees Letter; Fried Frank Letter. We note that rule 204–3 requires only that brochures be delivered to "clients." We further note that the Court of Appeals for the D.C. Circuit stated that the "client" of an investment adviser managing a hedge fund is the fund itself, not an investor in the fund. Goldstein v. SEC, 451 F.3d 873 (D.C. Cir. 2006).

[193] See Instruction 7 for Part 2A of Form ADV.

[194] See rule 204–3(b) and Item 2 to Part 2A of Form ADV. The offer also must be accompanied by a Web site address and a telephone number and e-mail address for obtaining the complete brochure pursuant to the Instructions for Part 2, as well as the Web site address for obtaining information about the adviser through IAPD. We also are adopting an amendment to our recordkeeping rule that will require the adviser choosing this approach to preserve a copy of the summary of material changes, so that our examination staff has access to such separately provided summaries. See rule 204–2(a)(14)(i). See Section IV below.

If an adviser includes the summary of material changes in its brochure, and amends its brochure

must make this annual delivery no later than 120 days after the end of its fiscal year.[195] Advisers may deliver a brochure and summary of material changes or summary of material changes, along with an offer to provide the brochure to clients electronically in accordance with the Commission's guidelines regarding electronic delivery of information.[196] An adviser that does not include, and therefore file, its summary of material changes as part of its brochure (on the cover page or the page immediately following the cover) must file its summary as an exhibit, included with its brochure when it files its annual updating amendment with us, so that the summary of material changes is available to the public through IAPD.[197]

We proposed that each adviser annually deliver an updated brochure to its clients because we were concerned that clients may be relying on "stale" brochures. Many commenters representing advisers objected, arguing that this requirement would cause advisers to incur significant costs,[198] and that clients are not interested in receiving an annual brochure.[199] We believe our revised approach—permitting advisers to deliver annually the summary of material changes, which was suggested by several commenters[200]—addresses our concern that clients may today be relying on "stale" brochures, while alleviating commenters' concerns regarding the costs and burdens of annual delivery of the brochure.[201]

Some commenters urged that we revise our electronic delivery guidance[202] so that disclosure placed on the adviser's web page or on IARD would be deemed to be delivered to its clients, regardless of whether the clients have provided consent to electronic delivery.[203] We note that an adviser's fiduciary duties may require it to obtain client consent to many of the disclosures required by Part 2 and that electronic access, without evidence that the adviser's delivery obligation has been met (such as by obtaining the client's consent to electronic delivery along with appropriate notice and access) would not, in our judgment, serve to adequately protect client interests.[204]

Some commenters recommended that advisers be required to send clients a notice providing a Web site link to where the brochure is posted on the Internet, rather than having to deliver the actual brochure to clients initially.[205] Another commenter objected, arguing that many investors are not yet willing to use the Internet to receive disclosure documents and that an approach that would rely on electronic delivery would be premature for retail investors.[206] We are not making such changes at this time, but will continue to consider different approaches to delivering financial information to investors.

Interim Delivery. As proposed, rule 204–3 requires advisers to deliver an updated brochure (or a document describing the material facts relating to the amended disciplinary event) promptly whenever the adviser amends its brochure to add a disciplinary event or to change material information already disclosed in response to Item 9 of Part 2A.[207] One commenter opposed the interim updating requirement, expressing concern that it would result in "frequent interim disclosure of information of minimal relevance to clients."[208] We disagree. We believe that disclosure of disciplinary information is highly relevant to clients because it reflects on the integrity of the investment adviser, may affect a client's trust and confidence in the adviser, and may be of even greater interest if the adviser is adding disciplinary information frequently. Therefore, we are adopting this requirement as proposed.

b. Updating Part 2A of Form ADV

Similar to the existing requirements, the amended rules require advisers to keep the brochures they file with us current by updating them at least annually, and updating them promptly when any information in the brochures (except the summary of material changes and the amount of assets under management, which only has to be updated annually) becomes materially inaccurate.[209] In the case of both annual and interim updates, advisers will make changes to their brochures using their own computer systems and then simply file the revised versions of their brochures through IARD.[210]

In some cases, an adviser filing its annual updating amendment may not have any material changes to make to its brochure. If the adviser has not filed any interim amendments to its brochure since the last annual amendment and the brochure continues to be accurate in all material respects, the adviser would not have to prepare or deliver a summary of material changes to clients. The adviser also would not have to prepare and file an updated firm brochure as part of its annual updating amendment. If there was an interim amendment or the brochure contained a material inaccuracy, however, the adviser would have to file a summary of material changes describing any interim amendment(s) along with an updated firm brochure as part of its annual

on an interim basis between annual updating amendments, the adviser should consider whether it should update its summary of material changes to avoid confusing or misleading clients reading the updated brochure.

[195] See Rule 204–3(b) and Instruction 2 for Part 2A of Form ADV. As discussed below, rule 204–1 requires an adviser registered with the Commission to annually revise its Form ADV, including its brochure, within 90 days of its fiscal year end. Advisers typically provide clients with reports quarterly, and the 120-day period is designed to provide sufficient flexibility to allow advisers to include the updated brochure or summary in a routine quarterly mailing to clients. We expect that permitting an adviser to send this document together with these routine mailings could substantially reduce delivery costs. See Section VII below.

[196] Use of Electronic Media by Broker-Dealers, Transfer Agents, and Investment Advisers for Delivery of Information, Investment Advisers Act Release No. 1562 (May 9, 1996) [61 FR 24644 (May 15, 1996)] ("Electronic Media Release").

[197] See Instruction 6 for Part 2A of Form ADV. The adviser must upload its brochure and the summary (as an exhibit) together in a single, text-searchable file in Adobe Portable Document Format (PDF) on IARD. See Instruction 6 for Part 2A of Form ADV.

[198] See AICPA Letter; Eddy Letter; FPA Letter; IAA Letter; ICI Letter; Mercer Letter; Merrill Lynch Letter; Morgan Stanley Letter; MMI Letter; NAPFA Letter; NRS Letter; Pickard Letter; ProEquities Letter; Roundtable Letter; Schwab Letter; SIFMA Letter; Sutherland Letter; USAA Letter; comment letter of Wachovia Securities LLC (May 16, 2008) ("Wachovia Letter"); Wellington Letter, comment letter of Wall Street Financial Group (May 16, 2008) ("WSFG Letter").

[199] See, e.g., ASG Letter; comment letter of Clifford Swan Investment Counsel (May 5, 2008) ("Clifford Letter"); First Allied Letter; FPA Letter; FSI Letter; comment letter of Moody Aldrich Partners (May 15, 2008) ("Moody Aldrich Letter"); NRS Letter; Roundtable Letter; WSFG Letter.

[200] See ASG Letter; Clifford Letter; Federated Letter; First Allied Letter; FPA Letter; FSI Letter; comment letter of the Investment Adviser Association (Aug. 26, 2008); Merrill Lynch Letter; Moody Aldrich Letter; NRS Letter; Roundtable Letter; Schnase Letter; WSFG Letter.

[201] One commenter representing consumers agreed that such an approach could minimize the costs of delivery without significantly sacrificing investor protection. See Consumer Federation Letter.

[202] See Electronic Media Release, see supra note 196.

[203] See, e.g., ABA Committees Letter; IAA Letter; Mercer Letter; Roundtable Letter; Sutherland Letter; Wachovia Letter.

[204] See Electronic Media Release, supra note 196 at Section II.A.3.

[205] See, e.g., ASG Letter; Borek Letter; FSI Letter; ICI Letter; Lininger Letter; Merrill Lynch Letter; MMI Letter; Morgan Stanley Letter; NAPFA Letter; Pickard Letter; SIFMA Letter; Wellington Letter.

[206] See Consumer Federation Letter.

[207] See rule 204–3(b)(4).

[208] See FSI Letter.

[209] If an adviser is amending its brochure for a separate reason between annual amendments, and the amount of assets under management is materially inaccurate, the adviser should amend this disclosure. See Instruction 4 for Part 2A of Form ADV.

[210] See rule 204–1(b).

amendment filing. Although previously filed versions of an adviser's brochures will remain in the IARD system, only the most recent version of an adviser's brochure will be available to the public through the Commission's Web site.[211] The purpose of the public disclosure Web site is to provide the public with current information about advisers, rather than historic information.[212]

B. Part 2B: The Brochure Supplement

Rule 204–3 also requires that each firm brochure be accompanied by brochure supplements providing information about the advisory personnel on whom the particular client receiving the brochure relies for investment advice.[213] Among other things, the brochure supplements will contain information about the educational background, business experience, and disciplinary history (if any) of the supervised persons who provide advisory services to the client. The brochure supplement thus includes information that would not necessarily be included in the firm brochure about supervised persons of the adviser who actually provide the investment advice and interact with the client.

Several commenters supported the brochure supplement requirement.[214] One stated that the brochure supplement's "greater personal relevance to investors will make [it] among the most widely read of the disclosure documents they receive, particularly if they receive it in a timely fashion."[215] Another stated that the brochure items addressed areas of interest to clients and stated that "information on the qualifications and background of those who influence clients in connection with their investments are as relevant, if not more relevant, than the information currently required by Part 2 on senior executives of the firm that may have little or no direct contact with the client."[216]

Several advisers that also are registered as broker-dealers, however, urged that we not require a brochure supplement, arguing that the brochure supplement would prove excessively costly, that at least some of the information is available on the Financial Industry Regulatory Authority's (FINRA) web-based BrokerCheck system,[217] and that information not available through BrokerCheck (such as the "Educational Background," "Other Business Activities," "Additional Compensation," and "Supervision" sections) is either not important to clients or could be covered by general disclosure in the firm brochure about the firm's policies and procedures.[218] We disagree. We believe that the additional information required by the supplement will be important to many clients and, particularly for large advisers, cannot be sufficiently described by firm policies and procedures. For large advisers, such policies will by necessity tend to be general because they must cover a large number of supervised persons with a range of ancillary activities and conflicts. For example, we do not believe that a prospective client would find it particularly helpful to read in the firm brochure that all of the adviser's associated persons had earned a college degree. Or that some of their associated persons had additional business activities that may involve conflicts of interest. Disclosure of such generalized information about the firm's associated persons is unlikely to be meaningful to clients seeking to understand the background, particular conflicts and outside business activities of the individual providing investment advice to them.

Commenters have, however, persuaded us to permit advisers to make use of BrokerCheck as well as the IAPD system to disclose disciplinary information available on those systems when the client has received a brochure supplement electronically.[219] The instructions for Part 2B of Form ADV provide that the adviser may disclose in a supplement delivered electronically that the supervised person has a disciplinary event and provide a hyperlink to either the BrokerCheck or the IAPD systems.[220] We believe that this accommodation addresses commenters' concerns regarding duplication of disclosure requirements, while meeting our objective of providing advisory clients with convenient access to information necessary to assess the individuals they are relying on for investment advice.[221] In addition to this accommodation, we have made several other changes to the proposed brochure supplement requirements in response to comments, which we discuss below.

1. Format

As proposed, the amendments require advisers to write their supplements in plain English, but offer an adviser flexibility in presenting information in a format that is best suited to the advisory firm. This flexibility is designed to reduce the cost of preparing and delivering supplements. Advisers may include supplement information within the firm's brochure, an approach that may be attractive to smaller firms with few persons for whom they will be required to prepare supplements.[222] Advisers may elect to prepare a supplement for each supervised person. Alternatively, they can prepare separate supplements for different groups of supervised persons (e.g., all supervised persons in a particular office or work group). To promote comparability of brochure supplements, we are requiring that a brochure supplement must be organized in the same order, and contain the same headings, as the items appear in the form, whether provided in a brochure or separately.[223]

[211] In the case of an adviser that prepares, files and delivers to clients separate brochures for the various different advisory services it offers, the most recent version of each of its brochures will be available via the public disclosure Web site.

[212] Instructions for obtaining historic brochure filings may be found at *http://www.sec.gov/answers/publicdocs.htm.*

[213] See rule 204–3(b)(3). We believe that brochure supplements will be important to advisory clients in selecting an adviser because clients place great weight on the supervised person's qualifications and events that may reflect on the integrity of advisory personnel. See Proposing Release, supra note 8, at Section II.B.1.

[214] See ASG Letter; Consumer Federation Letter; CFA Institute Letter; FPA Letter; IAA Letter; Lininger Letter; NASAA Letter.

[215] Consumer Federation Letter.

[216] CFA Institute Letter.

[217] Another commenter argued against reliance on BrokerCheck. See Consumer Federation Letter.

[218] See, e.g., CGMI Letter; Merrill Lynch Letter; Morgan Stanley Letter; Schwab Letter; SIFMA Letter. BrokerCheck, which is designed to help investors check the professional background of current and former FINRA-registered securities firms and brokers, is available at *http://www.finra.org/Investors/ToolsCalculators/BrokerCheck/index.htm.* The following commenters argued that we should not require the brochure supplement because it would provide little new or useful information but would create significant costs and burdens. See, e.g., NAPFA Letter; Pickard Letter; Roundtable Letter; USAA Letter; comment letter of John H. Vineyard (Mar. 18, 2008) ("Vineyard Letter"). For the reasons discussed in the text, we disagree.

[219] IAPD was recently enhanced to allow investors to obtain disciplinary history of supervised persons. See *http://www.nasaa.org/NASAA_Newsroom/Current_NASAA_Headlines/12811.cfm* for a press release announcing the launch of an enhancement to IAPD to allow users to search for individuals.

[220] See Instruction 3 for Part 2B of Form ADV.

[221] We also believe that this approach addresses the concern expressed by one commenter that reliance on BrokerCheck would hurt those investors who are least sophisticated and therefore are most likely to need this information, but who are the very ones that are least likely to seek it out. See Consumer Federation Letter.

[222] IARD data as of May 3, 2010 indicate that 81% of advisers registered with us have 10 or fewer employees performing investment advisory functions on their behalf. Over 65% have five or fewer employees performing advisory functions.

[223] If provided in a brochure, supplements must be included at the end of the brochure and be sequenced for each supervised person. See

2. Supplement Items

Part 2B, as we proposed and as we are adopting it today, consists of six items. Many commenters who addressed the specific proposed items supported the content of the brochure supplements generally.[224] Others offered specific comments on certain items; we address these comments below.

Item 1. Cover Page. Each supplement's cover page must include information identifying the supervised person (or persons) covered by the supplement as well as the advisory firm. One commenter stated that the brochure supplement should not require a separate cover page.[225] We intended Item 1 of the brochure supplement to require that the information specified in the item be included on the front page of the supplement, not that this be the only information on a cover page. We have modified Item 1 accordingly to clarify that the information required by the item may be presented either on a separate cover page or at the top of the first page of the brochure supplement.

Item 2. Educational Background and Business Experience. Item 2 requires the supplement to describe the supervised person's formal education and his or her business background for the past five years.[226] If the supervised person either has no high school education, no formal education after high school, or no business background, the adviser must disclose this fact in the supplement. The business background section must identify the supervised person's positions at prior employers and not merely list the names of prior employers.[227]

Advisers may include information about professional designations in the supplement if they so choose. One commenter urged the Commission to require the listing of any professional designations held as long as the designations conform to the North American Securities Administrators Association (NASAA) model rules and state regulations that prohibit the misleading use of designations or certifications.[228] A few other commenters encouraged the Commission to require disclosure about the minimum qualifications required for any disclosed professional designation.[229] We are not electing to require a listing of professional designations as we do not require, nor do we endorse, any designations. We are concerned that the Commission requiring such disclosure could cause clients to mistakenly believe that we do endorse designations. We do believe, however, that some clients may be interested in learning of professional designations held by the individuals providing them with investment advice. However, we do not believe that such disclosure is meaningful without an explanation of the minimum qualifications required to obtain the designation. Accordingly, we are adding a requirement that if professional designations are disclosed in the supplement, the supplement must also provide a sufficient explanation of the minimum qualifications required for the designation to allow clients and potential clients to understand the value of the designation. The disclosure, of course, also cannot be materially false or misleading by suggesting, for example, that the designation implies more qualifications or experience than the actual designation standards require.[230]

Item 3. Disciplinary Information. Item 3 requires disclosure of any legal or disciplinary event that is material to a client's evaluation of the supervised person's integrity. It includes certain disciplinary events that the Commission presumes are material to such an evaluation if they occurred during the last 10 years.[231] Several commenters supported this requirement, and stated that such information would be of great interest to clients.[232]

As proposed, Item 3 of the supplement would have required disclosure of any event for which the supervised person had ever resigned or otherwise relinquished a professional attainment, designation or license in anticipation of it being suspended or revoked (other than for suspensions or revocations for failure to pay membership dues). Two commenters recommended that we not require this particular disclosure, stating that an adviser would not know a supervised person's reason for relinquishing a designation or license.[233] We recognize that an adviser may not always know why a supervised person is relinquishing a designation or license. We are modifying this requirement to clarify that this disclosure need only be made if the adviser knew or should have known that the supervised person relinquished his or her designation or license.

As discussed above, we are modifying Item 3 to permit advisers that send supplements electronically to clients to include hyperlinks to disciplinary information available through the FINRA BrokerCheck system as well as the IAPD system. A number of supervised persons of investment advisers also are registered representatives of a broker-dealer firm or are subject to state investment adviser reporting requirements and thus may have disciplinary disclosure available through BrokerCheck or IAPD. Permitting advisers to hyperlink to these systems may minimize the costs of brochure supplements by leveraging

Instruction 1 of General Instructions for Part 2 of Form ADV and Instruction 6 for Part 2B of Form ADV.

[224] See, e.g., CFA Institute Letter, CFP Board Letter; FPA Letter.

[225] See ASG Letter.

[226] Previously, Item 6 of Part 2 of Form ADV required this information about the adviser's principal executive officers and about individuals who determine general investment advice on behalf of the adviser.

[227] For example, clients may be interested in knowing that a supervised person was previously employed as an analyst at a hedge fund as opposed to being employed as a computer support specialist at a hedge fund.

[228] See CFP Board Letter.

[229] See ASG Letter; First Allied Letter; NASAA Letter. But see Vineyard Letter (stating that the supplement should not allow descriptions of professional designations since such disclosure could imply that the Commission advocated obtaining the particular designation).

[230] We note that our staff and other securities regulators have warned that investors may be confused by some professional designations, such as those that imply expertise in providing services to seniors. See Protecting Senior Investors: Report of Securities Firms Providing "Free Lunch" Sales Seminars, Joint Report by the Staff of the Commission's Office of Compliance Inspections and Examinations, NASAA, and FINRA (available at *http://www.sec.gov/spotlight/seniors/freelunchreport.pdf*); Staff Update, "Senior" Specialists and Advisors: What You Should Know About Professional Designations (available at *http://www.sec.gov/investor/pubs/senior-profdes.htm*). While we acknowledge that a number of well-regarded professional designations and attainments exist, the required credentials, training, and experience associated with different designations vary widely. FINRA has established and maintains a database of designations used across the financial services industry that contains basic information about the designation, such as the issuing organization, prerequisites, and educational requirements. *http://apps.finra.org/DataDirectory/1/prodesignations.aspx.*

[231] This list parallels the list of legal and disciplinary events in Item 9 of Part 2A that must be disclosed in the firm brochure and which are derived from the prior disclosure requirements set out in rule 206(4)–4. The list also is substantially similar to the list of disciplinary events advisers and their advisory affiliates are already required to disclose in response to Item 11 of Form ADV, Part 1A.

As under Item 9 of Part 2A, Item 3 of Part 2B permits an adviser to rebut the presumption with respect to a particular event, in which case no disclosure to clients about the event will be required. We require an adviser rebutting a presumption of materiality to document that determination in a memorandum and retain that record in order to better permit our staff to monitor compliance with this important disclosure requirement. As under Item 9 of Part 2A, a note in Item 3 explains four factors the adviser should consider when assessing whether the presumption can be rebutted.

[232] See CFA Institute Letter; CFP Board Letter; Consumer Federation Letter; FPA Letter; NASAA Letter.

[233] See First Allied Letter; IAA Letter.

existing infrastructure established by broker-dealer and adviser regulation. To take advantage of this provision, the brochure supplement must be delivered electronically and must include: (i) A statement that the supervised person has a disciplinary history, the details of which can be found on BrokerCheck or the IAPD (as the case may be); and (ii) a hyperlink to the relevant system with a brief explanation of how the client can access the disciplinary history.

Two commenters recommended that the Commission reconcile the disclosure requirements in Item 3 of the brochure supplement with Item 14 of Form U4, the uniform form used by broker-dealer and state investment advisory representatives to register (which includes certain disciplinary disclosure and is the source of such information that is available on BrokerCheck), stating that a lack of uniformity would complicate compliance.[234] We may consider in the future whether the disclosure requirements in Item 3 and in Form U4 should be conformed, as we recognize the substantial overlap between these disclosure items. We note, however, that although the disclosure requirements are not phrased identically, any disclosure required by the brochure supplement would also have to be disclosed on Form U4.

Item 4. Other Business Activities. Item 4 requires an adviser to describe other business activities of its supervised persons. The item specifically requires disclosure with respect to other capacities in which the supervised person participates in any investment-related business and any material conflicts of interest such participation may create.[235] In addition, the item requires the supplement to include information about any compensation, including bonuses and non-cash compensation, the supervised person receives based on the sales of securities or other investment products, as well as an explanation of the incentives this type of compensation creates.[236] We are adopting this item substantially as proposed. We believe that disclosure of any such compensation is important because it creates an incentive for the supervised person to base investment recommendations on his or her own compensation rather than on clients' best interests.

We also are adopting a requirement to disclose other business activities or occupations that the supervised person engages in if they involve a substantial amount of time or pay.[237] Clients may have different expectations of an individual whose sole business is providing investment advice than of an individual who is engaged in other substantial business activities. Several commenters supported inclusion of this item.[238] A few commenters urged that we not require disclosure of this information,[239] with one commenter arguing that such information is irrelevant to the adviser's competence in providing investment advice,[240] and another stating that such a requirement would be burdensome.[241] We are retaining this requirement because we believe that investors will find this information helpful in assessing the conflicts created by those activities.

Finally, some commenters stated that the Commission should define "substantial sources of income" and "substantial amount of time" by reference to specific percentages or in some other manner.[242] We believe that what amounts to "substantial" in many cases depends on particular facts and circumstances, and thus we are not establishing any specific definition of what is and is not substantial. However, we do understand the concern that there is likely some level at which a source of income or amount of time would rarely interfere or conflict with an adviser's business of providing investment advice. Accordingly, we are allowing advisers to make a presumption that if the other business activities represent less than 10 percent of the supervised person's time and income, they are not substantial.[243]

Item 5. Additional Compensation. This item requires that the supplement describe arrangements in which someone other than a client gives the supervised person an economic benefit (such as a sales award or other prize) for providing advisory services.[244]

Two commenters suggested that we not require this disclosure, with one of these commenters stating that disclosure of any conflicts arising out of such compensation arrangements is already required by an adviser's fiduciary duty and that firms should be free to make such disclosure in the firm's brochure or investment advisory contract, rather than in the brochure supplement.[245] We are adopting Item 5 as proposed. We believe clients need to know if their individual adviser has these arrangements in order to assess the advisory services of that particular supervised person and that general disclosure of this conflict in a firm-wide brochure or advisory contract is not an adequate substitute. As we stated above, general disclosure of this type of conflict in many firm-wide brochures or advisory contracts will by necessity tend to be general because it must cover a variety of supervised persons with a range of compensation arrangements. Such general disclosure is unlikely to be meaningful to clients seeking to understand the particular compensation arrangements and associated conflicts of the individual providing investment advice to them.

Item 6. Supervision. This item requires an adviser to explain how the firm monitors the advice provided by the supervised person addressed in the brochure supplement. It also requires a firm to provide the client with the name, title, and telephone number of the person responsible for supervising the advisory activities of the supervised person.

We are adopting Item 6 as proposed. One commenter supported this requirement, stating that it is important for clients to have the ability to locate a person within a firm to whom they can direct questions or voice concerns about their accounts.[246] Some commenters recommended that the Commission not require this item, asserting that investors would not be interested in this information and that this requirement would not make sense for smaller advisory firms.[247] We believe that it is important for clients to be able to contact an appropriate person at an advisory firm, regardless of the firm's size, if they have any questions or complaints about the handling of their account. This will allow clients to determine appropriate redress for their complaints without having to go through the particular supervised person that is the focus of the complaint. Therefore, we are requiring this disclosure.

Several commenters requested that the Commission permit advisers to

[234] See ICI Letter; NASAA Letter.

[235] See Item 4.A of Part 2B.

[236] See Item 4.A.2 of Part 2B.

[237] See Item 4.B of Part 2B.

[238] See, e.g., Berlin Letter; CFA Institute Letter; CFP Board Letter; NASAA Letter. The NASAA Letter urged disclosure of all outside business activities regardless of whether they occupied a substantial amount of that person's time or income.

[239] See IAA Letter; ProEquities Letter; Vineyard Letter.

[240] See IAA Letter.

[241] See ProEquities Letter.

[242] See Case Letter; FSI Letter; ProEquities Letter; TAG Letter.

[243] See Item 4.B of Part 2B.

[244] Bonuses based (in part or whole) on sales, client referrals or new accounts trigger required disclosure, but other bonuses do not. Regular salaries need not be disclosed.

[245] See Morgan Stanley Letter; Schwab Letter. Morgan Stanley made the comment regarding fiduciary duties.

[246] See CFA Institute Letter.

[247] See FPA Letter; FSI Letter; IAA Letter; Sutherland Letter.

furnish clients with a general contact number and email address instead of the name and contact information for the supervisor because supervisory personnel may change frequently, triggering the need for updated supplements, and because some supervised persons have multiple supervisors.[248] We do not agree with commenters' suggestion and are adopting this requirement as proposed. We believe that providing the name and telephone number of a specific individual responsible for supervising the representative's advisory activities will ensure that the client has ready access to the supervisor if the client has any complaints or concerns. In the unlikely event that a supervised person has more than one direct supervisor of his or her advisory services, the adviser may identify any one of those supervisors as long as that supervisor has the authority to respond to the client's question or complaint (or can raise the issue to a higher-level supervisor, if appropriate).

3. Delivery and Updating

a. Delivery

We are requiring as proposed that a client be given a brochure supplement for each supervised person who: (i) Formulates investment advice for that client and has direct client contact; or (ii) makes discretionary investment decisions for that client's assets, even if the supervised person has no direct client contact. We believe that clients are most interested in learning about the background and experience of these individuals from whom they receive investment advice.

In the Proposing Release, we stated that an adviser would not, however, have to provide a supplement for a supervised person who provides discretionary advice only as part of a team and has no direct client contact.[249] We explained our view that, when investment advice is formulated by a team, specific information about each individual team member takes on less importance. A few commenters stated that all representatives providing advice as part of a team will likely have direct client contact from time to time, and thus that the Commission's proposed exemption from the brochure supplement delivery requirement for supervised persons that provide advice as part of a team and that have no direct client contact, in fact, would not exempt any team members from this requirement as a practical matter, despite the limited utility of disclosure about each supervised person comprising a large advisory team.[250] We agree with commenters that volumes of disclosure about a large group of supervised persons likely would not be meaningful to investors. Accordingly, we are modifying this requirement, as suggested by one commenter,[251] based on the approach to disclosure under the Company Act where a team of individuals is jointly and primarily responsible for the day-to-day management of a mutual fund's portfolio.[252] If investment advice is provided by a team comprised of more than five supervised persons, brochure supplements need only be provided for the five supervised persons with the most significant responsibility for the day-to-day advice provided to the client.[253]

Another commenter urged the Commission to exempt from the brochure supplement requirement any supervised persons providing non-discretionary advice (even if not part of a team).[254] A commenter representing investors strongly opposed this recommendation, arguing that investors do not differentiate the advice they receive on this basis.[255] We believe that, where a supervised person is providing investment advice directly to a client, disclosure relating to the background and integrity of that person would be important to a client. It assists the client in evaluating the value of that investment advice, an evaluation we believe clients make regardless of whether the advice is non-discretionary.[256]

An adviser generally must provide its clients with a brochure supplement for each supervised person who provides the advisory services as described above. However, advisers are not required to deliver supplements to three types of clients: (i) Clients to whom an adviser is not required to deliver a firm brochure (e.g., registered investment companies and business development companies); (ii) clients who receive only impersonal investment advice; [257] and (iii) certain "qualified clients" who also are officers, directors, employees and other persons related to the adviser.[258] An adviser that does not have any clients to whom a supplement will have to be delivered will not have to prepare any supplements.[259] Similarly, an adviser will not have to prepare a supplement for any supervised person who does not have clients to whom the adviser must deliver a supplement.

We proposed exempting advisers from delivering the brochure supplement to certain sophisticated clients,[260] and received several comments from those representing advisers supporting the exemption or urging its expansion.[261] The brochure supplement is intended to contain fundamental information about the qualifications of persons providing investment advice. Sophisticated clients are likely to request this type of information, even if not affirmatively provided by an investment adviser. Given that advisers will be preparing and delivering brochure supplements anyway, we believe the incremental burden of meeting the rule's obligations with respect to these sophisticated clients will be minimal and would not justify an exemption. We are therefore requiring that advisers deliver brochure supplements to all clients other than, as described above: (i) Those clients to whom the adviser is not required to deliver a firm brochure; (ii) clients who receive only impersonal investment advice; and (iii) certain "qualified clients" who also are officers, directors, employees and other persons related to the adviser.

The supervised person's supplement initially must be given to each client at or before the time when that specific supervised person begins to provide advisory services to that specific

[248] See FPA Letter; FSI Letter; Roundtable Letter; USAA Letter; Wachovia Letter.

[249] See Proposing Release, supra note 8, at n.164.

[250] See, e.g., Federated Letter; ICI Letter; NAPFA Letter.

[251] See ICI Letter.

[252] See Instruction 2 for Item 5(b) of Form N–1A.

[253] See rule 204–3(b)(3).

[254] See SIFMA Letter.

[255] See Consumer Federation Letter.

[256] We note that an adviser's fiduciary duties to its clients under the Advisers Act do not turn on whether its advice is provided on a discretionary or non-discretionary basis.

[257] This exception from the supplement delivery requirement differs slightly from the exception from the brochure delivery requirement, in that it does not depend on the cost of the impersonal advisory services involved. This is because in situations involving impersonal advisory services, the nature of the services are such that supervised persons of the adviser are unlikely to be directly providing advisory services to clients. As a result, we believe that in such situations requiring supplement delivery will result in an unnecessary expense with little appreciable benefit. We believe, however, that delivery of a firm brochure will be useful where the cost of the impersonal advisory services is significant, that is $500 or above.

[258] Rule 205–3(d)(1)(iii) also defines certain related persons of an adviser as "qualified clients," including: (i) Any executive officers, directors, trustees, general partners, or persons serving in a similar capacity, of the advisory firm; or (ii) any employees of the advisory firm (other than employees performing solely clerical, secretarial or administrative functions) who, in connection with their regular functions or duties, participate in the investment activities of the firm and have been performing such functions or duties for at least 12 months.

[259] See note to rule 203–1(a) and (b); Instruction 1 for Part 2B of Form ADV.

[260] See Proposing Release at Section II.B.1.

[261] See, e.g., IAA Letter; ICI Letter; Pickard Letter; T. Rowe Letter.

client.[262] A few commenters argued that a large adviser with thousands of supervised persons may have staff changes on any given day and suggested that delivery be permitted promptly after the time the supervised person begins providing advisory services to the client.[263] But the brochure supplement is intended to assist investors in determining whether to retain the services of a particular adviser and in evaluating the individual advice they are receiving. This function could not be fully served if a client did not receive the supplement until after the supervised person already had begun providing advice to the client. As a result, we are adopting this delivery requirement as proposed.

b. Updating

We are adopting as proposed, the requirement that advisers deliver an updated supplement to clients only when there is new disclosure of a disciplinary event, or a material change to disciplinary information already disclosed, in response to Item 3 of Part 2B.[264] Because the final rule allows advisers to reference BrokerCheck or IAPD for disclosure of a supervised person's disciplinary information when the supplement is delivered electronically, if the supplement refers to BrokerCheck or IAPD a change in disclosure required by Part 2B would require the adviser to electronically deliver an updated supplement (or sticker) to clients when BrokerCheck or IAPD has been updated with new disclosure of a disciplinary event, or a material change to disciplinary information already disclosed, with the updated supplement (or sticker) indicating that the disciplinary information for the supervised person has changed and providing a hyperlink to BrokerCheck or IAPD. We believe this information is critical for clients because it reflects upon the supervised person's integrity and may affect a client's trust and confidence in that person and the adviser that employs the supervised person.

As with the brochure, advisers must amend a brochure supplement promptly if information in it becomes materially inaccurate.[265] Any new clients to whom the adviser is obligated to deliver a supplement under our amended rule must be given an amended supplement (or the "old" supplement and a sticker). Supplements, like brochures, may be delivered on paper or electronically.[266] Because we believe most information in the supplement is unlikely to become materially inaccurate over time, advisers are not required to deliver supplements to existing clients annually. These requirements have not been modified from the proposal.

C. Filing Requirements, Public Availability

The Commission is amending rule 204–1 to require advisers to file their new brochures with us electronically through the IARD system.[267] Advisers are not required to file brochure supplements or supplement amendments with the Commission, and they will not be available on the Commission's public website.[268]Advisers are required to maintain copies of all supplements and amendments in their files.[269]

The IARD will accept brochure filings using the text-searchable Adobe Portable Document Format ("PDF").[270] The IARD provides advisers with online access to the Part 2A Items and instructions. Instead of completing Part 2A online, advisers will create their brochure on their own computers, convert it to a PDF, and then attach the completed document to their filing on IARD, much like attaching a document to an e-mail. To update brochures, advisers will make the necessary changes to the source file on their own computers and then attach the revised versions to their IARD filing. The IARD will not accept an annual updating amendment without an updated brochure, a representation by that adviser that the brochure on file does not contain any materially inaccurate information, or a representation that the adviser does not have to prepare a brochure because it does not have to deliver it to any clients (e.g., the adviser's clients are limited to registered investment companies). The IARD also will not accept an annual updating amendment without a representation that the summary of material changes is attached as an exhibit to or included in the updated brochure or a representation that no summary of material changes is required because there have been no material changes to the adviser's brochure since its last annual updating amendment.[271] If an adviser using multiple brochures discontinues using a particular brochure, the IARD system will permit the adviser to eliminate that brochure from its current filing.[272]

Most commenters addressing electronic filing supported the new filing requirement and public availability of the brochures.[273] Some, however, expressed concern that public disclosure of advisers' brochures through IAPD could reveal proprietary and confidential business information to competitors.[274] We have reviewed our requirements and do not believe that they would require disclosure of proprietary or confidential business information. Indeed, the information that would be disclosed is very similar to that which we have long required to be disclosed by advisers in their brochures and which until 2000 was filed in paper with the Commission and publicly available.[275] We believe that there is a substantial public interest in having this information readily available to prospective clients, which may assist them in their search for an investment adviser. In addition, we believe that public disclosure will have a beneficial effect on business practices by, for example, discouraging advisers

[262] See rule 204–3(b)(3) and Instruction 3 for Part 2B of Form ADV.

[263] See IAA Letter; ICI Letter.

[264] See rule 204–3(b)(4). We note that an adviser's fiduciary duty may require it to inform a client of material changes to disclosures in the supplement even if rule 204–3 does not require delivery of an updated supplement to clients.

[265] See Instruction 4 for Part 2B of Form ADV.

[266] See Instruction 5 for Part 2B of Form ADV.

[267] Rule 204–1 had required advisers to file only "Part 1A of Form ADV" electronically. We are amending it to require Part 1A and Part 2A of Form ADV to be filed electronically.

[268] See rules 203–1(a) and 204–1(b) and Instruction 9 for Part 2B of Form ADV. Because brochure supplements would not be filed with us, they would not be deemed filed and would not be required as part of any state notice filing. Section 307(a) of the National Securities Market Improvement Act of 1996, Public Law 104–290, 110 Stat. 3416 (1996) (state securities authorities may only require SEC-registered advisers to file with the states copies of those documents advisers have filed with the Commission).

[269] See rule 204–2(a)(14)(i) and Instruction 9 for Part 2B of Form ADV.

[270] FINRA will assist investment advisers with converting brochures into a text-searchable PDF format using software available to the adviser or, if necessary, providing the adviser with PDF conversion software.

[271] If the adviser's summary of material changes is a separate document, the adviser must attach the summary as an exhibit to its brochure and upload the brochure and the summary in one single, text-searchable, PDF file on IARD.

[272] Similarly, if an adviser is no longer required to prepare a brochure for delivery, the IARD system will permit the adviser to eliminate that brochure from its current filing.

[273] See CGMI Letter; Fried Frank Letter; CFA Institute Letter; Katten Letter; NAPFA Letter; NASAA Letter; NRS Letter; NSCP Letter; Sidley Letter.

[274] See comment letter of Brown & Brown Financial Services, Inc. (Mar. 27, 2008) ("Brown Letter"), comment letter of Executive Advisers, Inc. (May 14, 2008); comment letter of Larry Laws and Associates, Inc. (May 14, 2008); comment letter of James E. Wernli (May 20, 2008) ("Wernli Letter").

[275] Until 2000, our rules required advisers to file both Part I and Part 2 of Form ADV with us and it was available in our public reference room. See Section I.C.2 of Electronic Filing by Investment Advisers; Amendments to Form ADV, Investment Advisers Act Release No. 1897 (Sept. 12, 2000) [65 FR 57438 (Sept. 22, 2000)].

from engaging in certain practices because those practices would have to be publicly disclosed.

Other commenters expressed concern that a fund adviser's required public disclosure of Part 2 through IAPD could jeopardize the reliance of any private funds that it advised on the private offering exemption in the Securities Act of 1933 and the safe harbor for offshore transactions from the registration provisions in Section 5 of that statute.[276] We believe registrants can provide information required by Part 2 without jeopardizing reliance on those exemptions. The inclusion of private fund information beyond that required in Part 2, however, such as subscription instructions, performance information, and financial statements, may jeopardize such reliance by constituting a public offering or conditioning the market for the securities issued by those funds.

D. Transition to New Requirements

As discussed below in the discussion of compliance and effective dates,[277] we are adopting transition requirements that, as proposed, provide advisers with at least six months to comply with the amended rules and forms.[278] While a few commenters asked for more time to prepare the brochures and brochure supplements,[279] we believe the proposed transition period is sufficient. Advisers that are currently registered with us will have at least 8 months (from the end of July 2010 through the end of March 2011) to prepare and file narrative brochures as a result of the compliance dates discussed below. We also note that we have changed the period by which firms must deliver the new brochure and brochure supplements to their existing clients after this electronic filing compliance date from 30 days to 60 days to make sure that advisers have enough time to comply with the requirement.[280]

III. Amendments to Form ADV Instructions and Glossary

Together with the Part 2 amendments, we also are making conforming amendments to the General Instructions and the Glossary of Terms for Form ADV. We are amending the General Instructions to Form ADV to include instructions regarding brochure filing requirements. Similarly, we are amending the Glossary of Terms to add the following five terms that are used in Part 2: (i) "brochure;"[281] (ii) "brochure supplement;"[282] (iii) "custody;"[283] (iv) "investment adviser representative;"[284] (v) "supervised person;"[285] and (vi) "wrap brochure or wrap fee program brochure."[286] We also are updating the Glossary to reflect cross-references to these new terms, and cross-references to existing Glossary entries used in the revised portions of the Form.

We also are updating the Glossary to correct a discrepancy in the definition of "Non-Resident" to make it consistent with the definition in rule 0–2, the Advisers Act rule related to the procedures for serving process, pleadings, and other papers on non-resident investment advisers, and advisers' non-resident general partners and managing agents. This revision properly reflects the Commission's intent at the time the Glossary was originally adopted, that the definition of "Non-Resident" in the Glossary be the same as that in rule 0–2.[287] Although technical in nature, this amendment may potentially result in an increased number of corporate entities qualifying as non-resident general partners or managing agents of registered advisers. Certain entities will need to file Form ADV–NR with the Commission to appoint agents for service of process because they relied on the glossary definition and therefore were not required to file the form. We received no comments on these changes and are adopting them as proposed.

IV. Amendments to Rule 204–2

We also are adopting conforming amendments to Advisers Act rule 204–2, the rule that sets forth the requirements for maintaining and preserving specified books and records, to require registered investment advisers to retain copies of each brochure, brochure supplement, and each amendment to the brochure and supplements that are prepared as required under the rule 204–3.[288] Additionally, the amendments require registered advisers to prepare and preserve documentation of the method they use to calculate managed assets for purposes of Item 4.E in Part 2A of Form

[276] 15 U.S.C. 77e. Some expressed specific concern that the public disclosure may be deemed to violate the prohibition on "general solicitation" and "general advertising" that applies to private offerings conducted in accordance with Rule 506 of Regulation D. See AICA Letter; AIMA Letter; Fried Frank Letter; Janus Letter; NSCP Letter. One mentioned that the public disclosure could raise questions as to whether there are "directed selling efforts" in the United States, which would be inconsistent with the rules applicable to offshore offerings under Regulation S under the Securities Act. See Sidley Letter.

[277] See Section V of this Release.

[278] Rule 204–1(c). We proposed a transition schedule requiring advisers to comply with the new Part 2 requirements by the date they must make their next annual updating amendment to Form ADV following six months after the date the revised form becomes effective.

[279] See AICPA Letter; First Allied Letter; NAPFA Letter; T. Rowe Letter.

[280] Two commenters suggested a rolling transition over several months to avoid an inordinate demand on outside consulting and legal services by many advisers at the same time. See Fried Frank Letter; NAPFA Letter. We believe that the transition period we have provided to comply with the new Part 2 requirement permits advisers to work with their service providers in advance of the date their filings are required.

[281] "Brochure" means: "A written disclosure statement that you must provide to clients and prospective clients." See Form ADV: Glossary.

[282] "Brochure supplement" means: "A written disclosure statement containing information about certain of your supervised persons that your firm is required by Part 2B of Form ADV to provide to clients and prospective clients." See Form ADV: Glossary.

[283] "Custody" means "holding, directly or indirectly, client funds or securities, or having any authority to obtain possession of them. You have custody if a related person holds, directly or indirectly, client funds or securities, or has any authority to obtain possession of them, in connection with advisory services you provide to clients. Custody includes: (i) Possession of client funds or securities (but not of checks drawn by clients and made payable to third parties) unless you receive them inadvertently and you return them to the sender promptly but in any case within three business days of receiving them; (ii) Any arrangement (including a general power of attorney) under which you are authorized or permitted to withdraw client funds or securities maintained with a custodian upon your instruction to the custodian; and (iii) Any capacity (such as general partner of a limited partnership, managing member of a limited liability company or a comparable position for another type of pooled investment vehicle, or trustee of a trust) that gives you or your supervised person legal ownership of or access to client funds or securities." See rule 206(4)–2(d)(2).

[284] "Investment adviser representative" means: "Any of your firm's supervised persons (except those that provide only impersonal investment advice) is an investment adviser representative, if—(i) the supervised person regularly solicits, meets with, or otherwise communicates with your firm's clients, (ii) the supervised person has more than five clients who are natural persons and not high net worth individuals, and (iii) more than ten percent of the supervised person's clients are natural persons and not high net worth individuals." See Form ADV: Glossary. Cf. rule 203A–3(a).

[285] "Supervised person" means: "Any of your officers, partners, directors (or other persons occupying a similar status or performing similar functions), or employees, or any other person who provides investment advice on your behalf and is subject to your supervision or control." See Form ADV: Glossary.

[286] "Wrap brochure or wrap fee program brochure" means: "The written disclosure statement that sponsors of wrap fee programs are required to provide to each of their wrap fee program clients." See Form ADV: Glossary.

[287] This amendment will change the definition of "Non-Resident" to include "a corporation incorporated in or having its principal place of business in any place not subject to the jurisdiction of the United States." (emphasis added). See rule 0–2(b)(2) [17 CFR 275.0–2(b)(2)].

[288] See rule 204–2(a)(14)(i). The rule also will require advisers to keep and maintain a copy of the summary of material changes that is not included in the brochure, as well as a record of the dates that each brochure, amendment, and summary of material change was given to any client.

ADV, if that method differs from the method used to calculate "assets under management" in Part 1A of Form ADV.[289] The amendments also require advisers to prepare and preserve a memorandum describing any legal or disciplinary event listed in Item 9 in Part 2A and Item 3 in Part 2B for the period the event is presumed material, if the event is not disclosed in the adviser's brochure or the relevant brochure supplement.[290] These records will be required to be maintained in the same manner, and for the same period of time, as other books and records required to be maintained under rule 204–2(a). We received no comments on these changes and are adopting them as proposed.

V. Effective and Compliance Dates

The amended rules and forms will be effective on October 12, 2010.

A. New Investment Advisers

Each adviser applying for registration with the Commission after January 1, 2011 must file a brochure or brochures that meet the requirements of amended Part 2A as part of the application for registration on Form ADV.[291] Such advisers must, upon registering, begin to deliver to their clients and prospective clients a brochure and brochure supplements that meet the requirements of the amended form in accordance with the amended rules discussed above.[292]

B. Registered Advisers

Each adviser registered with the Commission whose fiscal year ends on or after December 31, 2010, must include in its next annual updating amendment to its Form ADV a brochure or brochures that meet the requirements of the amended form.[293] Accordingly, each adviser with a fiscal year end of December 31, 2010 must file an annual updating amendment with the new brochures no later than March 31, 2011. Within 60 days of filing such amendment, the adviser must deliver to its existing clients a brochure and brochure supplement that meet the requirements of amended Form ADV.[294] Each adviser must, after the initial filing of the brochures, begin to deliver to new clients and prospective clients a new brochure and brochure supplements in order to satisfy its obligations under the brochure rule.[295]

VI. Paperwork Reduction Act

As explained in the Proposing Release, certain provisions of the rule and form amendments that we are adopting today contain "collection of information" requirements within the meaning of the Paperwork Reduction Act of 1995 ("PRA").[296] In the Proposing Release, the Commission published notice soliciting comment on the collection of information requirements. The Commission submitted the collection of information requirements to the Office of Management and Budget ("OMB") for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11, and OMB approved these collections of information under control numbers 3235–0049 (expiring 2/28/2011), 3235–0278 (expiring 3/31/2011), 3235–0047 (expiring 2/28/2011), and 3235–0345 (expiring 3/31/2011). The titles for these collections of information are "Form ADV," "Rule 204–2," "Rule 204–3," and "Rule 206(4)–4," respectively, all under the Advisers 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 currently valid control number.

The respondents to the collections of information are investment advisers registered or applying for registration with us. We use the information to determine eligibility for registration with us and to manage our regulatory and examination programs. Clients use certain of the information to determine whether to hire or retain an adviser.

The rule and form amendments that we are adopting involve three distinct "collections of information" for purposes of the Paperwork Reduction Act. The first is the collection of information connected with Form ADV itself, specifically our amendments to Part 2 of Form ADV. The second collection of information involved is that under the amendment to rule 204–2, which requires advisers to maintain and preserve specified books and records. The third collection involved is that related to an amendment to rule 204–3, which requires advisers to deliver certain information required under Form ADV to their clients.

In addition, we are withdrawing rule 206(4)–4, the rule requiring advisers to disclose certain disciplinary and financial information, because the disclosure required by that rule is incorporated into the amendments to Part 2 of Form ADV that we are adopting.

A. Summary of Comment Letters

We requested comment on the Paperwork Reduction Act analysis contained in the Proposing Release. A number of commenters expressed concerns that the paperwork burdens associated with our proposed amendments to Part 2 of Form ADV were understated.[297] Several commenters stated that our estimates of the burdens of preparing and delivering brochure supplements were too low and that the requirement would impose heavy burdens on advisers, in particular, large advisory firms with thousands of employees and clients.[298] Several commenters noted that these costs would increase particularly in the context of wrap fee programs.[299] In response to comments on the requirements of Form ADV Part 2, we have made several substantive modifications to the proposed amendments that we believe in general will reduce the paperwork burdens associated with the rule and form amendments. For example, we have modified the annual brochure delivery requirement to allow it to be satisfied by delivering just a summary of material changes in the brochure. We have revised Item 5 so that advisers do not need to include a fee schedule in brochures provided only to clients that are "qualified purchasers." We have not adopted proposed disclosure of cash balance practices and proxy voting services from Items 8 and 17, respectively. We are permitting supervised persons with certain disciplinary information disclosed through FINRA's BrokerCheck system or the IAPD system to refer clients to that information in their brochure supplements (if they are provided electronically and contain a hyperlink to the BrokerCheck or the IAPD system, as relevant) rather than reproducing that information. When investment advice is provided to a client by a team, we are requiring that brochure supplements need only be provided for the five supervised persons with the most significant responsibility for the day-to-day advice provided to the client.

[289] See discussion at supra note 40 and accompanying text.

[290] See discussion at supra notes 86—89 and accompanying text.

[291] Rule 203–1(b). This requirement applies only if the adviser is required to deliver a brochure. See note to Rule 203–1.

[292] Rule 204–3(b).

[293] Rule 204–1(c). This filing requirement applies only if the adviser is required to deliver a brochure. See note to Rule 203–1.

[294] Rule 204–3(g)(1).

[295] Rule 204–3(g)(2).

[296] 44 U.S.C. 3501.

[297] See ASG Letter; Berlin Letter; Federated Letter; First Allied Letter; Fried Frank Letter; FSI Letter; IAA Letter; Jackson Letter; NAPFA Letter; NRS Letter; Pickard Letter; Sutherland Letter; Vineyard Letter.

[298] See Merrill Lynch Letter; Morgan Stanley Letter; Schwab Letter; SIFMA Letter; Sutherland Letter.

[299] See Federated Letter; MMI Letter; Morgan Stanley Letter.

B. Revisions to Paperwork Reduction Act Burden Estimates

After considering commenters' concerns that the Commission's estimated paperwork burdens for firms complying with the amended Form ADV Part 2 were too low, and in light of revisions we have made to our proposed amendments to Part 2, we are revising our estimates for purposes of the Paperwork Reduction Act.

1. Amendments to Form ADV

a. Part 2 of Form ADV

The information required by the amendments to Form ADV is mandatory. Advisers are required to disclose this information to their clients and, therefore, it is not kept confidential. The currently approved total annual burden for all advisers completing, amending, and filing revised Form ADV with us is 132,599 hours. As stated in the Proposing Release, we continue to believe that most of the paperwork burden will be incurred in advisers' initial preparation of a revised brochure and brochure supplements, as most advisers will have to draft a narrative brochure and all advisers will have to prepare new brochure supplements, and that over time this burden will decrease substantially because the paperwork burden will be limited to updating information. The paperwork burdens of preparing a narrative firm brochure and brochure supplements are likely to vary substantially among advisers, because Part 2 gives an adviser considerable flexibility in structuring its disclosure, the amount of disclosure required will vary among advisers, and the number of supplements that will need to be prepared depends on the number of supervised persons at a firm that provide investment advice. We believe that the revisions to Part 2 will impose a small burden on advisers in collecting information because there is a significant overlap between the information required by the previous Part 2 and the new Part 2A requirements and because advisers already collect information on the business background and disciplinary histories of their supervised persons to comply with state investment adviser representative registration requirements.[300] Accordingly, we expect that most of the paperwork burden from amended Part 2 will arise from an adviser drafting the narrative disclosure for its brochure and brochure supplements based on disclosures it and its supervised persons already made in Schedule F of Part 2 and in Form U4, and in expanding its discussion of how the adviser addresses certain conflicts of interest.

As noted above, we have revised our estimated burdens for purposes of the Paperwork Reduction Act to take into account comments received as well as substantive modifications to Part 2 from the form that was proposed.

In the Proposing Release, we estimated the average initial annual burden associated with Form ADV to be 5 hours for smaller advisers.[301] We received several comments that provided estimates of the paperwork burden associated with the proposed rule and form amendments for small advisers. One commenter estimated that preparing the initial Form ADV Part 2 would require 16 to 40 hours, depending on the nature of the firm's business, and that each subsequent amendment to that form would take 10 to 32 hours, depending on the nature of the amendments.[302] Another said that a small firm would take 60 hours to draft the initial brochure.[303] A small firm commenter estimated that it would take 40 to 60 hours to prepare the initial brochure and another 20 to 40 hours per year thereafter to update it.[304] A compliance consulting firm estimated that it would take on average 15 hours for a small firm to prepare the initial brochure.[305] One law firm estimated that smaller advisers would spend at least 44.5 hours preparing the new brochure.[306] We do not believe that small advisers will require as many as 60 hours for their initial revision of Part 2A because, as discussed above, firms already have collected much of the information for Part 2A, many of the disclosures were already required under previous Part 2 requirements or other Advisers Act rules or as a result of the adviser's fiduciary obligations, and small advisers are unlikely to have extensive conflicts of interest that would necessitate lengthy brochure disclosures. We have reviewed several brochures of small investment advisers drafted in a narrative format that would appear to be generally responsive to the requirements we are adopting today, and these brochures are short, likely because of the relative simplicity of most small advisers' business models.[307] We also do not believe that small advisers will spend significant amounts of time preparing brochure supplements because they have a small number of supervised persons. Based on these considerations, we estimate that the average initial annual burden associated with Form ADV to be at the low end of the 15 to 60 hour range provided by commenters, or 15 hours for each small adviser.

In the Proposing Release, we estimated that the average initial annual burden associated with Form ADV for medium-sized advisers would be approximately 50 hours. We received a comment from a medium-sized adviser stating that it currently spends approximately 45 hours per year to update its Part 2 brochure.[308] This commenter did not estimate how long it took to prepare its initial Part 2 brochure under the prior format and did not estimate how long it would take to prepare or update the new Part 2A brochure and brochure supplements. We received a comment from another medium-sized adviser estimating that it would take a minimum of 163 hours for the initial preparation and internal handling of the brochure supplement.[309] Most of our medium-sized advisers are closer to the size of small advisers than large advisers, with 77% of medium-sized advisers having between 11 and 50 employees.[310] Accordingly, we expect that while these advisers will have a higher burden than smaller advisers due to the greater size and complexity of their business model, the majority will not have burdens dramatically greater than small advisers. We also estimated that each medium adviser, on average, will require 30 minutes to prepare each brochure supplement, based on an estimate of

[300] There are three entirely new items in the Part 2A we are adopting today—Item 2's summary of material changes, Item 6's performance fee disclosure requirement, and Item 15's custody disclosure requirement. The remainder of the items in Part 2A either were generally covered by the previous Part 2 or were required disclosure under other Advisers Act rules, such as rule 206(4)–6 regarding proxy voting and rule 206(4)–4 regarding financial and disciplinary information. In addition, most states require that supervised persons of SEC-registered investment advisers that are investment adviser representatives file Form U4, which requires similar business background and disciplinary information as the brochure supplement.

[301] For purposes of the estimates in this section, we have categorized small advisers as those with 10 or fewer employees, medium-sized advisers as those with between 11 and 1,000 employees, and large advisers as those with over 1,000 employees. Unless otherwise noted, the IARD data cited below is based on advisers' responses to questions on Part 1A of Form ADV as of May 3, 2010.

[302] ASG Letter.

[303] NAPFA Letter.

[304] Jackson Letter.

[305] NCS Letter.

[306] Fried Frank Letter.

[307] We note that advisers that choose to disclose more than is required by Part 2A (or their fiduciary obligations) will create lengthier brochures than those that take a more focused approach.

[308] See Federated Letter.

[309] See First Allied Letter. The First Allied Letter stated that it had approximately 325 investment advisory representatives and assumed that each supplement would take 30 minutes to prepare.

[310] Based on IARD data as of May 3, 2010.

brochure supplement preparation time provided by one medium adviser commenter.[311] Based on these considerations and the comments on small firm burdens, we have revised our estimate of the average initial annual burden associated with Form ADV for each medium-sized adviser to be 97.5 hours.[312]

Finally, in the Proposing Release we estimated that the average initial annual burden associated with Form ADV for large advisers would be approximately 3,300 hours. We received no estimates from commenters of the burden on large advisers from preparing the new brochure. We received estimates from two of the largest advisers that the brochure supplement would require between 30,000 to 45,000 hours initially.[313] Unlike with respect to small and medium advisers, the brochure supplement dramatically increases the estimated burden associated with preparing Form ADV for large advisers because of their significantly larger number of employees that provide investment advice (some with over 1,000 per firm according to IARD data). The primary difference between the burden associated with preparing the brochure for large and smaller firms is the likelihood that there will be additional items to which large firms will have to respond and the likelihood that large firms will have additional conflicts of interest to address. We estimate that these additional brochure disclosures will add a relatively small amount compared to the burden estimate for medium advisers, but that the brochure supplement requirement will add a significant burden compared to medium advisers. We do not expect the burden for most large firms to be as substantial, on average, as estimated in the Merrill Lynch and Morgan Stanley comment letters, however, because these firms based their estimate on substantially more supervised persons providing investment advisory services than an average large adviser.[314] We estimate that preparing Part 1 and Part 2A of Form ADV would take each large adviser on average 100 hours per year.[315] Based on commenters' estimates, we now estimate that the brochure supplement will take each large adviser on average 30 minutes per supervised person to collect and prepare a supplement.[316] As a result, we now estimate the initial average burden associated with preparing Form ADV for each large adviser to be 1,989 hours.[317]

In the Proposing Release, we estimated that an average investment adviser's collection of information burden associated with initial preparation of Form ADV would be 22.25 hours per year. According to IARD data, there are 9,482 small advisers, 2,140 medium-sized advisers, and 36 large advisers. Based on the revised hourly burden estimates discussed above, we now believe that 36.24 hours is an accurate reflection of the time that it will take the average adviser to initially complete revised Form ADV (including both Parts 1 and 2).[318] This is an increase of 13.99 hours over our initial estimate.

Respondents under this collection of information will be advisers registered with the Commission as well as new applicants for investment adviser registration with the Commission. We estimate that approximately 1000 new investment advisers will register with us each year.[319] Thus, in combination with the approximately 11,658 existing investment advisers registered with the Commission, we estimate that the total number of respondents under this collection of information will be 12,658 advisers. Based on the estimated average collection of information burden of 36.24 hours per adviser, the total initial collection of information would amount to 458,726 hours for new registrants and for currently registered advisers that re-file Form ADV (including Part 2) through the IARD system.[320] Amortizing this total burden imposed by Form ADV over a three-year period to reflect the anticipated period of time that advisers would use the revised Form would result in an average burden of an estimated 152,909 hours per year,[321] or 12.08 hours per year for each new applicant and for each adviser currently registered with the Commission that would re-file through the IARD.[322]

We estimate that some advisers may incur a one-time initial cost for outside legal and compliance consulting fees in connection with preparation of Part 2 of Form ADV. While we received no specific comments on our estimate regarding outside legal costs in the Proposing Release, one commenter did state that compliance consultants assist a significant percentage of advisers in preparing their Form ADV.[323] As a result, we are changing our estimate to reflect a quarter of small advisers using compliance consulting services and a

[311] First Allied Letter.

[312] We assume that preparing Part 1 and Part 2A of Form ADV would take each medium adviser on average 60 hours per year based on our estimate for smaller advisers, the fact that the average medium adviser is closer in size to a small adviser than a large adviser, the discussion above that advisers already have much of the information required by the new Part 2A and it is largely a matter of converting it to a narrative format, and the one comment we did receive from a medium sized adviser on the time it took to amend its brochure annually. We estimate that each medium adviser, on average, has 75 supervised persons based on the average number of employees performing investment advisory functions at medium sized advisers according to IARD data. We thus estimated that each medium adviser on average would spend 37.5 hours preparing the initial brochure supplements (75 supervised persons x 30 minutes per supervised person = 37.5 hours per year), for a total of 97.5 hours for the initial preparation of all of Form ADV.

[313] The Merrill Lynch Letter estimated that the brochure supplement requirement would require 45,000 hours per year. The Morgan Stanley Letter estimated that it would take in the range of 30,000 to 35,000 hours for it to comply with the brochure supplement requirement initially and 8,000 to 10,000 hours annually to comply going forward. In their comment letters, Merrill Lynch and Morgan Stanley stated that approximately 8,000 and 14,000 employees, respectively, performed investment advisory functions at their firms. These employee numbers place these two commenters at the highest end of the range of the 36 advisers in our large category with only four other firms reporting as of May 3, 2010 that they had 8,000 or more employees performing such functions.

[314] See supra note 114.

[315] This estimate is based on our estimate for medium advisers, the discussion above that advisers already have much of the information required by the new Part 2A and it is largely a matter of converting it to a narrative format, and our view that the additional disclosure required by large advisers' business models is not so substantial as to require dramatically more brochure preparation time than medium advisers.

[316] We estimate that each large adviser, on average, has 3,777 supervised persons based on the average number of employees performing investment advisory functions at large advisers according to IARD data. The Merrill Lynch Letter estimated that each supplement would require 3 hours to prepare. We believe that this estimate includes the burden to track and update brochure supplements which we discuss and account for separately, and which are not part of this burden estimate. We do not expect that brochure supplements for supervised persons at large advisers are likely to require more preparation time than supplements at medium advisers, particularly when more supervised persons at large advisers than medium advisers are likely to have information available through BrokerCheck or the IAPD that can be referenced in those supervised persons' supplements, reducing supplement preparation time. Brochure supplements consist of only 6 disclosure items, several of which (i.e., cover page, supervision, education) are simple to collect and draft in a few minutes). Accordingly, we estimate that an adviser would spend 30 minutes per supervised person to collect and prepare a supplement.

[317] We estimate that each large adviser on average would spend 1,889 hours preparing the initial brochure supplements (3,777 supervised persons x 30 minutes per supervised person = 1,889 hours per year), for a total of 1,989 hours per year on average per large adviser for the initial preparation of all of Form ADV.

[318] 9,482 small advisers × an estimated 15 hours/adviser + 2,140 medium-sized advisers × an estimated 97.5 hours/adviser + 36 large advisers × an estimated 1,989 hours/adviser = 422,484 hours total. 422,484 hours/11,658 total advisers = 36.24 hours/adviser.

[319] Based on IARD data over the last five years.

[320] (12,658 advisers × 36.24 hours) = 458,726 hours.

[321] 458,726 hours/3 years = 152,909 hours/year.

[322] 152,909 hours/12,658 advisers = 12.08 hours/adviser.

[323] See NCS Letter.

quarter of small advisers using outside legal services and to reflect half of medium advisers using compliance consulting services in lieu of outside legal services and a quarter of medium advisers still using outside legal services. We estimate that the initial per adviser cost for legal services related to preparation of Part 2 of Form ADV would be $3,200 for small advisers, $4,400 for medium-sized advisers, and $10,400 for larger advisers.[324] We estimate that the initial per adviser cost for compliance consulting services related to initial preparation of the amended Form ADV will range from $3,000 for smaller advisers to $5,000 for medium-sized advisers.[325] We estimate that a quarter of small and half of medium advisers, or 2,371 and 1,070 advisers, respectively, are likely to seek outside compliance consulting services in their preparation of Form ADV.[326] We estimate that a quarter of small advisers, or 2,370 advisers, and a quarter of medium advisers, or 535 advisers, are likely to engage outside legal services.[327] We estimate that all of the 36 large advisers will engage outside legal services in preparation of Form ADV. Thus, we estimate that approximately 2,941 advisers will elect to obtain outside legal assistance and approximately 3,441 advisers will elect to obtain outside consulting services, for a total cost among all respondents of $22,775,400.[328]

In addition to the burdens associated with initial completion and filing of the revised form, we estimate that, on average, each adviser filing Form ADV through the IARD system will likely amend its form two times during the year.[329] A few commenters believed that we had underestimated the information burden associated with amending Form ADV.[330] As a result, we are revising our estimate of the collection of information burden for preparing amendments. One of the two amendments that firms on average make each year will be an interim updating amendment, and we estimate that this amendment will require 0.5 hours per amendment because interim amendments typically only amend one or two items [331] in Form ADV and thus should not require much time to prepare. The other amendment is the firm's annual updating amendment of Form ADV. Part 2A requires only a few additional requirements with the annual updating amendment than is required throughout the year—the summary of material changes since the last annual updating amendment, an updated fee schedule, and an updated figure for assets under management. We also expect that advisers will not have to spend a significant amount of time generally reviewing their brochure before filing their annual updating amendment as the instructions to the form and their fiduciary obligations require them to keep information they provide to clients free of material inaccuracies. Based on these considerations, we estimate that the average adviser will spend 6 hours per year completing their annual updating amendment to Form ADV. Finally, we believe that the information required in the brochure supplements is unlikely to change frequently for any particular supervised person, and, as a result, that brochure supplements will be amended infrequently.[332] We also estimate that changes to most of the supplement information is already tracked by advisers in order to allow them to keep Forms U4 for their investment advisory representatives current, and that tracking changes to this information for brochure supplement purposes as well will impose negligible additional costs. Accordingly, we estimate that it will require an average burden per adviser of one hour per year for interim amendments to brochure supplements, for a total burden on all advisers of 11,658 hours per year.[333] Thus, we estimate that the total paperwork burden on advisers of amendments to Form ADV will be 87,435 hours per year.[334]

Commenters also highlighted the fact that the particular supervised persons for whom the adviser will have to deliver brochure supplements to particular clients will change over time and that these changes will generate costs.[335] The adviser may hire new employees who may begin providing investment advisory services that require preparation of a brochure supplement. We estimate that advisers on average will hire two new supervised persons each year for which a brochure supplement would have to be prepared.[336] We further estimate that, on average, an adviser will spend 0.5 hours preparing each new brochure supplement.[337] Preparation of these new supplements thus would require all advisers to spend 11,658 hours per year.[338]

The revised total annual collection of information burden for advisers to file and complete the revised Form ADV (Parts 1 and 2), including the initial burden for both existing and anticipated new registrants plus the burden associated with amendments to the form as well as creating new supplements for new employees, is estimated to be approximately 252,002 hours per

[324] Outside legal fees are in addition to the projected hourly per adviser burden discussed above. $400 per hour for legal services × 8 hours per small adviser = $3,200. $400 per hour for legal services × 11 hours per medium-sized adviser = $4,400. $400 per hour for legal services × 26 hours per large adviser = $10,400. The hourly cost estimate of $400 on average is based on our consultation with advisers and law firms who regularly assist them in compliance matters.

[325] Outside compliance consulting fees are in addition to the projected hourly per adviser burden discussed above. Based on consultation with compliance consulting firms who regularly assist investment advisers in Form ADV preparation, we estimate that small advisers will incur expenses of $3000 per year for the initial preparation of the new Form ADV and medium advisers will incur expenses of $5000 per year for the initial preparation of the new Form ADV.

[326] 9,482 small advisers × 0.25 = 2,371. 2,140 medium-sized advisers × 0.5 = 1,070.

[327] 2,140 medium-sized advisers × 0.25 = 535.

[328] For outside legal services, ($4,400 × 535 medium advisers) + ($3,200 × 2,370 small advisers)) + ($10,400 × 36 large advisers) = $ 10,312,400. For compliance consulting services, ($3,000 × 2,371 small advisers) + ($5,000 × 1,070 medium advisers) = $12,463,000. $10,312,400+$12,463,000 = $22,775,400

[329] In the Proposing Release, we estimated that each adviser, on average, filing Form ADV through the IARD system amended its form 1.5 times per year. We have updated this estimate based on IARD system data regarding the number of filings of Form ADV amendments.

[330] In the Proposing Release, we estimated that each adviser, on average, would spend 0.75 hours per year amending its Form ADV. The ASG Letter estimated that amendments to Part 2 would take 10 to 32 hours, depending on the nature of the amendments. The Jackson Letter estimated that it would take small firms 20 to 40 hours per year to update Part 2. The Federated Letter stated that they currently spend approximately 45 hours per year amending the previous Part 2.

[331] Based on IARD system data.

[332] Largely for this reason, we have not broken down our estimated burden for preparing the annual updating amendment to Form ADV based on the size of the adviser since most of the difference in the initial Form ADV preparation burden was driven by the brochure supplement. We also do not believe that the burden for preparing an annual updating amendment to Part 2A of Form ADV will vary significantly based on the size of the adviser.

[333] 1 hour per year × 11,658 advisers = 11,658 hours per year.

[334] 11,658 advisers × 1 interim brochure amendment per year × 0.5 hours = 5,829 hours per year for interim amendments. 11,658 advisers × 1 annual brochure amendment per year × 6 hours = 69,948 hours per year for annual amendments. 11,658 advisers × 1 hour per year for supplement amendments = 11,658 hours per year for supplement amendments. 5,829 + 69,948 + 11,658 = 87,435 hours.

[335] See, e.g., Schwab Letter; SIFMA Letter; Sutherland Letter.

[336] Estimate is weighted average based on analysis of changes in aggregate responses to Item 5.B(1) of Part 1A of Form ADV over the last 5 years and the number of investment advisers registered with the Commission.

[337] See discussion at supra note 311 and accompanying text.

[338] Two new supervised persons per year × 0.5 hours per supplement × 11,658 investment advisers = 11,658.

year.[339] This burden represents an increase of 151,026 hours over that estimated in the Proposing Release.[340] This increase is attributable primarily to our increased estimates of the hourly preparation burden associated with Part 2 in response to comments. As discussed in the Proposing Release, in addition to these estimated burdens, under this collection of information there is also a burden of 16,455 hours associated with advisers' obligations to deliver to clients copies of their adviser codes of ethics upon request.[341] Thus, the estimated revised total annual hourly burden under this collection of information would be 268,457 hours.[342] This represents an increase of 135,858 hours per year from the currently approved burden.[343]

b. Rule 206(4)–4

Rule 206(4)–4 currently requires advisers to disclose certain disciplinary and financial information to clients. We are rescinding rule 206(4)–4 and incorporating its substantive provisions into Part 2 of Form ADV. The collection of information burden associated with the requirements of rule 206(4)–4 has been incorporated into the collection of information requirements for Form ADV, discussed above. Thus, the currently approved burden estimate for Form ADV already includes an estimate of the burdens associated with the disclosure of disciplinary and financial information connected with Part 2.

2. Rule 204–2

This requirement is found at 17 CFR 275.204–2 and is mandatory. The Commission staff uses the collection of information in its examination and oversight program, and the information generally is kept confidential.[344] The likely respondents to this collection of information requirement are all of the approximately 11,658 advisers currently registered with the Commission.

The amendments to rule 204–2 require advisers to prepare and preserve a memorandum describing any legal or disciplinary event listed in Item 9 in Part 2A of Form ADV and Item 3 in Part 2B of Form ADV, if the event is not disclosed in the adviser's brochure or the relevant brochure supplement. Additionally, the amendments require advisers to prepare and preserve documentation of the method they use to calculate managed assets for purposes of Item 4.E. in Part 2A of Form ADV, if that method differs from the method used to calculate "assets under management" in Part 1A of Form ADV. These records are required to be maintained in the same manner, and for the same period of time, as other books and records required to be maintained under rule 204–2(a).

As we stated in the Proposing Release, we believe that the amendments to rule 204–2 will result in an increased burden of four hours for each adviser subject to the additional requirements. We received no comments on the Commission's burden estimates relating to rule 204–2 and are leaving these estimates unchanged, except to update collection estimates based on IARD data.

We estimate that 350 advisers will use a method for calculating managed assets in Part 2A that differs from the method used to compute assets under management in Part 1A and thus would be required to prepare and preserve documentation describing the method used in Part 2A.[345] We also estimate that 156 advisers will conclude that the materiality presumption in Part 2 has been overcome with respect to a legal or disciplinary event, will determine not to disclose that event, and therefore would be required to prepare and preserve a memorandum describing the event.[346]

We estimate that a total of 506 advisers will have to prepare and preserve additional records in accordance with amendments to rule 204–2.[347] Only 487 of these are already accounted for in the currently approved burden estimate. We estimate that adding 19 advisers to those subject to the amended provisions of rule 204–2 will yield a 76 hour increase in burden under the rule.[348]

The approved annual aggregate burden for rule 204–2 is currently 1,954,109 hours based on an estimate of 10,787 registered advisers, or 181.15 per registered adviser.[349] Taking into account the estimated increased burden of 76 hours as discussed above, as well as an increase of 871 registered advisers,[350] the revised annual aggregate burden for all respondents to the recordkeeping requirements under rule 204–2 is therefore estimated to be 2,111,967 total hours.[351]

We further estimate that some advisers may incur a one-time cost for outside legal fees in connection with preparing a memorandum explaining their basis for not disclosing a legal event listed in Part 2 in their brochures and supplements. We estimate this one-time cost would include fees for approximately three hours of outside legal review and would amount on average to approximately $1,200 per adviser.[352] We believe that approximately 80 percent of the advisers preparing such memoranda would likely engage outside legal services to assist in their preparation.[353]

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[339] 152,909 hours per year attributable initial preparation of Form ADV + 87,435 hours per year for amendments to Form ADV + 11,658 hours per year for supplements for new employees = 252,002 hours.

[340] Revised burden 252,002 hours − proposing release burden of 100,976 hours = 151,026 hours.

[341] See Code of Ethics Adopting Release, supra note 114. As we estimated in the Proposing Release (and on which we received no comment), we estimate that only one percent of an adviser's clients actually request a copy the adviser's code of ethics. 0.01 × 1,300 (the estimated average number of clients per adviser) = 13 requests per registrant. See infra note 357 regarding the estimated average number of clients. We continue to estimate that responding to each such request involves a burden of 0.10 hours, amounting to an annual burden of 1.3 hours for each adviser stemming from the obligation to deliver copies of their codes of ethics to clients. 13 requests per adviser × 0.10 hours = 1.3 hours/adviser. This obligation applies to both currently-registered (11,658 respondents) and newly-registered advisers (1000 respondents), for a total annual burden of 16,455 hours. 12,658 respondents × 1.3 hours = 16,455 hours.

[342] 16,455 hours + 252,002 hours = 268,457 hours.

[343] Revised burden 268,457 hours − currently approved burden of 132,599 hours = 135,858 hours.

[344] See section 210(b) of the Advisers Act (15 U.S.C. 80b–10(b)).

[345] Based on the Commission staff's conversations with industry professionals, we anticipate that approximately three percent of the 11,658 advisers registered with us as of May 3, 2010 will use a method for computing managed assets in Part 2A of Form ADV that differs from the method used to compute assets under management in Part 1A of Form ADV. 11,658 advisers × 0.03 = 350 advisers.

[346] Approximately 1,559 advisers registered with the Commission report disciplinary information in Part 1A of their Form ADV as of May 3, 2010. We anticipate that most of these advisers will include all disciplinary information in their brochures and supplements, but that approximately 10% of these advisers, or 156, will need to prepare and preserve a memorandum explaining their basis for not disclosing a legal or disciplinary event listed in Part 2 in their brochures and supplements. 1,559 advisers × 0.10 = 156 advisers.

[347] 350 advisers that we estimate would prepare memoranda regarding an alternative method for calculating assets under management + 156 advisers that we estimate would prepare memoranda regarding unreported nonmaterial disciplinary events = 506 advisers.

[348] 506 advisers − 487 advisers = 19 advisers. 19 advisers × 4.0 hours = 76 hours.

[349] 1,954,109 hours/10,787 registered advisers = 181.15 hours per adviser.

[350] As stated above, our IARD data show that as of May 3, 2010 there were 11,658 advisers registered with the SEC. 11,658 − 10,787 = 871.

[351] (1,954,109 current burden hours + 76 hours due to an increase in the estimated number of registered advisers subject to additional recordkeeping under the amendments + (871 due to an increase of total number of registered advisers × 181.15 hours per adviser)) = 2,111,967. The annual average burden per registered adviser is therefore 181.16 hours. 2,111,967 total hours/11,658 advisers = 181.16 hours per adviser.

[352] Outside legal fees are in addition to the projected hourly per adviser burden discussed above. $400 per hour for legal services × 3 hours per adviser = $1,200. The hourly cost estimate is based on our consultation with advisers and law firms who regularly assist them in compliance matters.

[353] We made the same estimate in the Proposing Release and received no comment on this estimate.

Thus, we estimate that approximately 125 advisers will incur these costs, for a total cost among all respondents of $150,000.[354]

3. Rule 204–3

Rule 204–3 contains a collection of information requirement. This collection of information is found at 17 CFR 275.204–3 and is mandatory. Responses are not kept confidential. The likely respondents to this information collection are the approximately 11,658 investment advisers registered with the Commission.

Rule 204–3 previously required an investment adviser to deliver to clients, at the start of an advisory relationship, a copy of Part 2 of Form ADV or a written document containing at least the information required by Part 2. The rule previously required no further brochure delivery unless the client accepted the adviser's required annual offer. The brochure assists the client in determining whether to hire or retain an adviser.

The amendments to rule 204–3 require advisers to deliver their brochures and brochure supplements at the start of an advisory relationship and to deliver annually thereafter the full updated brochure or a summary of material changes to their brochure.[355] The amendments also require that advisers deliver an amended brochure or brochure supplement (or just a statement describing the amendment) to clients only when disciplinary information in the brochure or supplement becomes materially inaccurate.[356]

The total annual burden currently approved by OMB for rule 204–3 is 6,902,278 hours. This currently approved burden is based on each adviser having, on average, an estimated 670 clients. Our records now currently indicate that the 11,658 advisers registered with the Commission have, on average, 1,300 clients.[357] This change, along with our amendments permitting annual delivery of a summary of material changes to the brochure (instead of the entire brochure) alters the collection of information burden from that currently approved.

We expect that advisers will send their brochure or summary of material changes annually in a "bulk mailing" to clients that may include clients' account statements, periodic reports, or other important documents. We estimate that, with a bulk mailing, an adviser will require no more than 0.02 hours to send the adviser's brochure or summary of material changes to each client, or an annual burden of 26 hours per adviser.[358] Thus, we estimate the total burden hours for 11,658 advisers to distribute their firm brochure to existing clients initially and annually thereafter to be 303,108 hours per year.[359] We have revised our estimate of the amount of time it will take an adviser to deliver its brochure or summary of material changes based on our view that most advisers will make their annual delivery as part of the mailing of an account statement or other periodic report that they already make to clients, and thus the additional burden will be adding a few pages to the mailing.

Advisers also will be required to distribute interim updates disclosing new or revised disciplinary information in their brochure or supplements. We anticipate that in any given year, the number of such interim updates that advisers will be required to deliver is approximately 583.[360] We further estimate that an adviser will require no more than 0.1 hours per client for delivery of each such update.[361] This represents about 130 hours per interim update.[362] Thus, the aggregate annual hour burden for affected advisers to deliver interim updates to their brochures or supplements will be approximately 75,790 hours per year.[363]

Several commenters noted that some advisers will incur costs in creating systems to track which brochure supplements need to be delivered to which clients as supervised persons providing investment advice to particular clients change over time.[364] Because most medium advisers tend to resemble small advisers in terms of the number of employees providing investment advisory services,[365] we estimate that only large advisers will need to design and implement systems to track changes in supervised persons providing investment advice to particular clients. We estimate that on average each of the 36 large advisers will spend 200 hours per year designing and implementing such systems, for a total of 7,200 hours per year.[366]

Thus, the rule amendments requiring annual delivery and interim updating of advisers' brochures and supplements yields a total collection of information burden for rule 204–3 of 386,098 hours per year, or 33.1 hours per adviser.[367] This represents a decrease of 6,516,180 hours from the currently approved PRA burden.[368] The decreased burden results primarily from our revised estimate of the time it will take firms to deliver their brochures, supplements and amendments.

VII. Cost-Benefit Analysis

A. Background

The Commission is sensitive to the costs and benefits of its rules. This rulemaking will revise Part 2 of Form

[354] 156 advisers × 0.80 = 125. $1,200 × 125 = $150,000.

[355] See rule 204–3(b).

[356] See rule 204–3(b).

[357] This average is based on advisers' responses to Item 5.C of Part 1A of Form ADV as of May 3, 2010, excluding the three advisers that reported the largest number of clients. Those advisers account for over 50% of all advisory clients of SEC registrants and not excluding them would raise the average client count to 2,576 clients. These three firms provide advisory services primarily over the Internet and currently meet their brochure obligations electronically, thus essentially entirely eliminating for these advisers any PRA burden associated with delivery under this rule. Therefore, we believe that it is appropriate to exclude these firms from our calculations.

[358] (0.02 hours per client × 1,300 clients per adviser based on IARD data as of May 3, 2010) = 26 hours per adviser. We note that the burden for preparing brochures is already incorporated into the burden estimate for Form ADV discussed above. The Proposing Release estimated that it would require 0.25 hours to send the adviser's brochure to each client. Upon further consideration we determined that it would not take an adviser 15 minutes to mail or e-mail an adviser's brochure to a client.

[359] (0.02 hours per client × 1,300 clients per adviser) × 11,658 advisers based on IARD data as of May 3, 2010 = 303,108 hours.

[360] Of the advisers registered with the Commission, 13% report disciplinary events on their Form ADVs (as of May 10, 2010, only 1,559 of all 11,658 registered advisers indicated at least one "yes" answer to a question related to disciplinary events in Form ADV, Part 1A, Item 11). Thus, we anticipate that a correspondingly small number of advisers will be required to disclose new or updated disciplinary information. The Commission staff estimates that in any given year, 5% of advisers will be required to deliver a single interim update to each of their clients, resulting in a total of approximately 583 interim updates per year. 0.05 × 11,658 × 1 update = 583 updates.

[361] This burden estimate relates only to the amount of time it will take advisers to deliver interim updates to clients, as required by the rule amendments. The burden for preparing interim updates is already incorporated into the burden estimate for Form ADV discussed above. Since this mailing may not be included with a mailing of a statement or other periodic report, we estimate that it will take slightly more time than to deliver the annual brochure or summary of material changes. We also revised this estimate based on our belief that it would only take one or two minutes, not fifteen minutes to mail a brochure or summary of material changes. See supra note 358.

[362] 0.1 hours per client × 1,300 clients per adviser = 130 hours per update.

[363] 583 updates × 130 hours = 75,790 hours.

[364] See, e.g., Schwab Letter; SIFMA Letter; Sutherland Letter.

[365] According to IARD data, only 4% of medium advisers report in response to Item 5.B(1) of Part 1A of Form ADV that more than 250 employees perform investment advisory functions.

[366] 36 large advisers × 200 hours per year per large adviser = 7,200 hours per year.

[367] 303,108 hours (initial and annual delivery) + 75,790 hours (interim delivery of updates to disciplinary information) + 7,200 (supplement tracking systems) = 386,098 hours. 386,098 hours/11,658 advisers = 33.1 hours per adviser.

[368] 6,902,278 hours − 386,098 hours = 6,516,180 hours.

ADV to require advisers to prepare plain English narrative brochures discussing their business practices and conflicts of interest and to prepare brochure supplements discussing the background and disciplinary history of certain supervised persons who formulate investment advice or exercise investment discretion for clients. The revisions to the form also essentially move into the form itself existing rule provisions that require advisers to disclose certain disciplinary and financial information.[369]

The amendments require that advisers deliver this narrative brochure to clients at the outset of the advisory relationship and deliver an updated brochure or a summary of material changes to that brochure annually thereafter. Advisers generally will have to deliver to each client an initial brochure supplement for each supervised person who provides advisory services to that client. Advisers must deliver to clients interim updates to their brochure and brochure supplements that involve a change to disciplinary information required by Part 2. The rules provide exceptions to the brochure and supplement delivery requirements for certain types of clients, and excuse the adviser from preparing a brochure and supplements if there is no client to whom they must be delivered. The rule amendments also require advisers to file their narrative brochures electronically through the IARD, and to keep certain records relating to the brochures and supplements.

We have identified certain costs and benefits, discussed below, that may result from the rule and form amendments. In the Proposing Release,[370] we analyzed costs and benefits of the proposed amendments to Part 2 and the related rules and requested comment and data on the effect they would have on individual investment advisers and on the advisory industry as a whole. Several commenters thought that the costs of the proposed annual brochure delivery requirement would be substantial and would not be offset by a significant corresponding benefit since they believed that few clients would read the brochure on an annual basis.[371] We note that, in response to these concerns, we have made several changes that are designed to reduce costs to advisers, including eliminating the proposed requirement for advisers to deliver an updated brochure annually to clients and instead allowing advisers to deliver to clients a summary of the material changes made to the brochure. Several commenters also argued that the Proposing Release had underestimated the costs of the brochure supplement, and urged that we not impose this disclosure requirement.[372] For many of the same reasons we discussed in the Paperwork Reduction Act section above, we are revising certain estimates of costs as described below.

B. Form ADV Part 2 and IARD Filing

As discussed above, the revisions to Part 2 require substantially all advisers to prepare plain English narrative brochures.[373] Advisers file their brochures electronically through the IARD in a process much like attaching a file to an e-mail.

The new narrative brochures and electronic filing provide substantial benefits to advisory clients and prospective clients. The brochures present clients with critically important information they need to determine whether to hire or continue the services of a particular adviser. This information will be presented in a uniform format easy for most investors to understand. Investors searching for an adviser will be able to access the firm's brochures through our public disclosure Web site even before contacting the firm, and thus will be in a better position to know whether they wish to inquire further about the services the firm is offering or conflicts raised by the adviser's business activities or practices. The narrative brochure will enable prospective clients to determine more easily whether they wish to engage an adviser that does not have certain conflicts, that does not have a disciplinary history, or that does not engage in certain business practices. The electronic availability of the brochures will provide further benefits. Clients will be able to compare business practices, strategies, and conflicts of a number of advisers, which may help them to select the most appropriate adviser for them. Third parties will be able to access adviser brochure information, which would allow academics, businesses and others to access additional information about registered investment advisers, which they can use to study the industry.

Brochure supplements will provide benefits to clients and prospective clients by providing them, for the first time, with information about the educational background, business experience, disciplinary history (if any) and conflicts of the individuals providing them with investment advice. This information will allow clients and prospective clients to determine whether there are safeguards or precautions that they would like to take before receiving investment advice from that person or whether they would prefer to receive investment advice from someone else. A prospective client could be satisfied with its selection of an advisory firm based on the firm brochure disclosures, but then determine that the firm is not the right fit once he or she reviewed the supplements of the actual individuals that would provide investment advice to him or her. Alternatively, the prospective client could retain the firm but request that other individuals provide advice in their place, potentially preventing costly or disruptive replacement or termination at a later date. This is a substantial improvement over the more limited information available today to clients and prospective clients about individuals in which clients place great trust.

To the extent that clients and prospective clients feel more confident as a result of the revised brochure that they understand the business, practices, and conflicts of an adviser, these clients may be more willing to place their trust in investment advisers, seek professional investment advice, and invest their financial assets. This could have benefits for the clients, and possibly impact capital formation and the economy.

[369] Accordingly, the Commission is withdrawing rule 206(4)–4 as duplicative.

[370] See supra note 8.

[371] See, e.g., Berlin Letter; CGMI Letter; FSI Letter; Jackson Letter; Merrill Lynch Letter.

[372] See supra note 298 and accompanying text. These commenters often asserted that the costs of the supplement outweighed any benefits but did not discuss the benefits the supplement would provide to clients and how these benefits may outweigh the costs. In addition to the supplement cost estimates in the Merrill Lynch Letter and the Morgan Stanley Letter discussed above, the Schwab Letter estimated that it would cost it in excess of $5 million to design, build, and implement systems associated with supplement creation and compliance for its approximately 1,600 investment advisory representatives. The SIFMA Letter estimated that the supplement would impose industry-wide costs in excess of $100 million.

[373] Under the amendments, advisers that are not required to deliver a brochure to clients are not required to prepare one. Advisers that provide only impersonal advice costing less than $500 per year per client, and advisers only to registered investment companies or business development companies, therefore, are not required to prepare a brochure. We estimate, based on information filed with us on Form ADV, that approximately 292 advisers provide their services only to registered investment companies and therefore would not need to prepare a brochure. Based on Form ADV filings, we estimate that 14 advisers offer advisory services only by publishing periodicals and newsletters. We estimate that approximately half of these charge less than $500 per year per client and would not need to prepare a brochure. Moreover, because advisers need not deliver supplements to clients that do not receive a brochure, these advisers also would be excused from preparing any brochure supplements.

Most commenters strongly supported the narrative, plain English format, and viewed it as a significant improvement over the current form.[374] They agreed that the new brochures would greatly benefit clients by requiring advisers to present important information about their firms in a clear and more meaningful way.[375] They observed that the enhanced disclosure required by the revised form would benefit clients by improving their ability to thoroughly evaluate advisers, their business practices and their conflicts of interest,[376] and by better equipping them with the knowledge to make informed decisions about whether to hire or retain a particular adviser.[377] Commenters also generally supported making the brochures available to the public through the Commission's Web site.[378]

The new amendments provide significant guidance to advisers in terms of highlighting the types of disclosures they, as fiduciaries, are already required to make. We believe the enhanced clarity provided by the new form will yield substantial benefits for advisers.

We recognize, however, that revised Part 2 also imposes costs on advisers. Advisers will be required to replace their previous Part 2 with the new narrative brochure and brochure supplements, and will be required to file their brochures electronically with us. In addition, the disclosure in the new brochure may be more extensive than what was previously required, although there is significant overlap between the items in new and old Part 2. Drafting the new narrative brochure will likely entail additional expenses. As discussed above, we believe that most of the costs that advisers will incur in connection with preparing the new narrative firm brochure and supplements will be in the initial drafting of these documents. We do not, however, expect advisers to face substantial costs in gathering the required disclosure. Advisers already are required to provide us and/or their clients with much of the information required in the new narrative brochure. In addition, much of the information needed for the brochure supplements can be found in an adviser's current Form ADV or an investment adviser representative's registration application (i.e., Form U4) filed with state securities authorities.

The cost of preparing a narrative brochure likely will vary significantly among advisers, depending on the complexity of their operations and the choices advisers make about how to structure their disclosure given the flexibility permitted by Part 2. Some firms may choose to prepare multiple brochures for several different services. These firms likely will face only incrementally higher drafting costs than an advisory firm that uses a single brochure to make the required disclosure about the services it provides because there will be substantial overlap between the multiple brochures of such advisers. We understand that some smaller- and medium-sized firms outsource the initial preparation of their brochures to compliance consultants. These compliance consultants likely will achieve certain economies of scale in preparing many brochures complying with the new Form ADV Part 2 requirements which may lessen the costs imposed by the amendments on these advisers. Because compliance consultants work on many firms Part 2 disclosures and are familiar with industry practices generally, they will begin their review of a firm's Part 2 with more familiarity with the requirements of Part 2 and conflicts that should be addressed.

Most of the comments relating to the costs of the brochure focused not on the costs of brochure preparation, but rather on the costs of annual delivery of an updated brochure. As noted above, in the rule amendments we are adopting today, we are permitting advisers to satisfy their annual brochure delivery obligation by delivering a summary of material changes to the brochure with information about how clients can receive the full updated brochure if they desire. This change should reduce costs significantly for advisers relating to annual brochure delivery but should improve client experiences with the disclosures they receive by focusing their attention on the material changes in the brochure. The timing of brochure and supplement delivery should allow these documents to be included in other packages that the adviser is already mailing to clients, providing additional cost savings. The primary comment we received on brochure preparation cost was that we had underestimated the time and thus costs of drafting the new narrative brochure. As noted above, we have increased this estimate in response to these comments.

Similarly, the costs of preparing brochure supplements will vary from one adviser to the next. Costs will vary most significantly depending on the number of supervised persons for whom an adviser must provide disclosure. An adviser with very few supervised persons for whom a supplement must be prepared will incur lower costs than a large adviser. Costs associated with preparing supplements also will vary greatly depending on the amount of disciplinary information, if any, required to be disclosed about a particular supervised person. Many large advisers, who will have to prepare the largest number of brochure supplements, have significant numbers of supervised persons that are also registered representatives of broker-dealers and thus may be able to reference the BrokerCheck or IAPD systems for disciplinary disclosure, which will reduce preparation costs of the supplement for these firms. The preparation of brochure supplements would be most demanding for those few advisers whose supervised persons have disciplinary records that must be disclosed, and less taxing for the vast majority of advisers, whose supervised persons have no disciplinary records and whose supplements would therefore likely be a page or less in length.[379]

Many comments on the brochure supplement asserted that for a large adviser registered both as an investment adviser and as a broker-dealer, the supplement would impose substantial costs in creating systems to track this information among a changing group of supervised persons providing investment advice. Yet these same commenters also often stated that much of the information required by the supplement is available on FINRA's BrokerCheck system and thus collected on Form U4. Accordingly, we assume that these firms already have in place systems to track much of this information for a changing workforce (because Form U4 also must be updated as responses to its information requests change). Therefore, we believe that the supplement should impose negligible new costs in this regard since we believe these same systems could be used for supplement information tracking at negligible additional costs. We also are allowing advisers that have supervised persons with disciplinary information available through

[374] See supra note 16.

[375] See, e.g., ICI Letter; MMI Letter; NASAA Letter; Wellington Letter.

[376] See, e.g., AICPA Letter; Janus Letter.

[377] See Consumer Federation Letter.

[378] See, e.g., AICPA Letter; CAPIS Letter; CFA Institute Letter; CGMI Letter; Fried Frank Letter; NAPFA Letter; NASAA Letter; NRS Letter. But see, e.g., Brown Letter; Wernli Letter (stating that public Web site disclosure of Part 2 was a violation of an adviser's privacy).

[379] As of May 3, 2010, IARD data indicate that in response to Item 11 in Part 1A of Form ADV, only 1,559, or 13%, of the 11,658 advisers registered with us report any disciplinary information about their firms or advisory affiliates, including their advisory employees.

BrokerCheck or IAPD to reference that information in their electronically delivered supplements rather than reproducing that information in the supplement. This also should further decrease the costs and burdens cited by these firms in their comment letters. We do recognize, however, that large advisers may need to implement systems to track which supplements need to be provided to which clients as personnel advising clients will change from time to time. In our Paperwork Reduction Act analysis, we added an estimate of the burden for designing and implementing these systems and the cost estimate for this burden is reflected below.

We expect that only a few advisers would incur substantial costs in preparing supplements. IARD data indicate that less than one third of one percent of advisers registered with us has over 1,000 employees performing investment advisory functions on their behalf.[380] Indeed, less than five percent of our registrants have over 50 employees performing investment advisory functions. The vast majority of SEC-registered advisers—approximately 81 percent—have 10 or fewer employees performing advisory functions on their behalf. We believe most, if not all, of these firms may choose to incorporate required information about their supervised persons into their firm brochures instead of preparing separate brochure supplements, thus reducing costs of preparation.

For purposes of the Paperwork Reduction Act, we have estimated the number of hours the average adviser would spend in the initial preparation of its brochure and supplements.[381] Based on those estimates, we estimate that advisers would incur costs of approximately $33,639,980 in drafting these documents in the first year.[382] Furthermore, for Paperwork Reduction Act purposes we also have estimated that advisers may incur costs of approximately $22,775,400 in connection with their use of outside legal services and compliance consulting services to assist in preparation of their Form ADV.

Advisers will incur annual expenses in addition to the initial costs of preparing firm brochures and supplements, but we believe these costs will be modest and similar to current costs. The rule amendments, similar to the current requirements, would require advisers to revise their disclosure documents promptly when any information in them becomes materially inaccurate, and would require advisers to update their brochures each year at the time of their required annual updating amendment. For Paperwork Reduction Act purposes, we have estimated that advisers in the aggregate would spend 87,435 hours per year on Part 2 amendments. We estimate that advisers would incur annual costs of $12,153,465 in meeting these requirements.[383] We also estimated for Paperwork Reduction Act purposes that advisers would spend some time creating brochure supplements for new employees hired each year. We estimate that advisers would incur annual costs of $1,620,462 in creating these new supplements.[384]

Finally, advisers would incur some costs in filing their brochures with us through the IARD. Advisers would prepare their brochures on their own computers and, as noted earlier, the filing of a brochure would be similar to attaching a file to an email.[385] We believe conversion of an adviser's brochure to PDF format and filing of that brochure through the IARD would impose minimal costs on advisers.

C. Brochure and Supplement Delivery

Advisers will be required to deliver their updated brochure or a summary of material changes in their brochure to clients annually. The amended rules require that, between annual brochure deliveries, advisers deliver brochure and supplement amendments to existing clients only if there is an addition or change to disciplinary disclosure.

Advisers already are required to deliver a copy of Part 2 to new clients. Thus, this requirement should present no new costs to advisers. Moreover, we believe that because advisers must deliver brochures to new clients, the cost of delivering brochure supplements to new clients should not increase the existing cost of delivery. Annual delivery of the updated brochures or summary of material changes in the advisers' brochures will benefit advisory clients by ensuring that they are kept apprised of material changes to their advisers' business practices and procedures for managing conflicts and will enable clients to make decisions with respect to the adviser using the most currently available information. The shorter summary will focus clients' attention on the material changes in its adviser's business practices and conflicts and, unlike the prior annual offer requirement, permit them to evaluate when they would like a full copy of the brochure or to determine whether they want to take some other action in response to the change. Previously, clients were just given notice that they could request an updated brochure. In those circumstances, the client would have to read through the entire brochure and try to determine what had changed. Many clients may have determined that this would not be a fruitful exercise and thus declined to request the brochure. Now clients will be able to easily determine what has changed in the brochure and thus decide if they would like to take any action in response.

In addition, we believe that changes to disciplinary information disclosed in the brochure and supplements are of such importance to clients that they merit interim delivery of these amendments. This disciplinary information reflects on the integrity of the advisory firm and the individuals providing the client with advice. Given

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[380] Moreover, it may not be necessary to prepare a brochure supplement for all of these employees.

[381] See Section VI.A of this Release. Unless otherwise noted, the IARD data cited below is based on advisers' responses to questions on Part 1A of Form ADV as of May 3, 2010.

[382] We expect that this function will most likely be performed by a senior compliance examiner at small firms, a compliance manager at medium firms, and a compliance attorney at large firms. Data from the Securities Industry and Financial Markets Association's Report on Management & Professional Earnings in the Securities Industry 2008, modified to account for an 1,800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead, suggest that costs for these positions are $212, $258, and $270 per hour, respectively. Based on the number of small, medium and large advisers (and assuming that the 1,000 additional advisers per year are small advisers as is typically the case), this results in a blended rate of $220 per hour. ((10,482 small advisers × $212) + (2,140 medium advisers × $258) + (36 large advisers × $270)) divided by 12,658 advisers = $220. 152,909 hours × $220 per hour = $33,639,980.

[383] We expect that preparing the amendments to Part 2 will also most likely be performed equally by compliance managers (as described in supra note 382) and compliance clerks. Data from the Securities Industry and Financial Markets Association's Report on Management & Professional Earnings in the Securities Industry 2008, modified to account for an 1,800-hour work-year and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead, suggest that costs for a compliance clerk is $63 per hour. Blending this rate with the blended rate for a compliance manager of $215 per hour results in a cost per hour of $139. ($63 × 0.5) + ($215 × 0.5) = $139. 87,435 hours per year for amendments × $139 per hour = $12,153,465.

[384] We expect that preparing the new supplements will most likely be performed equally by compliance managers (as described in supra note 382) and compliance clerks. The blended rate for this work is $139 per year. See supra note 383. 11,658 hours per year for new supplements × $139 per hour = $1,620,462.

[385] We note that all advisers registered with the Commission currently file Form ADV electronically via the IARD system and, since implementation of the electronic filing requirements in 2000, no adviser has applied for a permanent hardship exemption available to advisers for whom filing electronically would constitute an undue hardship. See rule 203–3(b) [17 CFR 275.203–3(b)].

that clients entrust their financial assets and financial well being to these firms and individuals, this information is vital to clients. Moreover, advisers are already required to make disclosures regarding disciplinary information under rule 206(4)–4. Based on the experiences of examination staff, we believe that most advisers likely already make these disclosures in writing so that they can demonstrate compliance with the requirements of rule 206(4)–4 and thus are unlikely to incur additional costs as a result of this requirement. The brochure supplement will increase costs relating to disseminating disciplinary disclosure, but it will not impose new costs in collecting this information since firms already had to collect this information to respond to Part 1A of Form ADV. The cost of disseminating brochure supplements is reflected below.

For Paperwork Reduction Act Purposes, we have estimated that the total annual paperwork burden associated with annual and interim delivery of brochures, supplements and the summary of material changes is approximately 386,098 hours. This includes estimated time for large advisers to design and implement systems to track that the right supplements are delivered to the right clients as personnel providing investment advice to those clients change. We estimate the burden associated with annual and interim delivery of brochures, supplements and the summary of material changes would represent an annual cost of $18,918,802.[386]

Advisers may significantly minimize the costs associated with delivery of brochures, supplements and the summary of material changes by arranging to deliver these documents to some or all clients by electronic media.[387] Advisers also may minimize delivery costs by mailing some of these documents along with quarterly statements or other routine mailings they already send to clients. No commenters indicated the extent to which they collectively mail such documents. Our rule and form amendments do not require advisers to take advantage of any of these cost saving options—advisers alone bear this choice. Accordingly, the extent to which advisers will take advantage of these and other techniques to reduce costs is difficult to predict, but we believe it will be significant.

D. Amendments to Rule 204–2

The amendments to rule 204–2 require registered advisers to retain certain records relating to brochures and supplements. These records will benefit our examination staff by enhancing their ability to determine advisers' compliance with Form ADV's requirements. One of the revisions to the rule requires advisers to retain copies of brochure supplements and separate summaries of material changes prepared as required by Part 2. This provision generally imposes no additional costs because advisers currently are required to retain records relating to materials they distribute to their clients. Other revisions to the rule require advisers to maintain certain records in the event they use an alternative method to calculate assets under management in response to Item 4.E of Part 2A and if they do not disclose in their brochure a presumptively material legal or disciplinary event listed in Item 9 of Part 2A or Item 3 of Part 2B. These provisions benefit advisers by permitting them flexibility in drafting their firm brochures and supplements while providing for maintenance of records needed by our examination staff. Because we anticipate that only a relatively small number of advisers will be subject to these provisions, we expect that the cost of maintaining these records will be relatively minimal. We estimate that advisers would incur annual costs of $595,280 in meeting these requirements.[388]

VIII. Final Regulatory Flexibility Analysis

We have prepared this Final Regulatory Flexibility Analysis (FRFA) in accordance with section 4(a) of the Regulatory Flexibility Act (RFA).[389] It relates to the amendments to rules 203–1, 204–1, 204–2, 204–3, and 206(4)–4, and Form ADV under the Advisers Act. The rule and form amendments are designed to improve the disclosure that investment advisers provide to their clients. These amendments also revise the instructions for updating and filing Form ADV (including adviser brochures). We also are adopting conforming rule amendments that revise the recordkeeping requirements relating to Part 2 of Form ADV.

We included in the Proposing Release an Initial Regulatory Flexibility Analysis (IFRA). We received no comments specifically on that IRFA.

A. Need for the Rule and Form Amendments

The rule and form amendments are necessary to improve the quality of disclosure that advisers provide to their clients.[390] Form ADV with its two parts was adopted by the Commission in 1979 and advisers use it to register with the Commission (Part 1A) and to provide clients disclosure about their advisory firm and personnel (Part 2).[391] Over the years, however, experience has shown that the format and content of the previous Part 2 of Form ADV did not lend themselves to disclosure that is easy for clients to understand. Clients need clearer information about an adviser's services, fees, business practices, and conflicts of interests to be able to make an informed decision about whether to hire or retain that adviser.

B. Significant Issues Raised by Public Comment

In the Proposing Release, we requested comment on the IRFA. None of the comment letters specifically addressed the IRFA. A few commenters made specific comments about the proposed rule and form amendments' impact on smaller advisers. One commenter was concerned that disclosure of assets under management and financial information would unduly discriminate against smaller advisers.[392] As we discussed above with respect to Item 18 of Part 2, we believe that a client that becomes a creditor of an adviser because it prepays fees would

[386] Based on data from the Securities Industry and Financial Markets Association's Report on Management & Professional Earnings in the Securities Industry 2008, modified to account for an 1,800-hour work-year and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead, we expect that delivery of amendments to Part 2 will also most likely be performed by a clerk at an estimated cost for a general clerk of $49 per hour. 386,098 hours × $49 = $18,918,802. We estimate that advisers will not incur any incremental postage costs in these mailings because we assume that advisers will mail annual summary of material changes with another mailing the adviser was already delivering to clients and that advisers were already delivering to clients disclosure of new material disciplinary events on an interim basis under rule 206(4)–4.

[387] See Instruction 3 for Part 2A of Form ADV, which refers to the Commission's interpretive guidance on electronic delivery. See also supra note 198 for additional discussion of electronic delivery.

[388] For Paperwork Reduction Act purposes we estimate that only 506 advisers will be required to prepare additional records in accordance with the amendment to rule 204–2 and that each adviser would spend approximately four hours to satisfy the obligation for a total burden of 2,024 hours per year and that such advisers will incur $150,000 per year in outside legal expenses relating to such records. We expect that preparing the records will most likely be performed by compliance managers (as described in supra note 382). 2,024 hours × $220 per hour = $445,280. $445,280 + $150,000 = $595,280.

[389] 5 U.S.C. 604(a).

[390] Sections I through IV of this Release describe in more detail the reasons for the amendments.

[391] See 1979 Adopting Release, supra note 6.

[392] Verbeck Letter.

want information about the adviser's financial condition. In addition, this information is currently required to be disclosed to clients, and the commenter did not persuade us that it should be omitted. Another commenter stated that Item 8's requirement that advisers primarily using a particular strategy discuss the risks involved in its strategy discriminates against smaller firms who are less likely to be multi-strategy firms.[393] As discussed earlier in this Release,[394] we agree that advisers should disclose material risks associated with their strategies, regardless of whether they use one strategy or many strategies but believe that the brochure may not always be the best place for a multi-strategy adviser to disclose these risks. Another commenter suggested that we permit smaller advisers to provide short-form brochures.[395] As discussed earlier in the release,[396] we have not determined to shorten the brochure for any type of advisers because we believe that the brochure contains important information upon which clients rely and much of which advisers are already required to make to satisfy their fiduciary duty to their clients. We have, however, allowed advisers to satisfy their annual brochure delivery obligation by delivering a summary of material changes in their brochure to their clients.

C. Small Entities Subject to the Rules

In developing the amendments, we have considered their potential impact on small entities that may be affected. The rule and form amendments will affect all advisers registered with the Commission, including small entities. Under Commission rules, for purposes of the Regulatory Flexibility Act, an investment adviser generally is a small entity if it: (i) Has assets under management having a total value of less than $25 million; (ii) did not have total assets of $5 million or more on the last day of its most recent fiscal year; and (iii) does not control, is not controlled by, and is not under common control with another investment adviser that has assets under management of $25 million or more, or any person (other than a natural person) that had $5 million or more on the last day of its most recent fiscal year.[397]

Our rule and form amendments will not affect most advisers that are small entities ("small advisers") because they are generally registered with one or more state securities authorities and not with us. Under section 203A of the Advisers Act, most small advisers are prohibited from registering with the Commission and are regulated by state regulators.[398] The Commission estimates that as of May 3, 2010, of the 11,658 registered with us, there were approximately 708 that were small entities that would be affected by the amendments.[399]

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements

The rule and form amendments impose certain reporting and compliance requirements on small advisers, requiring them to create and update narrative brochures containing certain information regarding their advisory business. The amendments also require advisers to deliver their brochures to clients and to file them electronically through the IARD. The amendments also impose new recordkeeping requirements. These requirements and the burdens on small advisers are discussed below.[400]

1. Amendments to Part 2 of Form ADV

The amendments to Part 2, because they require registered advisers to prepare and disseminate narrative brochures, impose additional costs on all registered advisers, including small advisers. We assume that all small advisers previously distributed Part 2 of Form ADV and did not draft the optional narrative brochure. If our assumption is correct, these advisers would have to redraft their brochures completely to comply with the new format, although a lot of information in the previous Part 2 will be transferable to the new narrative brochures.

The costs associated with preparing the new brochures will depend on the size of the adviser, the complexity of its operations, and the extent to which its operations present conflicts of interest with clients. Many of the new items imposing the most rigorous disclosure requirements may not apply to certain small advisers because, for example, those advisers may not have soft dollar or directed brokerage arrangements, or may not have custody of client assets. However, certain of the brochure compliance costs may be fixed and thus impose a disproportionate impact on small advisers. To the extent that some of the new disclosure burdens would apply to small advisers, these advisers are already obligated to make the disclosures to clients under the Advisers Act's antifraud provisions, although the disclosure currently is not required to be in the firm's written brochure.

For the first time, advisers also will be required to prepare and disseminate brochure supplements for certain supervised persons of their firm. To reduce the burdens on small advisers, however, we have drafted the new supplement rules so that firms with few employees would be permitted to include supplement information in their firm brochures and may choose to avoid preparing and distributing separate brochure supplements. We believe many small advisers would take advantage of this option and reduce their compliance burden. We also note that small advisers are unlikely to have many supervised persons for whom a brochure supplement is required, so the supplement should impose a proportionately smaller burden on small advisers. The rule amendments may increase compliance costs for investment advisers. Certain of these increased compliance costs attributable to supplements may be fixed and thus impose a disproportionate impact on small advisers.

2. Updating and Delivery Requirements

The amended rules, like the prior rules, require advisers to update their brochures and supplements whenever information in them becomes materially inaccurate. In updating its brochure and supplements on an interim basis, an adviser may minimize its burden by delivering a statement describing this updated information instead of reprinting its entire brochure or supplement.

The amendments require advisers to deliver an updated brochure or a summary of material changes in the adviser's brochure to clients annually and to deliver interim updates of the brochure and supplements to clients to disclose new or revised disciplinary information. To minimize the burden of delivery, advisers are permitted with client consent to deliver brochures, supplements and the summary of material changes, as well as updates, electronically.[401] To the extent that small advisers are more likely to have

[393] NAPFA Letter.

[394] See supra notes 71–75 and accompanying text.

[395] NSCP Letter.

[396] See supra notes 25–28 and accompanying text.

[397] See rule 0–7 [17 CFR 275.0–7].

[398] National Securities Markets Improvement Act of 1996 (Pub. L. 104–290, 110 Stat. 3438) (1996) ("NSMIA"). As a result of NSMIA, advisers with less than $25 million of assets under management generally are regulated by one or more state securities authority, while the Commission generally regulates those advisers with at least $25 million of assets under management. See section 203A of the Advisers Act [15 USC 80b–3a].

[399] This estimate is based on information advisers have filed with the Commission on Part 1A of Form ADV as of May 3, 2010.

[400] Sections I through IV of this Release describe these requirements in more detail.

[401] See supra notes 196–198.

fewer advisory clients than larger advisers, the delivery requirements should impose lower costs on small advisers than on larger firms.

3. Recordkeeping Requirements

The amendments impose new recordkeeping requirements on advisers, including small advisers. As under the previous rules, advisers will be required to maintain copies of their brochures. The amendments also require all advisers to maintain copies of their brochure supplements. Advisers will be required to maintain a copy of any summary of material changes in their brochure that is separate from the brochure. In addition, the amendments require advisers, including small advisers, to maintain certain records if they determine that a disciplinary event that is presumptively material does not have to be disclosed, or if they calculate their managed assets for purpose of their brochures differently than in Part 1A of Form ADV.

E. Agency Action To Minimize Effect on Small Entities

We have considered various alternatives in connection with the rule and form amendments that might minimize their effect on small advisers, including: (i) Establishing different compliance or reporting requirements or timetables that take into account the resources available to small advisers; (ii) clarifying, consolidating, or simplifying compliance and reporting requirements under the proposed amendments for small advisers; (iii) using performance rather than design standards; and (iv) exempting small advisers from coverage of all or part of the proposed amendments.

Regarding the first alternative, the Commission believes that establishing different compliance or reporting requirements for small advisers would be inappropriate under these circumstances. The amendments are designed to improve the quality and timeliness of critically important disclosure that advisory clients receive from their advisers. To establish different disclosure requirements for small entities would diminish this investor protection for clients of small advisers. We note, however, that small advisers, by the nature of their business, likely would spend fewer resources in completing their brochures and any brochure supplements. Small advisers have few supervised persons providing investment advice, so they will need to prepare few brochure supplements. Moreover, certain rule and form amendments were designed specifically to reduce the burden on small advisers. For example, the Part 2 instructions give advisers the flexibility to incorporate required information about their supervised persons into their firm brochures rather than presenting it in separate brochure supplements, thereby saving additional printing and mailing costs.

Regarding the second alternative, the amendments clarify requirements for all advisers, including small advisers. The amended Part 2 instructions are designed to present requirements for advisers' brochures and supplements clearly and simply to all advisers, including small entities.

Regarding the third alternative, the Commission believes that the amendments already appropriately use performance rather than design standards in many instances. The amendments permit advisers flexibility in designing their brochures and supplements so as best to communicate the required information to clients. In preparing brochure supplements, advisers also have the flexibility of adapting the format of the supplements to best suit their firm. An adviser may: (i) Prepare a separate supplement for each supervised person; (ii) prepare a single supplement containing the required information for all of its supervised persons; (iii) prepare multiple supplements for groups of supervised persons (e.g., all supervised persons in a particular office or work group); or (iv) include all information about supervised persons in the firm brochure and prepare no separate supplements.[402] The amendments clarify that advisers may, with client consent, deliver their brochures and supplements, along with any updates, to clients electronically.[403] Advisers may incorporate their supplements into the brochure or provide them separately.

Regarding the fourth alternative, it would be inconsistent with the purposes of the Advisers Act to exempt small advisers from the rule and form amendments. The information in an adviser's brochure is necessary for the client to evaluate the adviser's services, fees, and business practices, and to apprise the client of potential conflicts of interest and, when necessary, of the adviser's financial condition. Since we view the protections of the Advisers Act to apply equally to clients of both large and small advisers, it would be inconsistent with the purposes of the Act to specify different requirements for small entities.

IX. Efficiency, Competition, and Capital Formation

Section 23(a)(2) of the Exchange Act requires the Commission, in adopting rules under the Exchange Act, to consider the impact that any new rule would have on competition, and 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.[404] Section 3(f) of the Exchange Act requires the Commission, when engaging in rulemaking that requires it 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 will promote efficiency, competition, and capital formation.[405] Section 202(c) of the Advisers Act requires the Commission, when engaging in rulemaking that requires it 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 will promote efficiency, competition, and capital formation.[406]

In the Proposing Release, we solicited comment on whether, if adopted, the proposed rule and form amendments would promote efficiency, competition and capital formation. We further encouraged commenters to provide empirical data to support their views on any burdens on efficiency, competition or capital formation that might result from adoption of the proposed amendments. We did not receive any empirical data in this regard concerning the proposed amendments. We received one comment stating that the proposed amendments would not promote efficiency, competition, and capital formation, but the commenter did not state why.[407] Accordingly, since the

[402] See Section II.B of this Release. A brochure supplement, however, must be organized in the same order, and use the same headings, as the items appear in the form, whether incorporated in a brochure or provided separately. See Instruction 1 of General Instructions for Part 2 of Form ADV.

[403] See supra notes 196–198.

[404] 15 U.S.C. 78w(a)(2).

[405] 15 U.S.C. 78c(f).

[406] 15 U.S.C. 80b–2(c).

[407] Jackson Letter. Another commenter stated that the requirement to disclose the amount of assets under management in the brochure would discriminate against smaller firms because of a perceived notion that a larger company does a better job. See Verbeck Letter. As discussed at supra 181 and accompanying text, assets under management is an objective measure that provides important information to clients. Clients have different preferences and some, for example, may view a smaller adviser as being more likely to provide more personal service. In addition, the NAPFA Letter stated that Item 8's requirement that advisers primarily using a particular strategy discuss the risks involved in its strategy discriminates against smaller firms who are less

Continued

adopted rule and form amendments are similar to the proposed rule and amendments, we continue to believe the amendments will contribute to efficiency, competition and capital formation.

Today the Commission is adopting amendments to Part 2 of Form ADV and related Advisers Act rules that would require investment advisers registered with us to deliver to clients and prospective clients brochures and brochure supplements written in plain English. We believe that the rule and form amendments that we are adopting today are likely to promote efficiency and competition in the marketplace for advisory services provided by advisers registered with us by improving the disclosure that they must provide to clients.[408] These amendments are designed to require advisers to provide clients and prospective clients with clear, current, and more meaningful disclosure of the business practices, conflicts of interest, and background of investment advisers and the advisory personnel on whom clients rely for investment advice. As a result, we believe that advisory clients will be provided with improved disclosure from advisers that will allow them to select an adviser based on a clearer and more thorough understanding of the business practices, conflicts of interest, and disciplinary information than exists with the check-the-box format of the current brochure. While advisers currently have the option of providing a narrative brochure, few do so. Absent the actions we are taking today, based on our experience with administering the Advisers Act brochure requirement and inefficiencies in the marketplace, we do not believe that advisers have adequate incentives to produce clear and understandable brochures. We expect the amendments we are adopting today, by requiring clearer and more understandable brochures, are likely to increase competition among advisers.

Advisers will file their brochures with us electronically, and we will make them available to the public through our website. Today, while advisers' brochures are "deemed" filed with us, it is difficult for the public to obtain them unless the adviser provides a brochure upon request or makes it available on its own website, which also makes it very difficult for prospective clients to compare more than a few investment advisers. With the public availability through our website of more thorough and current disclosure of advisers' services, fees, business practices and conflicts of interests, investors will be able to make more informed decisions about whether to hire or retain a particular adviser and will have an easier time comparing investment advisers. The supplements will allow clients and prospective clients to compare the qualifications and conflicts not only of the advisory firm but also of the personnel that will be providing investment advice to them. By having more information about the individuals and firms providing investment advice to them, as well as the ability to compare advisory firms, a client may be more likely to select initially an appropriate investment adviser for that client, promoting competition on the basis of improved disclosure of conflicts of interest and business practices and avoiding the burdens and costs associated with switching advisers or supervised persons at a later date, and thereby potentially creating efficiency gains in the marketplace. The availability of this information about advisers and their personnel also may enhance competition if, for example, firms and personnel with better disciplinary records outcompete those with worse records. Secondarily, the electronic filing requirements are expected to expedite and simplify the process of filing firm brochures and amendments for the advisory firms, thus improving the efficiency of advisers that are required to file and update the brochure.

A few commenters stated that certain information required to be disclosed in the brochure is duplicative of information required to be reported in Part 1A of Form ADV and that such information should only be required disclosure in one place in Form ADV.[409] While we are conscious of these commenters' goal of generating efficiency by eliminating duplicative disclosure in Form ADV, we do not believe that it is appropriate to allow disclosure in Part 1A to satisfy disclosure obligations in Part 2B, or vice versa, because, these parts serve different functions and clients and prospective clients access these documents in different ways. Part 1A is used for regulatory purposes and thus the information it collects is that which our examination staff has identified as important for us to have for our examination program and other regulatory functions. While an adviser's responses to Part 1A of Form ADV generally are available to the public through our website, they are not delivered to clients or prospective clients and they are not written in a manner designed to be meaningful to clients or prospective clients—rather they are largely a series of "check-the-box" responses. Part 2A of Form ADV, on the other hand, is disclosure aimed at and delivered to clients and prospective clients. Accordingly, while certain topics of disclosure may be covered by both parts, we believe the different functions of, and delivery methods for, these two parts justifies the replication of disclosure topics.

On the other hand, the amendments we are adopting today are designed to generate efficiencies and reduce duplicative disclosure by allowing an adviser who sends supplements electronically, and whose supervised persons have disciplinary disclosure available on FINRA's BrokerCheck system or the IAPD system, to respond to those portions of Item 3 of the brochure supplement by including in the brochure supplement (i) a statement that the supervised person has a disciplinary history, the details of which can be found on FINRA's BrokerCheck system or the IAPD, and (ii) a hyperlink to the relevant system with a brief explanation of how the client can access the disciplinary history. In this instance, we believe that permitting cross-referencing is appropriate since it will only be allowed if the supplement is delivered electronically and the disclosure is duplicative. The BrokerCheck and IAPD systems are aimed at investor disclosure and are designed to be user-friendly, and clients will still receive delivery of a supplement which contains the other information (e.g., educational background and other business activities) about that supervised person.

In addition to the competitive impact mentioned above, we believe that the rule amendments may have certain other impacts on competition. The brochure supplement may impose greater costs on larger advisers that have

likely to be multi-strategy firms. As discussed at supra notes 72–75 and accompanying text, we disagree.

[408] Along with the brochure amendments, the Commission also is adopting conforming amendments to the General Instructions and Glossary of Form ADV to include instructions regarding brochure filing requirements and to add glossary terms and definitions that are used in Part 2. Additionally, the Commission also is adopting conforming amendments to the Advisers Act books and records rule. These amendments require advisers to maintain copies of their brochures, brochure supplements, amendments, and summaries of material changes, and are intended to update the books and records rule in light of our changes to Part 2. None of these conforming amendments are expected to have an independent impact on efficiency, competition, or capital formation. To the extent that they facilitate the purposes of the amendments, the conforming amendments may, however, contribute to the expected effects on efficiency, competition and capital formation that would stem from the amendments and which are discussed below.

[409] See, e.g., ACLI Letter; IAA Letter.

to create systems to track appropriate delivery of supplements that smaller advisers would not need. To the extent these costs are passed on to clients, a client's choice of investment advisers may be impacted. As we noted in the Cost-Benefit Analysis section above, however, many of these systems costs should be mitigated by systems that large advisers already have in place to track Form U4 information for their investment advisory representatives and broker-dealer registered representatives, which these firms should be able to leverage for use in the brochure supplement context. The rule amendments also may increase compliance costs for investment advisers. Certain of these increased compliance costs may be fixed and thus impose a disproportionate impact on small advisers, which may have anticompetitive impacts on small advisers.

The competitive impacts discussed previously primarily focused on the impact of the rule amendments on investment advisers that are registered with us. We acknowledge that there may also be competitive impacts as a result of the amendments between those persons providing investment advice that are, and those that are not, registered with us as investment advisers. For example, banks, insurance companies, broker-dealers, and exempt advisers provide financial services that may compete, in some cases, for the same clients that would retain SEC-registered investment advisers. We have carefully considered the potential competitive implications of these rule amendments and do not believe that they will put advisers registered with us at a significant competitive disadvantage. Moreover, notwithstanding the potential competitive effect, we believe that the concerns that the amendments are designed to address justify adoption of the rule amendments. Pursuant to Section 23(a)(2) of the Exchange Act, the Commission does not believe that the amendments to Form ADV impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

As stated previously, the rule amendments are designed to provide advisory clients with clearer, more concise and understandable information regarding the business practices and conflicts of interest of investment advisers. Improved disclosure by SEC-registered investment advisers could result in enhanced efficiencies for clients in selecting an investment adviser and improved allocation of client assets among investment advisers. To a more limited extent, if better disclosure increases clients' and prospective clients' trust in investment advisers, it may encourage them to seek professional investment advice and encourage them to invest their financial assets. This also may enhance capital formation by making more funds available for investment and enhancing the allocation of capital generally. On the other hand, if the rule amendments increase costs at investment advisers and these costs increases are passed on to clients, this may deter clients from seeking professional investment advice and investing their financial assets. This may result in inefficiencies in the market for advisory services and hinder capital formation.

X. Statutory Authority

We are adopting amendments to rule 203–1 under sections 203(c)(1), 204, and 211(a) of the Investment Advisers Act of 1940 [15 U.S.C. 80b–3(c)(1), 80b–4, and 80b–11(a)].

We are adopting amendments to rule 204–1 under sections 203(c)(1) and 204 of the Investment Advisers Act of 1940 [15 U.S.C. 80b–3(c)(1) and 80b–4].

We are adopting amendments to rule 204–2 under sections 204 and 206(4) of the Investment Advisers Act of 1940 [15 U.S.C. 80b–4 and 80b–6(4)].

We are adopting amendments to rule 204–3 under sections 204, 206(4), and 211(a) of the Investment Advisers Act of 1940 [15 U.S.C. 80b–4, 80b–6(4), and 80b–11(a)].

We are adopting amendments to rule 279.1, Form ADV, under section 19(a) of the Securities Act of 1933 [15 U.S.C. 77s(a)], sections 23(a) and 28(e)(2) of the Securities Exchange Act of 1934 [15 U.S.C. 78w(a) and 78bb(e)(2)], section 319(a) of the Trust Indenture Act of 1939 [15 U.S.C. 77sss(a)], section 38(a) of the Investment Company Act of 1940 [15 U.S.C. 78a–37(a)], and sections 203(c)(1), 204, and 211(a) of the Investment Advisers Act of 1940 [15 U.S.C. 80b–3(c)(1), 80b–4, and 80b–11(a)].

We are removing and reserving rule 206(4)–4 under section 206(4) of the Investment Advisers Act of 1940 [15 U.S.C. 80b–6(4)].

List of Subjects in 17 CFR Parts 275 and 279

Reporting and recordkeeping requirements; Securities.

Text of Rule and Form Amendments

■ For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

■ 1. The general authority citation for Part 275 continues to read as follows:

Authority: 15 U.S.C. 80b–2(a)(11)(G), 80b–2(a)(17), 80b–3, 80b–4, 80b–4a, 80b–6(4), 80b–6a, and 80b–11, unless otherwise noted.

* * * * *

■ 2. Section 275.203–1 is amended by revising paragraphs (a) and (b) to read as follows:

§ 275.203–1 Application for investment adviser registration.

(a) *Form ADV.* Subject to paragraph (b), to apply for registration with the Commission as an investment adviser, you must complete Form ADV [17 CFR 279.1] by following the instructions in the form and you must file Part 1A of Form ADV and the firm brochure(s) required by Part 2A of Form ADV electronically with the Investment Adviser Registration Depository (IARD) unless you have received a hardship exemption under § 275.203–3. You are not required to file with the Commission the brochure supplements required by Part 2B of Form ADV.

(b) *Transition to electronic filing.* If you apply for registration after January 1, 2011, you must file a brochure(s) that satisfies the requirements of Part 2A of Form ADV electronically with the IARD, unless you have received a continuing hardship exemption under § 275.203–3.

Note to paragraphs (a) and (b): Information on how to file with the IARD is available on the Commission's Web site at *http://www.sec.gov/iard*. If you are not required to deliver a brochure to any clients, you are not required to prepare or file a brochure with the Commission. If you are not required to deliver a brochure supplement to any clients for any particular supervised person, you are not required to prepare a brochure supplement for that supervised person.

* * * * *

■ 3. Section 275.204–1 is amended by removing the notes to paragraphs (a) and (c) and revising paragraphs (b) and (c) to read as follows:

§ 275.204–1 Amendments to application for registration.

* * * * *

(b) *Electronic filing of amendments.* (1) Subject to paragraph (c), you must file all amendments to Part 1A of Form ADV and Part 2A of Form ADV electronically with the IARD, unless you have received a continuing hardship exemption under § 275.203–3. You are not required to file with the Commission amendments to brochure

supplements required by Part 2B of Form ADV.

(2) If you have received a continuing hardship exemption under § 275.203–3, you must, when you are required to amend your Form ADV, file a completed Part 1A and Part 2A of Form ADV on paper with the SEC by mailing it to FINRA.

Note to paragraphs (a) and (b): Information on how to file with the IARD is available on our Web site at *http://www.sec.gov/iard.* For the annual updating amendment: summaries of material changes that are not included in the adviser's brochure must be filed with the Commission as an exhibit to Part 2A in the same electronic file; and if you are not required to prepare a summary of material changes or an annual updating amendment to your brochure, you are not required to file them with the Commission. See the instructions for Part 2A of Form ADV.

(c) *Transition to electronic filing.* If your fiscal year ends on or after December 31, 2010, you must amend your Form ADV by electronically filing with the IARD one or more brochures that satisfy the requirements of Part 2A of Form ADV (as amended effective October 12, 2010) as part of the next annual updating amendment that you are required to file.

* * * * *

■ 4. Section 275.204–2is amended by revising paragraph (a)(14) to read as follows:

§ 275.204–2 Books and records to be maintained by investment advisers.

(a) * * *

(14)(i) A copy of each brochure and brochure supplement, and each amendment or revision to the brochure and brochure supplement, that satisfies the requirements of Part 2 of Form ADV [17 CFR 279.1]; any summary of material changes that satisfies the requirements of Part 2 of Form ADV but is not contained in the brochure; and a record of the dates that each brochure and brochure supplement, each amendment or revision thereto, and each summary of material changes not contained in a brochure was given to any client or to any prospective client who subsequently becomes a client.

(ii) Documentation describing the method used to compute managed assets for purposes of Item 4.E of Part 2A of Form ADV, if the method differs from the method used to compute assets under management in Item 5.F of Part 1A of Form ADV.

(iii) A memorandum describing any legal or disciplinary event listed in Item 9 of Part 2A or Item 3 of Part 2B (Disciplinary Information) and presumed to be material, if the event involved the investment adviser or any of its supervised persons and is not disclosed in the brochure or brochure supplement described in paragraph (a)(14)(i) of this section. The memorandum must explain the investment adviser's determination that the presumption of materiality is overcome, and must discuss the factors described in Item 9 of Part 2A of Form ADV or Item 3 of Part 2B of Form ADV.

* * * * *

■ 5. Section 275.204–3 is revised to read as follows:

§ 275.204–3 Delivery of brochures and brochure supplements.

(a) *General requirements.* If you are registered under the Act as an investment adviser, you must deliver a brochure and one or more brochure supplements to each client or prospective client that contains all information required by Part 2 of Form ADV [17 CFR 279.1].

(b) *Delivery requirements.* Subject to paragraph (g), you (or a supervised person acting on your behalf) must:

(1) Deliver to a client or prospective client your current brochure before or at the time you enter into an investment advisory contract with that client.

(2) Deliver to each client, annually within 120 days after the end of your fiscal year and without charge, if there are material changes in your brochure since your last annual updating amendment:

(i) A current brochure, or

(ii) The summary of material changes to the brochure as required by Item 2 of Form ADV, Part 2A that offers to provide your current brochure without charge, accompanied by the Web site address (if available) and an e-mail address (if available) and telephone number by which a client may obtain the current brochure from you, and the Web site address for obtaining information about you through the Investment Adviser Public Disclosure (IAPD) system.

(3) Deliver to each client or prospective client a current brochure supplement for a supervised person before or at the time that supervised person begins to provide advisory services to the client; provided, however, that if investment advice for a client is provided by a team comprised of more than five supervised persons, a current brochure supplement need only be delivered to that client for the five supervised persons with the most significant responsibility for the day-to-day advice provided to that client. For purposes of this section, a supervised person will provide advisory services to a client if that supervised person will:

(i) Formulate investment advice for the client and have direct client contact; or

(ii) Make discretionary investment decisions for the client, even if the supervised person will have no direct client contact.

(4) Deliver the following to each client promptly after you create an amended brochure or brochure supplement, as applicable, if the amendment adds disclosure of an event, or materially revises information already disclosed about an event, in response to Item 9 of Part 2A of Form ADV or Item 3 of Part 2B of Form ADV (Disciplinary Information), respectively, (i) the amended brochure or brochure supplement, as applicable, along with a statement describing the material facts relating to the change in disciplinary information, or (ii) a statement describing the material facts relating to the change in disciplinary information.

(c) *Exceptions to delivery requirement.* (1) You are not required to deliver a brochure to a client:

(i) That is an investment company registered under the Investment Company Act of 1940 [15 U.S.C. 80a–1 to 80a–64] or a business development company as defined in that Act, provided that the advisory contract with that client meets the requirements of section 15(c) of that Act [15 U.S.C. 80a–15(c)]; or

(ii) Who receives only impersonal investment advice for which you charge less than $500 per year.

(2) You are not required to deliver a brochure supplement to a client:

(i) To whom you are not required to deliver a brochure under subparagraph (c)(1) of this section;

(ii) Who receives only impersonal investment advice; or

(iii) Who is an officer, employee, or other person related to the adviser that would be a "qualified client" of your firm under § 275.205–3(d)(1)(iii).

(d) *Wrap fee program brochures.* (1) If you are a sponsor of a wrap fee program, then the brochure that paragraph (b) of this section requires you to deliver to a client or prospective client of the wrap fee program must be a wrap fee program brochure containing all the information required by Part 2A, Appendix 1 of Form ADV. Any additional information in a wrap fee program brochure must be limited to information applicable to wrap fee programs that you sponsor.

(2) You do not have to deliver a wrap fee program brochure if another sponsor of the wrap fee program delivers, to the client or prospective client of the wrap fee program, a wrap fee program

brochure containing all the information required by Part 2A, Appendix 1 of Form ADV.

Note to paragraph (d): A wrap fee program brochure does not take the place of any brochure supplements that you are required to deliver under paragraph (b) of this section.

(e) *Multiple brochures.* If you provide substantially different advisory services to different clients, you may provide them with different brochures, so long as each client receives all information about the services and fees that are applicable to that client. The brochure you deliver to a client may omit any information required by Part 2A of Form ADV if the information does not apply to the advisory services or fees that you will provide or charge, or that you propose to provide or charge, to that client.

(f) *Other disclosure obligations.* Delivering a brochure or brochure supplement in compliance with this section does not relieve you of any other disclosure obligations you have to your advisory clients or prospective clients under any federal or state laws or regulations.

(g) *Transition rule.* (1) Within 60 days after the date by which you are first required by § 275.204–1(c) to electronically file your brochure(s) with the Commission, you must deliver to each of your existing clients your current brochure and all current brochure supplements as required by Part 2 of Form ADV.

(2) As of the date by which you are first required to electronically file your brochure(s) with the Commission, you must begin using your current brochure and current brochure supplements as required by Part 2 of Form ADV to comply with the requirements of this section pertaining to initial delivery to new and prospective clients.

(h) *Definitions.* For purposes of this section:

(1) *Impersonal investment advice* means investment advisory services that do not purport to meet the objectives or needs of specific individuals or accounts.

(2) *Current brochure* and *current brochure supplement* mean the most recent revision of the brochure or brochure supplement, including all amendments to date.

(3) *Sponsor* of a wrap fee program means an investment adviser that is compensated under a wrap fee program for sponsoring, organizing, or administering the program, or for selecting, or providing advice to clients regarding the selection of, other investment advisers in the program.

(4) *Supervised person* means any of your officers, partners or directors (or other persons occupying a similar status or performing similar functions) or employees, or any other person who provides investment advice on your behalf.

(5) *Wrap fee program* means an advisory program under which a specified fee or fees not based directly upon transactions in a client's account is charged for investment advisory services (which may include portfolio management or advice concerning the selection of other investment advisers) and the execution of client transactions.

§ 275.206(4)–4 [Removed and Reserved]

■ 6. Section 275.206(4)–4 is removed and reserved.

PART 279—FORMS PRESCRIBED UNDER THE INVESTMENT ADVISERS ACT OF 1940

■ 7. The authority citation for Part 279 continues to read as follows:

Authority: 15 U.S.C. 80b–1, *et seq.*

■ 8. Form ADV [referenced in § 279.1] is amended by:

■ a. In the instructions to the form, revising the section entitled "Form ADV: General Instructions." The revised version of Form ADV: General Instructions is attached as Appendix A;

■ b. In the instructions to the form, revising the section entitled "Glossary of Terms." The revised version of Glossary of Terms is attached as Appendix B; and

■ c. Removing Form ADV, Part II, and adding Form ADV, Part 2. Form ADV, Part 2 is attached as Appendix C.

Note: The amendments to and text of Form ADV will not appear in the Code of Federal Regulations.

* * * * *

BILLING CODE 8011–01–P

Appendix A

FORM ADV (Paper Version)
UNIFORM APPLICATION FOR INVESTMENT ADVISER REGISTRATION

Form ADV: General Instructions

Read these instructions carefully before filing Form ADV. Failure to follow these instructions, properly complete the form, or pay all required fees may result in your application being delayed or rejected.

In these instructions and in Form ADV, "you" means the investment adviser (i.e., the advisory firm) applying for registration or amending its registration. If you are a "separately identifiable department or division" (SID) of a bank, "you" means the SID, rather than your bank, unless the instructions or the form provide otherwise. Terms that appear in *italics* are defined in the Glossary of Terms to Form ADV.

1. Where can I get more information on Form ADV, electronic filing, and the IARD?

The SEC provides information about its rules and the Advisers Act on its website: <http://www.sec.gov/iard>.

NASAA provides information about state investment adviser laws and state rules, and how to contact a *state securities authority*, on its website: <http://www.nasaa.org>.

FINRA provides information about the IARD and electronic filing on the IARD website: <http://www.iard.com>.

2. What is Form ADV used for?

Investment advisers use Form ADV to:

- Register with the Securities and Exchange Commission
- Register with one or more *state securities authorities*
- Amend those registrations

3. How is Form ADV organized?

Form ADV contains four parts:

- Part 1A asks a number of questions about you, your business practices, the *persons* who own and *control* you, and the *persons* who provide investment advice on your behalf. All advisers registering with the SEC or any of the *state securities authorities* must complete Part 1A.

Part 1A also contains several supplemental schedules. The items of Part 1A let you know which schedules you must complete.

- Schedule A asks for information about your direct owners and executive officers.
- Schedule B asks for information about your indirect owners.
- Schedule C is used by paper filers to update the information required by Schedules A and B (see Instruction 14).
- Schedule D asks for additional information for certain items in Part 1A.
- Disclosure Reporting Pages (or DRPs) are schedules that ask for details about disciplinary events involving you or your *advisory affiliates*.

- Part 1B asks additional questions required by *state securities authorities*. Part 1B contains three additional DRPs. If you are applying for registration or are registered only with the SEC, you do not have to complete Part 1B. (If you are filing electronically and you do not have to complete Part 1B, you will not see Part 1B.)

- Part 2A requires advisers to create narrative *brochures* containing information about the advisory firm. The requirements in Part 2A apply to all investment advisers registered with or applying for registration with the SEC. If you are registered with or applying for registration with one or more of the *state securities authorities*, you should contact the appropriate *state securities authorities* to determine whether the requirements in Part 2A apply to you.

- Part 2B requires advisers to create *brochure supplements* containing information about certain *supervised persons*. The requirements in Part 2B apply to all investment advisers registered with or applying for registration with the SEC. If you are registered with or applying for registration with one or more of the *state securities authorities*, you should contact the appropriate *state securities authorities* to determine whether the requirements in Part 2B apply to you.

4. When am I required to update my Form ADV?

You must amend your Form ADV each year by filing an *annual updating amendment* within 90 days after the end of your fiscal year. When you submit your *annual updating amendment*, you must update your responses to all items. You must submit your summary of material changes required by Item 2 of Part 2 either in the *brochure* (cover page or the page immediately thereafter) or as an exhibit to your *brochure*.

In addition to your *annual updating amendment*, you must amend your Form ADV by filing additional amendments (other-than-annual amendments) promptly if:

- information you provided in response to Items 1, 3, 9 (except 9.A.(2), 9.B.(2), and 9.(E)), or 11 of Part 1A or Items 1, 2.A. through 2.F., or 2.I. of Part 1B becomes inaccurate in any way;

- information you provided in response to Items 4, 8, or 10 of Part 1A or Item 2.G. of Part 1B becomes materially inaccurate; or

- information you provided in your *brochure* becomes materially inaccurate (see note below for exceptions).

Notes: Part 1: If you are submitting an other-than-annual amendment, you are not required to update your responses to Items 2, 5, 6, 7, 9.A.(2), 9.B.(2), 9.E., or 12 of Part 1A or Items 2.H. or 2.J. of Part 1B even if your responses to those items have become inaccurate.

Part 2: You must amend your *brochure supplements* (see Form ADV, Part 2B) promptly if any information in them becomes materially inaccurate. If you are submitting an other-than-annual amendment to your brochure, you are not required to update your summary of material changes as required by Item 2. You are not required to update your *brochure* between annual amendments solely because the amount of *client* assets you manage has changed or because your fee schedule has changed. However, if you are updating your *brochure* for a separate reason in between annual amendments, and the amount of *client* assets you manage listed in response to Item 4.E or your fee schedule listed in response to Item 5.A has become materially inaccurate, you should update that item(s) as part of the interim amendment.

- If you are an SEC-registered adviser, you are required to file your brochure amendments electronically through IARD. You are not required to file amendments to your brochure supplements with the SEC, but you must maintain a copy of them in your files.

- If you are a state-registered adviser, you are required to file your *brochure* amendments and *brochure supplement* amendments with the appropriate *state securities authorities through IARD.*

Failure to update your Form ADV, as required by this instruction, is a violation of SEC rule 204-1 or similar state rules and could lead to your registration being revoked.

5. Part 2 of Form ADV was amended recently. When do I have to comply with the new requirements?

If you are applying for registration with the SEC:

- Beginning January 1, 2011, your application for registration must include a narrative *brochure* prepared in accordance with the requirements of (amended) Part 2A of Form ADV. See SEC rule 203-1. After that date, the SEC will not accept any application that does not include a *brochure*(s) that satisfies the requirements of (amended) Part 2 of Form ADV.

- Until that date, you may (but are not required to) include in your application a narrative *brochure* that meets the requirements of (amended) Part 2A of Form ADV. If you do not do this, you must comply with the requirements for preparing, delivering, and offering "old" Part II of Form ADV.

If you already are registered with or have submitted an application for registration with the SEC:

- If your fiscal year ends on or after December 31, 2010, you must amend your Form ADV to add a narrative *brochure* that meets the requirements of (amended) Part 2A of Form ADV when you file your next *annual updating amendment*.

- Until that date, you may (but are not required to) submit a narrative *brochure* that meets the requirements of (amended) Part 2A of Form ADV. If you do not do this, you must continue to comply with the requirements for preparing, delivering, and offering "old" Part II of Form ADV.

Note: Until you are required to meet the requirements of (amended) Part 2, you can satisfy the requirements related to "old" Part II by updating the information in your "old" Part II whenever it becomes materially inaccurate. You must deliver "old" Part II or a brochure containing at least the information contained in "old" Part II to prospective *clients* and annually offer it to current *clients*. You are not required to file "old" Part II with the SEC, but you must keep a copy in your files, and provide it to the SEC staff upon request.

If you are applying for registration or are registered with one or more *state securities authorities*, contact the appropriate *state securities authorities* or check <http://www.nasaa.org> for more information about the implementation deadline for the amended Part 2.

6. Where do I sign my Form ADV application or amendment?

You must sign the appropriate Execution Page. There are three Execution Pages at the end of the form. Your initial application and all amendments to Form ADV must include at least one Execution Page.

- If you are applying for or are amending your SEC registration, you must sign and submit either a:
  - Domestic Investment Adviser Execution Page, if you (the advisory firm) are a resident of the United States; or
  - *Non-Resident* Investment Adviser Execution Page, if you (the advisory firm) are not a resident of the United States.
- If you are applying for or are amending your registration with a *state securities authority*, you must sign and submit the State-Registered Investment Adviser Execution Page.

7. Who must sign my Form ADV or amendment?

The individual who signs the form depends upon your form of organization:

- For a sole proprietorship, the sole proprietor.
- For a partnership, a general partner.
- For a corporation, an authorized principal officer.
- For a "separately identifiable department or division" (SID) of a bank, a principal officer of your bank who is directly engaged in the management, direction, or supervision of your investment advisory activities.
- For all others, an authorized individual who participates in managing or directing your affairs.

The signature does not have to be notarized, and in the case of an electronic filing, should be a typed name.

8. How do I file my Form ADV?

Complete Form ADV electronically using the Investment Adviser Registration Depository (IARD) if:

- You are filing with the SEC (and submitting *notice filings* to any of the *state securities authorities*), or

- You are filing with a *state securities authority* that requires or permits advisers to submit Form ADV through the IARD.

  Note: SEC rules require advisers that are registered or applying for registration with the SEC to file electronically through the IARD system. See SEC rule 203-1. Check with the *state securities authorities* of each state in which you have a filing obligation to determine whether you can or must file Form ADV electronically through the IARD.

To file electronically, go to the IARD website (<www.iard.com>), which contains detailed instructions for advisers to follow when filing through the IARD.

Complete Form ADV (Paper Version) on paper if:

- You are filing with the SEC or a *state securities authority* that requires electronic filing, but you have been granted a continuing hardship exemption. Hardship exemptions are described in Instruction 14.

- You are filing with a *state securities authority* that permits (but does not require) electronic filing and you do not file electronically.

9. How do I get started filing electronically?

- First, get a copy of the IARD Entitlement Package from the following web site: <http://www.iard.com/GetStarted.asp>. Second, request access to the IARD system for your firm by completing and submitting the IARD Entitlement Package. The IARD Entitlement Package must be submitted on paper. Mail the forms to: FINRA Entitlement Group, P.O. Box 9495, Gaithersburg, MD 20898-9495.

- When FINRA receives your Entitlement Package, they will assign a *CRD* number (identification number for your firm) and a user I.D. code and password (identification number and system password for the individual(s) who will submit Form ADV filings for your firm). Your firm may request an I.D. code and password for more than one individual. FINRA also will create a financial account for you from which the IARD will deduct filing fees and any state fees you are required to pay. If you already have a *CRD* account with FINRA, it will also serve as your IARD account; a separate account will not be established.

- Once you receive your *CRD* number, user I.D. code and password, and you have funded your account, you are ready to file electronically.

- Questions regarding the Entitlement Process should be addressed to FINRA at 240.386.4848.

10. If I am applying for registration with the SEC, or amending my SEC registration, how do I make *notice filings* with the *state securities authorities*?

If you are applying for registration with the SEC or are amending your SEC registration, one or more *state securities authorities* may require you to provide them with copies of your SEC filings. We call these filings "*notice filings*." Your *notice filings* will be sent electronically to the states that you check on Item 2.B. of Part 1A. The *state securities authorities* to which you send *notice filings* may charge fees, which will be deducted from the account you establish with FINRA. To determine which *state securities authorities* require SEC-registered advisers to submit *notice filings* and to pay fees, consult the relevant state investment adviser law or *state securities authority*. See General Instruction 1.

If you are granted a continuing hardship exemption to file Form ADV on paper, FINRA will enter your filing into the IARD and your *notice filings* will be sent electronically to the *state securities authorities* that you check on Item 2.B. of Part 1A.

11. I am registered with a state. When must I switch to SEC registration?

If you report on your *annual updating amendment* that your assets under management have increased to $30 million or more, you must register with the SEC within 90 days after you file that *annual updating amendment*. If your assets under management increase to $25 million or more but not $30 million, you may, but are not required to, register with the SEC (assuming you are not otherwise required to register with the SEC). Once you register with the SEC, you are subject to

SEC regulation, regardless of whether you remain registered with one or more states. Each of your *investment adviser representatives*, however, may be subject to registration in those states in which the representative has a place of business. See SEC rule 203A-1(b). For additional information, consult the investment adviser laws or the *state securities authority* for the particular state in which you are "doing business." See General Instruction 1.

Note: The amount of assets under management that determines whether you register with the SEC or states will change in 2011 as a result of amendments to the Investment Advisers Act.

12. I am registered with the SEC. When must I switch to registration with a *state securities authority*?

If you report on your *annual updating amendment* that you have assets under management of less than $25 million and you are not otherwise eligible to register with the SEC, you must withdraw from SEC registration within 180 days after the end of your fiscal year by filing Form ADV-W. You should consult state law in the states that you are doing business to determine if you are required to register in these states. See General Instruction 1. Until you file your Form ADV-W with the SEC, you will remain subject to SEC regulation, and you also will be subject to regulation in any states where you register. See SEC rule 203A-1(b).

Note: The amount of assets under management that determines whether you register with the SEC or states will change in 2011 as a result of amendments to the Investment Advisers Act.

13. Are there filing fees?

Yes. These fees go to support and maintain the IARD. The IARD filing fees are in addition to any registration or other fee that may be required by state law. You must pay an IARD filing fee for your initial application and each *annual updating amendment.* There is no filing fee for an other-than-annual amendment or Form ADV-W. The IARD filing fee schedule is published at <http://www.sec.gov/iard>; <http://www.nasaa.org>; and <http://www.iard.com>.

If you are submitting a paper filing under a continuing hardship exemption (see Instruction 14), you are required to pay an additional fee. The amount of the additional fee depends on whether you are filing Form ADV or Form ADV-W. (There is no additional fee for filings made on Form ADV-W.) The hardship filing fee schedule is available by contacting FINRA at 240.386.4848.

14. What if I am not able to file electronically?

If you are required to file electronically but cannot do so, you may be eligible for one of two types of hardship exemptions from the electronic filing requirements.

- A **temporary hardship exemption** is available if you file electronically, but you encounter unexpected difficulties that prevent you from making a timely filing with the IARD, such as a computer malfunction or electrical outage. This exemption does not

permit you to file on paper; instead, it extends the deadline for an electronic filing for seven business days. See SEC rule 203-3(a).

- A **continuing hardship exemption** may be granted if you are a small business and you can demonstrate that filing electronically would impose an undue hardship. You are a small business, and may be eligible for a continuing hardship exemption, if you are required to answer Item 12 of Part 1A (because you have assets under management of less than $25 million) and you are able to respond "no" to each question in Item 12. See SEC rule 0-7.

  If you have been granted a continuing hardship exemption, you must complete and submit the paper version of Form ADV to FINRA. FINRA will enter your responses into the IARD. As discussed in General Instruction 13, FINRA will charge you a fee to reimburse it for the expense of data entry.

  Before applying for a continuing hardship exemption, consider engaging a firm that assists investment advisers in making filings with the IARD. Check the SEC's web site (<http://www.sec.gov/iard>) to obtain a list of firms that provide these services.

15. I am eligible to file on paper. How do I make a paper filing?

When filing on paper, you must:

- Type all of your responses.
- Include your name (the same name you provide in response to Item 1.A. of Part 1A) and the date on every page.
- If you are amending your Form ADV:
  - complete page 1 and circle the number of any item for which you are changing your response.
  - include your SEC 801-number (if you have one) and your *CRD* number (if you have one) on every page.
  - complete the amended item in full and circle the number of the item for which you are changing your response.
  - to amend Schedule A or Schedule B, complete and submit Schedule C.

Where you submit your paper filing depends on why you are eligible to file on paper:

- If you are filing on paper because you have been granted a continuing hardship exemption, submit one manually signed Form ADV and one copy to: IARD Document Processing, FINRA, P.O. Box 9495, Gaithersburg, MD 20898-9495.

  If you complete Form ADV on paper and submit it to FINRA but you do not have a continuing hardship exemption, the submission will be returned to you.

- If you are filing on paper because a state in which you are registered or in which you are applying for registration allows you to submit paper instead of electronic filings, submit

one manually signed Form ADV and one copy to the appropriate *state securities authorities*.

16. Who is required to file Form ADV-NR?

Every *non-resident* general partner and *managing agent* of all SEC-registered advisers, whether or not the adviser is resident in the United States, must file Form ADV-NR in connection with the adviser's initial application. A general partner or *managing agent* of an SEC-registered adviser who becomes a *non-resident* after the adviser's initial application has been submitted must file Form ADV-NR within 30 days. Form ADV-NR must be filed on paper (it cannot be filed electronically).

Submit Form ADV-NR to the SEC at the following address:

Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549; Attn: Branch of Registrations and Examinations.

Failure to file Form ADV-NR promptly may delay SEC consideration of your initial application.

Federal Information Law and Requirements

Sections 203(c) and 204 of the Advisers Act [15 U.S.C. §§ 80b-3(c) and 80b-4] authorize the SEC to collect the information required by Form ADV. The SEC collects the information for regulatory purposes, such as deciding whether to grant registration. Filing Form ADV is mandatory for advisers who are required to register with the SEC. The SEC maintains the information submitted on this form and makes it publicly available. The SEC may return forms that do not include required information. Intentional misstatements or omissions constitute federal criminal violations under 18 U.S.C. § 1001 and 15 U.S.C. § 80b-17.

SEC's Collection of Information

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 control number. The Advisers Act authorizes the SEC to collect the information on Form ADV from applicants. See 15 U.S.C. §§ 80b-3(c)(1) and 80b-4. Filing the form is mandatory.

The main purpose of this form is to enable the SEC to register investment advisers. Every applicant for registration with the SEC as an adviser must file the form. See 17 C.F.R. § 275.203-1. By accepting a form, however, the SEC does not make a finding that it has been completed or submitted correctly. The form is filed annually by every adviser, no later than 90 days after the end of its fiscal year, to amend its registration. It is also filed promptly during the year to reflect material changes. See 17 C.F.R. § 275.204-1. The SEC maintains the information on the form and makes it publicly available through the IARD.

Form ADV: General Instructions

Anyone may send the SEC comments on the accuracy of the burden estimate on page 1 of the form, as well as suggestions for reducing the burden. The Office of Management and Budget has reviewed this collection of information under 44 U.S.C. § 3507.

The information contained in the form is part of a system of records subject to the Privacy Act of 1974, as amended. The SEC has published in the Federal Register the Privacy Act System of Records Notice for these records.

Appendix B

GLOSSARY OF TERMS

1. **Advisory Affiliate:** Your advisory affiliates are (1) all of your officers, partners, or directors (or any ***person*** performing similar functions); (2) all ***persons*** directly or indirectly ***controlling*** or ***controlled*** by you; and (3) all of your current ***employees*** (other than ***employees*** performing only clerical, administrative, support or similar functions).

   If you are a "separately identifiable department or division" (SID) of a bank, your ***advisory affiliates*** are: (1) all of your bank's ***employees*** who perform your investment advisory activities (other than clerical or administrative ***employees***); (2) all ***persons*** designated by your bank's board of directors as responsible for the day-to-day conduct of your investment advisory activities (including supervising the ***employees*** who perform investment advisory activities); (3) all ***persons*** who directly or indirectly ***control*** your bank, and all ***persons*** whom you ***control*** in connection with your investment advisory activities; and (4) all other ***persons*** who directly manage any of your investment advisory activities (including directing, supervising or performing your advisory activities), all ***persons*** who directly or indirectly ***control*** those management functions, and all ***persons*** whom you ***control*** in connection with those management functions. *[Used in: Part 1A, Items 7, 11, DRPs; Part 1B, Item 2]*

2. **Annual Updating Amendment:** Within 90 days after your firm's fiscal year end, your firm must file an "annual updating amendment," which is an amendment to your firm's Form ADV that reaffirms the eligibility information contained in Item 2 of Part 1A and updates the responses to any other item for which the information is no longer accurate. *[Used in: General Instructions; Part 1A Instructions, Introductory Text, Item 2; Part 2A, Instructions, Appendix 1 Instructions; Part 2B, Instructions]*

3. **Brochure:** A written disclosure statement that you must provide to ***clients*** and prospective ***clients***. See SEC rule 204-3; Form ADV, Part 2A. *[Used in: General Instructions; Used throughout Part 2]*

4. **Brochure Supplement:** A written disclosure statement containing information about certain of your supervised persons that your firm is required by Part 2B of Form ADV to provide to clients and prospective clients. See SEC rule 204-3; Form ADV, Part 2B. *[Used in: General Instructions; Used throughout Part 2]*

5. **Charged:** Being accused of a crime in a formal complaint, information, or indictment (or equivalent formal charge). *[Used in: Part 1A, Item 11; DRPs]*

6. **Client:** Any of your firm's investment advisory clients. This term includes clients from which your firm receives no compensation, such as members of your family. If your firm also provides other services (e.g., accounting services), this term does not include clients that are not investment advisory clients. *[Used throughout Form ADV and Form ADV-W]*

Form ADV: Glossary

7. **Control:** Control means the power, directly or indirectly, to direct the management or policies of a ***person***, whether through ownership of securities, by contract, or otherwise.

   - Each of your firm's officers, partners, or directors exercising executive responsibility (or ***persons*** having similar status or functions) is presumed to control your firm.

   - A ***person*** is presumed to control a corporation if the ***person***: (i) directly or indirectly has the right to vote 25 percent or more of a class of the corporation's voting securities; or (ii) has the power to sell or direct the sale of 25 percent or more of a class of the corporation's voting securities.

   - A ***person*** is presumed to control a partnership if the ***person*** has the right to receive upon dissolution, or has contributed, 25 percent or more of the capital of the partnership.

   - A ***person*** is presumed to control a limited liability company ("LLC") if the ***person***: (i) directly or indirectly has the right to vote 25 percent or more of a class of the interests of the LLC; (ii) has the right to receive upon dissolution, or has contributed, 25 percent or more of the capital of the LLC; or (iii) is an elected manager of the LLC.

   - A ***person*** is presumed to control a trust if the ***person*** is a trustee or ***managing agent*** of the trust.

   [Used in: General Instructions; Part 1A, Instructions, Items 2, 7, 10, 11, 12, Schedules A, B, C, D; DRPs]

8. **Custody:** Custody means holding, directly or indirectly, client funds or securities, or having any authority to obtain possession of them. You have custody if a related person holds, directly or indirectly, client funds or securities, or has any authority to obtain possession of them, in connection with advisory services you provide to clients. Custody includes:

   - Possession of client funds or securities (but not of checks drawn by clients and made payable to third parties) unless you receive them inadvertently and you return them to the sender promptly but in any case within three business days of receiving them;

   - Any arrangement (including a general power of attorney) under which you are authorized or permitted to withdraw client funds or securities maintained with a custodian upon your instruction to the custodian; and

   - Any capacity (such as general partner of a limited partnership, managing member of a limited liability company or a comparable position for another type of pooled investment vehicle, or trustee of a trust) that gives you or your supervised person legal ownership of

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or access to client funds or securities. *[Used in: Part 1A, Item 9; Part 1B, Instructions, Item 2; Part 2A, Items 15, 18]*

9. **Discretionary Authority or Discretionary Basis:** Your firm has discretionary authority or manages assets on a discretionary basis if it has the authority to decide which securities to purchase and sell for the ***client***. Your firm also has discretionary authority if it has the authority to decide which investment advisers to retain on behalf of the ***client***. *[Used in: Part 1A, Instructions, Item 8; Part 1B, Instructions; Part 2A, Items 4, 16, 18; Part 2B, Instructions]*

10. **Employee:** This term includes an independent contractor who performs advisory functions on your behalf. *[Used in: Part 1A, Instructions, Items 1, 5, 11; Part 2B, Instructions]*

11. **Enjoined:** This term includes being subject to a mandatory injunction, prohibitory injunction, preliminary injunction, or a temporary restraining ***order***. *[Used in: Part 1A, Item 11; DRPs]*

12. **Felony:** For jurisdictions that do not differentiate between a felony and a ***misdemeanor***, a felony is an offense punishable by a sentence of at least one year imprisonment and/or a fine of at least $1,000. The term also includes a general court martial. *[Used in: Part 1A, Item 11; DRPs; Part 2A, Item 9; Part 2B, Item 3]*

13. **FINRA CRD** or **CRD:** The Web Central Registration Depository ("CRD") system operated by FINRA for the registration of broker-dealers and broker-dealer representatives. *[Used in: General Instructions, Part 1A, Item 1, Schedules A, B, C, D, DRPs; Form ADV-W, Item 1]*

14. **Foreign Financial Regulatory Authority:** This term includes (1) a foreign securities authority; (2) another governmental body or foreign equivalent of a ***self-regulatory organization*** empowered by a foreign government to administer or enforce its laws relating to the regulation of ***investment-related*** activities; and (3) a foreign membership organization, a function of which is to regulate the participation of its members in the activities listed above. *[Used in: Part 1A, Items 1, 11; DRPs; Part 2A, Item 9; Part 2B, Item 3]*

15. **Found:** This term includes adverse final actions, including consent decrees in which the respondent has neither admitted nor denied the findings, but does not include agreements, deficiency letters, examination reports, memoranda of understanding, letters of caution, admonishments, and similar informal resolutions of matters. *[Used in: Part 1A, Item 11; Part 1B, Item 2; Part 2A, Item 9; Part 2B, Item 3]*

16. **Government Entity:** Any state or political subdivision of a state, including (i) any agency, authority, or instrumentality of the state or political subdivision; (ii) a plan or pool of assets ***controlled*** by the state or political subdivision or any agency, authority, or instrumentality thereof; and (iii) any officer, agent, or employee of the state or political subdivision or any

agency, authority, or instrumentality thereof, acting in their official capacity. *[Used in: Part 1A, Item 5]*

17. **High Net Worth Individual:** An individual with at least $750,000 managed by you, or whose net worth your firm reasonably believes exceeds $1,500,000, or who is a "qualified purchaser" as defined in section 2(a)(51)(A) of the Investment Company Act of 1940. The net worth of an individual may include assets held jointly with his or her spouse. *[Used in: Part 1A, Item 5]*

18. **Home State:** If your firm is registered with a ***state securities authority***, your firm's "home state" is the state where it maintains its ***principal office and place of business***. *[Used in: Part 1B, Instructions]*

19. **Impersonal Investment Advice:** Investment advisory services that do not purport to meet the objectives or needs of specific individuals or accounts. *[Used in: Part 1A, Instructions; Part 2A, Instructions; Part 2B, Instructions]*

20. **Investment Adviser Representative:** Investment adviser representatives of SEC-registered advisers may be required to register in each state in which *they have a* ***place of business.*** *Any of your firm's* ***supervised persons*** *(except* those that provide only ***impersonal investment advice***) is an investment adviser representative, if --

    - the ***supervised person*** regularly solicits, meets with, or otherwise communicates with your firm's ***clients***,
    - the ***supervised person*** has more than five ***clients*** who are natural persons and not ***high net worth individuals***, and
    - more than ten percent of the ***supervised person's*** clients are natural persons and not ***high net worth individuals.***

NOTE: If your firm is registered with the ***state securities authorities*** and not the SEC, your firm may be subject to a different state definition of "investment adviser representative."

[Used in: General Instructions; Part 1A, Item 7; Part 2B, Item 1]

21. **Investment-Related:** Activities that pertain to securities, commodities, banking, insurance, or real estate (including, but not limited to, acting as or being associated with an investment adviser, broker-dealer, municipal securities dealer, government securities broker or dealer, issuer, investment company, futures sponsor, bank, or savings association). *[Used in: Part 1A, Items, 7, 11, DRPs; Part 1B, Item 2; Part 2A, Items 9 and 19; Part 2B, Items 3, 4 and 7]*

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22. **Involved:** Engaging in any act or omission, aiding, abetting, counseling, commanding, inducing, conspiring with or failing reasonably to supervise another in doing an act. *[Used in: Part 1A, Item 11; Part 2A, Items 9 and 19; Part 2B, Items 3 and 7]*

23. **Management Persons:** Anyone with the power to exercise, directly or indirectly, a ***controlling*** influence over your firm's management or policies, or to determine the general investment advice given to the ***clients*** of your firm.

    Generally, all of the following are management persons:

    - Your firm's principal executive officers, such as your chief executive officer, chief financial officer, chief operations officer, chief legal officer, and chief compliance officer; your directors, general partners, or trustees; and other individuals with similar status or performing similar functions;

    - The members of your firm's investment committee or group that determines general investment advice to be given to ***clients***; and

    - If your firm does not have an investment committee or group, the individuals who determine general investment advice provided to ***clients*** (if there are more than five people, you may limit your firm's response to their supervisors).

    [Used in: Part 1B, Item 2; Part 2A, Items 9, 10 and 19]

24. **Managing Agent:** A managing agent of an investment adviser is any ***person***, including a trustee, who directs or manages (or who participates in directing or managing) the affairs of any unincorporated organization or association that is not a partnership. *[Used in: General Instructions; Form ADV-NR; Form ADV-W, Item 8]*

25. **Minor Rule Violation:** A violation of a ***self-regulatory organization*** rule that has been designated as "minor" pursuant to a plan approved by the SEC. A rule violation may be designated as "minor" under a plan if the sanction imposed consists of a fine of $2,500 or less, and if the sanctioned ***person*** does not contest the fine. (Check with the appropriate ***self-regulatory organization*** to determine if a particular rule violation has been designated as "minor" for these purposes.) *[Used in: Part 1A, Item 11]*

26. **Misdemeanor:** For jurisdictions that do not differentiate between a ***felony*** and a misdemeanor, a misdemeanor is an offense punishable by a sentence of less than one year imprisonment and/or a fine of less than $1,000. The term also includes a special court martial. *[Used in: Part 1A, Item 11; DRPs; Part 2A, Item 9; Part 2B, Item 3]*

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27. **Non-Resident:** (a) an individual who resides in any place not subject to the jurisdiction of the United States; (b) a corporation incorporated in or having its ***principal office and place of business*** in any place not subject to the jurisdiction of the United States; and (c) a partnership or other unincorporated organization or association that has its ***principal office and place of business*** in any place not subject to the jurisdiction of the United States. *[Used in: General Instructions; Form ADV-NR]*

28. **Notice Filing:** SEC-registered advisers may have to provide ***state securities authorities*** with copies of documents that are filed with the SEC. These filings are referred to as "notice filings." *[Used in: General Instructions; Part 1A, Item 2; Execution Page(s); Form ADV-W]*

29. **Order:** A written directive issued pursuant to statutory authority and procedures, including an order of denial, exemption, suspension, or revocation. Unless included in an order, this term does not include special stipulations, undertakings, or agreements relating to payments, limitations on activity or other restrictions. *[Used in: Part 1A, Items 2 and 11; Schedule D; DRPs; Part 2A, Item 9; Part 2B, Item 3]*

30. **Performance-Based Fee:** An investment advisory fee based on a share of capital gains on, or capital appreciation of, ***client*** assets. A fee that is based upon a percentage of assets that you manage is not a performance-based fee. *[Used in: Part 1A, Item 5; Part 2A, Items 6 and 19]*

31. **Person:** A natural person (an individual) or a company. A company includes any partnership, corporation, trust, limited liability company ("LLC"), limited liability partnership ("LLP"), sole proprietorship, or other organization. *[Used throughout Form ADV and Form ADV-W]*

32. **Principal Place of Business** or **Principal Office and Place of Business:** Your firm's executive office from which your firm's officers, partners, or managers direct, ***control***, and coordinate the activities of your firm. *[Used in: Part 1A, Instructions, Items 1 and 2; Schedule D; Form ADV-W, Item 1]*

33. **Proceeding:** This term includes a formal administrative or civil action initiated by a governmental agency, ***self-regulatory organization*** or ***foreign financial regulatory authority***; a ***felony*** criminal indictment or information (or equivalent formal charge); or a ***misdemeanor*** criminal information (or equivalent formal charge). This term does not include other civil litigation, investigations, or arrests or similar charges effected in the absence of a formal criminal indictment or information (or equivalent formal charge). *[Used in: Part 1A, Item 11; DRPs; Part 1B, Item 2; Part 2A, Item 9; Part 2B, Item 3]*

34. **Related Person:** Any ***advisory affiliate*** and any ***person*** that is under common ***control*** with your firm. *[Used in: Part 1A, Items 7, 8, 9; Schedule D; Form ADV-W, Item 3; Part 2A, Items 10, 11, 12, 14; Part 2A, Appendix 1, Item 6]*

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35. **Self-Regulatory Organization** or **SRO:** Any national securities or commodities exchange, registered securities association, or registered clearing agency. For example, the Chicago Board of Trade ("CBOT"), FINRA and New York Stock Exchange ("NYSE") are self-regulatory organizations. *[Used in: Part 1A, Item 11; DRPs; Part 1B, Item 2; Part 2A, Items 9 and 19; Part 2B, Items 3 and 7]*

36. **Sponsor:** A sponsor of a ***wrap fee program*** sponsors, organizes, or administers the program or selects, or provides advice to ***clients*** regarding the selection of, other investment advisers in the program. *[Used in: Part 1A, Item 5; Schedule D; Part 2A, Instructions, Appendix 1 Instructions]*

37. **State Securities Authority:** The securities commission (or any agency or office performing like functions) of any state of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, or any other possession of the United States. *[Used throughout Form ADV]*

38. **Supervised Person:** Any of your officers, partners, directors (or other ***persons*** occupying a similar status or performing similar functions), or ***employees***, or any other ***person*** who provides investment advice on your behalf and is subject to your supervision or ***control***. *[Used throughout Part 2]*

39. **Wrap Brochure** or **Wrap Fee Program Brochure:** The written disclosure statement that ***sponsors*** of ***wrap fee programs*** must provide to each of their ***wrap fee program clients***. *[Used in: Part 2, General Instructions; Used throughout Part 2A, Appendix 1]*

40. **Wrap Fee Program:** Any advisory program under which a specified fee or fees not based directly upon transactions in a ***client's*** account is charged for investment advisory services (which may include portfolio management or advice concerning the selection of other investment advisers) and the execution of ***client*** transactions. *[Used in: Part 1, Item 5; Schedule D; Part 2A, Instructions, Item 4, used throughout Appendix 1; Part 2B, Instructions]*

Appendix C

FORM ADV (Paper Version)
UNIFORM APPLICATION FOR INVESTMENT ADVISER REGISTRATION

PART 2: Uniform Requirements for the Investment Adviser *Brochure* and *Brochure Supplements*

General Instructions for Part 2 of Form ADV

Under SEC and similar state rules you are required to deliver to *clients* and prospective *clients* a *brochure* disclosing information about your firm. You also may be required to deliver a *brochure supplement* disclosing information about one or more of your *supervised persons.* Part 2 of Form ADV sets out the minimum required disclosure that your *brochure* (Part 2A for a firm *brochure*, or Appendix 1 for a *wrap fee program brochure*) and *brochure supplements* (Part 2B) must contain.

Read all the instructions, including General Instructions for Form ADV, General Instructions for Part 2 of Form ADV, Instructions for Part 2A of Form ADV, Instructions for Part 2B of Form ADV, and (if you are preparing or updating a *wrap fee program brochure*) Instructions for Part 2A Appendix 1 of Form ADV, before preparing or updating your *brochure* or *brochure supplements*.

1. Narrative Format. Part 2 of Form ADV consists of a series of items that contain disclosure requirements for your firm's *brochure* and any required supplements. The items require narrative responses. You must respond to each item in Part 2. You must include the heading for each item provided by Part 2 immediately preceding your response to that item and provide responses in the same order as the items appear in Part 2. If an item does not apply to your business, you must indicate that item is not applicable. If you have provided information in response to one item that is also responsive to another item, you may cross-reference that information in response to the other item.

2. Plain English. The items in Part 2 of Form ADV are designed to promote effective communication between you and your *clients*. Write your *brochure* and supplements in plain English, taking into consideration your *clients*' level of financial sophistication. Your *brochure* should be concise and direct. In drafting your *brochure* and *brochure supplements*, you should: (i) use short sentences; (ii) use definite, concrete, everyday words; (iii) use active voice; (iv) use tables or bullet lists for complex material, whenever possible; (v) avoid legal jargon or highly technical business terms unless you explain them or you believe that your *clients* will understand them; and (vi) avoid multiple negatives. Consider providing examples to illustrate a description of your practices or policies. The brochure should discuss only conflicts the adviser has or is reasonably likely to have, and practices in which it engages or is reasonably likely to engage. If a conflict arises or the adviser decides to engage in a practice that it has not disclosed, supplemental disclosure must be provided to clients to obtain their consent. If you have a conflict or engage in a practice with respect to some (but not all) types or classes of clients, advice, or transactions, indicate as such rather than disclosing that you "may" have the conflict or engage in the practice.

   Note: The SEC's Office of Investor Education and Advocacy has published A Plain English Handbook. You may find the handbook helpful in writing your *brochure* and supplements. For a copy of this handbook, visit the SEC's web site at<www.sec.gov/news/extra/handbook.htm> or call 1-800-732-0330.

3. Disclosure Obligations as a Fiduciary. Under federal and state law, you are a fiduciary and must make full disclosure to your *clients* of all material facts relating to the advisory relationship. As a fiduciary, you also must seek to avoid conflicts of interest with your clients, and, at a minimum, make full disclosure of all material conflicts of interest between you and your *clients* that could affect the advisory relationship. This obligation

requires that you provide the client with sufficiently specific facts so that the client is able to understand the conflicts of interest you have and the business practices in which you engage, and can give informed consent to such conflicts or practices or reject them. To satisfy this obligation, you therefore may have to disclose to *clients* information not specifically required by Part 2 of Form ADV or in more detail than the brochure items might otherwise require. You may disclose this additional information to *clients* in your *brochure* or by some other means.

4. Full and Truthful Disclosure. All information in your *brochure* and *brochure supplements* must be true and may not omit any material facts.

5. Filing. You must file your *brochure(s)* (and amendments) through the IARD system using the text-searchable Adobe Portable Document Format ("PDF"). See SEC rules 203-1 and 204-1 and similar state rules. If you are registered or are registering with the SEC, you are not required to file your *brochure supplements* through the IARD or otherwise. You must, however, preserve a copy of the supplements and make them available to SEC staff upon request. See SEC rule 204-2(a)(14). If you are registered or are registering with one or more *state securities authorities*, you must file a copy of the *brochure supplement* for each *supervised person* doing business in that state.

Instructions for Part 2A of Form ADV: Preparing Your Firm *Brochure*

1. To whom must we deliver a firm *brochure*? You must give a firm *brochure* to each *client*. You must deliver the *brochure* even if your advisory agreement with the *client* is oral. See SEC rule 204-3(b) and similar state rules.

   If you are registered with the SEC, you are not required to deliver your *brochure* to either (i) *clients* who receive only *impersonal investment advice* from you and who will pay you less than $500 per year or (ii) *clients* that are SEC-registered investment companies or business development companies (the *client* must be registered under the Investment Company Act of 1940 or be a business development company as defined in that Act, and the advisory contract must meet the requirements of section 15(c) of that Act). See SEC rule 204-3(c).

   Note: Even if you are not required to give a *brochure* to a *client*, as a fiduciary you may still be required to provide your *clients* with similar information, particularly material information about your conflicts of interest and about your disciplinary information. If you are not required to give a *client* a *brochure*, you may make any required disclosures to that *client* by delivery of your *brochure* or through some other means.

2. When must we deliver a *brochure* to *clients*?

   - You must give a firm *brochure* to each *client* before or at the time you enter into an advisory agreement with that *client*. See SEC rule 204-3(b) and similar state rules.

   - Each year you must (i) deliver, within 120 days of the end of your fiscal year, to each *client* a free updated *brochure* that either includes a summary of material changes or is accompanied by a summary of material changes, or (ii) deliver to each *client* a summary of material changes that includes an offer to provide a copy of the updated *brochure* and information on how a *client* may obtain the *brochure*. See SEC rule 204-3(b) and similar state rules.

   - You do not have to deliver an interim amendment to *clients* unless the amendment includes information in response to Item 9 of Part 2A (disciplinary information). An interim amendment can be in the form of a document describing the material facts relating to the amended disciplinary event. See SEC rule 204-3(b) and similar state rules.

   Note: As a fiduciary, you have an ongoing obligation to inform your *clients* of any material information that could affect the advisory relationship. As a result, between *annual updating amendments* you must disclose material changes to such information to *clients* even if those changes do not trigger delivery of an interim amendment. See General Instructions for Part 2 of Form ADV, Instruction 3.

3. May we deliver our *brochure* electronically? Yes. The SEC has published interpretive guidance on delivering documents electronically, which you can find at <www.sec.gov/rules/concept/33-7288.txt>.

4. When must we update our *brochure*? You must update your *brochure*: (i) each year at the time you file your *annual updating amendment*; and (ii) promptly whenever any information in the *brochure* becomes materially inaccurate. You are not required to update your *brochure* between annual amendments solely because the amount of *client* assets you manage has changed or because your fee schedule has changed. However, if you are updating your *brochure* for a separate reason in between annual amendments, and the amount of *client* assets you manage listed in response to Item 4.E or your fee schedule listed in response to Item 5.A has become materially inaccurate, you should update that item(s) as part of the interim amendment. All updates to your *brochure* must be filed through the IARD system and maintained in your files. See SEC rules 204-1 and 204-2(a)(14) and similar state rules.

5. We are filing our *annual updating amendment*. The last *brochure*(s) that we filed does not contain any materially inaccurate information. Do we have to prepare a summary of material changes? No, as long as you

have not filed any interim amendments making material changes to the *brochure* that you filed with last year's *annual updating amendment*. If you do not have to prepare a summary of material changes, you do not have to deliver a summary of material changes or a *brochure* to your existing *clients* that year. See SEC rule 204-3(b). If you are a state-registered adviser, you should contact the appropriate *state securities authorities* to determine whether you must make an annual offer of the brochure.

6. Do we need to include the summary of material changes that we prepare in response to Item 2 with *our annual updating amendment* filing on IARD? Yes, you need to include the summary in your *annual updating amendment*. Item 2 permits you to include the summary as part of the *brochure* (on the cover page or the page immediately following the cover page) or to create a separate document containing the summary. If you include the summary as part of your *brochure,* the summary will be part of the *annual updating amendment* filing that you submit on IARD. If your summary of material changes is a separate document, you must attach the summary as an exhibit to your *brochure* and upload your *brochure* and the summary together in a single, text-searchable file in Adobe Portable Document Format on IARD for your *annual updating amendment*.

   Note: If you include the summary of material changes in your *brochure*, and you revise or update your *brochure* between *annual updating amendments*, you should consider whether you should update the summary as part of that other-than annual amendment to avoid confusing or misleading *clients* reading the updated *brochure*.

7. We have determined that we have no *clients* to whom we must deliver a *brochure*. Must we prepare one? No, but see note to Instruction 1 above.

8. May we include a summary of the *brochure* at the beginning of our *brochure*? Yes. Although it is not required, you may choose to include a summary of the *brochure* at the beginning of your *brochure*. Such summary, however, may not substitute for the summary of material changes required by Item 2 of Part 2A.

9. We offer several advisory services. May we prepare multiple firm *brochures*? Yes. If you offer substantially different types of advisory services, you may opt to prepare separate *brochures* so long as each *client* receives all applicable information about services and fees. Each *brochure* may omit information that does not apply to the advisory services and fees it describes. For example, your firm *brochure* sent to your *clients* who invest only in the United States can omit information about your advisory services and fees relating to offshore investments. See SEC rule 204-3(e) and similar state rules. If you prepare separate *brochures* you must file each *brochure* (and any amendments) through the IARD system as required in SEC rules 203-1 and 204-1 and similar state rules.

10. We *sponsor* a *wrap fee program*. Is there a different *brochure* that we need to deliver to our wrap fee *clients*? Yes. If you *sponsor* a *wrap fee program*, you must deliver a *wrap fee program brochure* to your wrap fee *clients*. The disclosure requirements for preparing a *wrap fee program brochure* appear in Part 2A, Appendix 1 of Form ADV. If your entire advisory business is *sponsoring wrap fee programs*, you do not need to prepare a firm *brochure* separate from your *wrap fee program brochure(s)*. See SEC rule 204-3(d) and similar state rules.

11. We provide portfolio management services to *clients* in *wrap fee programs* that we do not *sponsor*. Which *brochure* must we deliver to these *clients*? You must deliver your *brochure* prepared in accordance with Part 2A (not Appendix 1) to your wrap fee *clients*. You also must deliver to these *clients* any *brochure supplements* required by Part 2B of Form ADV.

12. May we include information not required by an item in our *brochure*? Yes. If you include information not required by an item, however, you may not include so much additional information that the required information is obscured.

13. Item 18 requires us to give our *clients* an audited balance sheet. May any public accountant perform the audit? Your auditor must be independent. Article 2 of SEC Regulation S-X sets out the general rules for auditor

independence. Please note that these requirements may be different from the rules of professional organizations.

14. We are a new firm. Do we need a *brochure*? Yes. Respond to items in Part 2A of Form ADV based on the advisory services you propose to provide and the practices, policies and procedures you propose to adopt.

15. We are a "separately identifiable department or division" (SID) of a bank. Must our *brochure* discuss our bank's general business practices? No. Information you include in your firm *brochure* (or in *brochure supplements*) should be information about you, the SID, and your business practices, rather than general information about your bank.

Part 2A of Form ADV: Firm *Brochure*

Item 1 Cover Page

A. The cover page of your *brochure* must state your name, business address, contact information, website address (if you have one), and the date of the *brochure*.

Note: If you primarily conduct advisory business under a name different from your full legal name, and you have disclosed your business name in Item 1.B of Part 1A of Form ADV, then you may use your business name throughout your *brochure*.

B. Display on the cover page of your *brochure* the following statement or other clear and concise language conveying the same information, and identifying the document as a "brochure":

This brochure provides information about the qualifications and business practices of [your name]. If you have any questions about the contents of this brochure, please contact us at [telephone number and/or email address]. The information in this brochure has not been approved or verified by the United States Securities and Exchange Commission or by any state securities authority.

Additional information about [your name] also is available on the SEC's website at www.adviserinfo.sec.gov.

C. If you refer to yourself as a "registered investment adviser" or describe yourself as being "registered," include a statement that registration does not imply a certain level of skill or training.

Item 2 Material Changes

If you are amending your *brochure* for your annual update and it contains material changes from your last annual update, identify and discuss those changes on the cover page of the *brochure* or on the page immediately following the cover page, or as a separate document accompanying the *brochure*. You must state clearly that you are discussing only material changes since the last annual update of your *brochure*, and you must provide the date of the last annual update of your *brochure*.

Note: You do not have to separately provide this information to a *client* or prospective *client* who has not received a previous version of your *brochure*.

Item 3 Table of Contents

Provide a table of contents to your *brochure*.

Note: Your table of contents must be detailed enough so that your *clients* can locate topics easily. Your *brochure* must follow the same order, and contain the same headings, as the items listed in Part 2A.

Item 4 Advisory Business

A. Describe your advisory firm, including how long you have been in business. Identify your principal owner(s).

Notes: (1) For purposes of this item, your principal owners include the *persons* you list as owning 25% or more of your firm on Schedule A of Part 1A of Form ADV (Ownership Codes C, D or E). (2) If you are a publicly held company without a 25% shareholder, simply disclose that you are publicly held. (3) If an individual or company owns 25% or more of your firm through subsidiaries, you must identify the individual or parent company and intermediate subsidiaries. If you are an SEC-registered adviser, you

must identify intermediate subsidiaries that are publicly held, but not other intermediate subsidiaries. If you are a state-registered adviser, you must identify all intermediate subsidiaries.

B. Describe the types of advisory services you offer. If you hold yourself out as specializing in a particular type of advisory service, such as financial planning, quantitative analysis, or market timing, explain the nature of that service in greater detail. If you provide investment advice only with respect to limited types of investments, explain the type of investment advice you offer, and disclose that your advice is limited to those types of investments.

C. Explain whether (and, if so, how) you tailor your advisory services to the individual needs of *clients*. Explain whether *clients* may impose restrictions on investing in certain securities or types of securities.

D. If you participate in *wrap fee programs* by providing portfolio management services, (1) describe the differences, if any, between how you manage wrap fee accounts and how you manage other accounts, and (2) explain that you receive a portion of the wrap fee for your services.

E. If you manage *client* assets, disclose the amount of *client* assets you manage on a *discretionary basis* and the amount of *client* assets you manage on a non-*discretionary basis*. Disclose the date "as of" which you calculated the amounts.

Note: Your method for computing the amount of "*client* assets you manage" can be different from the method for computing "assets under management" required for Item 5.F in Part 1A. However, if you choose to use a different method to compute "*client* assets you manage," you must keep documentation describing the method you use. The amount you disclose may be rounded to the nearest $100,000. Your "as of" date must not be more than 90 days before the date you last updated your *brochure* in response to this Item 4.E.

Item 5 Fees and Compensation

A. Describe how you are compensated for your advisory services. Provide your fee schedule. Disclose whether the fees are negotiable.

Note: If you are an SEC-registered adviser, you do not need to include this information in a *brochure* that is delivered only to qualified purchasers as defined in section 2(a)(51)(A) of the Investment Company Act of 1940.

B. Describe whether you deduct fees from *clients*' assets or bill *clients* for fees incurred. If *clients* may select either method, disclose this fact. Explain how often you bill *clients* or deduct your fees.

C. Describe any other types of fees or expenses *clients* may pay in connection with your advisory services, such as custodian fees or mutual fund expenses. Disclose that *clients* will incur brokerage and other transaction costs, and direct *clients* to the section(s) of your *brochure* that discuss brokerage.

D. If your *clients* either may or must pay your fees in advance, disclose this fact. Explain how a *client* may obtain a refund of a pre-paid fee if the advisory contract is terminated before the end of the billing period. Explain how you will determine the amount of the refund.

E. If you or any of your *supervised persons* accepts compensation for the sale of securities or other investment products, including asset-based sales charges or service fees from the sale of mutual funds, disclose this fact and respond to Items 5.E.1, 5.E.2, 5.E.3 and 5.E.4.

1. Explain that this practice presents a conflict of interest and gives you or your *supervised persons* an incentive to recommend investment products based on the compensation received, rather than on a *client's* needs. Describe generally how you address conflicts that arise, including your procedures for

disclosing the conflicts to *clients*. If you primarily recommend mutual funds, disclose whether you will recommend "no-load" funds.

2. Explain that *clients* have the option to purchase investment products that you recommend through other brokers or agents that are not affiliated with you.

3. If more than 50% of your revenue from advisory *clients* results from commissions and other compensation for the sale of investment products you recommend to your *clients*, including asset-based distribution fees from the sale of mutual funds, disclose that commissions provide your primary or, if applicable, your exclusive compensation.

4. If you charge advisory fees in addition to commissions or markups, disclose whether you reduce your advisory fees to offset the commissions or markups.

Note: If you receive compensation in connection with the purchase or sale of securities, you should carefully consider the applicability of the broker-dealer registration requirements of the Securities Exchange Act of 1934 and any applicable state securities statutes.

Item 6 *Performance-Based Fees* and Side-By-Side Management

If you or any of your *supervised persons* accepts *performance-based fees* – that is, fees based on a share of capital gains on or capital appreciation of the assets of a *client* (such as a *client* that is a hedge fund or other pooled investment vehicle) – disclose this fact. If you or any of your *supervised persons* manage both accounts that are charged a *performance-based fee* and accounts that are charged another type of fee, such as an hourly or flat fee or an asset-based fee, disclose this fact. Explain the conflicts of interest that you or your *supervised persons* face by managing these accounts at the same time, including that you or your *supervised persons* have an incentive to favor accounts for which you or your *supervised persons* receive a *performance-based fee*, and describe generally how you address these conflicts.

Item 7 Types of *Clients*

Describe the types of *clients* to whom you generally provide investment advice, such as individuals, trusts, investment companies, or pension plans. If you have any requirements for opening or maintaining an account, such as a minimum account size, disclose the requirements.

Item 8 Methods of Analysis, Investment Strategies and Risk of Loss

A. Describe the methods of analysis and investment strategies you use in formulating investment advice or managing assets. Explain that investing in securities involves risk of loss that *clients* should be prepared to bear.

B. For each significant investment strategy or method of analysis you use, explain the material risks involved. If the method of analysis or strategy involves significant or unusual risks, discuss these risks in detail. If your primary strategy involves frequent trading of securities, explain how frequent trading can affect investment performance, particularly through increased brokerage and other transaction costs and taxes.

C. If you recommend primarily a particular type of security, explain the material risks involved. If the type of security involves significant or unusual risks, discuss these risks in detail.

Form ADV: Part 2A

Item 9 Disciplinary Information

If there are legal or disciplinary events that are material to a *client's* or prospective *client's* evaluation of your advisory business or the integrity of your management, disclose all material facts regarding those events.

Items 9.A, 9.B, and 9.C list specific legal and disciplinary events presumed to be material for this Item. If your advisory firm or a *management person* has been *involved* in one of these events, you must disclose it under this Item for ten years following the date of the event, unless (1) the event was resolved in your or the *management person's* favor, or was reversed, suspended or vacated, or (2) you have rebutted the presumption of materiality to determine that the event is not material (see Note below). For purposes of calculating this ten-year period, the "date" of an event is the date that the final *order*, judgment, or decree was entered, or the date that any rights of appeal from preliminary *orders*, judgments or decrees lapsed.

Items 9.A, 9.B, and 9.C do not contain an exclusive list of material disciplinary events. If your advisory firm or a *management person* has been *involved* in a legal or disciplinary event that is not listed in Items 9.A, 9.B, or 9.C, but nonetheless is material to a *client's* or prospective *client's* evaluation of your advisory business or the integrity of its management, you must disclose the event. Similarly, even if more than ten years have passed since the date of the event, you must disclose the event if it is so serious that it remains material to a *client's* or prospective *client's* evaluation.

A. A criminal or civil action in a domestic, foreign or military court of competent jurisdiction in which your firm or a *management person*

1. was convicted of, or pled guilty or nolo contendere ("no contest") to (a) any *felony*; (b) a *misdemeanor* that *involved* investments or an *investment-related* business, fraud, false statements or omissions, wrongful taking of property, bribery, perjury, forgery, counterfeiting, or extortion; or (c) a conspiracy to commit any of these offenses;

2. is the named subject of a pending criminal *proceeding* that involves an *investment-related* business, fraud, false statements or omissions, wrongful taking of property, bribery, perjury, forgery, counterfeiting, extortion, or a conspiracy to commit any of these offenses;

3. was *found* to have been *involved* in a violation of an *investment-related* statute or regulation; or

4. was the subject of any *order*, judgment, or decree permanently or temporarily enjoining, or otherwise limiting, your firm or a *management person* from engaging in any *investment-related* activity, or from violating any *investment-related* statute, rule, or *order*.

B. An administrative *proceeding* before the SEC, any other federal regulatory agency, any state regulatory agency, or any *foreign financial regulatory authority* in which your firm or a *management person*

1. was *found* to have caused an *investment-related* business to lose its authorization to do business; or

2. was *found* to have been *involved* in a violation of an *investment-related* statute or regulation and was the subject of an *order* by the agency or authority

(a) denying, suspending, or revoking the authorization of your firm or a *management person* to act in an *investment-related* business;

(b) barring or suspending your firm's or a *management person's* association with an *investment-related* business;

(c) otherwise significantly limiting your firm's or a *management person's investment-related* activities; or

Form ADV: Part 2A

(d) imposing a civil money penalty of more than $2,500 on your firm or a *management person.*

C. A *self-regulatory organization (SRO) proceeding* in which your firm or a *management person*

1. was *found* to have caused an *investment-related* business to lose its authorization to do business; or

2. was *found* to have been *involved* in a violation of the *SRO's* rules and was: (i) barred or suspended from membership or from association with other members, or was expelled from membership; (ii) otherwise significantly limited from *investment-related* activities; or (iii) fined more than $2,500.

Note: You may, under certain circumstances, rebut the presumption that a disciplinary event is material. If an event is immaterial, you are not required to disclose it. When you review a legal or disciplinary event involving your firm or a *management person* to determine whether it is appropriate to rebut the presumption of materiality, you should consider all of the following factors: (1) the proximity of the *person involved* in the disciplinary event to the advisory function; (2) the nature of the infraction that led to the disciplinary event; (3) the severity of the disciplinary sanction; and (4) the time elapsed since the date of the disciplinary event. If you conclude that the materiality presumption has been overcome, you must prepare and maintain a file memorandum of your determination in your records. See SEC rule 204-2(a)(14)(iii).

Item 10 Other Financial Industry Activities and Affiliations

A. If you or any of your *management persons* are registered, or have an application pending to register, as a broker-dealer or a registered representative of a broker-dealer, disclose this fact.

B. If you or any of your *management persons* are registered, or have an application pending to register, as a futures commission merchant, commodity pool operator, a commodity trading advisor, or an associated person of the foregoing entities, disclose this fact.

C. Describe any relationship or arrangement that is material to your advisory business or to your *clients* that you or any of your *management persons* have with any *related person* listed below. Identify the *related person* and if the relationship or arrangement creates a material conflict of interest with *clients*, describe the nature of the conflict and how you address it.

1. broker-dealer, municipal securities dealer, or government securities dealer or broker
2. investment company or other pooled investment vehicle (including a mutual fund, closed-end investment company, unit investment trust, private investment company or "hedge fund," and offshore fund)
3. other investment adviser or financial planner
4. futures commission merchant, commodity pool operator, or commodity trading advisor
5. banking or thrift institution
6. accountant or accounting firm
7. lawyer or law firm
8. insurance company or agency
9. pension consultant
10. real estate broker or dealer
11. sponsor or syndicator of limited partnerships.

D. If you recommend or select other investment advisers for your *clients* and you receive compensation directly or indirectly from those advisers that creates a material conflict of interest, or if you have other business relationships with those advisers that create a material conflict of interest, describe these practices and discuss the material conflicts of interest these practices create and how you address them.

Form ADV: Part 2A

Item 11 Code of Ethics, Participation or Interest in *Client* Transactions and Personal Trading

A. If you are an SEC-registered adviser, briefly describe your code of ethics adopted pursuant to SEC rule 204A-1 or similar state rules. Explain that you will provide a copy of your code of ethics to any *client* or prospective *client* upon request.

B. If you or a *related person* recommends to *clients*, or buys or sells for *client* accounts, securities in which you or a *related person* has a material financial interest, describe your practice and discuss the conflicts of interest it presents. Describe generally how you address conflicts that arise.

Examples: (1) You or a *related person*, as principal, buys securities from (or sells securities to) your *clients*; (2) you or a *related person* acts as general partner in a partnership in which you solicit *client* investments; or (3) you or a *related person* acts as an investment adviser to an investment company that you recommend to *clients*.

C. If you or a *related person* invests in the same securities (or related securities, *e.g.*, warrants, options or futures) that you or a *related person* recommends to *clients*, describe your practice and discuss the conflicts of interest this presents and generally how you address the conflicts that arise in connection with personal trading.

D. If you or a *related person* recommends securities to *clients*, or buys or sells securities for *client* accounts, at or about the same time that you or a *related person* buys or sells the same securities for your own (or the *related person's* own) account, describe your practice and discuss the conflicts of interest it presents. Describe generally how you address conflicts that arise.

Note: The description required by Item 11.A may include information responsive to Item 11.B, C or D. If so, it is not necessary to make repeated disclosures of the same information. You do not have to provide disclosure in response to Item 11.B, 11.C, or 11.D with respect to securities that are not "reportable securities" under SEC rule 204A-1(e)(10) and similar state rules.

Item 12 Brokerage Practices

A. Describe the factors that you consider in selecting or recommending broker-dealers for *client* transactions and determining the reasonableness of their compensation (*e.g.*, commissions).

1. Research and Other Soft Dollar Benefits. If you receive research or other products or services other than execution from a broker-dealer or a third party in connection with *client* securities transactions ("soft dollar benefits"), disclose your practices and discuss the conflicts of interest they create.

Note: Your disclosure and discussion must include all soft dollar benefits you receive, including, in the case of research, both proprietary research (created or developed by the broker-dealer) and research created or developed by a third party.

a. Explain that when you use *client* brokerage commissions (or markups or markdowns) to obtain research or other products or services, you receive a benefit because you do not have to produce or pay for the research, products or services.

b. Disclose that you may have an incentive to select or recommend a broker-dealer based on your interest in receiving the research or other products or services, rather than on your *clients'* interest in receiving most favorable execution.

Form ADV: Part 2A

c. If you may cause *clients* to pay commissions (or markups or markdowns) higher than those charged by other broker-dealers in return for soft dollar benefits (known as paying-up), disclose this fact.

d. Disclose whether you use soft dollar benefits to service all of your *clients*' accounts or only those that paid for the benefits. Disclose whether you seek to allocate soft dollar benefits to *client* accounts proportionately to the soft dollar credits the accounts generate.

e. Describe the types of products and services you or any of your *related persons* acquired with *client* brokerage commissions (or markups or markdowns) within your last fiscal year.

Note: This description must be specific enough for your *clients* to understand the types of products or services that you are acquiring and to permit them to evaluate possible conflicts of interest. Your description must be more detailed for products or services that do not qualify for the safe harbor in section 28(e) of the Securities Exchange Act of 1934, such as those services that do not aid in investment decision-making or trade execution. Merely disclosing that you obtain various research reports and products is not specific enough.

f. Explain the procedures you used during your last fiscal year to direct *client* transactions to a particular broker-dealer in return for soft dollar benefits you received.

2. Brokerage for *Client* Referrals. If you consider, in selecting or recommending broker-dealers, whether you or a *related person* receives *client* referrals from a broker-dealer or third party, disclose this practice and discuss the conflicts of interest it creates.

a. Disclose that you may have an incentive to select or recommend a broker-dealer based on your interest in receiving *client* referrals, rather than on your *clients*' interest in receiving most favorable execution.

b. Explain the procedures you used during your last fiscal year to direct *client* transactions to a particular broker-dealer in return for *client* referrals.

3. Directed Brokerage.

a. If you routinely recommend, request or require that a *client* direct you to execute transactions through a specified broker-dealer, describe your practice or policy. Explain that not all advisers require their *clients* to direct brokerage. If you and the broker-dealer are affiliates or have another economic relationship that creates a material conflict of interest, describe the relationship and discuss the conflicts of interest it presents. Explain that by directing brokerage you may be unable to achieve most favorable execution of *client* transactions, and that this practice may cost *clients* more money.

b. If you permit a *client* to direct brokerage, describe your practice. If applicable, explain that you may be unable to achieve most favorable execution of *client* transactions. Explain that directing brokerage may cost *clients* more money. For example, in a directed brokerage account, the *client* may pay higher brokerage commissions because you may not be able to aggregate orders to reduce transaction costs, or the *client* may receive less favorable prices.

Note: If your *clients* only have directed brokerage arrangements subject to most favorable execution of *client* transactions, you do not need to respond to the last sentence of Item 12.A.3.a. or to the second or third sentences of Item 12.A.3.b.

Form ADV: Part 2A

B. Discuss whether and under what conditions you aggregate the purchase or sale of securities for various *client* accounts. If you do not aggregate orders when you have the opportunity to do so, explain your practice and describe the costs to *clients* of not aggregating.

Item 13 Review of Accounts

A. Indicate whether you periodically review *client* accounts or financial plans. If you do, describe the frequency and nature of the review, and the titles of the *supervised persons* who conduct the review.

B. If you review *client* accounts on other than a periodic basis, describe the factors that trigger a review.

C. Describe the content and indicate the frequency of regular reports you provide to *clients* regarding their accounts. State whether these reports are written.

Item 14 *Client* Referrals and Other Compensation

A. If someone who is not a *client* provides an economic benefit to you for providing investment advice or other advisory services to your *clients*, generally describe the arrangement, explain the conflicts of interest, and describe how you address the conflicts of interest. For purposes of this Item, economic benefits include any sales awards or other prizes.

B. If you or a *related person* directly or indirectly compensates any *person* who is not your *supervised person* for *client* referrals, describe the arrangement and the compensation.

Note: If you compensate any *person* for *client* referrals, you should consider whether SEC rule 206(4)-3 or similar state rules regarding solicitation arrangements and/or state rules requiring registration of *investment adviser representatives* apply.

Item 15 *Custody*

If you have *custody* of *client* funds or securities and a qualified custodian sends quarterly, or more frequent, account statements directly to your *clients*, explain that *clients* will receive account statements from the broker-dealer, bank or other qualified custodian and that *clients* should carefully review those statements. If your *clients* also receive account statements from you, your explanation must include a statement urging *clients* to compare the account statements they receive from the qualified custodian with those they receive from you.

Item 16 Investment Discretion

If you accept *discretionary authority* to manage securities accounts on behalf of *clients*, disclose this fact and describe any limitations *clients* may (or customarily do) place on this authority. Describe the procedures you follow before you assume this authority (*e.g.,* execution of a power of attorney).

Item 17 Voting *Client* Securities

A. If you have, or will accept, authority to vote *client* securities, briefly describe your voting policies and procedures, including those adopted pursuant to SEC rule 206(4)-6. Describe whether (and, if so, how) your *clients* can direct your vote in a particular solicitation. Describe how you address conflicts of interest between you and your *clients* with respect to voting their securities. Describe how *clients* may obtain information from you about how you voted their securities. Explain to *clients* that they may obtain a copy of your proxy voting policies and procedures upon request.

Form ADV: Part 2A

B. If you do not have authority to vote *client* securities, disclose this fact. Explain whether *clients* will receive their proxies or other solicitations directly from their custodian or a transfer agent or from you, and discuss whether (and, if so, how) *clients* can contact you with questions about a particular solicitation.

Item 18 Financial Information

A. If you require or solicit prepayment of more than $1,200 in fees per *client*, six months or more in advance, include a balance sheet for your most recent fiscal year.

1. The balance sheet must be prepared in accordance with generally accepted accounting principles, audited by an independent public accountant, and accompanied by a note stating the principles used to prepare it, the basis of securities included, and any other explanations required for clarity.

2. Show parenthetically the market or fair value of securities included at cost.

3. Qualifications of the independent public accountant and any accompanying independent public accountant's report must conform to Article 2 of SEC Regulation S-X.

Note: If you are a sole proprietor, show investment advisory business assets and liabilities separate from other business and personal assets and liabilities. You may aggregate other business and personal assets unless advisory business liabilities exceed advisory business assets.

Note: If you have not completed your first fiscal year, include a balance sheet dated not more than 90 days prior to the date of your *brochure*.

Exception: You are not required to respond to Item 18.A of Part 2A if you also are: (i) a qualified custodian as defined in SEC rule 206(4)-2 or similar state rules; or (ii) an insurance company.

B. If you have *discretionary authority* or *custody* of *client* funds or securities, or you require or solicit prepayment of more than $1,200 in fees per *client*, six months or more in advance, disclose any financial condition that is reasonably likely to impair your ability to meet contractual commitments to *clients*.

Note: With respect to Items 18.A and 18.B, if you are registered or are registering with one or more of the *state securities authorities*, the dollar amount reporting threshold for including the required balance sheet and for making the required financial condition disclosures is more than $500 in fees per *client*, six months or more in advance.

C. If you have been the subject of a bankruptcy petition at any time during the past ten years, disclose this fact, the date the petition was first brought, and the current status.

If you are registering or are registered with one or more *state securities authorities*, you must respond to the following additional Item.

Item 19 Requirements for State-Registered Advisers

A. Identify each of your principal executive officers and *management persons*, and describe their formal education and business background. If you have supplied this information elsewhere in your Form ADV, you do not need to repeat it in response to this Item.

B. Describe any business in which you are actively engaged (other than giving investment advice) and the approximate amount of time spent on that business. If you have supplied this information elsewhere in your Form ADV, you do not need to repeat it in response to this Item.

Form ADV: Part 2A

C. In addition to the description of your fees in response to Item 5 of Part 2A, if you or a *supervised person* are compensated for advisory services with *performance-based fees*, explain how these fees will be calculated. Disclose specifically that performance-based compensation may create an incentive for the adviser to recommend an investment that may carry a higher degree of risk to the *client*.

D. If you or a *management person* has been *involved* in one of the events listed below, disclose all material facts regarding the event.

1. An award or otherwise being *found* liable in an arbitration claim alleging damages in excess of $2,500, *involving* any of the following:

   (a) an investment or an *investment-related* business or activity;
   (b) fraud, false statement(s), or omissions;
   (c) theft, embezzlement, or other wrongful taking of property;
   (d) bribery, forgery, counterfeiting, or extortion; or
   (e) dishonest, unfair, or unethical practices.

2. An award or otherwise being *found* liable in a civil, *self-regulatory organization*, or administrative *proceeding involving* any of the following:

   (a) an investment or an *investment-related* business or activity;
   (b) fraud, false statement(s), or omissions;
   (c) theft, embezzlement, or other wrongful taking of property;
   (d) bribery, forgery, counterfeiting, or extortion; or
   (e) dishonest, unfair, or unethical practices.

E. In addition to any relationship or arrangement described in response to Item 10.C. of Part 2A, describe any relationship or arrangement that you or any of your *management persons* have with any issuer of securities that is not listed in Item 10.C. of Part 2A.

Instructions for Part 2A Appendix 1 of Form ADV:
Preparing Your *Wrap Fee Program Brochure*

Read all the instructions, including General Instructions for Form ADV, General Instructions for Part 2 of Form ADV, Instructions for Part 2A of Form ADV, and the instructions below, before preparing or updating your *wrap fee program brochure*.

1. Who must deliver a *wrap fee program brochure*? If you *sponsor* a *wrap fee program*, you must give a *wrap fee program brochure* to each *client* of the *wrap fee program*.

   However, if a *wrap fee program* that you *sponsor* has multiple *sponsors* and another *sponsor* creates and delivers to your *wrap fee program clients* a *wrap fee program brochure* that includes all the information required in your *wrap brochure,* you do not have to create or deliver a separate *wrap fee program brochure.*

   A *wrap fee program brochure* takes the place of your advisory firm *brochure* required by Part 2A of Form ADV, but only for *clients* of *wrap fee programs* that you *sponsor*. See SEC rule 204-3(d) and similar state rules.

2. When must a *wrap fee program brochure* be delivered?

   - You must give a *wrap fee program brochure* to each *client* of the *wrap fee program* before or at the time the *client* enters into a *wrap fee program* contract. See SEC rule 204-3(b) and similar state rules.
   - Each year you must (i) deliver, within 120 days of the end of your fiscal year, to each *client* a free updated *wrap fee program brochure* that either includes a summary of material changes or is accompanied by a summary of material changes, or (ii) deliver to each *client* a summary of material changes that includes an offer to provide a copy of the updated *wrap fee program brochure* and information on how a *client* may obtain the *wrap fee program brochure*. See SEC rule 204-3(b) and similar state rules.
   - You do not have to deliver an interim amendment to *clients* unless the amendment includes information in response to Item 9 of Part 2A (disciplinary information). An interim amendment can be in the form of a document describing the material facts relating to the amended disciplinary event. See SEC rule 204-3(b) and similar state rules.

   Note: As a fiduciary, you have an ongoing obligation to inform your *clients* of any material information that could affect the advisory relationship. As a result, between *annual updating amendments* you must disclose material changes to such information to *clients* even if those changes do not trigger delivery of an interim amendment. See General Instructions for Part 2 of Form ADV, Instruction 3.

3. When must we update our *wrap fee program brochure*? You must update your *wrap fee program brochure*: (i) each year at the time you file your *annual updating amendment*, and (ii) promptly whenever any information in the *wrap fee program brochure* becomes materially inaccurate. You are not required to update your *wrap fee program brochure* between annual amendments solely because your fee schedule has changed. However, if you are updating your *wrap fee program brochure* for a separate reason in between annual amendments, and your fee schedule listed in response to Item 4.A has become materially inaccurate, you should update that item as part of the interim amendment. All updates to your *wrap fee program brochure* must be filed through the IARD system and maintained in your files. See SEC rules 204-1 and 204-2(a)(14) and similar state rules.

4. May we deliver our *wrap fee program brochure* electronically? Yes. The SEC has published interpretive guidance on delivering documents electronically, which you can find at <www.sec.gov/rules/concept/33-7288.txt>.

5. What if we *sponsor* more than one *wrap fee program*? You may prepare a single *wrap fee program brochure* describing all the *wrap fee programs* you *sponsor*, or you may prepare separate *wrap fee program brochures* that describe one or more of your *wrap fee programs*. If you prepare separate *brochures*, each *brochure* must state that you *sponsor* other *wrap fee programs* and must explain how the *client* can obtain *brochures* for the other programs.

Form ADV: Instructions for Part 2A Appendix 1

6. We provide portfolio management services under a *wrap fee program* that we *sponsor*. Must we deliver both our *wrap fee program brochure* and our firm *brochure* to our *wrap fee program clients*? No, just the *wrap fee program brochure*. If you or your *supervised persons* provide portfolio management services under a *wrap fee program* that you also *sponsor*, your *wrap fee program brochure* must describe the investments and investment strategies you (or your *supervised persons*) will use as portfolio managers. This requirement appears in Item 6.C of this Appendix.

7. We provide other advisory services outside of our *wrap fee programs*. May we combine our *wrap fee program brochure* into our firm *brochure* for *clients* receiving these other services? No. Your *wrap fee program brochure* must address only the *wrap fee programs* you *sponsor*. See SEC rule 204-3(d)(1) and similar state rules.

8. Must we also deliver *brochure supplements* to *wrap fee program clients*? Yes. A *wrap fee program brochure* does not take the place of any supplements required by Part 2B of Form ADV.

Part 2A Appendix 1 of Form ADV: *Wrap Fee Program Brochure*

Item 1 Cover Page

A. The cover page of your *wrap fee program brochure* must state your name, business address, contact information, web site address (if you have one), and the date of the *wrap fee program brochure.*

Note: If you primarily conduct advisory business under a name different from your full legal name, and you have disclosed your business name in Item 1.B of Part 1A of Form ADV, then you may use your business name throughout your *wrap fee program brochure.*

B. Display on the cover page of your *wrap fee program brochure* the following (or other clear and concise language conveying the same information) and identifying the document as a "wrap fee program brochure":

This wrap fee program brochure provides information about the qualifications and business practices of [your name]. If you have any questions about the contents of this brochure, please contact us at [telephone number and/or email address]. The information in this brochure has not been approved or verified by the United States Securities and Exchange Commission or by any state securities authority.

Additional information about [your name] also is available on the SEC's website at www.adviserinfo.sec.gov.

D. If you refer to yourself as a "registered investment adviser" or describe yourself as being "registered," include a statement that registration does not imply a certain level of skill or training.

Item 2 Material Changes

If you are amending your *wrap fee program brochure* for your annual update and it contains material changes from your last annual update, identify and discuss those changes on the page immediately following the cover page of the *wrap fee program brochure* or as a separate document accompanying the *brochure.* You must clearly state that you are discussing only material changes since the last annual update of the *wrap fee program brochure*, and must provide the date of the last annual update to the *wrap fee program brochure.*

Notes: You do not have to provide this information to a *client* or prospective *client* who has not received a previous version of your *wrap fee program brochure.*

Item 3 Table of Contents

Provide a table of contents to your *wrap fee program brochure.*

Note: Your table of contents must be detailed enough so that your *clients* can locate topics easily. Your *wrap fee program brochure* must follow the same order, and contain the same headings, as the items listed in this Appendix 1.

Item 4 Services, Fees and Compensation

A. Describe the services, including the types of portfolio management services, provided under each program. Indicate the wrap fee charged for each program or, if fees vary according to a schedule, provide your fee schedule. Indicate whether fees are negotiable and identify the portion of the total fee, or the range of fees, paid to portfolio managers.

B. Explain that the program may cost the *client* more or less than purchasing such services separately and describe the factors that bear upon the relative cost of the program, such as the cost of the services if provided separately and the trading activity in the *client's* account.

C. Describe any fees that the *client* may pay in addition to the wrap fee, and describe the circumstances under which *clients* may pay these fees, including, if applicable, mutual fund expenses and mark-ups, mark-downs, or spreads paid to market makers.

D. If the *person* recommending the *wrap fee program* to the *client* receives compensation as a result of the *client's* participation in the program, disclose this fact. Explain, if applicable, that the amount of this compensation may be more than what the *person* would receive if the *client* participated in your other programs or paid separately for investment advice, brokerage, and other services. Explain that the *person*, therefore, may have a financial incentive to recommend the *wrap fee program* over other programs or services.

Item 5 Account Requirements and Types of *Clients*

If a *wrap fee program* imposes any requirements to open or maintain an account, such as a minimum account size, disclose these requirements. If there is a minimum amount for assets placed with each portfolio manager as well as a minimum account size for participation in the *wrap fee program*, disclose and explain these requirements. To the extent applicable to your *wrap fee program clients*, describe the types of *clients* to whom you generally provide investment advice, such as individuals, trusts, investment companies, or pension plans.

Item 6 Portfolio Manager Selection and Evaluation

A. Describe how you select and review portfolio managers, your basis for recommending or selecting portfolio managers for particular *clients*, and your criteria for replacing or recommending the replacement of portfolio managers for the program and for particular *clients*.

1. Describe any standards you use to calculate portfolio manager performance, such as industry standards or standards used solely by you.

2. Indicate whether you review, or whether any third-party reviews, performance information to determine or verify its accuracy or its compliance with presentation standards. If so, briefly describe the nature of the review and the name of any third party conducting the review.

3. If applicable, explain that neither you nor a third-party reviews portfolio manager performance information, and/or that performance information may not be calculated on a uniform and consistent basis.

B. Disclose whether any of your *related persons* act as a portfolio manager for a *wrap fee program* described in the *wrap fee program brochure*. Explain the conflicts of interest that you face because of this arrangement and describe how you address these conflicts of interest. Disclose whether *related person* portfolio managers are subject to the same selection and review as the other portfolio managers that participate in the *wrap fee program*. If they are not, describe how you select and review *related person* portfolio managers.

C. If you, or any of your *supervised persons* covered under your investment adviser registration, act as a portfolio manager for a *wrap fee program* described in the *wrap fee program brochure*, respond to Items 4.B, 4.C, 4.D (Advisory Business), 6 (*Performance-Based Fees* and Side-By-Side Management), 8.A (Methods of Analysis, Investment Strategies and Risk of Loss) and 17 (Voting *Client* Securities) of Part 2A of Form ADV.

Form ADV: Part 2A Appendix 1

Item 7 *Client* Information Provided to Portfolio Managers

Describe the information about *clients* that you communicate to the *clients*' portfolio managers, and how often or under what circumstances you provide updated information.

Item 8 *Client* Contact with Portfolio Managers

Explain any restrictions placed on *clients*' ability to contact and consult with their portfolio managers.

Item 9 Additional Information

A. Respond to Item 9 (Disciplinary Information) and Item 10 (Other Financial Industry Activities and Affiliations) of Part 2A of Form ADV.

B. Respond to Items 11 (Code of Ethics, Participation or Interest in *Client* Transactions and Personal Trading), 13 (Review of Accounts), 14 (*Client* Referrals and Other Compensation), and 18 (Financial Information) of Part 2A of Form ADV, as applicable to your wrap fee *clients*.

If you are registered or are registering with one or more *state securities authorities*, you must respond to the following additional Item.

Item 10 Requirements for State-Registered Advisers

Respond to Item 19.E of Part 2A of Form ADV.

Instructions for Part 2B of Form ADV: Preparing a *Brochure Supplement*

1. For which *supervised persons* must we prepare a *brochure supplement*? As an initial matter, if you have no *clients* to whom you must deliver a *brochure supplement* (see Instruction 2 below), then you need not prepare any *brochure supplements*. Otherwise, you must prepare a *brochure supplement* for the following *supervised persons*:

   (i) Any *supervised person* who formulates investment advice for a *client* and has direct *client* contact; and

   (ii) Any *supervised person* who has *discretionary authority* over a *client's* assets, even if the *supervised person* has no direct *client* contact. See SEC rule 204-3(b)(2) and similar state rules.

   Note: No supplement is required for a *supervised person* who has no direct *client* contact and has *discretionary authority* over a *client*'s assets only as part of a team. In addition, if discretionary advice is provided by a team comprised of more than five *supervised persons*, *brochure supplements* need only be provided for the five *supervised persons* with the most significant responsibility for the day-to-day discretionary advice provided to the *client*. See SEC rule 204-3(b) and similar state rules.

2. To whom must we deliver *brochure supplements*? Are there any exceptions?

   You must deliver to a *client* the *brochure supplements* for each *supervised person* who provides advisory services to that *client*. However, there are three categories of *clients* to whom you are not required to deliver *supplements*. See SEC rule 204-3(c) and similar state rules.

   First, you are not required to deliver supplements to *clients* to whom you are not required to deliver a firm *brochure* (or a *wrap fee program brochure*).

   Second, you are not required to deliver supplements to *clients* who receive only *impersonal investment advice*, even if they receive a firm *brochure*.

   Third, you are not required to deliver supplements to *clients* who are individuals who would be "qualified clients" of your firm under SEC rule 205-3(d)(1)(iii). Those *persons* are:

   (i) Any executive officers, directors, trustees, general partners, or *persons* serving in a similar capacity, of your firm; or

   (ii) Any employees of your firm (other than employees performing solely clerical, secretarial or administrative functions) who, in connection with their regular functions or duties, participate in the investment activities of your firm and have been performing such functions or duties for at least 12 months.

3. When must we deliver a supplement to a *client*?

- You must deliver the supplement for a *supervised person* before or at the time that *supervised person* begins to provide advisory services to a *client*.
- You also must deliver to *clients* any update to the supplement that amends information in response to Item 3 of Part 2B (disciplinary information). Such an amendment can be in the form of a "sticker" that identifies the information that has become inaccurate and provides the new information and the date of the sticker.

  Note: As a fiduciary, you have a continuing obligation to inform your *clients* of any material information that could affect the advisory relationship. As a result, between *annual updating amendments* you must disclose material changes to *clients* even if those changes do not trigger delivery of an updated supplement.

You may have a *supervised person* deliver supplements (including his own) on your behalf. Furthermore, if you are an SEC-registered adviser, you not required to file *brochure supplements* or updates, but you must maintain copies of them. See Instruction 5 of SEC General Instructions for Part 2 of Form ADV.

Form ADV: Part 2B

4. When must we update *brochure supplements*? You must update *brochure supplements* promptly whenever any information in them becomes materially inaccurate.

5. May we deliver *brochure supplements* electronically? Yes. You may deliver supplements using electronic media. The SEC has published interpretive guidance on delivering documents electronically, which you can find at <www.sec.gov/rules/concept/33-7288.txt>. If you deliver a supplement electronically, you may disclose in that supplement that the *supervised person* has a disciplinary event and provide a hyperlink to either the BrokerCheck or the IAPD systems.

6. Must *brochure supplements* be separate documents? No. If your firm *brochure* includes all the information required in a *brochure supplement*, you do not need a separate supplement. Smaller firms with just a few *supervised persons* may find it easier to include all supplement information in their firm *brochure*, while larger firms may prefer to use a firm *brochure* and separate supplements. If supplement information is included in the firm *brochure*, however, the supplements must be included at the end of the brochure. In addition, each supplement must follow the same order as the supplement items listed in Part 2B, and contain the same headings.

   You may prepare supplements for groups of *supervised persons*. A group supplement, or a firm *brochure* presenting supplement information about *supervised persons*, must present information in a separate section for each *supervised person*.

7. Must an adviser who is a sole proprietor provide his own *brochure supplement* to *clients*? No, if that information is included in the firm *brochure*.

8. May we include information not required by an item in a *brochure supplement*? Yes. If you include information not required by an item, however, you may not include so much additional information that the required information is obscured.

9. Are we required to file the *brochure supplements*? If you are registered or are registering with the SEC, you are not required to file your *brochure supplements*, but you are required to maintain copies of all supplements and amendments to supplements in your files. See SEC rule 204-2(a)(14)(i). If you are registered or are registering with one or more *state securities authorities*, you must file through IARD a copy of the *brochure supplement* for each *supervised person* doing business in that state.

Part 2B of Form ADV: *Brochure Supplement*

Item 1 Cover Page

A. Include the following on the cover page of the supplement:

1. The *supervised person's* name, business address and telephone number (if different from yours).
2. Your firm's name, business address and telephone number. If your firm *brochure* uses a business name for your firm, use the same business name for the firm in the supplement.
3. The date of the supplement.

B. Display on the cover page statements containing the following or other clear and concise language conveying the same information, and identifying the document as a "brochure supplement:"

This brochure supplement provides information about [name of *supervised person*] that supplements the [name of advisory firm] brochure. You should have received a copy of that brochure. Please contact [service center or name and/or title of your contact *person*] if you did not receive [name of advisory firm]'s brochure or if you have any questions about the contents of this supplement.

Additional information about [name of *supervised person*] is available on the SEC's website at www.adviserinfo.sec.gov.

Note: You do not have to include this statement directing *clients* to the public website unless the *supervised person* is an *investment adviser representative* required to register with *state securities authorities*. The above information must be on the cover page of the supplement but need not be the only information on the cover page of the supplement. If other information is included on the cover page of the supplement, the above information must be on the top of the first page of the supplement.

Item 2 Educational Background and Business Experience

Disclose the *supervised person's* name, age (or year of birth), formal education after high school, and business background (including an identification of the specific positions held) for the preceding five years. If the *supervised person* has no high school education, no formal education after high school, or no business background, disclose this fact. You may list any professional designations held by the *supervised person*, but if you do so, you must provide a sufficient explanation of the minimum qualifications required for each designation to allow *clients* to understand the value of the designation.

Item 3 Disciplinary Information

If there are legal or disciplinary events material to a *client's* or prospective *client's* evaluation of the *supervised person*, disclose all material facts regarding those events.

Items 3.A, 3.B, 3.C, and 3.D below list specific legal and disciplinary events presumed to be material for this Item. If the *supervised person* has been *involved* in one of these events, you must disclose it under this Item for ten years following the date of the event, unless (1) the event was resolved in the *supervised person's* favor, or was reversed, suspended or vacated, or (2) you have rebutted the presumption of materiality to determine that the event is not material (see Note below). For purposes of calculating this ten-year period, the "date" of an event is the date the final *order*, judgment, or decree was entered, or the date any rights of appeal from preliminary *order*s, judgments or decrees lapsed.

Items 3.A, 3.B, 3.C, and 3.D do not contain an exclusive list of material disciplinary events. If the *supervised person* has been *involved* in a legal or disciplinary event that is not listed in Items 3.A, 3.B, 3.C, or 3.D but is material to a *client's* or prospective *client's* evaluation of the *supervised person's* integrity, you must disclose the

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event. Similarly, even if more than ten years have passed since the date of the event, you must disclose the event if it is so serious that it remains currently material to a *client's* or prospective *client's* evaluation.
If you deliver a supplement electronically and if a particular disclosure required below for the *supervised person* is provided through either the Financial Industry Regulatory Authority's (FINRA) BrokerCheck system or the IAPD, you may satisfy that particular disclosure obligation by including in that supplement (i) a statement that the *supervised person* has a disciplinary history, the details of which can be found on FINRA's BrokerCheck system or the IAPD, and (ii) a hyperlink to the relevant system with a brief explanation of how the *client* can access the disciplinary history. The BrokerCheck link is www.finra.org/brokercheck; the IAPD link is www.adviserinfo.sec.gov.

A. A criminal or civil action in a domestic, foreign or military court of competent jurisdiction in which the *supervised person*

1. was convicted of, or pled guilty or nolo contendere ("no contest") to (a) any *felony*; (b) a *misdemeanor* that *involved* investments or an *investment-related* business, fraud, false statements or omissions, wrongful taking of property, bribery, perjury, forgery, counterfeiting, or extortion; or (c) a conspiracy to commit any of these offenses;

2. is the named subject of a pending criminal *proceeding* that involves an *investment-related* business, fraud, false statements or omissions, wrongful taking of property, bribery, perjury, forgery, counterfeiting, extortion, or a conspiracy to commit any of these offenses;

3. was *found* to have been *involved* in a violation of an *investment-related* statute or regulation; or

4. was the subject of any *order*, judgment, or decree permanently or temporarily enjoining, or otherwise limiting, the *supervised person* from engaging in any *investment-related* activity, or from violating any *investment-related* statute, rule, or *order*.

B. An administrative *proceeding* before the SEC, any other federal regulatory agency, any state regulatory agency, or any *foreign financial regulatory authority* in which the *supervised person*

1. was *found* to have caused an *investment-related* business to lose its authorization to do business; or

2. was *found* to have been *involved* in a violation of an *investment-related* statute or regulation and was the subject of an *order* by the agency or authority

   (a) denying, suspending, or revoking the authorization of the *supervised person* to act in an *investment-related* business;

   (b) barring or suspending the *supervised person's* association with an *investment-related* business;

   (c) otherwise significantly limiting the *supervised person's investment-related* activities; or

   (d) imposing a civil money penalty of more than $2,500 on the *supervised person.*

C. A *self-regulatory organization* (*SRO*) *proceeding* in which the *supervised person*

1. was *found* to have caused an *investment-related* business to lose its authorization to do business; or

2. was *found* to have been *involved* in a violation of the *SRO's* rules and was: (i) barred or suspended from membership or from association with other members, or was expelled from membership; (ii) otherwise significantly limited from *investment-related* activities; or (iii) fined more than $2,500.

Form ADV: Part 2B

D. Any other *proceeding* in which a professional attainment, designation, or license of the *supervised person* was revoked or suspended because of a violation of rules relating to professional conduct. If the *supervised person* resigned (or otherwise relinquished his attainment, designation, or license) in anticipation of such a *proceeding* (and the adviser knows, or should have known, of such resignation or relinquishment), disclose the event.

Note: You may, under certain circumstances, rebut the presumption that a disciplinary event is material. If an event is immaterial, you are not required to disclose it. When you review a legal or disciplinary event involving the *supervised person* to determine whether it is appropriate to rebut the presumption of materiality, you should consider all of the following factors: (1) the proximity of the *supervised person* to the advisory function; (2) the nature of the infraction that led to the disciplinary event; (3) the severity of the disciplinary sanction; and (4) the time elapsed since the date of the disciplinary event. If you conclude that the materiality presumption has been overcome, you must prepare and maintain a file memorandum of your determination in your records. See SEC rule 204-2(a)(14)(iii) and similar state rules.

Item 4 Other Business Activities

A. If the *supervised person* is actively engaged in any *investment-related* business or occupation, including if the *supervised person* is registered, or has an application pending to register, as a broker-dealer, registered representative of a broker-dealer, futures commission merchant ("FCM"), commodity pool operator ("CPO"), commodity trading advisor ("CTA"), or an associated *person* of an FCM, CPO, or CTA, disclose this fact and describe the business relationship, if any, between the advisory business and the other business.

1. If a relationship between the advisory business and the *supervised person's* other financial industry activities creates a material conflict of interest with *clients*, describe the nature of the conflict and generally how you address it.

2. If the *supervised person* receives commissions, bonuses or other compensation based on the sale of securities or other investment products, including as a broker-dealer or registered representative, and including distribution or service ("trail") fees from the sale of mutual funds, disclose this fact. If this compensation is not cash, explain what type of compensation the *supervised person* receives. Explain that this practice gives the *supervised person* an incentive to recommend investment products based on the compensation received, rather than on the *client's* needs.

B. If the *supervised person* is actively engaged in any business or occupation for compensation not discussed in response to Item 4.A, above, and the other business activity or activities provide a substantial source of the *supervised person's* income or involve a substantial amount of the *supervised person's* time, disclose this fact and describe the nature of that business. If the other business activities represent less than 10 percent of the *supervised person's* time and income, you may presume that they are not substantial.

Item 5 Additional Compensation

If someone who is not a *client* provides an economic benefit to the *supervised person* for providing advisory services, generally describe the arrangement. For purposes of this Item, economic benefits include sales awards and other prizes, but do not include the *supervised person's* regular salary. Any bonus that is based, at least in part, on the number or amount of sales, *client* referrals, or new accounts should be considered an economic benefit, but other regular bonuses should not.

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Item 6 Supervision

Explain how you *supervise* the *supervised person*, including how you monitor the advice the *supervised person* provides to *clients*. Provide the name, title and telephone number of the *person* responsible for supervising the *supervised person's* advisory activities on behalf of your firm.

If you are registered or are registering with one or more *state securities authorities*, you must respond to the following additional Item.

Item 7 Requirements for State-Registered Advisers

A. In addition to the events listed in Item 3 of Part 2B, if the *supervised person* has been *involved* in one of the events listed below, disclose all material facts regarding the event.

1. An award or otherwise being *found* liable in an arbitration claim alleging damages in excess of $2,500, *involving* any of the following:

(a) an investment or an *investment-related* business or activity;
(b) fraud, false statement(s), or omissions;
(c) theft, embezzlement, or other wrongful taking of property;
(d) bribery, forgery, counterfeiting, or extortion; or
(e) dishonest, unfair, or unethical practices.

2. An award or otherwise being *found* liable in a civil, *self-regulatory organization*, or administrative *proceeding involving* any of the following:

(a) an investment or an *investment-related* business or activity;
(b) fraud, false statement(s), or omissions;
(c) theft, embezzlement, or other wrongful taking of property;
(d) bribery, forgery, counterfeiting, or extortion; or
(e) dishonest, unfair, or unethical practices.

B. If the *supervised person* has been the subject of a bankruptcy petition, disclose that fact, the date the petition was first brought, and the current status.

Dated: July 28, 2010.

By the Commission.
Elizabeth M. Murphy,
Secretary.

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Federal Register

Thursday,
August 12, 2010

Part IV

Federal Housing Finance Board

Federal Housing Finance Agency

Department of Housing and Urban Development

Office of Federal Housing Enterprise Oversight

12 CFR Parts 908, 1209, 1780
Rules of Practice and Procedure; Proposed Rule

FEDERAL HOUSING FINANCE BOARD

12 CFR Part 908

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1209

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Federal Housing Enterprise Oversight

12 CFR Part 1780

RIN 2590–AA14

Rules of Practice and Procedure

AGENCY: Federal Housing Finance Board; Federal Housing Finance Agency; and Office of Federal Housing Enterprise Oversight, HUD.

ACTION: Notice of proposed rulemaking; request for comment.

SUMMARY: The Federal Housing Finance Agency (FHFA) solicits written comment on a proposed rule to implement the Housing and Economic Recovery Act of 2008 (HERA) amendments to the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (Safety and Soundness Act) and the Federal Home Loan Bank Act (Bank Act) pertaining to the civil enforcement powers of FHFA, and the Rules of Practice and Procedure for enforcement proceedings. The Safety and Soundness Act, as amended by sections 1151–1158 of HERA, authorizes FHFA to initiate enforcement proceedings against the Federal National Mortgage Association and the Federal Home Loan Mortgage Corporation (together, the Enterprises) and the Federal Home Loan Banks (the Banks) (collectively, the regulated entities), and entity-affiliated parties as defined in the Safety and Soundness Act. When final, the rule will replace the existing Rules of Practice and Procedure promulgated by the Office of Federal Housing Enterprise Oversight (OFHEO) and the Federal Housing Finance Board (Finance Board) formerly charged with overseeing the regulated entities. The proposed rule may provide FHFA personnel, the regulated entities, entity-affiliated parties, and other interested parties with the clear guidance necessary to prepare for and participate in the administrative enforcement action process to increase the efficiency and transparency of FHFA's administrative enforcement hearings.

DATES: Comments on the proposed rule must be received in writing on or before October 12, 2010.

ADDRESSES: You may submit your written comments on the proposed rulemaking, identified by RIN number 2590–AA14, by any of the following methods:

- *E-mail:* Comments to Alfred M. Pollard, General Counsel, may be sent by e-mail at *RegComments@fhfa.gov*. Please include "RIN 2590–AA14" in the subject line of the message.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the Federal eRulemaking Portal, please also send it by e-mail to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by the Agency. Please include "RIN 2590–AA14" in the subject line of the message.
- *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:* The mailing address for comments is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590–AA14, Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552.
- *Hand Delivery/Courier:* The hand delivery address is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590–AA14, Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. A hand-delivered package should be logged at the Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Charlotte A. Reid, Associate General Counsel, Federal Housing Finance Agency, 1700 G Street, NW., Fourth Floor, Washington, DC 20552, telephone (202) 414–3810 (not a toll-free number). The telephone number for the Telecommunications Device for the Deaf is: (800) 877–8339.

SUPPLEMENTARY INFORMATION: The Supplementary Information is organized according to this table of contents:

I. Comments

The Federal Housing Finance Agency (FHFA) invites comments on all aspects of the proposed Rules of Practice and Procedure (proposed rule), including legal and policy considerations, and will take all comments into consideration before issuing the final rule. All comments received by the deadline will be posted for public inspection on FHFA Web site at *http://www.fhfa.gov*. Copies of all comments timely received will be available for public inspection and copying at the address above on government-business days between the hours of 10 a.m. and 3 p.m. To make an appointment to inspect comments please call the Office of General Counsel at (202) 414–6924.

II. Background

A. Establishment of FHFA

Effective July 30, 2008, Division A of HERA, Public Law 110–289, 122 Stat. 2654 (2008), titled the Federal Housing Finance Regulatory Reform Act of 2008, created FHFA as an independent agency of the Federal government.[1] HERA amended the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (Safety and Soundness Act) (12 U.S.C. 4501 *et seq.*) and the Federal Home Loan Bank Act (Bank Act) (12 U.S.C. 1421 through 1449), respectively, to provide that the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (together, the Enterprises) and the Federal Home Loan Banks (Banks) (collectively, the regulated entities), are subject to the supervision and regulation of FHFA.[2]

Additionally, section 1101 of HERA amended section 1311(b)(2) of the Safety and Soundness Act to provide that the regulated entities and the Office of Finance are subject to the general regulatory authority of the Director of FHFA. 12 U.S.C. 4511(b)(2).[3,4] Under this provision the Director has broad general regulatory authority to "ensure that the purposes of [HERA], the

[1] *See generally,* HERA, Division A, Titles I–III, Public Law 110–289, 122 Stat. 2654, sections 1101 *et seq.* (July 30, 2008). Specifically, section 1101 of HERA amended section 1311(a) of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (Safety and Soundness Act), Title XIII, Public Law 102–550, 106 Stat. 3672, 3941–4012, sections 1301 *et seq.* (1993), to establish FHFA as an independent agency of the Federal government. *See* 12 U.S.C. 4511(a).

[2] *See* section 1101 of HERA, amending section 1311(b)(1) of the Safety and Soundness Act, which provides that each regulated entity [defined at section 1303(20) of the Safety and Soundness Act to include the Enterprises and Banks] is subject to the supervision and regulation of FHFA. 12 U.S.C. 4511(b)(1).

[3] The Office of Finance acts as agent of the Banks in the issuance of Bank debt called consolidated obligations. *See* 12 U.S.C. 1431. HERA defined the Office of Finance as an "entity-affiliated party." 12 U.S.C. 4502(11)(E). In some cases, under the HERA amendments, executive officers, directors or management of the Office of Finance may be subject to the requirements of the enforcement provisions and rules.

[4] Section 1101 of HERA established the position of Director, as head of FHFA, in section 1312(a) of the Safety and Soundness Act. 12 U.S.C. 4512(a).

authorizing statutes, and any other applicable law are carried out." *See id.* 4511(b)(2).[5]

HERA transferred to FHFA the supervisory, mission, and oversight responsibilities over the Enterprises and Banks from the U.S. Department of Housing and Urban Development (HUD), including OFHEO, and the Federal Housing Finance Board (Finance Board), respectively.[6] FHFA was established as the financial safety and soundness regulator to oversee the prudential operations of the Enterprises and Banks (*i.e.,* the regulated entities) and to ensure that they operate in a safe and sound manner; remain adequately capitalized; foster liquid, efficient, competitive and resilient national housing finance markets; comply with the Safety and Soundness Act and their respective authorizing statutes, as well as all rules, regulations, guidelines, and orders issued under law; and carry out their missions through activities that are authorized by law and are consistent with the public interest.[7]

B. Statutory Background

Together, Freddie Mac and Fannie Mae owned or guaranteed nearly $5.34 trillion of residential mortgages in the United States (U.S.) as of December 31, 2009. The Banks support the U.S. housing market by making advances (*i.e.,* loans secured by eligible collateral) to their member commercial banks, thrifts, and credit unions, assuring a ready flow of mortgage funding. Bank advances stood at $631.2 billion as of December 31, 2009. Thus, the regulated entities play a key role in housing finance and the U.S. economy.

The mission of FHFA is to provide effective supervision, regulation, and housing mission oversight of the Enterprises and the Banks to promote their safety and soundness, support housing finance and affordable housing, and support a stable and liquid mortgage market. Accordingly, the HERA amendments to the Safety and Soundness Act make explicit the general regulatory and supervisory authority of FHFA and the Director, and grant specific supervisory and enforcement powers to the Director. *See e.g.,* 12 U.S.C. 4511, 4513, 4517, 4518, 4526, 4631 through 4641.

By design, the Safety and Soundness Act provides the Director with broad supervisory and regulatory authority to ensure the safety and soundness of the regulated entities: the Director "shall exercise such general regulatory authority, including such duties and authorities set forth under section 1313 of the Safety and Soundness Act, to ensure that the purposes of this Act, the authorizing statutes, and any other applicable law are carried out." *See* 12 U.S.C. 4511(b)(2). The Director's general regulatory authority is joined to more specific powers, such as those invoked under section 1313 of the Safety and Soundness Act, and the examination authority under section 1317 of the Safety and Soundness Act, thereby constructing a comprehensive framework for safety and soundness regulation of the regulated entities. *See* 12 U.S.C. 4513, 4517.

Specifically, section 1313(a)(1) of the Safety and Soundness Act prescribes the principal duties of the Director. The Director shall "oversee the prudential operations of each regulated entity." 12 U.S.C. 4513(a)(1)(A). Similarly, section 1313(a)(1)(B) of the Safety and Soundness Act enumerates the principal duties of the Director to ensure that: each regulated entity operates in a safe and sound manner, including maintenance of adequate capital and internal controls; the operations and activities of each regulated entity promote the efficiency, competitiveness, and liquidity of national housing finance markets; each regulated entity complies with the Safety and Soundness Act and the rules, regulations, guidelines, and orders issued under the Safety and Soundness Act and the authorizing statutes; each regulated entity executes its statutory mission through authorized activities; and the activities of each regulated entity are consistent with the public interest. 12 U.S.C. 4513(a)(1)(B).[8]

Further underscoring the Director's ongoing authority to ensure that the operations and management of the regulated entities comport with the Safety and Soundness Act and their respective authorizing statutes, section 1313(a)(2)(B) of the Safety and Soundness Act expressly authorizes the Director to "exercise such incidental powers as may be necessary or appropriate to fulfill the duties and responsibilities of the Director in the supervision and regulation of each regulated entity." *See* 12 U.S.C. 4513(a)(2)(B).[9] Thus, the Director may undertake such regulatory and supervisory actions as deemed to be necessary or appropriate to fulfilling the duties and responsibilities of FHFA with respect to the regulated entities.[10]

When promulgating regulations that may relate to the Banks, under section 1313(f)[sic] of the Safety and Soundness Act (as amended by section 1201 of HERA) the Director is required to consider the differences between the Banks and the Enterprises with respect to the Banks' cooperative ownership structure; mission of providing liquidity to members; affordable housing and community development mission; capital structure; and joint and several liability. The Director may also consider any other differences that are deemed appropriate. *See* 12 U.S.C. 4513(f)[sic].[11] In preparing the proposed rule, the Director considered the differences between the Banks and the Enterprises as they relate to the above factors. The Director is requesting comments from the public about whether differences related to these factors should result in a revision of the proposed rule as it may relate to the Banks.

[5] Section 1303(3) of the Safety and Soundness Act, as amended by section 1002 of HERA, provides that the term "authorizing statutes" means the Federal National Mortgage Association Charter Act, the Federal Home Loan Mortgage Corporation Act, and the Federal Home Loan Bank Act. *See* 12 U.S.C. 4502(3).

[6] HERA abolished OFHEO and the Finance Board one year after the date of its enactment. By operation of law, the regulated entities and the Office of Finance continue to operate under existing regulations promulgated by OFHEO and the Finance Board. Those existing regulations are enforceable by the Director until such time as they are modified, terminated, set aside, or superseded by the Director. *See* sections 1302 and 1312 of HERA, 122 Stat. 2795, 2798. When final, FHFA Rules of Practice and Procedure (12 CFR part 1209) will supersede the Rules of Practice and Procedure previously promulgated by OFHEO (12 CFR part 1780) and the Finance Board (12 CFR part 908). *See also* note 17, and accompanying text.

[7] *See* Section 1102 of HERA, amending section 1313 of the Safety and Soundness Act (12 U.S.C. 4513).

[8] *See* 12 U.S.C. 4513(a)(1)(B)(i) through (v).

[9] The Supreme Court has held that the incidental powers provision applicable to national banks constitutes "an independent grant of authority," and that courts should view "the specific powers set forth thereafter as exemplary, not exclusive." *NationsBank of N.C., N.A.* v. *Variable Annuity Life Ins. Co.,* 513 U.S. 251, 258 (1995).

[10] Furthermore, other provisions in the Safety and Soundness Act reinforce the independence and general regulatory authority of the Director. For example, section 1311(c) of the Safety and Soundness Act, as amended by section 1101 of HERA, provides that the authority of the Director "to take actions under subtitles B and C [of Title I of Division A of HERA] shall not in any way limit the general supervisory and regulatory authority granted to the Director under subsection (b)." *See* 12 U.S.C. 4511(c). Section 1313B of the Safety and Soundness Act provides that the Director shall establish certain prudential management and operations standards, by regulation or guideline, for each regulated entity. *See* 12 U.S.C. 4513b. Finally, section 1319G(a) of the Safety and Soundness Act provides ample, independent authority for the issuance of "any regulations, guidelines, or orders necessary to carry out the duties of the Director under this title or the authorizing statutes, and to ensure that the purposes of this title and the authorizing statutes are accomplished." 12 U.S.C. 4526

[11] So in original; paragraph designation should be (d).

C. Enforcement Authority of the Director Under Sections 1371 Through 1379D of the Safety and Soundness Act, as Amended by HERA

To carry out its statutory mission, FHFA must have effective enforcement tools. The HERA amendments to the Safety and Soundness Act and the Bank Act provide that clear authority. The Enterprises and entity-affiliated parties are subject to administrative enforcement proceedings as provided in sections 1371 through 1379D of the Safety and Soundness Act, as amended by sections 1151 through 1158 of HERA (12 U.S.C. 4631 through 4641). HERA also amended the Bank Act and the Safety and Soundness Act to provide that the Banks and the Office of Finance, respectively, are subject to this enforcement framework.[12] As amended, sections 1371 through 1379D of the Safety and Soundness Act (12 U.S.C. 4631 through 4641) subject the Enterprises, the Banks, the Office of Finance, and entity-affiliated parties to the authority of the Director to initiate proceedings to issue cease and desist orders, to issue temporary cease and desist orders, to impose civil money penalties, or to obtain removal and prohibition orders, in accordance with applicable law.

In particular, the HERA provisions in section 1377(a) of the Safety and Soundness Act (12 U.S.C. 4636a(a)), give the Director express authority to suspend or remove from office, or to prohibit any further participation in the conduct of the affairs of a regulated entity, an entity-affiliated party, or any officer, director, or management of the Office of Finance, for any violation, practice, or breach of such party's fiduciary duty, as set forth therein. Additionally, in accordance with section 1377(b) of the Safety and Soundness Act (12 U.S.C. 4636a(b)), the Director can take immediate action to suspend or remove from office, or to prohibit the participation in any manner in the conduct of the affairs of the regulated entity, any party subject to an action under section 1377(a) of the Safety and Soundness Act.

Finally, under section 1377(h) of the Safety and Soundness Act (12 U.S.C. 4636a(h)), with respect to any entity-affiliated party who is charged with a Federal or State crime involving dishonesty or breach of trust, which is punishable by imprisonment for more than one year, in any criminal information, indictment or complaint, the Director is authorized to suspend such party from office or prohibit him or her from any further involvement in the conduct of the affairs of a regulated entity if continued service or participation by such party could pose a threat to, or impair public confidence in, the regulated entity. *See* 12 U.S.C. 4636a(h)(1)(A). The statute prescribes that a copy of the suspension notice shall be served on each relevant regulated entity. *See* 12 U.S.C. 4636a(h)(1)(B)(i).

Thus, under these enhanced powers, the Director has at his or her disposal a broad range of enforcement actions to enforce, as needed, applicable law, rules, orders, and agreements pertaining to the safe and sound operation of the Enterprises and Banks.[13] Because this enforcement authority parallels that of the enforcement tools available to bank regulatory agencies, the procedures for pursuing such actions, by design, are similar. The Federal bank and thrift regulators' uniform rules of practice and procedure for enforcement actions adopted under section 916 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989 (FIRREA), Public Law 101–73, 103 Stat. 183 (1989) (the Uniform Rules) set the standard for formal enforcement proceedings, and served as the model for the enforcement regulations later adopted by OFHEO and the Finance Board.[14] Thus, the proposed regulation builds upon the Uniform Rules, as well as the existing enforcement regulations adopted by OFHEO in 1999 (and amended in 2001) (12 CFR part 1780), and the Finance Board's Rules of Practice and Procedure adopted in 2002 (12 CFR part 908).

Cease and desist enforcement proceedings are commenced by serving a notice of charges that is to set forth the facts constituting the practice or violation and fix a time and place for a hearing to determine on the record whether an order to cease and desist from such practice or violation should issue. *See* 12 U.S.C. 4631(c)(1). Such hearings are governed by section 1373 of the Safety and Soundness Act. *See generally,* 12 U.S.C. 4633. In fact, section 1373(a)(1) of the Safety and Soundness Act (12 U.S.C. 4633(a)(1)) provides that any hearing under sections 1371 (cease and desist order), 1376(c) (civil money penalty assessment) or 1377 (removal or suspension orders; except removal actions under section 1377(h) of the Safety and Soundness Act) be held on the record. *See* 12 U.S.C. 4633(a)(1). Therefore, prior to issuing a cease-and-desist order, imposing civil money penalties, or ordering the suspension or removal of an entity-affiliated party or any officer, director, or management of the Office of Finance, FHFA must conduct a hearing on the record and provide the subject of such an order with notice and the opportunity to participate in a hearing that is to be conducted in accordance with chapter 5 of title 5 of the United States Code.[15] Sections 554, 556, and 557 of the Administrative Procedure Act govern hearings on the record.[16] The Rules of Practice and Procedure as proposed (proposed rule) establish the procedural requirements for any hearing on the record in an enforcement proceeding brought under subtitle C of the Safety

[12] Section 1204 of HERA repealed the enforcement authority of the Finance Board over the Banks and specified parties in section 2B(a)(5) of the Bank Act (12 U.S.C. 1422b(a)(5)). Therefore, the Banks, the Office of Finance, and specified parties are subject to FHFA enforcement authority as set forth in sections 1371 through 1379D of subtitle C of the Safety and Soundness Act, as amended. *See* 12 U.S.C. 4631 through 4641.

[13] The Director has broad safety and soundness enforcement authority under sections 1371 through 1379D of the Safety and Soundness Act, (subtitle C—Enforcement Provisions) (12 U.S.C. 4631 through 4641), in furtherance of the Director's general safety and soundness regulatory authority. Additionally, the Director has authority under subtitle B of the Safety and Soundness Act (sections 1361 through 1369E) to set and enforce capital levels or appoint FHFA as conservator or receiver for a regulated entity. More important, as amended by HERA, section 1311(c) of the Safety and Soundness Act expressly preserves these powers in addition to the Director's general supervisory and regulatory authority under subsection (b) of section 1311 of the Safety and Soundness Act, as amended: "[t]he authority of the Director to take actions under subtitles B and C shall not in any way limit the general supervisory and regulatory authority granted to the Director under subsection (b)." *See* 12 U.S.C. 4511(c).

[14] The Federal Financial Institutions Examination Council (FFIEC) members adopted the Uniform Rules as noted: the Office of the Comptroller of the Currency (OCC), 12 CFR part 19 (56 FR 38028, August 9, 1991) (as amended 61 FR 20334, May 6, 1996; 70 FR 69638, November 17, 2005); the Office of Thrift Supervision (OTS), 12 CFR Part 509 (56 FR 38306, August 12, 1991) (as amended 56 FR 59866, November 26, 1991; 61 FR 20353, May 6, 1996; 70 FR 69641, November 17, 2005, and 72 FR 25955, May 8, 2007); the Federal Deposit Insurance Corporation (FDIC), 12 CFR Part 308 (56 FR 37975, August 9, 1991) (as amended 61 FR 20347, May 6, 1996; 70 FR 69639, November 17, 2005); the Board of Governors of the Federal Reserve (FED) 12 CFR Part 263 (56 FR 38052, August 9, 1991) (as amended 61 FR 20341, May 6, 1996; 70 FR 69638, Nov. 17, 2005; 73 FR 58032, Oct. 6, 2008); and the National Credit Union Administration (NCUA), 12 CFR Part 747 (56 FR 37767, August 8, 1991) (as amended 57 FR 523, January 7, 1992; 61 FR 28024, June 4, 1996; 71 FR 67440, November 22, 2006).

[15] *See* section 1373(a)(3) of the Safety and Soundness Act (12 U.S.C. 4633(a)(3)).

[16] Public Law 89–554, 80 Stat. 381 (1966) (codified at 5 U.S.C. 551–559; 701–706). Formal adjudications (*i.e.,* hearings "on the record") are governed by chapters 5 and 7 of the Administrative Procedure Act (5 U.S.C. 554, 556, and 557) (APA). The APA grants each agency "the authority necessary to comply with the requirements of [chapter 5] through the issuance of rules or otherwise." *See* 5 U.S.C. 559.

and Soundness Act in conformity with the APA.

D. Rules of Practice and Procedure

As stated, the proposed Rules of Practice and Procedure are designed to govern hearings on the following matters that FHFA by law must conduct on the record in accordance with APA formal hearing requirements:

(1) Enforcement proceedings under sections 1371 through 1379D of the Safety and Soundness Act (12 U.S.C. 4631 *through* 4641) (except section 1377(h) (12 U.S.C. 4636a));

(2) Removal, prohibition, and civil money penalty proceedings for violations of post-employment restrictions imposed by applicable law; and

(3) Proceedings under section 102 of the Flood Disaster Protection Act of 1973, as amended (42 U.S.C. 4012a) to assess civil money penalties.

To ensure that comprehensive hearing procedures are in place to conduct such hearings, the proposed rule departs from the organizational structure of the existing OFHEO rule and delinks the procedural steps for hearings on the record from the underlying statutory enforcement authority set forth in sections 1371 through 1379D of the Safety and Soundness Act (12 U.S.C. 4631 through 4641). To make this distinction clear, the enforcement authority is set out in subpart B of the proposed rule, whereas the formal hearing procedures are separately stated in subpart C of the proposed rule.

The stand alone formal hearing procedures in subpart C of Part 1209 also could govern civil money penalty proceedings authorized under section 1345 of the Safety and Soundness Act that require a hearing on the record, but that specifically provides for remedies that differ from those under sections 1371 and 1376 of the Safety and Soundness Act. *See* 12 U.S.C. 4582, 4585, 4631(a)(2) and 4636(a). In addition to the housing goals enforcement proceedings under sections 1341 and 1345 of the Safety and Soundness Act, the formal hearing procedures in subpart C of this part could apply to the enforcement of the regulated entities' reporting requirements under section 1314 of the Safety and Soundness Act (12 U.S.C. 4514).

The Rules of Practice and Procedure, when final, will replace the Rules of Practice and Procedure previously adopted by OFHEO (12 CFR part 1780) and the Finance Board (12 CFR part 908).[17] The OFHEO rule serves as the template for the proposed rule.[18] Specifically, the proposed rule sets out the requirements for the commencement of an enforcement proceeding by service of a notice of charges; the appointment of a presiding officer; hearing procedures and permissible activities; the conduct of the trial-like testimonial phase of the hearing process; the presiding officer's filing with the Director of a recommended decision and order, along with the hearing record; the decision by the Director; and the qualifications and disciplinary rules for practice before FHFA.[19] During the course of the hearing, the presiding officer controls virtually all aspects of the proceeding. In particular, the presiding officer: determines the hearing schedule; presides over all conferences; rules on non-dispositive motions, discovery, and evidentiary issues; and ensures that the proceeding is prompt, fair, and impartial, and allows for the creation of a written record upon which the recommended decision is based.[20]

The current requirement that the Director issue a final ruling within ninety (90) days of the date on which the Director serves notice upon the parties that the hearing record is complete and the case has been submitted for final decision also is retained in the proposed FHFA Rules of Practice and Procedure. Importantly, the presiding officer does not have the authority to make a ruling that disposes of the proceeding. Only the Director has the authority to dismiss the proceeding, in whole or in part, or to make a final determination of the merits of the proceeding. This ensures that FHFA and the respondent receive full and fair consideration of the matters at issue.

Many of the proposed revisions to the Rules of Practice and Procedure were informed by OFHEO's prior experience in conducting enforcement proceedings under its rule. From that practice, FHFA has identified certain issues for clarification. Accordingly, FHFA is suggesting revisions in the proposed rule to make the adjudication process more efficient, fair, and transparent. For example, the proposed rule includes a definition of "notice of charges." The notice of charges is the charging document that is served by FHFA on a regulated entity or party as provided in sections 1371 through 1377 of the Safety and Soundness Act (12 U.S.C. 4631 through 4636a) to initiate enforcement proceedings. Additionally, to resolve any confusion, the definition as proposed in § 1209.3 clarifies that a "notice of charges" is to be distinguished from an "effective notice" within the meaning of 12 U.S.C. 4635(a), and that that provision does not confer jurisdiction upon a Federal district court over an agency enforcement proceeding.

FHFA also is proposing to make the presiding officer's authority more explicit in several respects. First, § 1209.11 of the proposed rule (Authority of the Presiding Officer) affords the presiding officer support for holding an initial scheduling conference to control the proceedings. Thus, § 1209.11(b)(1) of the proposed rule states that the date for the testimonial phase of the hearing is to be set in a scheduling order issued in conjunction with the initial scheduling conference set under § 1209.36 of the proposed rule. Second, the proposed rule permits the presiding officer more leeway to control the pace and context of discovery; and, if necessary, discretion to prohibit unnecessary or burdensome discovery. Accordingly, § 1209.11(b)(5) of the proposed rule confirms that, among other things, the presiding officer may issue and enforce discovery orders. Section 1209.11(b)(8) of the proposed rule restates the broad powers of the

[17] The Finance Board's enforcement authority, as enacted in sections 2B(a)(2) and (5) of the Bank Act in 1999, was derived in part from OFHEO's enforcement authority under sections 1371 through 1379D of the Safety and Soundness Act of 1992. *Compare* 12 U.S.C. 1422b(a)(2), (5) *with* 12 U.S.C. 4631 through 4641. With the exception of the grounds for cease and desist actions and removal authority accorded the Finance Board, the provisions were nearly indistinguishable. Accordingly, the Finance Board Rules of Practice and Procedure (12 CFR part 908) were highly aligned with the pre-existing OFHEO Rules of Practice and Procedure (12 CFR part 1780). In many respects these procedural rules are nearly identical. The term "existing provision," is used to refer to those co-extensive provisions.

[18] As stated, the Finance Board Rules of Practice and Procedure (12 CFR part 908) were modeled on, and are nearly identical to, the OFHEO rule in most procedural respects. For convenience, the OFHEO rule served as the basic template for the proposed FHFA rule. In some cases, however, the Finance Board rule informed the drafting, for example, in defining certain terms such as notice (*i.e.,* notice of charges), hearing, and the Safety and Soundness Act.

[19] 5 U.S.C. 1305 sets forth the authority of the Office of Personnel Management (OPM) relating to the appointment of an administrative law judge (ALJ). In practice, an OPM-appointed ALJ serves as presiding officer.

[20] As with the Uniform Rules, parties to an FHFA enforcement proceeding have the right to present evidence and to examine and cross-examine the witnesses at the evidentiary hearing stage. Upon completion of the testimonial phase of the hearing, the parties may submit proposed findings of fact and conclusions of law and a proposed order. After taking the evidence and considering the record, the presiding officer makes a recommended decision and submits the complete record to the Director, which includes recommended findings of fact and conclusions of law, and a proposed order. The record also includes all transcripts, exhibits, rulings, motions, briefs and memoranda, expert witness reports, and all supporting papers filed in connection with the hearing.

presiding officer to regulate the scope, timing, and completion of discovery of any non-privileged matter that is materially relevant to the charges or allowable defenses in the proceeding. Third, FHFA has determined to make more explicit the requirement that matters or documents subject to discovery must be "materially relevant" to the charges or allowable defenses in the proceeding to support the presiding officer's ability to deny discovery requests that are not so framed. ("Materially relevant" is generally understood to mean that the information sought must have a logical connection to a consequential fact that tends to prove or disprove a matter in issue.) Similarly, § 1209.11(b)(11) of the proposed rule underscores that the presiding officer has ample authority to admit, exclude, or limit evidence according to its material relevance to the legally cognizable claims and defenses presented by a notice of charges. Finally, as a corollary to the authority of the presiding officer to set the date of the evidentiary hearing in a scheduling order, § 1209.23 of the proposed rule clarifies that the notice of charges is to specify that the testimonial hearing date will be determined when the presiding officer holds the initial scheduling conference and issues a scheduling order within thirty (30) to sixty (60) days of service of the notice of charges.

FHFA believes that these and other enhancements to the rule as proposed will ensure that any enforcement action taken by FHFA is governed by a process that is expeditious, thorough, and fair.

III. Synopsis of the Proposed Rule

FHFA is proposing to revise the Rules of Practice and Procedure to be codified in a new part 1209 that would supersede the existing OFHEO and Finance Board Rules of Practice and Procedure governing enforcement proceedings, which are nearly identical procedurally. For ease of drafting, the template for the proposed rule is the OFHEO Rules of Practice and Procedure (12 CFR part 1708).[21] In addition, the proposed rule is faithful to the model Uniform Rules and meets or exceeds all applicable APA requirements for formal hearings. Part 1209 will govern the conduct of FHFA administrative hearings on the record for enforcement proceedings as provided in the Safety and Soundness Act. Many of the provisions in the existing OFHEO rule (and their identical counterparts in the Finance Board rule) are to be adopted unchanged. Other provisions, as noted below, are to be modified to reflect actual practices or current law, to make the process more efficient, or to ensure that the procedures, on their face, are fair and transparent.

The proposed rule is organized as follows: Part 1209 is to be divided into several topical subparts in order to more clearly delineate the specific enforcement authority of the Director under sections 1371 through 1379D of the Safety and Soundness Act (12 U.S.C. 4631 through 4641) as distinct from the procedural steps for hearings on the record for enforcement actions and proceedings as enumerated below. Thus, part 1209 of this title is segmented into subparts as follows:

Subpart A (Scope and Authority) sets out the purpose and authority of the rule, the rules of construction, and the definitions that have general applicability to part 1209, and provides that the rules of practice and procedure governing agency hearings on the record shall apply to:

(1) Enforcement proceedings under sections 1371 through 1379D of the Safety and Soundness Act (12 U.S.C. 4631 through 4641);

(2) Removal, prohibition, and civil money penalty proceedings for violations of post-employment restrictions imposed by applicable law; and

(3) Civil money penalty proceedings under section 102 of the Flood Disaster Protection Act of 1973, as amended (42 U.S.C. 4012a).

Subpart B (Enforcement Proceedings under sections 1371 through 1379D) summarizes the controlling law for enforcement proceedings set out in sections 1371 through 1379D of the Safety and Soundness Act (12 U.S.C. 4631 through 4641).

Subpart C (Rules of Practice and Procedure) the principal procedural subpart sets out the requisite procedures for formal agency hearings held on the record in accordance with this part.

Subpart D (Parties and Representational Practice before the Federal Housing Finance Agency; Standards of Conduct) sets out the responsibilities that govern every party or party's representative appearance in hearings on the record under these rules, or in any appearance before the Director or any agency representative.

Subpart E (Civil Money Penalty Inflation Adjustments) provides a stand alone framework for making inflation adjustments to the civil money penalty amounts periodically required (not less than every four years) under the Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law. 101–410, 104 Stat. 890, as amended by the Debt Collection Improvement Act of 1996, Public Law 104–134, title III, sec. 31001(s)(1), Apr. 26, 1996, 110 Stat. 1321–373; Public Law 105–362, title XIII, sec. 1301(a), Nov. 10, 1998, 112 Stat. 3293 (28 U.S.C. 2461 note) (Inflation Adjustment Act).

Subpart F (Suspension or Removal of Entity-Affiliated Party Charged with Felony) specifies the procedures for a hearing following suspension or removal of an entity-affiliated party charged with a felony under section 1377(h) of the Safety and Soundness Act (12 U.S.C. 4636a(h)) that are not governed by subpart C (Rules of Practice and Procedure).

The section-by-section analysis and discussion of subparts A–F address each section in more detail below.

IV. Section-by-Section Analysis and Discussion

Subpart A—Scope and Authority

Section 1209.1 Scope

This section sets out the authority for agency enforcement proceedings under sections 1371 through 1379D of the Safety and Soundness Act governing civil enforcement proceedings, including: removal, prohibition, and civil money penalty proceedings for violations of post-employment restrictions imposed by applicable law, and proceedings under section 102 of the Flood Disaster Protection Act of 1973, as amended (42 U.S.C. 4012a) to assess civil money penalties.

Section 1209.2 Rules of Construction

This section prescribes general rules of construction and provides that unless stated otherwise a party's representative of record may take any action required of a party.

Section 1209.3 Definitions

This section sets out definitions of terms applicable to this Part. Many of the definitions are drawn from the existing OFHEO and Finance Board rules. In addition, definitions of terms are added as required to address the HERA amendments to the Safety and Soundness Act and Bank Act, such as the inclusion of the Office of Finance and its executive officers, directors, or management where applicable under the HERA amendments, or where experience has shown that the process would benefit from greater clarity. In particular, the rule is to contain a definition of "notice of charges" to clarify that the term refers to the charging document served on a respondent in an enforcement

[21] As stated, when it was originally adopted, the Finance Board rule (12 CFR part 908) was based on the OFHEO rule (12 CFR part 1780), and the procedural requirements are substantively identical, unless otherwise noted. *See* notes 17 and 18 with accompanying text.

proceeding, and is not to be confused with an effective notice as that term is used in section 1375(a) of the Safety and Soundness Act (12 U.S.C. 4635(a)). Similarly, any notice of removal or suspension or intent to impose civil money penalties, is akin to a notice of charges in that respect. These charging documents are to be distinguished from effective notices and orders that are of immediate and enforceable effect under the Safety and Soundness Act.

Subpart B—Scope and Authority-Enforcement Proceedings Under Sections 1371–1379D

Section 1209.4 Scope and Authority

This section states the authority for enforcement proceedings under sections 1371 through 1379D of the Safety and Soundness Act (12 U.S.C. 4631 through 4641). Specifically, section 1373 of the Safety and Soundness Act (12 U.S.C. 4633) provides that the following actions must be held on the record: (1) Cease and desist proceedings under section 1371 of the Safety and Soundness Act (12 U.S.C. 4631), (2) civil money penalty assessment proceedings under section 1376 of the Safety and Soundness Act (12 U.S.C. 4636), and (3) proceedings under the removal and prohibition authority of section 1377 of the Safety and Soundness Act (12 U.S.C. 4636a) (except proceedings under section 1377(h) of the Safety and Soundness Act for the suspension or removal of an entity-affiliated party charged with a felony. (12 U.S.C. 4636a(h)).

Additionally, this section states that the cease and desist and civil money penalty provisions of sections 1371 and 1376 of the Safety and Soundness Act (12 U.S.C. 4631 and 4636) do not apply to cease and desist or civil money penalty proceedings relative to the enforcement of housing goals under sections 1331 through 1348 of the Safety and Soundness Act. In particular, section 1336(c) of the Safety and Soundness Act (12 U.S.C. 4566(c)) provides that actions to enforce housing goals must proceed under sections 1341 and 1345 of the Safety and Soundness Act. *See* 12 U.S.C. 4581, 4585, and 4631(a)(2).[22]

Prior to HERA, actions to enforce Enterprise housing goals were reserved to the Secretary of Housing and Urban Development (HUD). That division of enforcement authority was eliminated because HERA transferred to the Director of FHFA the responsibility for enforcing Enterprise housing goals. Thus, the requirement that housing goals enforcement actions are to proceed under sections 1341 through 1348 of the Safety and Soundness Act (12 U.S.C. 4581 through 4588) controls.[23] The grounds for initiating such cease and desist proceedings relative to housing goals are set forth in section 1341 of the Safety and Soundness Act (12 U.S.C. 4581), and section 1345 of the Safety and Soundness Act provides for civil money penalties for such violations that differ from the civil money penalty provisions in section 1376 of the Safety and Soundness Act (12 U.S.C. 4636). *See* 12 U.S.C. 4585. Like the enforcement proceedings under sections 1371 through 1376 of the Safety and Soundness Act (12 U.S.C. 4631 *et seq.*), housing goals enforcement actions proceed following the issuance and service of a notice of charges and are conducted as a hearing on the record. *See* 12 U.S.C. 4582(a)(1). Thus, the formal hearing procedures set out in subpart C of part 1209 as proposed are well-suited to govern housing goals enforcement proceedings.

Section 1209.5 Cease and Desist Proceedings

Generally, the statutory authority and requirements for cease and desist proceedings are set out in section 1371 of the Safety and Soundness Act (12 U.S.C. 4631), as amended by section 1151 of HERA. Assuming that the requisite conditions are met, a cease and desist proceeding is initiated by service of a notice of charges, and a hearing on the record is held to determine whether the grounds are satisfied. The hearing is administered by an independent presiding officer who makes recommended findings of fact and conclusions of law and transmits the entire administrative record to the Director who makes a final determination based on the record and issues an order.

Judicial review of an order is available pursuant to section 1374 of the Safety and Soundness Act (12 U.S.C. 4634), which provides that judicial review of any order issued under sections 1371, 1313B, 1376, or 1377 of the Safety and Soundness Act (12 U.S.C. 4631, 4513b, 4636, or 4636a) may be obtained by filing a petition in the United States Court of Appeals for the District of Columbia Circuit within thirty (30) days of the date of the order. An appeal does not operate as a stay of an order issued by the Director, unless specifically ordered by the court.

Under section 1375(a) of the Safety and Soundness Act, it is within the Director's discretion to seek enforcement of an effective and outstanding notice or order issued under subtitle C or subtitle B of the Safety and Soundness Act. Section 1375(b) of the Safety and Soundness Act prescribes that, except as otherwise expressly conferred, no court shall have jurisdiction to affect the issuance or enforcement of any notice or order under sections 1371, 1372, 1313B, 1376, or 1377 of the Safety and Soundness Act (12 U.S.C. 4631, 4513b, 4636, and 4636a).

The grounds for instituting cease and desist proceedings are set forth in section 1371(a) and (b) of the Safety and Soundness Act (12 U.S.C. 4631(a) and (b)). Specifically, an unsafe or unsound practice in conducting the business of a regulated entity or the Office of Finance, or violation of a law, rule, regulation, order, or any condition imposed in writing by the Director, may be grounds for a cease and desist order. Service of a notice of charges is governed by section 1371(c)(1) of the Safety and Soundness Act (12 U.S.C. 4631(c)(1)). Issuance of an order is governed by section 1371(c)(2) of the Safety and Soundness Act (12 U.S.C. 4631(c)(2)). If the Director finds on the basis of the record made at a hearing that any practice or violation has been established (or the regulated entity or entity-affiliated party consents to an order), the Director may issue and serve on the regulated entity or entity-affiliated party an order requiring the party to cease and desist from such practice or violation.

Under section 1371(d) of the Safety and Soundness Act (12 U.S.C. 4631(d)), a cease and desist order or a temporary cease and desist order may also require a party to take affirmative action to correct or remedy any condition resulting from any practice or violation with respect to which the order is issued. *See* 12 U.S.C. 4631(a), (c)(2), and (d). Additionally, section 1371(e) of the Safety and Soundness Act (12 U.S.C.

[22] The corollary provision in section 1371(a)(2) of the Safety and Soundness Act (12 U.S.C. 4631(a)(2)) states in pertinent part that the Director may not proceed under that section to "enforce compliance with any housing goal established under [sections 1331 through 1348 of the Safety and Soundness Act], with section 1336 or 1337 of this title, with subsection (m) or (n) of section 309 [of Fannie Mae's authorizing statute] (12 U.S.C. 1723a(m), (n)), with subsection (e) or (f) of section 307 [of Freddie Mac's authorizing statute] (12 U.S.C. 1456(e), (f)), or with paragraph (5) of section 10(j) of the Federal Home Loan Bank Act (12 U.S.C. 1430(j))."

[23] Section 1205 of HERA added a new section 10C of the Bank Act to provide that the housing goals for the Banks should be consistent with the housing goals for the Enterprises and applied the enforcement provisions of section 1336 of the Safety and Soundness Act to the Banks in the same manner and to the same extent as that section applies to the Enterprises. That effectively applies the same enforcement authority under sections 1341 and 1345 of the Safety and Soundness Act to the Banks. *See generally* 12 U.S.C. 1421.

4631(e)), states the authority of the Director to place limitations on the activities or functions of the regulated entity or entity-affiliated party or any executive officer or director of the regulated entity or entity-affiliated party in connection with the cease and desist order or temporary cease and desist order. Finally, section 1371(f) of the Safety and Soundness Act (12 U.S.C. 4631(f)), specifies the effective date of a cease and desist order and provides that such order shall remain effective and enforceable as provided in the order, except to the extent that the order is stayed, modified, terminated or set aside by the Director or otherwise as provided under the Safety and Soundness Act.

Section 1209.6 Temporary Cease and Desist Orders

Section 1372(a) of the Safety and Soundness Act (12 U.S.C. 4632(a)) provides that if the Director determines that the actions specified in the notice of charges served upon a regulated entity or any entity-affiliated party, or the continuation thereof, is likely to cause insolvency or significant dissipation of assets or earnings of that entity, or is likely to weaken the condition of that entity prior to the completion of the proceedings conducted pursuant to sections 1371 and 1373 of the Safety and Soundness Act (12 U.S.C. 4631, 4633), the Director may issue a temporary order requiring that party to cease and desist from any such violation or practice and that such party take affirmative action to prevent or remedy such insolvency, dissipation, condition, or prejudice pending completion of the proceedings.[24] In addition, the order may include any limitations on the activities or functions of a regulated entity or any entity-affiliated party in connection with the temporary cease and desist order permitted under section 1371(d) of the Safety and Soundness Act (12 U.S.C. 4631(d)).

Section 1372(b) of the Safety and Soundness Act (12 U.S.C. 4632(b)) provides that the effective date of a temporary order issued under section 1372(a) of the Safety and Soundness Act (12 U.S.C. 4632(a)) is the date of service on the party. Any such order, unless set aside, limited, or suspended by a court under the judicial review provisions of section 1372(d) of the Safety and Soundness Act (12 U.S.C. 4632(d)), shall remain in effect and enforceable pending the completion of the proceedings, and shall remain effective until the Director dismisses the charges or the order is superseded by a cease and desist order under section 1371 of the Safety and Soundness Act (12 U.S.C. 4631). *See* 12 U.S.C. 4632(b). Additionally, section 1372(c)(1) of the Safety and Soundness Act (12 U.S.C. 4632(c)(1)) prescribes the measures available where the notice of charges specifies that the books and records of the regulated entity are so incomplete or inaccurate that the Director is unable to determine the true financial condition of the regulated entity or the details of a transaction that may have a material effect on the financial condition of the entity. In brief, the Director may issue a temporary order requiring the entity to cease the practices giving rise to the incomplete or inaccurate records or take affirmative action to correct the records. *See* 12 U.S.C. 4631(c)(1).

Section 1372(c)(2) of the Safety and Soundness Act (12 U.S.C. 4632(c)(2)) specifies that the effective period of a temporary order pertaining to the books and records of an entity is effective upon service, and (unless set aside under 12 U.S.C. 4632(d)) shall remain in effect and enforceable until the earlier of the completion of the proceedings initiated under section 1371 of the Safety and Soundness Act (12 U.S.C. 4631) or the Director determines upon examination or otherwise that the books and records are accurate and reflect the financial condition of the regulated entity. Judicial review of a temporary order proceeds under section 1372(d) of the Safety and Soundness Act (12 U.S.C. 4632(d)) when a party served with a temporary order acts within ten (10) days to seek an injunction to set aside the order pending completion of the cease and desist proceeding. The district court's jurisdiction is limited to the issuance of such an injunction, and does not extend to the merits of the underlying enforcement proceeding. *See* 12 U.S.C. 4632(d). Without exception, the district court has no authority under this provision to assert subject matter jurisdiction over the underlying enforcement action or to remove the enforcement case from the presiding officer's jurisdiction to Federal district court.

Finally, section 1372(e) of the Safety and Soundness Act (12 U.S.C. 4632(e)), specifies that in the event of a violation or threatened violation of a temporary order issued under section 1372 of the Safety and Soundness Act (12 U.S.C. 4632), the Director may bring an action in the United States District Court for the District of Columbia for an injunction to enforce the order. The validity of the order is not at issue here and the court's action is a mandate. If the court finds any violation, threatened violation, or failure to obey an order issued under this provision, the court shall issue the injunction.

Section 1209.7 Civil Money Penalties

Section 1376 of the Safety and Soundness Act, as revised by section 1155 of HERA, governs civil money penalty enforcement proceedings under the Safety and Soundness Act, except as to housing goals violations addressed under section 1345(a) of the Safety and Soundness Act. *See* 12 U.S.C. 4636(a). The Director may impose a civil money penalty on any regulated entity or an entity-affiliated party in accordance with section 1376 of the Safety and Soundness Act (12 U.S.C. 4636(a)). HERA amendments to section 1376 of the Safety and Soundness Act strengthened the statutory authority, preserved the three-tiered structure for assessing civil money penalties (Tiers 1–3), and increased (and, in the case of the higher tiers, significantly increased) the maximum penalty amounts for each tier. Under the HERA amendments to the provisions governing Tier 1, a regulated entity or entity-affiliated party shall forfeit and pay a civil penalty of not more than $10,000 for each day during which a violation continues, if such regulated entity or party violates—(1) Any provision of the Safety and Soundness Act, the authorizing statutes, or any order, condition, rule or regulation under the Safety and Soundness Act or authorizing statutes; (2) any final or temporary order issued under the Safety and Soundness Act; (3) any condition imposed by the Director in connection with the grant of any application or other request by the regulated entity; or (4) any written agreement between the regulated entity and the Director. *See* 12 U.S.C. 4636(b)(1)(A)–(D) (Tier 1 violations).

As amended by HERA, section 1376(b)(2) of the Safety and Soundness Act (12 U.S.C. 4636(b)(2)) sets forth broader standards for Tier 2 violations and penalties. Moreover, with the addition of the caveat "notwithstanding paragraph (1)," the revised section allows that Tier 2 violations can stand independently of Tier 1 violations, while at the same time building on that set of violations. *See* 12 U.S.C. 4636(b)(2). Under the provisions

[24] FHFA notes that "prejudice," which is a carryover in the statute as amended by HERA, without more may appear to be misplaced. But consider that the term by itself does not provide a separate ground for issuing a temporary cease and desist order that requires affirmative action. Presumably, acts or omissions prejudicial to the financial interests of a regulated entity would fall under the "dissipation of assets" proviso, and actions prejudicial to other interests of the regulated entity could be subsumed by "condition." For that reason, FHFA has determined that it is not a term to be deleted as an anachronism, and invites public comment on this issue.

governing Tier 2 penalties, the Director can assess a higher daily civil money penalty of not more than $50,000 for each day during which a violation, practice, or breach continues, if (A) the regulated entity or entity-affiliated party: (1) Commits any Tier 1 violation described in 12 U.S.C. 4636(b)(1); (2) recklessly engages in an unsafe or unsound practice in conducting the affairs of the regulated entity; or (3) breaches any fiduciary duty, and (B) the violation, practice, or breach: (1) Is part of a pattern of misconduct, (2) causes or is likely to cause more than a minimal loss to the regulated entity, or (3) results in pecuniary gain or benefit to such party. *See id.*

Thus, section 1376(b) of the Safety and Soundness Act, among other things deleted the predicate "violation or conduct;" substituted "more than minimal loss" for the previous requirement of "material loss;" added both "breach of fiduciary duty" and "results in pecuniary gain" as culpability standards; deleted the requirement of "recklessness;" and eliminated the distinction in the prior statutory scheme that had allowed for lesser penalty amounts to be assessed against individuals than for regulated entities for the same Tier 2 violations. *See id.* The revised statutory scheme underscores the Congressional purpose behind strengthening the Director's civil money penalty enforcement authority.

Section 1376(b)(3) of the Safety and Soundness Act, governs Tier 3 conduct and penalties. As with Tier 2, Tier 3 also can stand independent of the lower tiers. Specifically, Tier 3 provides that a regulated entity or entity-affiliated party shall forfeit and pay a civil penalty, in the amounts described below, for each day during which such violation, practice, or breach continues, if such party knowingly (1) commits any violation described in the Tier 1 provisions, (2) engages in any unsafe or unsound practice in conducting the affairs of the regulated entity, or (3) breaches any fiduciary duty, and knowingly or recklessly causes a substantial loss to the regulated entity or a substantial pecuniary gain or other benefit to such party by reason of such violation, practice, or breach. *See* 12 U.S.C. 4636(b)(3). The Tier 3 penalty provisions set the daily maximum penalty at $2 million for a regulated entity. Whereas, the Director can assess against an entity-affiliated party a daily penalty not to exceed $2 million.

Section 1376(c)(2) of the Safety and Soundness Act sets out the factors to be considered by the Director in determining the penalties to be assessed under this section (12 U.S.C. 4636(c)(2)). Section 1376(c)(3) of the Safety and Soundness Act provides that the imposition of any penalty under section 1376 of the Safety and Soundness Act (12 U.S.C. 4636) is not reviewable, except as provided for in section 1374 of the Safety and Soundness Act (12 U.S.C. 4634). *See* 12 U.S.C. 4636(c)(3). Additionally, these revised amounts, which represent a large increase in the daily maximum penalty amounts (particularly by bringing penalties to be assessed against entity-affiliated parties in line with those assessed on a regulated entity), are adjusted periodically under the Inflation Adjustment Act, as provided in subpart E of this part.

Section 1209.8 Removal and Suspension Proceedings

Section 1153 of HERA provides that the statutory authority and requirements for removal and suspension enforcement proceedings are set forth in section 1377 of the Safety and Soundness Act (12 U.S.C. 4636a). The removal or suspension of an entity-affiliated party, or the officers, directors, or management of the Office of Finance, a joint office of the Banks—where the requisite conditions are met, is initiated by service of a notice, and a hearing on the record is held to determine whether the grounds are satisfied, as provided by section 1373(a)(1) of the Safety and Soundness Act (12 U.S.C. 4633(a)(1)). As with a cease and desist proceeding, the hearing (with the exception of removal proceedings under section 1377(h) of the Safety and Soundness Act (12 U.S.C. 4636a (h)) is presided over by an independent presiding officer who sets a date for an evidentiary hearing, presides over the proceeding, and then submits her recommended findings of fact and conclusions of law with the entire administrative record to the Director who makes a final determination on the merits and issues an order.

In particular, section 1377(a)(1) of the Safety and Soundness Act authorized the Director to serve upon a party described in paragraph (a)(2) of the section, or any officer, director, or management of the Office of Finance, written notice of the intention of the Director to suspend or remove such party from office, or prohibit any further participation by such party, in any manner, in the conduct of the affairs of a regulated entity. *See* 12 U.S.C. 4636a(a)(1). For purposes of this section, under section 1377(a)(2) of the Safety and Soundness Act, a party is an entity-affiliated party or any officer, director, or management of the Office of Finance, if the Director determines that a party, officer, or director directly or indirectly violated a law, regulation, final cease and desist order, or any written condition in connection with an application, notice, or other request of a regulated entity; engaged or participated in any unsafe or unsound practice in connection with any regulated entity or business institution; or breached a fiduciary duty, and by reason of such violation, practice, or breach, the regulated entity or business institution suffered or probably will suffer financial loss or other damage, or such party received financial gain or other benefit, and the violation, practice, or breach involves either personal dishonesty on the part of such party or demonstrates willful or continuing disregard by that party for the safety or soundness of the regulated entity or business institution. *See* 12 U.S.C. 4636a(a)(2).

Section 1377 of the Safety and Soundness Act subjects the officers, directors, and management of the Office of Finance to the suspension and removal authority of the Director, if the stated conditions are met. *See* 12 U.S.C. 4636a. The Office of Finance is included in the definition of entity-affiliated party in section 1303(11)(E) of the Safety and Soundness Act 12 (U.S.C. 4502(11)(E)). Presumably, the term "business institution," as used in section 1377 of the Safety and Soundness Act, too, refers to the Office of Finance, a joint office and agent of the Banks central to the issuance of consolidated obligations on which the Banks are jointly and severally liable.

Under section 1377(b) of the Safety and Soundness Act (12 U.S.C. 4636a(b)), the Director may issue an order to suspend or remove a party from office, or prohibit such party from participation in the affairs of the regulated entity, upon service of the notice under paragraph (a)(1) of section 1377 of the Safety and Soundness Act (12 U.S.C. 4636a(a)), if the Director makes a determination that the action is necessary for the protection of the regulated entity and such party is served with the order. *See* 12 U.S.C. 4636a(b)(1). An immediate order of suspension issued under paragraph (b) of this section is effective when served. *See* 12 U.S.C. 4636a(b)(2)(A).

Furthermore, section 1377(b)(2)(B) of the Safety and Soundness Act (12 U.S.C. 4636a(b)(2)(B)) provides that unless stayed by a court under paragraph (g) of section 1377 of the Safety and Soundness Act (12 U.S.C. 4636a(g)), any suspension order issued under paragraph (b) shall remain in effect and enforceable until the Director dismisses the charges set out in the notice served under paragraph (a)(1) of this section or

the effective date of the order issued under paragraph (b) [sic].[25] *See* 12 U.S.C. 4636a(b)(2)(B).

Under section 1377(b)(3) of the Safety and Soundness Act (12 U.S.C. 4636a(b)(3)), if the Director issues an order under paragraph (b) of this section, the Director shall serve a copy of such order upon any regulated entity with which the subject of the order is affiliated at the time the order is issued.

Section 1377(c) of the Safety and Soundness Act (12 U.S.C. 4636a(c)) governs the process for providing notice, setting the hearing, and issuing the order. Specifically, section 1377(c) of the Safety and Soundness Act sets the requirements for: (1) The notice—under section 1377(a) of the Safety and Soundness Act the notice shall contain a statement of the facts constituting grounds for such action and fix a time and place at which a hearing is to be held on the action; (2) the timing of the hearing—the same thirty (30) to sixty (60) day requirement as that pertaining to cease and desist orders, unless a request is made (by the party receiving the notice upon a showing of good cause, or the U.S. Attorney General) for an earlier or later date for the hearing to occur; (3) establishing consent of the party—a party shall be deemed to consent to the order by failing to appear; (4) issuance of an order of suspension—the Director may issue an order as he deems it appropriate if the party is deemed to consent or if the Director finds any of the grounds specified in the notice have been established upon the record developed at the hearing; and (5) effectiveness of an order—at the expiration of a thirty (30) day period after service upon the relevant regulated entity and the party, except where a party has consented, in which case the order shall become effective at the time stated in the order. Additionally, under section 1377(c)(5) of the Safety and Soundness Act (12 U.S.C. 4636a(c)(5)), the order remains effective and enforceable except to such extent as it is stayed, modified, terminated, or set aside by action of the Director or a reviewing court.

Section 1377(d) of the Safety and Soundness Act (12 U.S.C. 4636a(d)) specifies the activities that any person subject to a removal or suspension order under this section is prohibited from undertaking. Persons subject to these orders are barred from participating in conducting the affairs of a regulated entity or the Office of Finance, and they may not exercise any proxy or voting rights or violate any voting agreement previously approved by the Director with respect to a regulated entity, or vote for a director or serve in any capacity as an entity-affiliated party of a regulated entity or the Office of Finance.

Section 1377(e) of the Safety and Soundness Act (12 U.S.C. 4636a(e)) bars a person subject to a removal or suspension order from participating in the conduct of the affairs of a regulated entity or the Office of Finance. *See* 12 U.S.C. 4636a(e)(1). An exception is made where the Director provides his written consent, in which case the order—to the extent of the consent—shall cease to apply to the party and the consent shall be made public. *See* 12 U.S.C. 4636a(e)(2). Any violation of the prohibition on participating in the affairs of the regulated entity or the Office of Finance by any entity-affiliated party charged with a felony who is subject to a suspension or removal order under section 1377(h) of the Safety and Soundness Act (12 U.S.C. 4636a(h)) shall be treated as a violation of that order. *See* 12 U.S.C. 4636a(e)(3).

Section 1377(f) of the Safety and Soundness Act (12 U.S.C. 4636a(f)), states that the removal provisions apply to individuals only—unless the Director specifically finds that the provisions should apply to a corporation, firm, or other business entity. *See* 12 U.S.C. 4636a(f). Section 1377(g) of the Safety and Soundness Act (12 U.S.C. 4636a(g)) authorizes a subject of a removal or suspension order under this section to seek an injunction to stay the suspension or prohibition order pending completion of the administrative hearing to be held under section 1377(c) of the Safety and Soundness Act (12 U.S.C. 4636a(c)). This grant of subject matter jurisdiction to the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the regulated entity is headquartered, is limited to the authority to stay the suspension or prohibition. *See* 12 U.S.C. 4636a(g). It should not be read to confer jurisdiction over the underlying enforcement hearing.

Section 1209.9 Supervisory Actions Not Affected

This section underscores the independence of the Director to take such regulatory, supervisory, or enforcement action, as deemed necessary and in accordance with the Safety and Soundness Act or the Bank Act. In addition to the plenary regulatory and supervisory authority of the Director under section 1311(b)(1) of the Safety and Soundness Act (12 U.S.C. 4511(b)(1)), under section 1311(b)(2) of the Safety and Soundness Act the Director has express regulatory authority over the regulated entities and Office of Finance to ensure that the purposes of the Safety and Soundness Act, the authorizing statutes, and any other applicable law are carried out. (12 U.S.C. 4511(b)(2)).

Moreover, section 1311(c) of the Safety and Soundness Act (12 U.S.C. 4511(c)) preserves the Director's ability to avail himself of any of the broad powers conferred in the Safety and Soundness Act. Under section 1311(c) of the Safety and Soundness Act (12 U.S.C. 4511(c)), the Director may take any regulatory or supervisory action under section 1311(b) of the Safety and Soundness Act (12 U.S.C. 4511(b)), notwithstanding any action related to capital adequacy that may be taken under sections 1361 through 1369E of the Safety and Soundness Act (12 U.S.C. 4612 *et seq.*) or any enforcement action taken under sections 1371 through 1379E of the Safety and Soundness Act (12 U.S.C. 4631 through 4641). Thus, the Director's authority under subtitle B of the Safety and Soundness Act to set capital requirements for the regulated entities, to enter into enforceable written agreements, to appoint FHFA as conservator or receiver for a regulated entity, and to take enforcement actions under specified conditions, does not limit his general regulatory authority over the regulated entities and the Office of Finance.

Similarly, the Director's authority under sections 1371 through 1379E of the Safety and Soundness Act (12 U.S.C. 4631 through 4641) to prosecute administrative enforcement actions by serving a notice of charges to enforce any provision or requirement of the Safety and Soundness Act, or other applicable standard, is independent of and does not limit his general supervisory or regulatory authority. Indeed, the selection of one form of supervisory or regulatory action or a combination of actions is within the discretion of the Director, and does not foreclose the Director from pursuing any other supervisory or regulatory action authorized by law.

Subpart C—Rules of Practice and Procedure for Hearings on the Record

Section 1209.10 Authority of the Director

This section makes clear that enforcement proceedings are under the general authority of the Director to allow for interlocutory appeals or to permit actions to be performed before the appointment of the presiding officer.

[25] The reference should be to paragraph (c) of section 1377 of the Safety and Soundness Act (12 U.S.C. 4636a(c)), which concerns final orders.

The Director may perform, direct the performance of, or waive performance of any act that could be done or ordered by the presiding officer. This promotes efficiency in the hearing process, and should not be read to create an inherent, institutional bias on the part of the Director.

Section 1209.11 Authority of the Presiding Officer

This section states that hearings are to be held in accordance with the APA, and provides that the presiding officer is to have complete charge of the proceedings, to act in a fair and impartial manner, and to ensure that a full and complete record of the proceeding is made. This section lists the powers of the presiding officer to control the proceedings. First among these is the authority of the presiding officer to set the date, time, and place (within the District of Columbia) of the testimonial phase of the hearing process, *i.e.,* evidentiary hearing. Consistent with § 1209.23, the appearance hearing is to be set in the scheduling order issued by the presiding officer following the initial scheduling conference that must be held no later than sixty (60) days from the date of service of the notice of charges, notice of intention to assess a civil money penalty, or notice of intention to suspend or remove a party as provided in the Safety and Soundness Act. In accordance with § 1209.11(b)(1) setting of the evidentiary hearing may occur sooner upon motion of the respondent, or otherwise as the presiding officer finds in the best interest of justice.

The section prescribes the presiding officer's authority to: reset, continue, or recess the hearing in whole or in part for a reasonable period of time; hold conferences to ensure the legal, factual, or evidentiary issues addressed are materially relevant to the charges or allowable defenses; administer oaths and affirmations; issue and enforce subpoenas, subpoenas *duces tecum,* and discovery and protective orders, or modify, revoke, or quash such subpoenas; take and preserve testimony under oath; rule on motions, except that only the Director may dismiss the proceeding or make a final determination on the merits; take all actions necessary to regulate the scope, timing, and completion of discovery of any non-privileged matter that is materially relevant to the charges or allowable defenses; rule upon the admissibility of evidence, and exclude or limit evidence; regulate the course of the testimonial phase of the hearing; examine witnesses; upon motion of a party, take judicial notice of a fact; prepare and present to the Director a recommended decision; and establish the time, place, and limitations on public and media attendance at public proceedings.[26]

Section 1209.12 Public Hearings; Closed Hearings

Generally, appearance hearings are to be open to the public. But this section also reflects the authority of the Director, under section 1379B(b) of the Safety and Soundness Act (12 U.S.C. 4639(b)), to determine that holding an open hearing would be contrary to the public interest, and provides appropriate mechanisms for making and implementing such determinations. To make the determination, the Director must receive the party's motion, opposing briefs, and a recommended decision, from the presiding officer. A determination by the Director under this section is not a reviewable final agency action.

The authority to file documents under seal is reserved to agency counsel, who must make a written determination that the disclosure of the document would be contrary to the public interest. The presiding officer must preserve the confidentiality of the document and, if needed, issue a protective order that is acceptable to FHFA counsel of record. If a hearing is to be closed for the purpose of introducing testimony or documents filed under seal, certain prescriptive procedures (such as the Methods of Handling Confidential Information of general applicability in administrative proceedings under the Interim Manual) are to be followed. In any event, the presiding officer is bound to ensure that any objections to the introduction of confidential information or testimony into evidence will not obstruct the prosecution of the enforcement case.

Section 1209.13 Good Faith Certification

This section sets out the requirement that any filing or submission for the record must be signed by the movant's representative of record—or a party appearing *pro se*—to effectively certify that the pleading or motion is offered in good faith and not for any improper purpose. That certification is also imputed to any oral motion and or argument. The presiding officer must strike any unsigned document if it is not signed promptly after the omission is brought to the movant's attention.

Section 1209.14 Ex Parte Communications

This section defines and prohibits *ex parte* communications, and provides for procedures for dealing with such communications, including sanctions. The phrase "may be reasonably expected to be involved" suffices to protect contacting parties who could not reasonably be expected to know that an agency employee might be involved in the decisional process. FHFA thus intends to insulate those who lack sufficient notice of the exclusion, for example if their work is provided to the Director or a decisional employee after it was submitted to the agency in the usual course of business. This section also provides for the separation of functions of Agency personnel. Any employee or agent of FHFA that participated in the examination, investigative, or prosecutorial functions on the case may not participate in or advise in the recommended decision or the Directors' decision on the final determination (analysis of settlement offers and regulatory or supervisory matters are excepted from this prohibition).

Section 1209.15 Filing of Papers

This section, which specifies the filing requirements for papers, pleadings, motions, and memoranda in any proceeding governed by subpart C of this part, was updated to reflect electronic filing practices.

Section 1209.16 Service of Papers

This section, which specifies the service requirements for papers, pleadings, motions, and memoranda in any proceeding governed by subpart C of this part, was updated to reflect electronic service practices.

Section 1209.17 Time Computations

This section sets out the general rule for computing any time period prescribed by subpart C of this part and states when filing or service are deemed to be effective. Additionally, this section was updated to reflect electronic service practices. The rule also provides that the prescribed effective filing and service dates may be modified by the presiding officer or by agreement of the parties in the case of service. Finally, the rule prescribes the method for calculating of time for service and filing of responsive papers.

[26] This section reflects both the analogous provision in the Uniform Rules, and instructive portions of the Manual for Administrative Law Judges (Third Edition), the last official edition of the "Manual for Administrative Law Judges," published by the Administrative Conference of the United States. The Third Edition was edited and resurrected as the "2001 Interim Internet Edition," Morrell E. Mullins, ed. (Interim Manual). The preface to the Interim Manual traces the history of the manual and its application in administrative law practice.

Section 1209.18 Change of Time Limits

This section permits the presiding officer, upon a showing of good cause, to extend time limits set out in the regulation or any notice or order, either on a motion of a party or on his own initiative. Additionally, after the matter has been referred under § 1209.53 to the Director, the Director may also grant extensions of time.

Section 1209.19 Witness Fees and Expenses

This section specifies that the fees and expenses of witnesses shall be paid at the same rate as those paid in proceedings in United States district courts. Additionally, FHFA is not required to pay such fees in advance where FHFA has requested or issued the subpoena, and FHFA is not required to pay any fees or expenses of any witness who was not subpoenaed by FHFA.

Section 1209.20 Opportunity for Informal Settlement

This section permits any respondent at any time in the enforcement proceeding to make a written proposal for settlement without prejudice to any rights of any party. Any such settlement proposal, however, must be made only to FHFA counsel of record. Submission of a settlement offer does not operate to stay the proceeding or to provide a basis for adjourning or otherwise delaying the proceeding. Additionally, no settlement offer is admissible in any proceeding.

Section 1209.21 Conduct of Examination

This section clarifies that the prosecution of a notice of charges or a notice of imposition of a civil money penalty does not impact in any way FHFA's authority to continue or conduct any examination, investigation, inspection, or visitation of any regulated entity or entity-affiliated party authorized by law.

Section 1209.22 Collateral Attacks on Adjudicatory Proceeding

This section provides that the pendency in any court of a collateral attack on the enforcement proceeding shall have no effect on the enforcement proceeding which shall continue without regard to the collateral attack. Further, the section makes clear that a default or failure to act within timeframes and requirements prescribed in the administrative proceeding will not be excused on the basis of the collateral attack.

Section 1209.23 Commencement of Proceeding and Contents of Notice of Charges

This section states that an administrative enforcement proceeding is commenced by a notice of charges as defined in § 1209.3(p), and sets out the requirements for the contents of a notice of charges. In short, among other things, a notice must include: the legal authority for the proceeding; a statement of the law and fact showing that FHFA is entitled to relief; the relief sought; a statement that the presiding officer will set the date and location (within the District of Columbia) of the testimonial phase of the proceeding in a scheduling order to be issued in connection with the initial scheduling conference to be held thirty (30) to sixty (60) days from the date of service of the notice; contact information for the presiding officer and for FHFA counsel of record; citation to the Rules of Practice and Procedure; and a statement that the answer must be filed with the presiding officer within the time to file an answer as required by law or regulation. The rule also provides that the notice must include the time within which to request an earlier hearing. Ordinarily, however, such a request would be obviated by the scheduling conference and scheduling order.

Section 1209.24 Answer

This section provides that the respondent must file an answer within twenty (20) days of the service of the notice, unless the notice specifies otherwise, and sets out the required elements of a conforming answer. This section mandates that failure to file an answer within the required period constitutes a waiver of the respondent's right to appear and contest the allegations in the notice. FHFA counsel of record may file a motion for an entry of default, and the presiding officer, upon a finding of no good cause for the failure to answer, shall file a recommended decision with the findings and relief sought in the notice. A final order issued by the Director based on the respondent's failure to file an answer is deemed to be an order issued upon consent.

Section 1209.25 Amended Pleadings

This section allows for a notice or answer to be amended or supplemented at any stage in the proceeding, and states the deadline for an answer to an amended notice. The rule also provides guidance for when no formal amendment is necessary to conform such pleadings to the evidence and issues tried at the hearing. Additionally, the rule provides that the presiding officer may admit evidence despite timely objections (as to relevance or materiality with respect to issues raised in the notice of charges) when admission is likely to assist in adjudicating the merits of the action, if an objecting party fails to satisfy the presiding officer that the admission of such evidence would unfairly prejudice the party's action or defense upon the merits. In such cases, the presiding officer may grant a reasonable continuance to allow the objecting party to meet such evidence.

Section 1209.26 Failure To Appear

This section states that if a respondent fails to appear at a hearing in person or through a representative of record, that respondent waives his right to a testamentary hearing and is deemed to have admitted to all facts alleged and consented to the relief sought in the notice. As in the case where a respondent has failed to file an answer, the presiding officer shall file with the Director a recommended decision containing the findings and relief sought in the notice.

Section 1209.27 Consolidation and Severance of Actions

This section provides authority to the presiding officer, either upon a motion of a party or on his own initiative, to consolidate two or more proceedings (for some or all purposes), if the circumstances meet the stated test, unless consolidation would cause unreasonable delay or injustice. As to severance, however, the presiding officer may act only on a severance motion of a party if the presiding officer finds that undue prejudice or injustice to the moving party would result and would outweigh the interests of judicial economy in the complete and final resolution of the proceeding.

Section 1209.28 Motions

This section specifies that requests for an order must be in a written motion. The provision sets out the requirements for such motions, and provides that written memoranda, briefs, affidavits, or other relevant material may be submitted in support of a motion. On the other hand, the rule allows for oral motions to be made in a hearing, unless the presiding officer directs that the motion be reduced to writing. The rule has been revised to state that a response to a non-dispositive motion is due within ten (10) days, to distinguish it from a response to a dispositive motion, which is governed by § 1209.35, and to provide that reply briefs must be filed within five (5) days of a response,

unless the presiding officer or Director orders otherwise. The rule also was revised to provide that the presiding officer shall consider responses of parties having an interest in a motion before ruling on an oral or a written motion. A party's failure to oppose a motion is deemed to be consent to the motion and the relief sought. The rule has been clarified to bar frivolous, dilatory, or substantively repetitive motions, and continues to provide that the filing of such motions may form the basis for sanctions.

Section 1209.29 Discovery

Section 1209.29 of the rule, which readopts § 1780.26 of the existing OFHEO rule, has been amended in part to reflect actual practice experience and to clarify that the presiding officer is charged with restricting discovery to any matter not privileged that is materially relevant to the charges or allowable defenses in a pending proceeding. In particular, any document request that seeks privileged information or internal FHFA communications not materially relevant as stated, or that otherwise is unreasonable in form, excessive in scope, unduly burdensome, or substantially repetitive of prior discovery requests, shall be denied or modified.

Section 1209.29(a)(2) of the proposed rule is a new provision that requires the parties to meet and confer in good faith to agree upon and submit to the presiding officer a discovery plan for timely, cost-effective management of document discovery. This process was conceived to achieve the economies of pre-trial discovery embedded in similar requirements under the Federal Rules of Civil Procedure governing district court actions. Under this new provision, no party may commence discovery until the presiding officer has approved the parties' discovery plan. This process supports the authority of the presiding officer to control the proceedings and to minimize unnecessary or costly document discovery. In the absence of the parties' cooperation, however, the rule provides the presiding officer with ample authority to require the parties to conduct discovery in a reasonable manner.

Under § 1209.29(b)(3), as modified, any request for document discovery is unreasonable, oppressive, excessive in scope, or unduly burdensome—and shall be denied or modified—if, among other things, the request: (i) Fails to include limitations on the relevant subject matter or time period covered; (ii) fails to identify documents with sufficient specificity to permit identification of the repositories of official agency records to be searched; (iii) seeks material that is duplicative, cumulative, or obtainable from another source that is more accessible, less burdensome, or less expensive; (iv) calls for the production of documents, whether in hard copy or in electronic format, to be delivered to the requesting party or his designee and fails to provide a written agreement by the requestor to pay in advance for the costs of production, in accordance with § 1209.30, or otherwise fails to take into account costs associated with processing electronically stored information or any cost-sharing agreement between the parties; (v) fails to afford the responding party adequate time to respond; or (vi) fails to take into account retention policies or security protocols with respect to Federal information systems.

Discovery is limited to document requests. No other form of discovery is permitted; depositions (except as noted) and interrogatories are not permitted. This provision is not to be read to require the creation of any document. Additionally, this section reiterates that privileged documents are not discoverable. Applicable privileges include: attorney client, work product, and privileges available to government agencies (*e.g.,* deliberative process; examination; investigative; or any other privileges available under the U.S. Constitution, Federal law, or the principles of Federal common law). To preserve such privileges in productions, a new provision, § 1209.29(d)(1)(ii), provides that the parties may enter into so-called clawback agreements, and the presiding officer shall enter an order to ensure the enforceability of such agreements. Finally, § 1209.29(d)(2) is added to make clear that the limitations on the discovery process in this rule are not to be read otherwise to limit the examination, regulatory or supervisory authority of FHFA. Again, these provisions have been added to assist in resolving issues that may arise in practice under this rule.

Time limits on discovery under § 1209.29(e) of the proposed rule require that all discovery shall be completed at least twenty (20) days prior to the commencement of the testimonial phase of the hearing, unless the presiding officer finds on the record that good cause exists for waiving the twenty (20) day requirement. Additionally, the provision that responsive documents be produced as maintained in the usual course of business, or labeled and organized to correspond to the document requests, was moved from its former place in OFHEO's existing rule, § 1780.27(a) of this title, to make it applicable to document requests that are addressed either to parties or to non-parties. Finally, a provision was added to permit the parties to agree upon the production of documents as organized or otherwise, consistent with the discovery plan, to provide more flexibility to the parties to make discovery productions less onerous or costly.

Section 1209.30 Request for Document Discovery From Parties

This section would adopt the existing OFHEO rule, § 1780.27 of this title, with certain changes to the time limits for filing motions to strike or to limit discovery requests, guidance for the presiding officer on ruling on such motions, and revised procedures for compelling production of documents by parties. The rule now specifically requires that all document discovery from parties must conform to these requirements and be consistent with the discovery plan approved by the presiding officer under § 1209.29. Any party served with a discovery request may object to all or part of such request within twenty (20) days of service of the request by filing a motion to strike or limit the request under § 1209.28, which will also govern responses and replies, if any. No other party may file an objection. Any objections that do not conform to these requirements are waived.

The proposed rule recognizes instances where discovery may include electronically stored information, and the attendant costs and burdens. The rule adds a new provision to address the complexities and costs associated with the discovery of electronically stored information (e-discovery). In past practice, a party requesting document discovery was to agree in advance to pay for the costs of any document production—*e.g.,* reproduction (photocopies or electronic), and the responding party was permitted to require receipt of payment of any such charges prior to production. While this process is still available, under the revised rule, parties may agree to cost-sharing, especially where multiple parties present overlapping discovery requests, consistent with the discovery plan approved by the presiding officer. In sum, the revisions are intended to encourage transparency and early cooperation of the parties to identify and resolve issues commonly encountered in e-discovery, and to develop a coherent and cost-effective search protocol and format of production (such as searchable formats, optical character recognition, or load

files). This is particularly important where e-discovery may be problematic, too costly, or unduly burdensome.

Section 1209.30(d) is amended to permit a party receiving a discovery request to respond within thirty (30) days with a motion to strike or limit the discovery requests, replacing the ten (10) days provided for in the prior rule. Section 1209.28 of the proposed rule governs responses to such motions and replies, if any.

Section 1209.30(e) of the proposed rule governs the process for asserting privilege claims. A privilege log is required and documents may be identified by category on the log. The presiding officer has express discretion to determine when identification by category is sufficient. Section 1209.30(f) of the proposed rule provides that any motion to compel production must be filed in accordance with § 1209.28 within ten (10) days of the time of the assertion of the privilege or failure to produce is or becomes known to the requesting party. To oppose, the responding party must file a written response within five (5) days.

Section 1209.30(g) of the proposed rule clarifies that the presiding officer may grant in part or otherwise modify any request for production of documents, or deny any request for the production of any document that is privileged or otherwise not within the scope of permissible discovery. The proposed rule also adds a provision stating expressly that the interlocutory appeal of a privilege determination or ruling on a motion for a protective order is to be in accordance with § 1209.33, and reiterates that under § 1209.33, interlocutory review of a privilege determination or document discovery request shall not stay the proceeding, unless ordered by the presiding officer or the Director.

Under § 1209.30(h) of the proposed rule, pertaining to the enforcement of a document discovery subpoena, the Director or a party who obtained the subpoena may seek enforcement to the extent authorized under section 1379D(c)(1) of the Safety and Soundness Act (12 U.S.C. 4641(c)(1)) by seeking an order from the appropriate United States district court. Under § 1209.30(h)(2), the court's jurisdiction is limited to that remedy; the court will not gain jurisdiction to affect by injunction or otherwise the issuance or enforcement of any effective and outstanding notice or order issued by the Director under section 1313B, subtitle B, or subtitle C of the Safety and Soundness Act, or to review, modify, suspend, terminate, or set aside any such effective and outstanding notice or order. The proposed rule clarifies that seeking an order from a district court to enforce a subpoena or production order does not stay automatically the enforcement proceeding, unless the presiding officer or Director orders a stay. Finally, changes to the rule would make clear that the Director may order sanctions against a party who fails to produce or induces another to fail to produce subpoenaed documents.

Section 1209.31 Document Discovery Subpoenas to Nonparties

Section 1209.31 of the proposed rule governs document discovery subpoenas to nonparties. The proposed rule would adopt the existing rule with minor changes to headings and the addition of text requiring that the subpoenaing party seek only documents that are materially relevant to the charges and issues presented in the action, state its "unequivocal" intention to pay for document discovery of a non-party, and serve all other parties with the subpoena. The edits also make clear the discretion of the presiding officer to refuse to issue a subpoena to a non-party where the party's application for the subpoena does not set forth a valid basis of its issuance, or where the request is otherwise objectionable under § 1209.29(b).

Section 1209.31(b) of the proposed rule governs motions to quash or modify a document subpoena, and adds a provision to allow a non-party to enter a limited appearance in the proceeding to challenge the subpoena directed to it. The non-party may raise objections that may be raised by a party under § 1209.30 within the same time deadlines. The revised provision permits the party seeking the subpoena to respond to the non-party's objections within ten (10) days of service of motion to quash or modify. Absent the express leave of the presiding officer, no other party may respond to the non-party's motion. Additionally, the pending motion shall not operate as a stay on the proceeding or in any way limit the presiding officer's authority to impose sanctions on a party who induces another to fail to comply with a subpoena. No party may rely on the pendency of a motion to quash or modify to excuse performance of any action required of that party under this part.

Finally, enforcement of document subpoenas to non-parties also is authorized pursuant to section 1379D(c) of the Safety and Soundness Act (12 U.S.C. 4641(c)), and there is no automatic stay in that event. Here, again, a party's right to seek enforcement of a non-party document subpoena does not limit in any way the authority of the presiding officer to impose sanctions on a party who induces another to fail to comply with a subpoena.

Section 1209.32 Deposition of Witness Unavailable for Hearing

Section 1209.32 of the proposed rule provides for a subpoena to compel the attendance at a deposition of a witness who will not be at the evidentiary hearing in order to preserve the testimony of that witness for the record. The existing proposed rule would adopt existing provision with only two changes. First, the proposed rule would amend the existing rule to require that a witness unavailable for the hearing must have personal knowledge of the facts and that the testimony is reasonably expected to be materially relevant to claims, defenses, or matters determined to be at issue. This requirement parallels the presiding officer's authority to control the proceedings and ensure that only materially relevant evidence is adduced. Second, a requirement is added to create a full written record; recorded or videotaped depositions must be transcribed and copies of the recordings or videotapes and the transcriptions must be provided to each party.

Section 1209.33 Interlocutory Review

Section 1209.33 of the proposed rule prescribes the circumstances under which the Director may exercise interlocutory review of a ruling of the presiding officer prior to the certification of the record. The existing provision is adopted as stated.

Section 1209.34 Summary Disposition

Section 1209.34 of the proposed rule states the test for an order granting a motion for summary disposition of the matter and the process for hearing and deciding such motions. The existing provision is adopted with one change; the time period for filing a response to a dispositive motion is extended to thirty (30) days, in order to provide sufficient time to respond to arguments that may present novel or complex issues.

Section 1209.35 Partial Summary Disposition

Section 1209.35 of the proposed rule states that if the presiding officer determines that some of the claims are subject to summary disposition a hearing on the remaining claims shall be conducted, and following that, the recommended decision will address all of the claims. The proposed rule would adopt the existing provision as stated.

Section 1209.36 Scheduling and Pre-Hearing Conferences

Section 1209.36 sets out how the presiding officer manages the scheduling and pre-hearing conferences and the issuance of scheduling and pre-hearing orders. The proposed rule would adopt the existing provision with one change: paragraph (a) "scheduling conference" would be edited to conform to the proposed powers of the presiding officer. As proposed, it specifies that within thirty (30) days of service of the notice of charges, the presiding officer is to require each party or the party's representative to participate (in person or via teleconference at the option of the presiding officer) in an initial scheduling conference for the purpose of setting the time and place of the evidentiary hearing in the District of Columbia. In connection with this initial scheduling conference, the presiding officer will determine the course and conduct of the proceeding.

Section 1209.37 Pre-Hearing Submissions

Section 1209.37 of the proposed rule states the required submissions and sets the deadline for service of these items by each party on every other party. The existing provision, as stated, would be adopted.

Section 1209.38 Hearing Subpoenas

Section 1209.39 of the proposed rule sets forth the process for applying for a hearing subpoena and the circumstances under which the presiding officer may refuse to issue a subpoena or require a modification of a proposed subpoena. The provision would be adopted, as set forth in the existing provision with minor technical edits.

Sections 1209.39 Through 1209.49 [Reserved]

Section 1209.50 Conduct of Hearings

Section 1209.50 of the proposed rule prescribes the general rules for hearings, and the specific rule pertaining to the order of the hearing, the examination of witnesses, stipulations, and the hearing transcript. The existing provision would be adopted, as stated.

Section 1209.51 Evidence

Section 1209.51 of the proposed rule sets out the requirements for the admissibility of evidence, official notice, the introduction of documentary evidence, objections to the introduction of evidence, stipulations, and depositions of unavailable witnesses. The provision would be adopted, as stated in the existing provision with minor technical edits to require that stipulations as to any document to be admitted into evidence be made a part of the record.

Section 1209.52 Post-Hearing Filings

Section 1209.52 of the proposed rule establishes the briefing process and schedule for filing proposed findings and conclusions and supporting briefs. The provision would be adopted, as stated in the existing provision with minor technical edits to re-set filing deadlines as follows: proposed findings of fact and conclusions of law are to be filed with the presiding officer within thirty (30) days of receiving the notice that the transcript was filed with the presiding officer. The filing deadline was extended to ensure the parties would have sufficient time to address novel or complex issues of law or fact. Similarly, the response deadline was extended to fifteen (15) days. The requirement that reply briefs be limited to responding to new matters also was strengthened.

Section 1209.53 Recommended Decision and Filing of Record

Section 1209.53 of the proposed rule prescribes the process and time deadlines for the presiding officer to file the recommended decision and record with the Director. The provision would be adopted, as stated in the existing provision with minor technical edits to reset the filing deadline at forty-five (45) days after expiration of the time allowed for filing briefs. The filing deadline proposed time is extended to ensure that the presiding officer is afforded sufficient time to address multiple parties' arguments, complex factual matters, or novel legal issues that may arise in any given proceeding.

Section 1209.54 Exceptions to Recommended Decision

Section 1209.54 of the proposed rule establishes the process and time deadlines for the parties to respond to the presiding officer's recommended decision. The provision would be adopted, as stated in the existing provision with minor technical edits to reset the filing deadline at thirty (30) days after service of the recommended decision. The filing deadline was extended to afford the parties sufficient time to address issues raised in the recommended decision.

Section 1209.55 Review by Director

Section 1209.55 of the proposed rule provides for the Director to serve notice on the parties when the record is determined to be complete, allows that the Director may permit the parties to give an oral argument on the issues, and states the process for rendering the final decision. The provision would be adopted, as stated in the existing provision with minor technical edits to re-set the deadline for rendering the decision at ninety (90) days after notification to the parties that the case has been submitted for final decision. The time period was adjusted to enable the Director adequately to address any issue that may be presented by an enforcement action under the rule.

Section 1209.56 Exhaustion of Administrative Remedies

Section 1209.56 of the proposed rule provides that to meet the exhaustion requirement, a party must file with the Director exceptions to the recommended decision. This is a precondition to seeking judicial review of any decision issued by the Director under this part.

Section 1209.57 Stays Pending Judicial Review

Section 1209.57 of the proposed rule provides that the commencement of an action for judicial review does not operate as a stay of the Director's determination unless the Director orders a stay. As proposed, the existing provision would be adopted, as stated with no changes.

Sections 1209.58 Through 1209.69 [Reserved]

Subpart D—Parties and Representational Practice Before the Federal Housing Finance Agency; Standards of Conduct

Section 1209.70 Scope

Subpart D of this part contains rules governing practice by parties or their representatives before FHFA in an adjudicatory proceeding and standards of conduct under this part and in any appearance before the Director or any agency representative. This subpart outlines the sanctions that may be prescribed by a presiding officer or the Director against parties or their representatives who fail to conform to the requirements and conduct guidelines; such representation includes, but is not limited to, the practice of attorneys and accountants. Employees of FHFA are not subject to disciplinary proceedings under this subpart. This subpart, as proposed, would adopt the existing provision with minor edits as noted.

Section 1209.71 Definitions

Section 1209.71 of the proposed rule would adopt the existing rule provision that defines practice before FHFA, with minor edits to reflect that the representation is with reference to

regulated entities or entity-affiliated parties, rather than the Enterprises. The definition excludes any work prepared for a regulated entity or entity-affiliated party solely at the request of such party for use in the ordinary course of its business.

Section 1209.72 Appearance and Practice in Adjudicatory Proceedings

Section 1209.72 of the proposed rule would adopt, without amendment, the existing provision that delimits the representational practice of attorneys and non-attorneys before FHFA. A party may appear pro se. In the event of a pending proceeding any person appearing shall file a notice of appearance. The provision prescribes the requirements for such notices.

Section 1209.73 Conflicts of Interest

Section 1209.73 of the proposed rule would adopt, without amendment, the existing rule provision that sets out the prohibition on conflicts in representation and specifies applicable requirements pertaining to certification and waiver.

Section 1209.74 Sanctions

Section 1209.74 of the proposed rule would adopt the existing rule provision governing appropriate sanctions that may be imposed during the course of any proceeding when any party or representative of record has acted or failed to act in a manner clearly required by applicable statute, regulation, or order, and that act or failure to act constitutes contemptuous conduct, with minor technical edits. The edits clarify that such conduct may occur in connection with any phase of any proceeding, hearing, or appearance before a presiding officer or the Director. The proposed rule would reissue the definitions of contemptuous conduct, the procedure for imposition of sanctions, and sanctions for contemptuous conduct, without change.

Section 1209.75 Censure, Suspension, Disbarment, and Reinstatement

Section 1209.75 of the proposed rule would adopt, with minor edits, the existing rule provision governing the circumstances under which the Director may censure any individual who practices or attempts to practice before FHFA, or suspend or revoke the privilege to appear or practice before FHFA, after notice and a hearing in the matter.

The edit clarifies that legal or regulatory violations may pertain to any applicable law. Additionally, the proposed rule mirrors the existing rule in setting out the bases for mandatory suspension and debarment, and the requirements pertaining to notices, applications for reinstatement, hearings, and conferences in proceedings under Subpart D of this part.

Sections 1209.76 Through 1209.79 [Reserved]

Subpart E—Civil Money Penalty Inflation Adjustments

Section 1209.80 Inflation Adjustments

Section 1209.80 of the proposed rule would adopt, with minor edits, the existing rule provision governing the maximum amount of each civil money penalty within FHFA's jurisdiction, as set by the Safety and Soundness Act and thereafter adjusted in accordance with the Inflation Adjustment Act. In a change from the existing rule, the proposed rule establishes this process in subpart E to facilitate subsequent technical penalty amount adjustments as provided by law.

Section 1209.81 Applicability

Section 1209.81 of the proposed rule would adopt, with minor edits, the existing provision stating it is applicable to civil money penalties under section 1376 of the Safety and Soundness Act (12 U.S.C. 4636) for violations occurring after July 30, 2008, the effective date of HERA.

Sections 1209.82 Through 1209.99 [Reserved]

Subpart F—Suspension or Removal of Entity-Affiliated Party Charged With Felony

Section 1209.100 Scope

As proposed, new subpart F would adopt the requirements under section 1377(h) of the Safety and Soundness Act, as amended, governing informal hearings to be afforded to any entity-affiliated party who has been suspended, removed or prohibited from further participation in the business affairs of a regulated entity by a notice or order issued by the Director in accordance with section 1377(h)(4) of the Safety and Soundness Act (12 U.S.C. 4636a(h)). Importantly, the statute does not require a hearing on the record, thus the formal hearing procedures in subpart C are not applicable to proceedings under section 1377(h) of the Safety and Soundness Act. All that is required is an informal hearing that satisfies the basic elements of due process, notice and opportunity to respond. Subpart F establishes that informal hearing process.

Section 1209.101 Suspension, Removal, or Prohibition

Section 1209.101 of the proposed rule implements section 1377(h) of the Safety and Soundness Act and prescribes the circumstances under which the Director may suspend, remove, or prohibit the further participation of an entity-affiliated party who has been charged, in any information, indictment, or complaint, with the commission of or participation in a crime that involves dishonesty or breach of trust that is punishable by imprisonment for more than one (1) year under State or Federal law. The rule requires a notice or an order of removal, as appropriate, and prescribes the effective period, as well as the effect of acquittal. The notice must state the basis for the suspension and the right of the party to request an informal hearing as provided in § 1209.102.

Section 1209.102 Hearing on Removal or Suspension

Section 1209.102 of the proposed rule sets forth the requirements for an informal hearing on a removal or suspension under section 1377(h) of the Safety and Soundness Act (12 U.S.C. 46436a(h)), and the timing and procedural matters of such hearings. An APA-type full evidentiary hearing on the record is not required under the Safety and Soundness Act. But the hearing prescribed under this section will meet the essential notice and opportunity to respond requirements of due process. Therefore, the requirements as to form, timing, conduct, submissions, and the record of the hearing, are specified in this provision. The proposed rule allows that an entity-affiliated party may elect in writing to waive his right to appear in person or through counsel to make a statement and to have the matter determined solely on the basis of his written submission. A new provision clarifies that the purpose of the informal hearing is to determine whether the suspension or prohibition will be continued, modified, or terminated, or whether an order removing such party or prohibiting the party from participation in the affairs of the regulated entity will be rescinded or modified.

An action by the Director under this section shall not be deemed as a predicate or a bar to other regulatory, supervisory or enforcement action under the Safety and Soundness Act.

Section 1209.103 Recommended and Final Decisions

Section 1209.103 of the proposed rule sets forth the requirements for the recommended decision of a presiding officer. Under this provision the parties are afforded a five (5) day comment period, comments on the recommended decision are directed to the presiding officer, and no extensions of the stated time period are permitted. The decision of the Director is provided in writing to the entity-affiliated party within sixty (60) days. The decision is a final, non-appealable order. An individual who has been suspended or removed by order of the Director may request reconsideration of such an order under the prescribed requirements. There is no hearing on a petition for reconsideration, and the Director will inform the requestor of the disposition of the request in a timely manner. A decision on a request for reconsideration shall not constitute an appealable order.

V. Regulatory Impact

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that a regulation that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility analysis describing the regulation's impact on small entities. Such an analysis need not be undertaken if the agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). FHFA has considered the impact of the proposed regulation under the Regulatory Flexibility Act. FHFA certifies that the proposed regulation, if adopted, is not likely to have a significant economic impact on a substantial number of small business entities because the regulation applies to the Enterprises and Banks, which are not small entities for purposes of the Regulatory Flexibility Act. 5 U.S.C. 605(b).

List of Subjects

12 CFR Part 908

Administrative practice and procedure, Federal home loan banks, Penalties.

12 CFR Part 1209

Administrative practice and procedure, Federal home loan banks.

12 CFR Part 1780

Administrative practice and procedure, Penalties.

Accordingly, for the reasons set forth in the preamble, under the authority of 12 U.S.C. 4513b and 4526, the Federal Housing Finance Agency proposes to amend chapters IX, XII, and XVII of Title 12, Code of Federal Regulations, as follows:

CHAPTER IX—FEDERAL HOUSING FINANCE BOARD

Subchapter B—Federal Housing Finance Board Organization and Operations

PART 908—[REMOVED]

1. Remove 12 CFR Part 908.

CHAPTER XII—FEDERAL HOUSING FINANCE AGENCY

Subchapter A—Organization and Operations

2. Add part 1209 to subchapter A to read as follows:

PART 1209—RULES OF PRACTICE AND PROCEDURE

Subpart A—Scope and Authority

Sec.
1209.1 Scope.
1209.2 Rules of construction.
1209.3 Definitions.

Subpart B—Enforcement Proceedings Under Sections 1371 Through 1379D of the Safety and Soundness Act

1209.4 Scope and authority.
1209.5 Cease and desist proceedings.
1209.6 Temporary cease and desist orders.
1209.7 Civil money penalties.
1209.8 Removal and prohibition proceedings.
1209.9 Supervisory actions not affected.

Subpart C—Rules of Practice and Procedure

1209.10 Authority of the Director.
1209.11 Authority of the Presiding Officer.
1209.12 Public hearings; Closed hearings.
1209.13 Good faith certification.
1209.14 Ex parte communications.
1209.15 Filing of papers.
1209.16 Service of papers.
1209.17 Time computations.
1209.18 Change of time limits.
1209.19 Witness fees and expenses.
1209.20 Opportunity for informal settlement.
1209.21 Conduct of examination.
1209.22 Collateral attacks on adjudicatory proceeding.
1209.23 Commencement of proceeding and contents of notice of charges.
1209.24 Answer.
1209.25 Amended pleadings.
1209.26 Failure to appear.
1209.27 Consolidation and severance of actions.
1209.28 Motions.
1209.29 Discovery.
1209.30 Request for document discovery from parties.
1209.31 Document discovery subpoenas to nonparties.
1209.32 Deposition of witness unavailable for hearing.
1209.33 Interlocutory review.
1209.34 Summary disposition.
1209.35 Partial summary disposition.
1209.36 Scheduling and pre-hearing conferences.
1209.37 Pre-hearing submissions.
1209.38 Hearing subpoenas.
1209.39–49 [Reserved].
1209.50 Conduct of hearings.
1209.51 Evidence.
1209.52 Post-hearing filings.
1209.53 Recommended decision and filing of record.
1209.54 Exceptions to recommended decision.
1209.55 Review by Director.
1209.56 Exhaustion of administrative remedies.
1209.57 Stays pending judicial review.
1209.58–69 [Reserved].

Subpart D—Parties and Representational Practice Before the Federal Housing Finance Agency; Standards of Conduct

1209.70 Scope.
1209.71 Definitions.
1209.72 Appearance and practice in adjudicatory proceedings.
1209.73 Conflicts of interest.
1209.74 Sanctions.
1209.75 Censure, suspension, disbarment, and reinstatement.
1209.76–79 [Reserved].

Subpart E—Civil Money Penalty Inflation Adjustments

1209.80 Inflation adjustments.
1209.81 Applicability.
1209.82–99 [Reserved].

Subpart F—Suspension or Removal of an Entity-Affiliated Party Charged With Felony

1209.100 Scope.
1209.101 Suspension, removal, or prohibition.
1209.102 Hearing on removal or suspension.
1209.103 Recommended and final decisions.

Authority: 5 U.S.C. 551, 556, 557 and 701 *et seq.;* 12 U.S.C. 4501, 4503, 4511, 4513, 4513b, 4517, 4526, 4531, 4535, 4536, 4581, 4585, 4631–4641; and 28 U.S.C. 2461 note.

Subpart A—Scope and Authority

§ 1209.1 Scope.

(a) *Authority.* This part sets forth the Rules of Practice and Procedure in accordance with the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, title XIII of the Housing and Community Development Act of 1992, Public Law 102–550, sections 1301 *et seq.,* codified at 12 U.S.C. 4501 *et seq.,* as amended (the "Safety and Soundness Act").[1]

[1] As used in this part, the "Safety and Soundness Act" means the Federal Housing Enterprise Financial Safety and Soundness Act of 1992, as amended. *See* 12 CFR 1209.3. The Safety and Soundness Act was amended by the Housing and Economic Recovery Act of 2008, Public Law 110–289, sections 1101 *et seq.,* 122 Stat. 2654 (July 30,

Continued

(b) *Enforcement Proceedings.* Subpart B of this part (Enforcement Proceedings under sections 1371 through 1379D of the Safety and Soundness Act) sets forth the statutory authority for enforcement proceedings under sections 1371 through 1379D of the Safety and Soundness Act (12 U.S.C. 4631 through 4641) (Enforcement Proceedings).

(c) *Rules of Practice and Procedure.* Subpart C of this part (Rules of Practice and Procedure) prescribes the general rules of practice and procedure applicable to adjudicatory proceedings that the Director is required by statute to conduct on the record after opportunity for a hearing under the Administrative Procedure Act, 5 U.S.C. 554, 556, and 557, under the following statutory provisions:

(1) Enforcement proceedings under sections 1371 through 1379D of the Safety and Soundness Act (12 U.S.C. 4631 through 4641);

(2) Removal, prohibition, and civil money penalty proceedings for violations of post-employment restrictions imposed by applicable law; and

(3) Proceedings under section 102 of the Flood Disaster Protection Act of 1973, as amended (42 U.S.C. 4012a) to assess civil money penalties.

(d) Representation and conduct. Subpart D of this part (Parties and Representational Practice before the Federal Housing Finance Agency; Standards of Conduct) sets out the rules of representation and conduct that shall govern any appearance by any person, party, or representative of any person or party, before a presiding officer, the Director of FHFA, or a designated representative of the Director or FHFA staff, in any proceeding or matter pending before the Director.

(e) Civil money penalty inflation adjustments. Subpart E of this part (Civil Money Penalty Inflation Adjustments) sets out the requirements for the periodic adjustment of maximum civil money penalty amounts under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended (Inflation Adjustment Act) on a recurring four-year cycle.[2]

(f) Informal proceedings. Subpart F of this part (Suspension or Removal of an Entity-Affiliated Party Charged with Felony) sets out the scope and procedures for the suspension or removal of an entity-affiliated party charged with a felony under section 1377(h) of the Safety and Soundness Act (12 U.S.C. 4636a(h)), which provides for an informal hearing before the Director.

§ 1209.2 Rules of construction.

For purposes of this part:

(a) Any term in the singular includes the plural and the plural includes the singular, if such use would be appropriate;

(b) Any use of a masculine, feminine, or neuter gender encompasses all three, if such use would be appropriate; and

(c) Unless the context requires otherwise, a party's representative of record, if any, on behalf of that party, may take any action required to be taken by the party.

§ 1209.3 Definitions.

For purposes of this part, unless explicitly stated to the contrary:

Adjudicatory proceeding means a proceeding conducted pursuant to these rules, on the record, and leading to the formulation of a final order other than a regulation.

Agency has the meaning defined in section 1303(2) of the Safety and Soundness Act (12 U.S.C. 4502(2)).

Associated with the regulated entity means, for purposes of section 1379 of the Safety and Soundness Act (12 U.S.C. 4637), any direct or indirect involvement or participation in the conduct of operations or business affairs of a regulated entity, including engaging in activities related to the operations or management of, providing advice or services to, consulting or contracting with, serving as agent for, or in any other way affecting the operations or business affairs of a regulated entity—with or without regard to—any direct or indirect payment, promise to make payment, or receipt of any compensation or thing of value, such as money, notes, stock, stock options, or other securities, or other benefit or remuneration of any kind, by or on behalf of the regulated entity, except any payment made pursuant to a retirement plan or deferred compensation plan, which is determined by the Director to be permissible under section 1318(e) of the Safety and Soundness Act (12 U.S.C. 4518(e)), or by reason of the death or disability of the party, in the form and manner commonly paid or provided to retirees of the regulated entity, unless such payment, compensation, or such benefit is promised or provided to or for the benefit of said party for the provision of services or other benefit to the regulated entity.

Authorizing statutes has the meaning defined in section 1303(3) of the Safety and Soundness Act (12 U.S.C. 4502(3)).

Bank Act means the Federal Home Loan Bank Act, as amended (12 U.S.C. 1421 *et seq.*).

Board or Board of Directors means the board of directors of any Enterprise or Federal Home Loan Bank, as provided for in the respective authorizing statutes.

Decisional employee means any member of the Director's or the presiding officer's staff who has not engaged in an investigative or prosecutorial role in a proceeding and who may assist the Director or the presiding officer, respectively, in preparing orders, recommended decisions, decisions, and other documents under subpart C of this part.

Director has the meaning defined in section 1303(9) of the Safety and Soundness Act (12 U.S.C. 4502(9)); except, as the context requires in this part, "director" may refer to a member of the Board of Directors or any Board committee of an Enterprise, a Federal Home Loan Bank, or the Office of Finance.

Enterprise has the meaning defined in section 1303(10) of the Safety and Soundness Act (12 U.S.C. 4502(10)).

Entity-affiliated party has the meaning defined in section 1303(11) of the Safety and Soundness Act (12 U.S.C. 4502(11)), and may include an executive officer, any director, or management of the Office of Finance, as applicable under relevant provisions of the Safety and Soundness Act or FHFA regulations.

Executive officer has the meaning defined in section 1303(12) of the Safety and Soundness Act (12 U.S.C. 4502(12)), and may include an executive officer of the Office of Finance, as applicable under relevant provisions of the Safety and Soundness Act or FHFA regulations.

FHFA means the Federal Housing Finance Agency as defined in section 1303(2) of the Safety and Soundness Act (12 U.S.C. 4502(2)).

Notice of charges means the charging document served by FHFA to commence an enforcement proceeding under this part for the issuance of a cease and desist order; removal, suspension, or prohibition order; or an order to assess a civil money penalty, under 12 U.S.C. 4631 through 4641 and § 1209.23. A "notice of charges," as used or referred to as such in this part, is not an "effective notice" under section 1375(a) of the Safety and Soundness Act (12 U.S.C. 4635(a)).

2008) (HERA). Specifically, sections 1151 through 1158 of HERA amended sections 1371 through 1379D of the Safety and Soundness Act (codified at 12 U.S.C. 4631 through 4641) (hereafter, "Enforcement Proceedings").

[2] Public Law 101–410, 104 Stat. 890, as amended by the Debt Collection Improvement Act of 1996, Public Law 104–134, title III, sec. 31001(s)(1), Apr. 26, 1996, 110 Stat. 1321–373; Public Law 105–362, title XIII, sec. 1301(a), Nov. 10, 1998, 112 Stat. 3293 (28 U.S.C. 2461 note).

Office of Finance has the meaning defined in section 1303(19) of the Safety and Soundness Act (12 U.S.C. 4502(19)).

Party means any person named as a respondent in any notice of charges, or FHFA, as the context requires in this part.

Person means an individual, sole proprietor, partnership, corporation, unincorporated association, trust, joint venture, pool, syndicate, organization, regulated entity, entity-affiliated party, or other entity.

Presiding officer means an administrative law judge or any other person appointed by or at the request of the Director under applicable law to conduct an adjudicatory proceeding under this part.

Regulated entity has the meaning defined in section 1303(20) of the Safety and Soundness Act (12 U.S.C. 4502(20)).

Representative of record means an individual who is authorized to represent a person or is representing himself and who has filed a notice of appearance and otherwise has complied with the requirements under § 1209.72. FHFA's representative of record may be referred to as FHFA's counsel of record or enforcement counsel.

Respondent means any party that is the subject of a notice of charges under this part.

Safety and Soundness Act means title XIII of the Housing and Community Development Act of 1992, Public Law 102–550, known as the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended (12 U.S.C. 4501 *et seq.*)

Violation has the meaning defined in section 1303(25) of the Safety and Soundness Act (12 U.S.C. 4502(25)).

Subpart B—Enforcement Proceedings Under Sections 1371 Through 1379D of the Safety and Soundness Act

§ 1209.4 Scope and authority.

The rules of practice and procedure set forth in Subpart C (Rules of Practice and Procedure) of this part shall be applicable to any hearing on the record conducted by FHFA in accordance with sections 1371 through 1379D of the Safety and Soundness Act (12 U.S.C. 4631 through 4641), as follows:

(a) Cease-and-desist proceedings under sections 1371 through 1373 of the Safety and Soundness Act, (12 U.S.C. 4631 through 4633);

(b) Civil money penalty assessment proceedings under sections 1373 and 1376 of the Safety and Soundness Act, (12 U.S.C. 4633 and 4636); and

(c) Removal and prohibition proceedings under sections 1373 and 1377 of the Safety and Soundness Act, (12 U.S.C. 4633 and 4636a), except removal proceedings under section 1377(h) of the Safety and Soundness Act, (12 U.S.C. 4636a(h)).

§ 1209.5 Cease and desist proceedings.

(a) *Cease and desist proceedings.*—(1) *Authority.*—(i) *In general.* As prescribed by section 1371(a) of the Safety and Soundness Act (12 U.S.C. 4631(a)), the Director may issue and serve upon the regulated entity or entity-affiliated party, a notice of charges (as described in § 1209.23) to institute cease and desist proceedings, except with regard to the enforcement of housing goals that are addressed separately under sections 1341 and 1345 of the Safety and Soundness Act (12 U.S.C. 4581, 4585).

(ii) *Hearing on the record.* In accordance with section 1373 of the Safety and Soundness Act (12 U.S.C. 4633)), a hearing on the record shall be held in the District of Columbia. Subpart C of this part shall govern the hearing procedures.

(iii) *Consent to order.* Unless the party served with a notice of charges shall appear at the hearing personally or through an authorized representative, the party shall be deemed to have consented to the issuance of the cease and desist order.

(2) *Unsatisfactory rating.* In accordance with section 1371(b) of the Safety and Soundness Act (12 U.S.C. 4631(b)), if a regulated entity receives an unsatisfactory rating as specified therein, the Director may deem the regulated entity to be engaging in an unsafe or unsound practice within the meaning of section 1371(a) of the Safety and Soundness Act (12 U.S.C. 4631(a)).

(3) *Order.* As provided by section 1371(c)(2) of the Safety and Soundness Act (12 U.S.C. 4631(c)(2)), if the Director finds on the record made at a hearing in accordance with section 1373 of the Safety and Soundness Act (12 U.S.C. 4633) that any practice or violation specified in the notice of charges has been established (or the regulated entity or entity-affiliated party consents pursuant to section 1373(a)(4) of the Safety and Soundness Act (12 U.S.C. 4633(a)(4)), the Director may issue and serve upon the regulated entity, executive officer, director, or entity-affiliated party, an order (as set forth in § 1209.55) requiring such party to cease and desist from any such practice or violation and to take affirmative action to correct or remedy the conditions resulting from any such practice or violation.

(b) *Affirmative action to correct conditions resulting from violations or activities.* The authority to issue a cease and desist order or a temporary cease and desist order requiring a regulated entity, executive officer, director, or entity-affiliated party to take affirmative action to correct or remedy any condition resulting from any practice or violation with respect to which such cease and desist order or temporary cease and desist order is set forth in section 1371(a), (c)(2), and (d) of the Safety and Soundness Act (12 U.S.C. 4631(a), (c)(2), and (d)), and includes the authority to:

(1) Require the regulated entity or entity-affiliated party to make restitution, or to provide reimbursement, indemnification, or guarantee against loss, if—

(i) Such entity or party or finance facility was unjustly enriched in connection with such practice or violation, or

(ii) The violation or practice involved a reckless disregard for the law or any applicable regulations, or prior order of the Director;

(2) Require the regulated entity to seek restitution, or to obtain reimbursement, indemnification, or guarantee against loss;

(3) Restrict asset or liability growth of the regulated entity,

(4) Require the regulated entity to obtain new capital;

(5) Require the regulated entity to dispose of any loan or asset involved;

(6) Require the regulated entity to rescind agreements or contracts;

(7) Require the regulated entity to employ qualified officers or employees (who may be subject to approval by the Director at the direction of the Director); and

(8) Require the regulated entity to take such other action, as the Director determines appropriate, including limiting activities.

(c) *Authority to limit activities.* As provided by section 1371(e) of the Safety and Soundness Act (12 U.S.C. 4631(e)), the authority of the Director to issue a cease and desist order under section 1371 of the Safety and Soundness Act (12 U.S.C. 4631) or a temporary cease and desist order under section 1372 of the Safety and Soundness Act (12 U.S.C. 4632), includes the authority to place limitations on the activities or functions of the regulated entity or entity-affiliated party or any executive officer or director of the regulated entity or entity-affiliated party.

(d) *Effective date of order.* The effective date of an order is as set forth in section 1371(f) of the Safety and Soundness Act (12 U.S.C. 4631(f)).

§ 1209.6 Temporary cease and desist orders.

(a) *Temporary cease and desist orders.*—(1) *Grounds for issuance.* The grounds for issuance of a temporary cease and desist order are set forth in section 1372(a) of the Safety and Soundness Act (12 U.S.C. 4632(a)). In accordance with section 1372(a) of the Safety and Soundness Act (12 U.S.C. 4632(a)), the Director may:

(i) Issue a temporary order requiring that regulated entity or entity-affiliated party to cease and desist from any violation or practice specified in the notice of charges; and

(ii) Require that regulated entity or entity-affiliated party to take affirmative action to prevent or remedy any insolvency, dissipation, condition, or prejudice, pending completion of the proceedings.

(2) *Additional requirements.* As provided by section 1372(a)(2) of the Safety and Soundness Act (12 U.S.C. 4632(a)(2)), an order issued under section 1372(a)(1) of the Safety and Soundness Act (12 U.S.C. 4632(a)(1)) may include any requirement authorized under section 1371(d) of the Safety and Soundness Act (12 U.S.C. 4631(d)).

(b) *Effective date of temporary order.* The effective date of a temporary order is as provided by section 1372(b) of the Safety and Soundness Act (12 U.S.C. 4632(b)). And, unless set aside, limited, or suspended by a court in proceedings pursuant to the judicial review provisions of section 1372(d) of the Safety and Soundness Act (12 U.S.C. 4632(d)), shall remain in effect and enforceable pending the completion of the proceedings pursuant to such notice of charges, and shall remain effective until the Director dismisses the charges specified in the notice or until superseded by a cease-and-desist order issued pursuant to section 1371 of the Safety and Soundness Act (12 U.S.C. 4631).

(c) *Incomplete or inaccurate records.*—(1) *Temporary order.* As provided by section 1372(c) of the Safety and Soundness Act (12 U.S.C. 4632(c)), if a notice of charges served under section 1371(a) or (b) of the Safety and Soundness Act (12 U.S.C. 4631(a), (b)), specifies on the basis of particular facts and circumstances that the books and records of the regulated entity served are so incomplete or inaccurate that the Director is unable, through the normal supervisory process, to determine the financial condition of the regulated entity or the details or the purpose of any transaction or transactions that may have a material effect on the financial condition of that regulated entity, the Director may issue a temporary order requiring:

(i) The cessation of any activity or practice that gave rise, whether in whole or in part, to the incomplete or inaccurate state of the books or records; or

(ii) Affirmative action to restore the books or records to a complete and accurate state.

(2) *Effective period.* Any temporary order issued under section 1372(c)(1) of the Safety and Soundness Act (12 U.S.C. 4632(c)(1)) shall become effective upon service, and remain in effect and enforceable unless set aside, limited, or suspended in accordance with section 1372(d) of the Safety and Soundness Act (12 U.S.C. 4632(d)), as provided by section 1372(c)(2) of the Safety and Soundness Act (12 U.S.C. 4632(c)(2)).

(d) *Judicial review.* Section 1372(d) of the Safety and Soundness Act (12 U.S.C. 4632(d)), authorizes a regulated entity, executive officer, director, or entity-affiliated party that has been served with a temporary order pursuant to section 1372(a) or (b) of the Safety and Soundness Act (12 U.S.C. 4632(a), (b)) to apply to the United States District Court for the District of Columbia within ten (10) days after service of the temporary order for an injunction setting aside, limiting, or suspending the enforcement, operation, or effectiveness of the temporary order, pending the completion of the administrative enforcement proceeding. The district court has jurisdiction to issue such injunction.

(e) *Enforcement of temporary order.* As provided by section 1372(e) of the Safety and Soundness Act (12 U.S.C. 4632(e)), in the case of any violation, threatened violation, or failure to obey a temporary order issued pursuant to this section, the Director may bring an action in the United States District Court for the District of Columbia for an injunction to enforce a temporary order, and the district court is to issue such injunction upon a finding made in accordance with section 1372(e) of the Safety and Soundness Act (12 U.S.C. 4632(e)).

§ 1209.7 Civil money penalties.

(a) *Civil money penalty proceedings.*—(1) *In general.* As provided by section 1376(a) of the Safety and Soundness Act (12 U.S.C. 4636(a)), the Director may impose a civil money penalty in proceedings to be conducted under the procedural rules in subpart C of this part, on any regulated entity or any entity-affiliated party in accordance with section 1376 of the Safety and Soundness Act for any violation, practice, or breach addressed under sections 1371, 1372, or 1376 of the Safety and Soundness Act (12 U.S.C. 4631, 4632, 4636), except with regard to the enforcement of housing goals that are addressed separately under sections 1341 and 1345 of the Safety and Soundness Act (12 U.S.C. 4581, 4585).

(2) *Amount of penalty.*—(i) *First Tier.* Section 1376(b)(1) of the Safety and Soundness Act (12 U.S.C. 4636(b)(1)) prescribes the civil penalty for violations as stated therein, in the amount of $10,000.

(ii) *Second Tier.* Section 1376(b)(2) of the Safety and Soundness Act (12 U.S.C. 4636(b)(2)) provides that notwithstanding paragraph (b)(1) thereof, a regulated entity or entity-affiliated party shall forfeit and pay a civil penalty of not more than $50,000 for each day during which a violation, practice, or breach continues, if the regulated entity or entity-affiliated party commits any violation described in (b)(1) thereof, recklessly engages in an unsafe or unsound practice, or breaches any fiduciary duty, and the violation, practice, or breach is part of a pattern of misconduct; causes or is likely to cause more than a minimal loss to the regulated entity; or results in pecuniary gain or other benefit to such party.

(iii) *Third Tier.* Section 1376(b)(3) of the Safety and Soundness Act (12 U.S.C. 4636(b)(3)) provides that, notwithstanding paragraphs (b)(1) and (b)(2) thereof, any regulated entity or entity-affiliated party shall forfeit and pay a civil penalty, in accordance with section 1376(b)(4) of the Safety and Soundness Act (12 U.S.C. 4636(b)(4)), for each day during which such violation, practice, or breach continues, if such regulated entity or entity-affiliated party:

(A) Knowingly—

(1) Commits any violation described in any subparagraph of section 1376(b)(1) of the Safety and Soundness Act;

(2) Engages in any unsafe or unsound practice in conducting the affairs of the regulated entity; or

(3) Breaches any fiduciary duty; and

(B) Knowingly or recklessly causes a substantial loss to the regulated entity or a substantial pecuniary gain or other benefit to such party by reason of such violation, practice, or breach.

(b) *Maximum amounts.*—(1) *Maximum daily penalty.* Section 1376(b)(4) of the Safety and Soundness Act (12 U.S.C. 4636(b)(4)), prescribes the maximum daily amount of a civil penalty that may be assessed for any violation, practice, or breach pursuant to section 1376(b)(3) of the Safety and Soundness Act (12 U.S.C. 4636(b)(3)), in the case of any entity-affiliated party

(not to exceed $2,000,000.00), and in the case of any regulated entity ($2,000,000.00).

(2) *Inflation Adjustment Act.* The maximum civil penalty amounts are subject to periodic adjustment under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended (28 U.S.C. 2461 note), as provided in subpart E of this part.

(c) *Factors in determining amount of penalty.* In accordance with section 1376(c)(2) of the Safety and Soundness Act (12 U.S.C. 4636(c)(2)), in assessing civil money penalties on a regulated entity or an entity-affiliated party in amounts as provided in section 1376(b) of the Safety and Soundness Act (12 U.S.C. 4636(b)), the Director shall give consideration to factors as:

(1) The gravity of the violation, practice, or breach;

(2) Any history of prior violations or supervisory actions, or any attempts at concealment;

(3) The effect of the penalty on the safety and soundness of the regulated entity or the Office of Finance;

(4) Any loss or risk of loss to the regulated entity or to the Office of Finance;

(5) Any benefits received or derived, whether directly or indirectly, by the respondent(s);

(6) Any injury to the public;

(7) Any deterrent effect on future violations, practices, or breaches;

(8) The financial capacity of the respondent(s), or any unusual circumstance(s) of hardship upon an executive officer, director, or other individual;

(9) The promptness, cost, and effectiveness of any effort to remedy or ameliorate the consequences of the violation, practice, or breach;

(10) The candor and cooperation, if any, of the respondent(s); and

(11) Any other factors the Director may determine by regulation to be appropriate.

(d) *Review of imposition of penalty.* Section 1376(c)(3) of the Safety and Soundness Act (12 U.S.C. 4636(c)(3)) governs judicial review of a penalty order under section 1374 of the Safety and Soundness Act (12 U.S.C. 4634).

§ 1209.8 Removal and prohibition proceedings.

(a) *Removal and prohibition proceedings.*—(1) *Authority to issue order.* As provided by section 1377(a)(1) of the Safety and Soundness Act (12 U.S.C. 4636a(a)(1)), the Director may serve upon a party described in paragraph (a)(2) of this section, or any officer, director, or management of the Office of Finance, a notice of the intention of the Director to suspend or remove such party from office, or to prohibit any further participation by such party in any manner in the conduct of the affairs of the regulated entity. The notice shall conform with § 1209.23.

(2) *Applicability.* As provided by section 1377(a)(2) of the Safety and Soundness Act (12 U.S.C. 4636a(a)(2)), a party described in this paragraph is an entity-affiliated party or any officer, director, or management of the Office of Finance, if the Director determines that:

(i) That party, officer, or director has, directly or indirectly—

(A) Violated—

(1) Any law or regulation;

(2) Any cease and desist order that has become final;

(3) Any condition imposed in writing by the Director in connection with an application, notice, or other request by a regulated entity; or

(4) Any written agreement between such regulated entity and the Director;

(B) Engaged or participated in any unsafe or unsound practice in connection with any regulated entity or business institution; or

(C) Committed or engaged in any act, omission, or practice which constitutes a breach of such party's fiduciary duty;

(ii) By reason of such violation, practice, or breach—

(A) Such regulated entity or business institution has suffered or likely will suffer financial loss or other damage; or

(B) Such party directly or indirectly received financial gain or other benefit; and

(iii) The violation, practice, or breach described in subparagraph (i) of this section—

(A) Involves personal dishonesty on the part of such party; or

(B) Demonstrates willful or continuing disregard by such party for the safety or soundness of such regulated entity or business institution.

(3) *Applicability to business entities.* Under section 1377(f) of the Safety and Soundness Act (12 U.S.C. 4636a(f)), this remedy applies only to a person who is an individual, unless the Director specifically finds that it should apply to a corporation, firm, or other business entity.

(b) *Suspension order.*—(1) Suspension or prohibition authorized. If the Director serves written notice under section 1377(a) of the Safety and Soundness Act (12 U.S.C. 4636a(a)) upon a party subject to that section, the Director may, by order, suspend or remove such party from office, or prohibit such party from further participation in any manner in the conduct of the affairs of the regulated entity, if the Director:

(i) Determines that such action is necessary for the protection of the regulated entity; and

(ii) Serves such party with written notice of the order.

(2) *Effective period.* The effective period of any order is as provided in section 1377(b) of the Safety and Soundness Act (12 U.S.C. 4636a(b)).

(3) *Copy of order to be served on regulated entity.* In accordance with section 1377(b)(3) of the Safety and Soundness Act (12 U.S.C. 4636a(b)(3)), the Director will serve a copy of any order to suspend, remove, or prohibit participation in the conduct of the affairs on any regulated entity with which such party is affiliated at the time such order is issued.

(c) *Notice; hearing and order.*—(1) Written notice. A notice of the intention of the Director to issue an order under sections 1377(a) and (c) of the Safety and Soundness Act, (12 U.S.C. 4636a(a), (c)), shall conform with § 1209.23, and may include any such additional information as the Director may require.

(2) *Hearing.* A hearing on the record shall be held in the District of Columbia in accordance with sections 1373(a)(1) and 1377(c)(2) of the Safety and Soundness Act. *See* 12 U.S.C. 4633(a)(1), 4636a(c)(2).

(3) *Consent.* As provided by section 1377(c)(3) of the Safety and Soundness Act (12 U.S.C. 4636a(c)(3)), unless the party that is the subject of a notice delivered under paragraph (a) of this section appears in person or by a duly authorized representative, in the adjudicatory proceeding, such party shall be deemed to have consented to the issuance of an order under this section.

(4) *Issuance of order of suspension or removal.* As provided by section 1377(c)(4) of the Safety and Soundness Act (12 U.S.C. 4636a(c)(4)), the Director may issue an order under this part, as the Director may deem appropriate, if:

(i) A party is deemed to have consented to the issuance of an order under paragraph (d); or

(ii) Upon the record made at the hearing, the Director finds that any of the grounds specified in the notice have been established.

(5) *Effectiveness of order.* As provided by section 1377(c)(5) of the Safety and Soundness Act (12 U.S.C. 4636a(c)(5)), any order issued and served upon a party in accordance with this section shall become effective at the expiration of thirty (30) days after the date of service upon such party and any regulated entity or entity-affiliated party. An order issued upon consent under paragraph (c)(3) of this section, however, shall become effective at the

time specified therein. Any such order shall remain effective and enforceable except to such extent as it is stayed, modified, terminated, or set aside by action of the Director or a reviewing court.

(d) *Prohibition of certain activities and industry-wide prohibition.*—(1) Prohibition of certain activities. As provided by section 1377(d) of the Safety and Soundness Act (12 U.S.C. 4636a(d)), any person subject to an order issued under subpart B of this part shall not—

(i) Participate in any manner in the conduct of the affairs of any regulated entity or the Office of Finance;

(ii) Solicit, procure, transfer, attempt to transfer, vote, or attempt to vote any proxy, consent, or authorization with respect to any voting rights in any regulated entity;

(iii) Violate any voting agreement previously approved by the Director; or

(iv) Vote for a director, or serve or act as an entity-affiliated party of a regulated entity or as an officer or director of the Office of Finance.

(2) *Industry-wide prohibition.* As provided by section 1377(e)(1) of the Safety and Soundness Act (12 U.S.C. 4636a(e)(1)), except as provided in section 1377(e)(2) of the Safety and Soundness Act (12 U.S.C. 4636a(e)(2)), any person who, pursuant to an order issued under section 1377 of the Safety and Soundness Act (12 U.S.C. 4636a), has been removed or suspended from office in a regulated entity or the Office of Finance, or prohibited from participating in the conduct of the affairs of a regulated entity or the Office of Finance, may not, while such order is in effect, continue or commence to hold any office in, or participate in any manner in the conduct of the affairs of, any regulated entity or the Office of Finance.

(3) *Relief from industry-wide prohibition at the discretion of the Director.*—(i) Relief from order. As provided by section 1377(e)(2) of the Safety and Soundness Act (12 U.S.C. 4636a(e)(2)), if, on or after the date on which an order has been issued under section 1377 of the Safety and Soundness Act (12 U.S.C. 4636a) that removes or suspends from office any party, or prohibits such party from participating in the conduct of the affairs of a regulated entity or the Office of Finance, such party receives the written consent of the Director, the order shall, to the extent of such consent, cease to apply to such party with respect to the regulated entity or the Office of Finance as described in the written consent. Such written consent shall be on such terms and conditions as the Director therein may specify. Any such consent shall be publicly disclosed.

(ii) *No waiver; no private right of action.* Nothing in this paragraph shall be construed to require the Director to entertain or provide such written consent, or to confer any rights to such consideration or consent upon any party, regulated entity, entity-affiliated party, or the Office of Finance. Additionally, any refusal by the Director to consent to relief from an outstanding order under this part is committed wholly to the discretion of the Director, and shall not be a final agency action for purposes of seeking judicial review.

(4) *Violation of industry-wide prohibition.* As provided by section 1377(e)(3) of the Safety and Soundness Act (12 U.S.C. 4636a(e)(3)), any violation of section 1377(e)(1) of the Safety and Soundness Act (12 U.S.C. 4636a(e)(1)) by any person who is subject to an order issued under section 1377(h) of the Safety and Soundness Act (12 U.S.C. 4636a(h)) (suspension or removal of entity-affiliated party charged with felony) shall be treated as a violation of the order.

(e) *Stay of suspension or prohibition of entity-affiliated party.* As provided by section 1377(g) of the Safety and Soundness Act (12 U.S.C. 4636a(g)), not later than ten (10) days after the date on which any entity-affiliated party has been suspended from office or prohibited from participation in the conduct of the affairs of a regulated entity, such party may apply to the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the headquarters of the regulated entity is located, for a stay of such suspension or prohibition pending the completion of the administrative enforcement proceeding pursuant to section 1377(c) of the Safety and Soundness Act (12 U.S.C. 4636a(c)). The court shall have jurisdiction to stay such suspension or prohibition, but such jurisdiction does not extend to the administrative enforcement proceeding.

§ 1209.9 Supervisory actions not affected.

As provided by section 1311(c) of the Safety and Soundness Act (12 U.S.C. 4511(c)), the authority of the Director to take action under subtitle A of the Safety and Soundness Act (12 U.S.C. 4611 *et seq.*) (*e.g.,* the appointment of a conservator or receiver for a regulated entity; entering into a written agreement or pursuing an informal agreement with a regulated entity as the Director deems appropriate; and undertaking other such actions as may be applicable to undercapitalized, significantly undercapitalized or critically undercapitalized regulated entities), or to initiate enforcement proceedings under subtitle C of the Safety and Soundness Act (12 U.S.C. 4631 *et seq.*), shall not in any way limit the general supervisory or regulatory authority granted the Director under section 1311(b) of the Safety and Soundness Act (12 U.S.C. 4511(b)). The selection and form of regulatory or supervisory action under the Safety and Soundness Act is committed to the discretion of the Director, and the selection of one form of action or a combination of actions does not foreclose the Director from pursuing any other supervisory action authorized by law.

Subpart C—Rules of Practice and Procedure

§ 1209.10 Authority of the Director.

The Director may, at any time during the pendency of a proceeding, perform, direct the performance of, or waive performance of any act that could be done or ordered by the presiding officer.

§ 1209.11 Authority of the Presiding Officer.

(a) *General rule.* All proceedings governed by subpart C of this section shall be conducted consistent with the provisions of chapter 5 of title 5 of the United States Code. The presiding officer shall have complete charge of the adjudicative proceeding, conduct a fair and impartial hearing, avoid unnecessary delay, and assure that a record of the proceeding is made.

(b) *Powers.* The presiding officer shall have all powers necessary to conduct the proceeding in accordance with paragraph (a) of this section and 5 U.S.C. 556(c). The presiding officer is authorized to:

(1) *Control the proceedings.*—(i) Upon reasonable notice to the parties, not earlier than thirty (30) days or later than sixty (60) days after service of a notice of charges under the Safety and Soundness Act, set a date, time, and place for an evidentiary hearing on the record, within the District of Columbia, as provided in section 1373 of the Safety and Soundness Act (12 U.S.C. 4633), in a scheduling order that may be issued in conjunction with the initial scheduling conference set under § 1209.36, or otherwise as the presiding officer finds in the best interest of justice, in accordance with this part; and

(ii) Upon reasonable notice to the parties, reset or change the date, time, or place (within the District of Columbia) of an evidentiary hearing;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to address legal or factual issues, or evidentiary matters materially relevant to the charges or allowable defenses; to regulate the timing and scope of discovery and rule on discovery plans; or otherwise to consider matters that may facilitate an effective, fair, and expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue and enforce subpoenas, subpoenas *duces tecum,* discovery and protective orders, as authorized by this part, and to revoke, quash, or modify such subpoenas;

(6) Take and preserve testimony under oath;

(7) Rule on motions and other procedural matters appropriate in an adjudicatory proceeding, except that only the Director shall have the power to grant summary disposition or any motion to dismiss the proceeding or to make a final determination of the merits of the proceeding;

(8) Take all actions authorized under this part to regulate the scope, timing, and completion of discovery of any non-privileged documents that are materially relevant to the charges or allowable defenses;

(9) Regulate the course of the hearing and the conduct of representatives and parties;

(10) Examine witnesses;

(11) Receive materially relevant evidence, and rule upon the admissibility of evidence or exclude, limit, or otherwise rule on offers of proof;

(12) Upon motion of a party, take official notice of facts;

(13) Recuse himself upon his own motion or upon motion made by a party;

(14) Prepare and present to the Director a recommended decision as provided in this part;

(15) Establish time, place, and manner limitations on the attendance of the public and the media for any public hearing; and

(16) Do all other things necessary or appropriate to discharge the duties of a presiding officer.

§ 1209.12 Public hearings; Closed hearings.

(a) *General rule.* As provided in section 1379B(b) of the Safety and Soundness Act (12 U.S.C. 4639(b)), all hearings shall be open to the public, except that the Director, in his discretion, may determine that holding an open hearing would be contrary to the public interest. The Director may make such determination *sua sponte* at any time by written notice to all parties, or as provided in paragraphs (b) and (c) of this section.

(b) *Motion for closed hearing.* Within twenty (20) days of service of the notice of charges, any party may file with the presiding officer a motion for a private hearing and any party may file a pleading in reply to the motion. The presiding officer shall forward the motion and any reply, together with a recommended decision on the motion, to the Director, who shall make a final determination. Such motions and replies are governed by § 1209.28. A determination under this section is committed to the discretion of the Director and is not a reviewable final agency action.

(c) *Filing documents under seal.* FHFA counsel of record, in his discretion, may file or require the filing of any document or part of a document under seal, if such counsel makes a written determination that disclosure of the document would be contrary to the public interest. The presiding officer shall issue an order to govern confidential information, and take all appropriate steps to preserve the confidentiality of such documents in whole or in part, including closing any portion of a hearing to the public or issuing a protective order under such terms as may be acceptable to FHFA counsel of record.

(d) *Procedures for closed hearing.* An evidentiary hearing, or any part thereof, that is closed for the purpose of offering into evidence testimony or documents filed under seal as provided in paragraph (c) of this section shall be conducted under procedures that may include: prior notification to the submitter of confidential information; provisions for sealing portions of the record, briefs, and decisions; in camera arguments, offers of proof, and testimony; and limitations on representatives of record or other participants, as the presiding officer may designate. Additionally, at such proceedings the presiding officer may make an opening statement as to the confidentiality and limitations and deliver an oath to the parties, representatives of record, or other approved participants as to the confidentiality of the proceedings.

§ 1209.13 Good faith certification.

(a) *General requirement.* Every filing or submission of record following the issuance of a notice of charges by the Director shall be signed by at least one representative of record in his individual name and shall state that representative's business contact information which shall include his address, electronic mail address, and telephone number; and the names, addresses and telephone numbers of all other representatives of record for the person making the filing or submission.

(b) *Effect of signature.*—(1) By signing a document, a representative of record or party appearing pro se certifies that:

(i) The representative of record or party has read the filing or submission of record;

(ii) To the best of his knowledge, information and belief formed after reasonable inquiry, the filing or submission of record is well-grounded in fact and is warranted by existing law or a good faith, non-frivolous argument for the extension, modification, or reversal of existing law, regulation, or FHFA order or policy; and

(iii) The filing or submission of record is not made for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

(2) If a filing or submission of record is not signed, the presiding officer shall strike the filing or submission of record, unless it is signed promptly after the omission is called to the attention of the pleader or movant.

(c) *Effect of making oral motion or argument.* The act of making any oral motion or oral argument by any representative or party shall constitute a certification that to the best of his knowledge, information, and belief, formed after reasonable inquiry, his statements are well-grounded in fact and are warranted by existing law or a good faith, non-frivolous argument for the extension, modification, or reversal of existing law, regulation, or FHFA order or policy, and are not made for any improper purpose, such as to harass or to cause unnecessary delay or to needlessly increase litigation-related costs.

§ 1209.14 Ex parte communications.

(a) *Definition.*—(1) *Ex parte* communication means any material oral or written communication relevant to an adjudication of the merits of any proceeding under this subpart, that was neither on the record nor on reasonable prior notice to all parties that takes place between:

(i) An interested person outside FHFA (including the person's representative); and

(ii) The presiding officer handling that proceeding, the Director, a decisional employee assigned to that proceeding, or any other person who is or may be reasonably expected to be involved in the decisional process.

(2) A communication that is procedural in that it does not concern

the merits of an adjudicatory proceeding, such as a request for status of the proceeding, does not constitute an *ex parte* communication.

(b) *Prohibition of ex parte communications.* From the time a notice of charges commencing a proceeding under this part is issued by the Director until the date that the Director issues his final decision pursuant to § 1209.55, no person referred to in paragraph (a)(1)(i) of this section shall knowingly make or cause to be made an *ex parte* communication with the Director or the presiding officer. The Director, presiding officer, or a decisional employee shall not knowingly make or cause to be made an *ex parte* communication.

(c) *Procedure upon occurrence of ex parte communication.* If an *ex parte* communication is received by any person identified in paragraph (a) of this section, that person shall cause all such written communications (or, if the communication is oral, a memorandum stating the substance of the communication) to be placed on the record of the proceeding and served on all parties. All parties to the proceeding shall have an opportunity within ten (10) days of receipt of service of the *ex parte* communication, to file responses thereto, and to recommend sanctions that they believe to be appropriate under the circumstances, in accordance with paragraph (d) of this section.

(d) *Sanctions.* Any party or representative for a party who makes an *ex parte* communication, or who encourages or solicits another to make an *ex parte* communication, may be subject to any appropriate sanction or sanctions imposed by the Director or the presiding officer, including, but not limited to, exclusion from the proceedings, an adverse ruling on the issue that is the subject of the prohibited communication, or other appropriate and commensurate action(s).

(e) *Consultations by presiding officer.* Except to the extent required for the disposition of *ex parte* matters as authorized by law, the presiding officer may not consult a person or party on any matter relevant to the merits of the adjudication, unless upon notice to and opportunity for all parties to participate.

(f) *Separation of functions.* An employee or agent engaged in the performance of any investigative or prosecuting function for FHFA in a case may not, in that or in a factually related case, participate or advise in the recommended decision, the Director's review under § 1209.55 of the recommended decision, or the Director's final determination on the merits based upon his review of the recommended decision, except as a witness or counsel in the adjudicatory proceedings. This section shall not prohibit FHFA counsel from providing necessary and appropriate legal advice to the Director on supervisory or regulatory matters.

§ 1209.15 Filing of papers.

(a) *Filing.* All pleadings, motions, memoranda, and any other submissions or papers required to be filed in the proceeding shall be addressed to the presiding officer and filed with FHFA, 1700 G Street, NW., Fourth Floor, Washington, DC 20552, in accordance with paragraphs (b) and (c) of this section.

(b) *Manner of filing.* Unless otherwise specified by the Director or the presiding officer, filing shall be accomplished by:

(1) *Overnight delivery.* Overnight U.S. Postal Service delivery or delivery by a reliable commercial delivery service for same day or overnight delivery to the address stated above; or

(2) *U.S. Mail.* First class, registered, or certified mail via the U.S. Postal Service; and

(3) *Electronic media.* Transmission by electronic media shall be required by and upon any conditions specified by the Director or the presiding officer. FHFA shall provide a designated site for the electronic filing of all papers in a proceeding in accordance with any conditions specified by the presiding officer. All papers filed by electronic media shall be filed concurrently in a manner set out above and in accordance with paragraph (c) of this section.

(c) *Formal requirements as to papers filed.*—(1) *Form.* To be filed, all papers must set forth the name, address, telephone number, and electronic mail address of the representative or party seeking to make the filing. Additionally, all such papers must be accompanied by a certification setting forth when and how service has been made on all other parties. All papers filed must be double-spaced on 8½ × 11-inch paper and must be clear, legible, and formatted as required by paragraph (c)(5) of this section.

(2) *Signature.* All papers filed must be dated and signed as provided in § 1209.13.

(3) *Caption.* All papers filed must include at the head thereof, or on a title page, the FHFA caption, title and docket number of the proceeding, the name of the filing party, and the subject of the particular paper.

(4) *Number of copies.* Unless otherwise specified by the Director or the presiding officer, an original and one copy of all pleadings, motions and memoranda, or other such papers shall be filed, except that only one copy of transcripts of testimony and exhibits shall be filed.

(5) *Content format.* All papers filed shall be formatted in such program(s) (*e.g.,* MS WORD©, MS Excel©, or WordPerfect©) as the presiding officer or Director shall specify.

§ 1209.16 Service of papers.

(a) Except as otherwise provided, a party filing papers or serving a subpoena shall serve a copy upon the representative of record for each party to the proceeding so represented, and upon any party who is not so represented, in accordance with the requirements of this section.

(b) Except as provided in paragraphs (c)(2) and (d) of this section, a serving party shall use one or more of the following methods of service:

(1) Personal service;

(2) Overnight U.S. Postal Service delivery or delivery by a reliable commercial delivery service for same day or overnight delivery to the parties' respective street addresses; or

(3) First class, registered, or certified mail via the U.S. Postal Service; and

(4) For transmission by electronic media, each party shall promptly provide the presiding officer and all parties, in writing, an active electronic mail address where service will be accepted on behalf of such party. Any document transmitted via electronic mail for service on a party shall comply in all respects with the requirements of § 1209.15(c).

(5) Service of pleadings or other papers made by facsimile may not exceed a total page count of thirty (30) pages. Any paper served by facsimile transmission shall meet the requirements of § 1209.15(c).

(6) Any party serving a pleading or other paper by electronic media under paragraph (4) of this section also shall concurrently serve that pleading or paper by one of the methods specified in paragraphs (1) through (5) of this section.

(c) *By the Director or the presiding officer.*—(1) All papers required to be served by the Director or the presiding officer upon a party who has appeared in the proceeding in accordance with § 1209.72 shall be served by the means specified in paragraph (b) of this section.

(2) If a notice of appearance has not been filed in the proceeding for a party in accordance with § 1209.72, the Director or the presiding officer shall make service upon the party by any of the following methods:

(i) By personal service;

(ii) If the person to be served is an individual, by delivery to a person of

suitable age and discretion at the physical location where the individual resides or works;

(iii) If the person to be served is a corporation or other association, by delivery to an officer, managing or general agent, or to any other agent authorized by appointment or by law to receive service and, if the agent is one authorized by statute to receive service and the statute so requires, by also mailing a copy to the party;

(iv) By registered or certified mail addressed to the person's last known address; or

(v) By any other method reasonably calculated to give actual notice.

(d) *Subpoenas.* Service of a subpoena may be made:

(1) By personal service;

(2) If the person to be served is an individual, by delivery to a person of suitable age and discretion at the physical location where the individual resides or works;

(3) If the person to be served is a corporation or other association, by delivery to an officer, managing or general agent, or to any other agent authorized by appointment or by law to receive service and, if the agent is one authorized by statute to receive service and the statute so requires, by also mailing a copy to the party;

(4) By registered or certified mail addressed to the person's last known address; or

(5) By any other method reasonably calculated to give actual notice.

(e) *Area of service.* Service in any State or the District of Columbia, or any commonwealth, possession, territory or other place subject to the jurisdiction of the United States, or on any person doing business in any State or the District of Columbia, or any commonwealth, possession, territory or other place subject to the jurisdiction of the United States, or on any person as otherwise permitted by law, is effective without regard to the place where the hearing is held.

(f) *Proof of service.* Proof of service of papers filed by a party shall be filed before action is taken thereon. The proof of service, which shall serve as prima facie evidence of the fact and date of service, shall show the date and manner of service and may be by written acknowledgment of service, by declaration of the person making service, or by certificate of a representative of record. However, failure to file proof of service contemporaneously with the papers shall not affect the validity of actual service.

The presiding officer may allow the proof to be amended or supplied, unless to do so would result in material prejudice to a party.

§ 1209.17 Time computations.

(a) *General rule.* In computing any period of time prescribed or allowed under this part, the date of the act or event that commences the designated period of time is not included. Computations shall include the last day of the time period, unless the day falls on a Saturday, Sunday, or Federal holiday. When the last day is a Saturday, Sunday or Federal holiday, the period of time shall run until the end of the next day that is not a Saturday, Sunday, or Federal holiday. Intermediate Saturdays, Sundays and Federal holidays are included in the computation of time. However, when the time period within which an act is to be performed is ten (10) days or less, not including any additional time allowed for in paragraph (c) of this section, intermediate Saturdays, Sundays and Federal holidays are not included.

(b) *When papers are deemed to be filed or served.*–(1) Filing or service are deemed to be effective:

(i) In the case of personal service or same day reliable commercial delivery service, upon actual service;

(ii) In the case of U.S. Postal Service or reliable commercial overnight delivery service, or first class, registered, or certified mail, upon deposit in or delivery to an appropriate point of collection;

(iii) In the case of transmission by electronic media, as specified by the authority receiving the filing, in the case of filing; or

(iv) In the case of transmission by electronic media or facsimile, when the device through which the document was sent provides a reliable indicator that the document has been received by the opposing party, in the case of service.

(2) The effective filing and service dates specified in paragraph (b)(1) of this section may be modified by the Director or the presiding officer, or by agreement of the parties in the case of service.

(c) *Calculation of time for service and filing of responsive papers.* Whenever a time limit is measured by a prescribed period from the service of any notice, pleading or paper, the applicable time limits shall be calculated as follows:

(1) If service was made by delivery to the U.S. Postal Service for longer than overnight delivery service by first class, registered, or certified mail, add three (3) calendar days to the prescribed period for the responsive pleading or other filing.

(2) If service was personal, or was made by delivery to the U.S. Postal Service or any reliable commercial delivery service for overnight delivery, add one (1) calendar-day to the prescribed period for the responsive pleading or other filing.

(3) If service was made by electronic media transmission or facsimile, add one (1) calendar-day to the prescribed period for the responsive pleading or other filing—unless otherwise determined by the Director or the presiding officer *sua sponte,* or upon motion of a party in the case of filing or by prior agreement among the parties in the case of service.

§ 1209.18 Change of time limits.

Except as otherwise by law required, the presiding officer may extend any time limit that is prescribed above or in any notice or order issued in the proceedings. After the referral of the case to the Director pursuant to § 1209.53, the Director may grant extensions of the time limits for good cause shown. Extensions may be granted on the motion of a party after notice and opportunity to respond is afforded all nonmoving parties, or on the Director's or the presiding officer's own motion.

§ 1209.19 Witness fees and expenses.

Witnesses (other than parties) subpoenaed for testimony (or for a deposition in lieu of personal appearance at a hearing) shall be paid the same fees for attendance and mileage as are paid in the United States district courts in proceedings in which the United States is a party, provided that, in the case of a discovery subpoena addressed to a party, no witness fees or mileage shall be paid. Fees for witnesses shall be tendered in advance by the party requesting the subpoena, except that fees and mileage need not be tendered in advance where FHFA is the party requesting the subpoena. FHFA shall not be required to pay any fees to or expenses of any witness who was not subpoenaed by FHFA.

§ 1209.20 Opportunity for informal settlement.

Any respondent may, at any time in the proceeding, unilaterally submit to FHFA's counsel of record written offers or proposals for settlement of a proceeding without prejudice to the rights of any of the parties. No such offer or proposal shall be made to any FHFA representative other than FHFA's counsel of record. Submission of a written settlement offer does not provide a basis for adjourning, deferring or otherwise delaying all or any portion

of a proceeding under this part. No settlement offer or proposal, or any subsequent negotiation or resolution, is admissible as evidence in any proceeding.

§ 1209.21 Conduct of examination.

Nothing in this part limits or constrains in any manner any duty, authority, or right of FHFA to conduct or to continue any examination, investigation, inspection, or visitation of any regulated entity or entity-affiliated party.

§ 1209.22 Collateral attacks on adjudicatory proceeding.

If an interlocutory appeal or collateral attack is brought in any court concerning all or any part of an adjudicatory proceeding, the challenged adjudicatory proceeding shall continue without regard to the pendency of that court proceeding. No default or other failure to act as directed in the adjudicatory proceeding within the times prescribed in subpart C of this part shall be excused based on the pendency before any court of any interlocutory appeal or collateral attack.

§ 1209.23 Commencement of proceeding and contents of notice of charges.

Proceedings under subpart C of this part are commenced by the Director by the issuance of a notice of charges, as defined in § 1209.3(p), that must be served upon a respondent. A notice of charges shall state all of the following:

(a) The legal authority for the proceeding and for FHFA's jurisdiction over the proceeding;

(b) A statement of the matters of fact or law showing that FHFA is entitled to relief;

(c) A proposed order or prayer for an order granting the requested relief;

(d) Information concerning the nature of the proceeding and pertinent procedural matters, including: The requirement that the hearing shall be held in the District of Columbia; the presiding officer will set the date and location for an evidentiary hearing in a scheduling order to be issued not less than thirty (30) days or more than sixty (60) days after service of the notice of charges; contact information for FHFA enforcement counsel and the presiding officer, if known; submission information for filings and appearances, the time within which to request a hearing, and citation to FHFA Rules of Practice and Procedure; and

(e) Information concerning proper filing of the answer, including the time within which to file the answer as required by law or regulation, a statement that the answer shall be filed with the presiding officer or with FHFA as specified therein, and the address for filing the answer (and request for a hearing, if applicable).

§ 1209.24 Answer.

(a) *Filing deadline.* Unless otherwise specified by the Director in the notice, respondent shall file an answer within twenty (20) days of service of the notice of charges initiating the enforcement action.

(b) *Content of answer.* An answer must respond specifically to each paragraph or allegation of fact contained in the notice of charges and must admit, deny, or state that the party lacks sufficient information to admit or deny each allegation of fact. A statement of lack of information has the effect of a denial. Denials must fairly meet the substance of each allegation of fact denied; general denials are not permitted. When a respondent denies part of an allegation, that part must be denied and the remainder specifically admitted. Any allegation of fact in the notice that is not denied in the answer is deemed admitted for purposes of the proceeding. A respondent is not required to respond to the portion of a notice that constitutes the prayer for relief or proposed order. The answer must set forth affirmative defenses, if any, asserted by the respondent.

(c) *Default.* Failure of a respondent to file an answer required by this section within the time provided constitutes a waiver of such respondent's right to appear and contest the allegations in the notice. If no timely answer is filed, FHFA's counsel of record may file a motion for entry of an order of default. Upon a finding that no good cause has been shown for the failure to file a timely answer, the presiding officer shall file with the Director a recommended decision containing the findings and the relief sought in the notice. Any final order issued by the Director based upon a respondent's failure to answer is deemed to be an order issued upon consent.

§ 1209.25 Amended pleadings.

(a) *Amendments.* The notice or answer may be amended or supplemented at any stage of the proceeding. The respondent must answer an amended notice within the time remaining for the respondent's answer to the original notice, or within ten (10) days after service of the amended notice, whichever period is longer, unless the Director or presiding officer orders otherwise for good cause shown.

(b) *Amendments to conform to the evidence.* When issues not raised in the notice or answer are tried at the hearing by express or implied consent of the parties, or as the presiding officer may allow for good cause shown, such issues will be treated in all respects as if they had been raised in the notice or answer, and no formal amendments are required. If evidence is objected to at the hearing on the ground that it is not within the issues raised by the notice or answer, the presiding officer may admit the evidence when admission is likely to assist in adjudicating the merits of the action. The presiding officer will do so freely when the determination of the merits of the action is served thereby and the objecting party fails to satisfy the presiding officer that the admission of such evidence would unfairly prejudice that party's action or defense upon the merits. The presiding officer may grant a continuance to enable the objecting party to meet such evidence.

§ 1209.26 Failure to appear.

Failure of a respondent to appear in person at the hearing or by a duly authorized representative of record constitutes a waiver of respondent's right to a hearing and is deemed an admission of the facts as alleged and consent to the relief sought in the notice. Without further proceedings or notice to the respondent, the presiding officer shall file with the Director a recommended decision containing the agency findings and the relief sought in the notice.

§ 1209.27 Consolidation and severance of actions.

(a) *Consolidation.* On the motion of any party, or on the presiding officer's own motion, the presiding officer may consolidate, for some or all purposes, any two or more proceedings, if each such proceeding involves or arises out of the same transaction, occurrence or series of transactions or occurrences, or involves at least one common respondent or a material common question of law or fact, unless such consolidation would cause unreasonable delay or injustice. In the event of consolidation under this section, appropriate adjustment to the pre-hearing schedule must be made to avoid unnecessary expense, inconvenience, or delay.

(b) *Severance.* The presiding officer may, upon the motion of any party, sever the proceeding for separate resolution of the matter as to any respondent only if the presiding officer finds that undue prejudice or injustice to the moving party would result from not severing the proceeding and such undue prejudice or injustice would outweigh the interests of judicial

economy and expedition in the complete and final resolution of the proceeding.

§ 1209.28 Motions.

(a) *In writing.*—(1) Except as otherwise provided herein, an application or request for an order or ruling must be made by written motion.

(2) All written motions must state with particularity the relief sought and must be accompanied by a proposed order.

(3) No oral argument may be held on written motions except as otherwise directed by the presiding officer. Written memoranda, briefs, affidavits, or other relevant material or documents may be filed in support of or in opposition to a motion.

(b) *Oral motions.* A motion may be made orally on the record, unless the presiding officer directs that such motion be reduced to writing, in which case the motion will be subject to the requirements of this section.

(c) *Filing of motions.* Motions must be filed with the presiding officer and served on all parties; except that following the filing of a recommended decision, motions must be filed with the Director. Motions for pre-trial relief such as motions in limine or objections to offers of proof or experts shall be filed not less than ten (10) days prior to the date of the evidentiary hearing, except as provided with the consent of the presiding officer for good cause shown.

(d) *Responses and replies.*—(1) Except as otherwise provided herein, (i) any party may file a written response to a non-dispositive motion within ten (10) days after service of any written motion, or within such other period of time as may be established by the presiding officer or the Director; and (ii) the moving party may file a written reply to a written response to a non-dispositive motion within five (5) days after the service of the response, unless some other period is ordered by the presiding officer or the Director. The presiding officer shall not rule on any oral or written motion before each party with an interest in the motion has had an opportunity to respond as provided in this section.

(2) The failure of a party to oppose a written motion or an oral motion made on the record is deemed as consent by that party to the entry of an order substantially in the form of the order accompanying the motion.

(e) *Dilatory motions.* Frivolous, dilatory, or substantively repetitive motions are prohibited. The filing of such motions may form the basis for sanctions.

(f) *Dispositive motions.* Dispositive motions are governed by §§ 1209.34 and 1209.35.

§ 1209.29 Discovery.

(a) *General rule.*—(1) *Limits on discovery.* Subject to the limitations set out in paragraphs (a)(2), (b), (d), and (e) of this section, a party to a proceeding under this part may obtain document discovery by serving upon any other party in the proceeding a written request to produce documents. For purposes of such requests, the term "documents" may be defined to include records, drawings, graphs, charts, photographs, recordings, or data stored in electronic form or other data compilations from which information can be obtained or translated, if necessary, by the parties through detection devices into reasonably usable form (*e.g.,* electronically stored information), as well as written material of all kinds.

(2) *Discovery plan.*—(i) In the initial scheduling conference held in accordance with § 1209.36, or otherwise at the earliest practicable time, the presiding officer shall require the parties to confer in good faith to develop and submit a joint discovery plan for the timely, cost-effective management of document discovery (including, if applicable, electronically stored information). The discovery plan should provide for the coordination of similar discovery requests by multiple parties, if any, and specify how costs are to be apportioned among those parties. The discovery plan shall specify the form of electronic productions, if any. Documents are to be produced in accordance with the technical specifications described in the discovery plan.

(ii) Discovery in the proceeding may commence upon the approval of the discovery plan by the presiding officer. Thereafter, the presiding officer may interpret or modify the discovery plan for good cause shown or in his discretion due to changed circumstances.

(iii) Nothing in this paragraph shall be interpreted or deemed to require the production of documents that are privileged or not reasonably accessible because of undue burden or cost, or to require any document production otherwise inconsistent with the limitations on discovery set forth in this part.

(b) *Relevance and scope.*—(1) A party may obtain document discovery regarding any matter not privileged that is materially relevant to the charges or allowable defenses raised in the pending proceeding.

(2) The scope of available discovery shall be limited in accordance with subpart C of this part. Any request for the production of documents that seeks to obtain privileged information or documents not materially relevant under paragraph (b)(1) of this section, or that is unreasonable, oppressive, excessive in scope, unduly burdensome, cumulative, or repetitive of any prior discovery requests, shall be denied or modified.

(3) A request for document discovery is unreasonable, oppressive, excessive in scope, or unduly burdensome—and shall be denied or modified—if, among other things, the request:

(i) Fails to specify justifiable limitations on the relevant subject matter, time period covered, search parameters, or the geographic location(s) or data repositories to be searched;

(ii) Fails to identify documents with sufficient specificity;

(iii) Seeks material that is duplicative, cumulative, or obtainable from another source that is more accessible, cost-effective, or less burdensome;

(iv) Calls for the production of documents to be delivered to the requesting party or his designee and fails to provide a written agreement by the requestor to pay in advance for the costs of production in accordance with § 1209.30, or otherwise fails to take into account costs associated with processing electronically stored information or any cost-sharing agreements between the parties;

(v) Fails to afford the responding party adequate time to respond; or

(vi) Fails to take into account retention policies or security protocols with respect to Federal information systems.

(c) *Forms of discovery.* Discovery shall be limited to requests for production of documents for inspection and copying. No other form of discovery shall be allowed. Discovery by use of interrogatories is not permitted. This paragraph shall not be interpreted to require the creation of a document.

(d) *Privileged matter.*—(1) *Privileged documents are not discoverable.*

(i) Privileges include the attorney-client privilege, work-product privilege, any government's or government agency's deliberative process privilege and any other privileges provided by the Constitution, any applicable act of Congress, or the principles of common law.

(ii) The parties may enter into a written agreement to permit a producing party to assert applicable privileges of a document even after its production and to request the return or destruction of privileged matter (clawback agreement).

The parties shall file the clawback agreement with the presiding officer. To ensure the enforceability of the terms of any such clawback agreement, the presiding officer shall enter an order. Any party may petition the presiding officer for an order specifying clawback procedures for good cause shown.

(2) *No effect on examination authority.* The limitations on discoverable matter provided for in this part are not intended and shall not be construed to limit or otherwise affect the examination, regulatory or supervisory authority of FHFA.

(e) *Time limits.* All discovery matters, including all responses to discovery requests, shall be completed at least twenty (20) days prior to the date scheduled for the commencement of the testimonial phase of the hearing. No exception to this discovery time limit shall be permitted, unless the presiding officer finds on the record that good cause exists for waiving the twenty (20) day requirement of this paragraph.

(f) *Production.* Documents must be produced as they are kept in the usual course of business, or labeled and organized to correspond with the categories in the request, or otherwise produced in a manner determined by mutual agreement between the requesting party and the party or non-party to whom the request is directed in accordance with this part.

§ 1209.30 Request for document discovery from parties.

(a) *General rule.* Each request for the production of documents must conform to the requirements of this part.

(1) *Limitations.* Subject to applicable limitations on discovery in this part, a party may serve (requesting party) a request on another party (responding party) for the production of any non-privileged, discoverable documents in the possession, custody, or control of the responding party. A requesting party shall serve a copy of any such document request on all other parties. Each request for the production of documents must, with reasonable particularity, identify or describe the documents to be produced, either by individual item or by category, with sufficient specificity to enable the responding party to respond consistent with the requirements of this part.

(2) *Discovery plan.* Document discovery under subpart C of this part shall be consistent with any discovery plan approved by the presiding officer under § 1209.29.

(b) *Production and costs.*—(1) *General rule.* Subject to the applicable limitations on discovery in this part and the discovery plan, the requesting party shall specify a reasonable time, place and manner for the production of documents and the performance of any related acts. The responding party shall produce documents to the requesting party in a manner consistent with the discovery plan.

(2) *Costs.* All costs associated with document productions—including, without limitation, photocopying (as specified in paragraph (b)(4) of this section) or electronic processing (as specified in paragraph (b)(5) of this section)—shall be borne by the requesting party, or otherwise in accordance with any discovery plan approved by the presiding officer that may require such costs be apportioned between parties, or as otherwise ordered by the presiding officer. If consistent with the discovery plan approved by the presiding officer, the responding party may require receipt of payment of any such document production costs in advance before any such production of responsive documents.

(3) *Organization.* Unless otherwise provided for in any discovery plan approved by the presiding officer under § 1209.29, or by order of the presiding officer, documents must be produced as they are kept in the usual course of business or they shall be labeled and organized to correspond with the categories in the document request.

(4) *Photocopying charges.* Photocopying charges are to be set at the current rate per page imposed by FHFA under the fee schedule pursuant to § 1202.11(c) of this chapter for requests for documents filed under the Freedom of Information Act, 5 U.S.C. 552.

(5) *Electronic processing.* In the event that any party seeks the production of electronically stored information (*i.e.,* information created, stored, communicated, or used in digital format requiring the use of computer hardware and software), the parties shall confer in good faith to resolve common discovery issues related to electronically stored information, such as preservation, search methodology, collection, and need for such information; the suitability of alternative means to obtain it; and the format of production. Consistent with the discovery plan approved by the presiding officer under § 1209.29, costs associated with the processing of such electronic information (*i.e.,* imaging; scanning; conversion of "native" files to images that are viewable and searchable; indexing; coding; database or Web-based hosting; searches; branding of endorsements, such as "confidential" or document control numbering; privilege reviews; and copies of production discs) and delivery of any such document production, shall be borne by the requesting party, apportioned among the parties, or as otherwise ordered by the presiding officer. Nothing in this part shall be deemed to require FHFA to produce privileged documents or any electronic records in violation of applicable Federal law or security protocols.

(c) *Obligation to update responses.* A party who has responded to a discovery request is not required to supplement the response, unless:

(1) The responding party learns that in some material respect the information disclosed is incomplete or incorrect, and

(2) The additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing.

(d) *Motions to strike or limit discovery requests.*—(1) Any party served with a document discovery request may object within thirty (30) days of service of the request by filing a motion to strike or limit the request in accordance with the provisions of § 1209.28. No other party may file an objection. If an objection is made only to a portion of an item or category in a request, the objection shall specify that portion. Any objections not made in accordance with this paragraph and § 1209.28 are waived.

(2) The party who served the request that is the subject of a motion to strike or limit may file a written response in accordance with the provisions of § 1209.28. A reply by the moving party, if any, shall be governed by § 1209.28. No other party may file a response.

(e) *Privilege.* At the time other documents are produced, all documents withheld on a claim of privilege must be reasonably identified, together with a statement of the basis for the assertion of privilege on a privilege log. When similar documents that are protected by the government's deliberative process, investigative or examination privilege; the attorney work-product doctrine, or the attorney-client privilege are voluminous, such documents may be identified on the log by category instead of by individual document. The presiding officer has discretion to determine when the identification by category is sufficient.

(f) *Motions to compel production.*—(1) If a party withholds any document as privileged or fails to comply fully with a document discovery request, the requesting party may, within ten (10) days of the assertion of privilege or of the time the failure to comply becomes known to the requesting party, file a motion in accordance with the provisions of § 1209.28 for the issuance of a subpoena compelling the production of any such document.

(2) The party who asserted the privilege or failed to comply with the request may, within five (5) days of service of a motion for the issuance of a subpoena compelling production, file a written response to the motion. No other party may file a response.

(g) *Ruling on motions.*—(1) *Appropriate protective orders.* After the time for filing a response to a motion to compel pursuant to this section has expired, the presiding officer shall rule promptly on all such motions. The presiding officer may deny, grant in part, or otherwise modify any request for the production of documents, if he determines that a discovery request, or any one or more of its terms, seeks to obtain the production of documents that are privileged or otherwise not within the scope of permissible discovery under § 1209.29(b), and may issue appropriate protective orders, upon such conditions as justice may require.

(2) *No stay.* The pendency of a motion to strike or limit discovery, or to compel the production of any document, shall not stay or continue the proceeding, unless otherwise ordered by the presiding officer. Notwithstanding any other provision in this part, the presiding officer may not release, or order any party to produce, any document withheld on the basis of privilege, if the withholding party has stated to the presiding officer its intention to file with the Director a timely motion for interlocutory review of the presiding officer's privilege determination or order to produce the documents, until the Director has rendered a decision on the motion for interlocutory review.

(3) *Interlocutory review by the Director.* Interlocutory review of a privilege determination or document discovery subpoena of the presiding officer shall be in accordance with § 1209.33. To the extent necessary to rule promptly on such matters, the Director may request that the presiding officer provide additional information from the record. As provided by § 1209.33, a pending interlocutory review of a privilege determination or document discovery subpoena shall not stay the proceedings, unless otherwise ordered by the presiding officer or the Director.

(h) *Enforcement of document discovery subpoenas.*—(1) *Authority.* If the presiding officer or Director issues a subpoena compelling production of documents by a party in a proceeding under this part, in the event of noncompliance with the subpoena and to the extent authorized by section 1379D(c)(1) of the Safety and Soundness Act (12 U.S.C. 4641(c)(1)), the Director or the subpoenaing party may apply to the appropriate United States district court for an order requiring compliance with the subpoena.

(2) *United States district court jurisdiction.* As provided by section 1379D(c)(2) of the Safety and Soundness Act (12 U.S.C. 4641(c)(2)), the appropriate United States district court has the jurisdiction and power to order and to require compliance with any discovery subpoena issued under this part. Notwithstanding any other provision in this part, as provided by section 1375(b) of the Safety and Soundness Act (12 U.S.C. 4635(b)), in connection with the enforcement of a subpoena under this part, no district court has jurisdiction to affect by injunction or otherwise the issuance or enforcement of any effective and outstanding notice or order issued under section 1313B, subtitle B, or subtitle C of the Safety and Soundness Act, or to review, modify, suspend, terminate, or set aside any such effective and outstanding notice or order.

(3) *No stay; sanctions.* The judicial enforcement of a discovery subpoena shall not operate as a stay of the proceedings, unless the presiding officer or the Director orders a stay of such duration as the presiding officer or Director may find reasonable and in the best interest of the parties or as justice may require. A party's right to seek judicial enforcement of a subpoena shall not in any manner limit the sanctions that may be imposed by the presiding officer or Director against a party who fails to produce or induces another to fail to produce subpoenaed documents.

§ 1209.31 Document discovery subpoenas to nonparties.

(a) *General rules.*—(1) *Application for subpoena.* As provided under this part, any party may apply to the presiding officer for the issuance of a document discovery subpoena addressed to any person who is not a party to the proceeding. The application must contain the proposed document subpoena, and a brief statement of facts demonstrating that the documents are materially relevant to the charges and issues presented in the proceeding and the reasonableness of the scope of the document request. The subpoenaing party shall specify a reasonable time, place, and manner for production in response to the subpoena, and state its unequivocal intention to pay for the production of the documents as provided in this part.

(2) *Service of subpoena.* A party shall apply for a document subpoena under this section only within the time period during which such party could serve a discovery request under § 1209.30. The party obtaining the document subpoena is responsible for serving it on the subpoenaed person and for serving copies on all other parties. Document subpoenas may be served in the District of Columbia, or any State, Territory, possession, or other place subject to the jurisdiction of the United States, or as otherwise provided by law.

(3) *Presiding officer's discretion.* The presiding officer shall issue promptly any document subpoena applied for under this section subject to the application conditions set forth in this section and his discretion. If the presiding officer determines that the application does not set forth a valid basis for the issuance of the requested document subpoena, or that any of its terms are unreasonable, oppressive, excessive in scope, unduly burdensome, or otherwise objectionable under § 1209.29(b), he may refuse to issue the requested document subpoena or may issue it in a modified form upon such additional conditions as may be determined by the presiding officer.

(b) *Motion to quash or modify.*—(1) *Limited appearance.* Any non-party to a pending proceeding to whom a document subpoena is directed may enter a limited appearance, through a representative or on his own behalf, before the presiding officer to file with the presiding officer a motion to quash or modify such subpoena, accompanied by a statement of the basis for quashing or modifying the subpoena.

(2) *Objections.* Any motion to quash or modify a document subpoena must be filed on the same basis, including the assertion of any privileges, upon which a party could object to a discovery document request under § 1209.30 and during the same time limits during which such an objection could be filed.

(3) *Responses and replies.* The party who obtained the subpoena may respond to such motion within ten (10) days of service of the motion; the response shall be served on the non-party in accordance with this part. Absent express leave of the presiding officer, no other party may respond to the non-party's motion. The non-party may file a reply within five (5) days of service of a response.

(4) *No stay.* A non-party's right to seek to quash or modify a document subpoena shall not stay the proceeding, or limit in any manner the sanctions that may be imposed by the presiding officer against a party who induces another to fail to produce any such subpoenaed documents. No party may rely upon the pendency of a non-party's motion to quash or modify a document subpoena to excuse performance of any

action required of that party under this part.

(c) *Enforcing document subpoenas to non-parties.*—(1) Application for enforcement of subpoena. If a non-party fails to comply with any subpoena issued pursuant to this section or with any order of the presiding officer that directs compliance with all or any portion of a document subpoena issued pursuant to this section, the subpoenaing party or any other aggrieved party to the proceeding may, to the extent authorized by section 1379D(c) of the Safety and Soundness Act (12 U.S.C. 4641(c)), apply to an appropriate United States district court for an order requiring compliance with the subpoena.

(2) *No stay.* A party's right to seek district court enforcement of a non-party document production subpoena under this section shall not stay automatically an enforcement proceeding under of the Safety and Soundness Act.

(3) *Sanctions.* A party's right to seek district court enforcement of a non-party document subpoena shall in no way limit the sanctions that may be imposed by the presiding officer on a party who induces another to fail to comply with any subpoena issued under this section.

§ 1209.32 Deposition of witness unavailable for hearing.

(a) *General rules.*—(1) If a witness will not be available for the hearing, a party desiring to preserve that witness' testimony for the record may apply to the presiding officer in accordance with the procedures set forth in paragraph (a)(2) of this section for the issuance of a subpoena or subpoena *duces tecum* requiring the attendance of the witness at a deposition for the purpose of preserving that witness' testimony. The presiding officer may issue a deposition subpoena under this section upon a showing that:

(i) The witness will be unable to attend or may be prevented from attending the testimonial phase of the hearing because of age, sickness, or infirmity, or will be otherwise unavailable;

(ii) The subpoenaing party did not cause or contribute to the unavailability of the witness for the hearing;

(iii) The witness has personal knowledge and the testimony is reasonably expected to be materially relevant to claims, defenses, or matters determined to be at issue in the proceeding; and

(iv) Taking the deposition will not result in any undue burden to any other party and will not cause undue delay of the proceeding.

(2) The application must contain a proposed deposition subpoena and a brief statement of the reasons for the issuance of the subpoena. The subpoena must name the witness whose deposition is to be taken and specify the time and place for taking the deposition. A deposition subpoena may require the witness to be deposed anywhere within the United States, or its Territories and possessions, in which that witness resides or has a regular place of employment or such other convenient place as the presiding officer shall fix.

(3) Subpoenas must be issued promptly upon request, unless the presiding officer determines that the request fails to set forth a valid basis under this section for its issuance. Before making a determination that there is no valid basis for issuing the subpoena, the presiding officer shall require a written response from the party requesting the subpoena or require attendance at a conference to determine whether there is a valid basis upon which to issue the requested subpoena.

(4) The party obtaining a deposition subpoena is responsible for serving it on the witness and for serving copies on all parties. Unless the presiding officer orders otherwise, no deposition under this section shall be taken on fewer than ten (10) days' notice to the witness and all parties. Deposition subpoenas may be served anywhere within the United States or its Territories and possessions, or on any person doing business anywhere within the United States or its Territories and possessions, or as otherwise permitted by law.

(b) *Objections to deposition subpoenas.*—(1) The witness and any party who has not had an opportunity to oppose a deposition subpoena issued under this section may file a motion with the presiding officer under § 1209.28 to quash or modify the subpoena prior to the time for compliance specified in the subpoena, but not more than ten (10) days after service of the subpoena.

(2) A statement of the basis for the motion to quash or modify a subpoena issued under this section must accompany the motion. The motion must be served on all parties.

(c) *Procedure upon deposition.*—(1) Each witness testifying pursuant to a deposition subpoena must be duly sworn and each party shall have the right to examine the witness. Objections to questions or documents must be in short form, stating the grounds for the objection. Failure to object to questions or documents is not deemed a waiver except where the ground for objection might have been avoided if the objection had been presented timely. All questions, answers and objections must be recorded and transcribed. Videotaped depositions must be transcribed for the record; copies and transcriptions must be supplied to each party.

(2) Any party may move before the presiding officer for an order compelling the witness to answer any questions the witness has refused to answer or submit any evidence that, during the deposition, the witness has refused to submit.

(3) The deposition transcript must be subscribed by the witness, unless the parties and the witness, by stipulation, have waived the signing, or the witness is ill, cannot be found, or has refused to sign. If the deposition is not subscribed by the witness, the court reporter taking the deposition shall certify that the transcript is a true and complete transcript of the deposition.

(d) *Enforcing subpoenas.* If a subpoenaed person fails to comply with any subpoena issued pursuant to this section or with any order of the presiding officer made upon motion under paragraph (c)(2) of this section, the subpoenaing party or other aggrieved party may, to the extent authorized by section 1379D(c) of the Safety and Soundness Act (12 U.S.C. 4641(c)), apply to an appropriate United States district court for an order requiring compliance with the portions of the subpoena that the presiding officer has ordered enforced. A party's right to seek court enforcement of a deposition subpoena in no way limits the sanctions that may be imposed by the presiding officer on a party who fails to comply with or induces a failure to comply with a subpoena issued under this section.

§ 1209.33 Interlocutory review.

(a) *General rule.* The Director may review a ruling of the presiding officer prior to the certification of the record to the Director only in accordance with the procedures set forth in this section.

(b) *Scope of review.* The Director may exercise interlocutory review of a ruling of the presiding officer if the Director finds that—

(1) The ruling involves a controlling question of law or policy as to which substantial grounds exist for a difference of opinion;

(2) Immediate review of the ruling may materially advance the ultimate termination of the proceeding;

(3) Subsequent modification of the ruling at the conclusion of the proceeding would be an inadequate remedy; or

(4) Subsequent modification of the ruling would cause unusual delay or expense.

(c) *Procedure.* Any motion for interlocutory review shall be filed by a party with the presiding officer within ten (10) days of his ruling. Upon the expiration of the time for filing all responses, the presiding officer shall refer the matter to the Director for final disposition. In referring the matter to the Director, the presiding officer may indicate agreement or disagreement with the asserted grounds for interlocutory review of the ruling in question.

(d) *Suspension of proceeding.* Neither a request for interlocutory review nor any disposition of such a request by the Director under this section suspends or stays the proceeding unless otherwise ordered by the presiding officer or the Director.

§ 1209.34 Summary disposition.

(a) *In general.* The presiding officer shall recommend that the Director issue a final order granting a motion for summary disposition if the undisputed pleaded facts, admissions, affidavits, stipulations, documentary evidence, matters as to which official notice may be taken and any other evidentiary materials properly submitted in connection with a motion for summary disposition show that:

(1) There is no genuine issue as to any material fact; and

(2) The movant is entitled to a decision in its favor as a matter of law.

(b) *Filing of motions and responses.*—(1) Any party who believes there is no genuine issue of material fact to be determined and that such party is entitled to a decision as a matter of law may move at any time for summary disposition in its favor of all or any part of the proceeding. Any party, within thirty (30) days after service of such motion or within such time period as allowed by the presiding officer, may file a response to such motion.

(2) A motion for summary disposition must be accompanied by a statement of material facts as to which the movant contends there is no genuine issue. Such motion must be supported by documentary evidence, which may take the form of admissions in pleadings, stipulations, depositions, investigatory depositions, transcripts, affidavits and any other evidentiary materials that the movant contends support its position. The motion must also be accompanied by a brief containing the points and authorities in support of the contention of the movant. Any party opposing a motion for summary disposition must file a statement setting forth those material facts as to which the party contends a genuine dispute exists. Such opposition must be supported by evidence of the same type as that submitted with the motion for summary disposition and a brief containing the points and authorities in support of the contention that summary disposition would be inappropriate.

(c) *Hearing on motion.* At the request of any party or on his own motion, the presiding officer may hear oral argument on the motion for summary disposition.

(d) *Decision on motion.* Following receipt of a motion for summary disposition and all responses thereto, the presiding officer shall determine whether the movant is entitled to summary disposition. If the presiding officer determines that summary disposition is warranted, the presiding officer shall submit a recommended decision to that effect to the Director, under § 1209.53. If the presiding officer finds that the moving party is not entitled to summary disposition, the presiding officer shall make a ruling denying the motion.

§ 1209.35 Partial summary disposition.

If the presiding officer determines that a party is entitled to summary disposition as to certain claims only, he shall defer submitting a recommended decision to the Director as to those claims. A hearing on the remaining issues must be ordered. Those claims for which the presiding officer has determined that summary disposition is warranted will be addressed in the recommended decision filed at the conclusion of the hearing.

§ 1209.36 Scheduling and pre-hearing conferences.

(a) *Scheduling conference.* After service of a notice of charges commencing a proceeding under this part, the presiding officer shall order the representative(s) of record for each party, and any party not so represented who is appearing pro se, to meet with him in person or to confer with him by telephone at a specified time within thirty (30) days of service of such notice for the purpose of setting the time and place of the testimonial hearing on the record to be held within the District of Columbia and scheduling the course and conduct of the proceeding (the "scheduling conference"). The identification of potential witnesses, the time for and manner of discovery and the exchange of any pre-hearing materials including witness lists, statements of issues, stipulations, exhibits, and any other materials also may be determined at the scheduling conference.

(b) *Pre-hearing conferences.* The presiding officer may, in addition to the scheduling conference, on his own motion or at the request of any party, direct representatives for the parties to meet with him (in person or by telephone) at a pre-hearing conference to address any or all of the following:

(1) Simplification and clarification of the issues;

(2) Stipulations, admissions of fact and the contents, authenticity and admissibility into evidence of documents;

(3) Matters of which official notice may be taken;

(4) Limitation of the number of witnesses;

(5) Summary disposition of any or all issues;

(6) Resolution of discovery issues or disputes;

(7) Amendments to pleadings; and

(8) Such other matters as may aid in the orderly disposition of the proceeding.

(c) *Transcript.* The presiding officer, in his discretion, may require that a scheduling or pre-hearing conference be recorded by a court reporter. A transcript of the conference and any materials filed, including orders, becomes part of the record of the proceeding. A party may obtain a copy of the transcript at such party's expense.

(d) *Scheduling or pre-hearing orders.* Within a reasonable time following the conclusion of the scheduling conference or any pre-hearing conference, the presiding officer shall serve on each party an order setting forth any agreements reached and any procedural determinations made.

§ 1209.37 Pre-hearing submissions.

(a) Within the time set by the presiding officer, but in no case later than ten (10) days before the start of the hearing, each party shall serve on every other party the serving party's:

(1) Pre-hearing statement;

(2) Final list of witnesses to be called to testify at the hearing; including name and address of each witness and a short summary of the expected testimony of each witness;

(3) List of the exhibits to be introduced at the hearing along with a copy of each exhibit; and

(4) Stipulations of fact, if any.

(b) *Effect of failure to comply.* No witness may testify and no exhibit may be introduced at the hearing that is not listed in the pre-hearing submissions pursuant to paragraph (a) of this section, except for good cause shown.

§ 1209.38 Hearing subpoenas.

(a) *Issuance.*—(1) Upon application of a party to the presiding officer showing relevance and reasonableness of scope

of the testimony or other evidence sought, the presiding officer may issue a subpoena or a subpoena *duces tecum* requiring the attendance of a witness at the hearing or the production of documentary or physical evidence at such hearing. The application for a hearing subpoena must also contain a proposed subpoena specifying the attendance of a witness or the production of evidence from any place within the United States or its territories and possessions, or as otherwise provided by law, at the designated place where the hearing is being conducted. The party making the application shall serve a copy of the application and the proposed subpoena on every other party.

(2) A party may apply for a hearing subpoena at any time before the commencement of or during a hearing. During a hearing, a party may make an application for a subpoena orally on the record before the presiding officer.

(3) The presiding officer shall promptly issue any hearing subpoena applied for under this section; except that, if the presiding officer determines that the application does not set forth a valid basis for the issuance of the subpoena, or that any of its terms are unreasonable, oppressive, excessive in scope, or unduly burdensome, he may refuse to issue the subpoena or may issue the subpoena in a modified form upon any conditions consistent with subpart C of this part. Upon issuance by the presiding officer, the party making the application shall serve the subpoena on the person named in the subpoena and on each party.

(b) *Motion to quash or modify.*—(1) Any person to whom a hearing subpoena is directed or any party may file a motion to quash or modify such subpoena, accompanied by a statement of the basis for quashing or modifying the subpoena. The movant must serve the motion on each party and on the person named in the subpoena. Any party may respond to the motion within ten (10) days of service of the motion.

(2) Any motion to quash or modify a hearing subpoena must be filed prior to the time specified in the subpoena for compliance, but no more than ten (10) days after the date of service of the subpoena upon the movant.

(c) *Enforcing subpoenas.* If a subpoenaed person fails to comply with any subpoena issued pursuant to this section or any order of the presiding officer that directs compliance with all or any portion of a hearing subpoena, the subpoenaing party or any other aggrieved party may seek enforcement of the subpoena pursuant to § 1209.31. A party's right to seek court enforcement of a hearing subpoena shall in no way limit the sanctions that may be imposed by the presiding officer on a party who induces a failure to comply with subpoenas issued under this section.

§§ 1209.39 through 1209.49 [Reserved]

§ 1209.50 Conduct of hearings.

(a) *General rules.*—(1) *Conduct.* Hearings shall be conducted in accordance with 5 U.S.C. chapter 5 and other applicable law and so as to provide a fair and expeditious presentation of the relevant disputed issues. Except as limited by this subpart, each party has the right to present its case or defense by oral and documentary evidence and to conduct such cross examination as may be required for full disclosure of the facts.

(2) *Order of hearing.* FHFA's counsel of record shall present its case-in-chief first, unless otherwise ordered by the presiding officer or unless otherwise expressly specified by law or regulation. FHFA's counsel of record shall be the first party to present an opening statement and a closing statement and may make a rebuttal statement after the respondent's closing statement. If there are multiple respondents, respondents may agree among themselves as to their order or presentation of their cases, but if they do not agree, the presiding officer shall fix the order.

(3) *Examination of witnesses.* Only one representative for each party may conduct an examination of a witness, except that in the case of extensive direct examination, the presiding officer may permit more than one representative for the party presenting the witness to conduct the examination. A party may have one representative conduct the direct examination and another representative conduct re-direct examination of a witness, or may have one representative conduct the cross examination of a witness and another representative conduct the re-cross examination of a witness.

(4) *Stipulations.* Unless the presiding officer directs otherwise, all documents that the parties have stipulated as admissible shall be admitted into evidence upon commencement of the hearing.

(b) *Transcript.* The hearing shall be recorded and transcribed. The transcript shall be made available to any party upon payment of the cost thereof. The presiding officer shall have authority to order the record corrected, either upon motion to correct, upon stipulation of the parties, or following notice to the parties upon the presiding officer's own motion.

§ 1209.51 Evidence.

(a) *Admissibility.*—(1) Except as is otherwise set forth in this section, relevant, material and reliable evidence that is not unduly repetitive is admissible to the fullest extent authorized by the Administrative Procedure Act (5 U.S.C. 552 *et seq.*) and other applicable law.

(2) Evidence that would be admissible under the Federal Rules of Evidence is admissible in a proceeding conducted pursuant to subpart C of this part.

(3) Evidence that would be inadmissible under the Federal Rules of Evidence may not be deemed or ruled to be inadmissible in a proceeding conducted pursuant to subpart C of this part if such evidence is relevant, material, probative and reliable, and not unduly repetitive.

(b) *Official notice.*—(1) Official notice may be taken of any material fact that may be judicially noticed by a United States district court and any materially relevant information in the official public records of any Federal or State government agency.

(2) All matters officially noticed by the presiding officer or the Director shall appear on the record.

(3) If official notice is requested of any material fact, the parties, upon timely request, shall be afforded an opportunity to object.

(c) *Documents.*—(1) A duplicate copy of a document is admissible to the same extent as the original, unless a genuine issue is raised as to whether the copy is in some material respect not a true and legible copy of the original.

(2) Subject to the requirements of paragraph (a)(1) of this section, any document, including a report of examination, oversight activity, inspection or visitation prepared by FHFA or by another Federal or State financial institutions regulatory agency, is admissible either with or without a sponsoring witness.

(3) Witnesses may use existing or newly created charts, exhibits, calendars, calculations, outlines, or other graphic material to summarize, illustrate, or simplify the presentation of testimony. Such materials may, subject to the presiding officer's discretion, be used with or without being admitted into evidence.

(d) *Objections.*—(1) Objections to the admissibility of evidence must be timely made and rulings on all objections must appear in the record.

(2) When an objection to a question or line of questioning is sustained, the examining representative of record may make a specific proffer on the record of what he expected to prove by the expected testimony of the witness. The

proffer may be by representation of the representative or by direct interrogation of the witness.

(3) The presiding officer shall retain rejected exhibits, adequately marked for identification, for the record and transmit such exhibits to the Director.

(4) Failure to object to admission of evidence or to any ruling constitutes a waiver of the objection.

(e) *Stipulations.* The parties may stipulate as to any relevant matters of fact or the authentication of any document to be admitted into evidence. Such stipulations must be received in evidence at a hearing, are binding on the parties with respect to the matters therein stipulated, and shall be made part of the record.

(f) *Depositions of unavailable witnesses.*—(1) If a witness is unavailable to testify at a hearing and that witness has testified in a deposition in accordance with § 1209.32, a party may offer as evidence all or any part of the transcript of the deposition, including deposition exhibits, if any.

(2) Such deposition transcript is admissible to the same extent that testimony would have been admissible had that person testified at the hearing, provided that if a witness refused to answer proper questions during the depositions, the presiding officer may, on that basis, limit the admissibility of the deposition in any manner that justice requires.

(3) Only those portions of a deposition or related exhibits received in evidence at the hearing in accordance with this section shall constitute a part of the record.

§ 1209.52 Post-hearing filings.

(a) *Proposed findings and conclusions and supporting briefs.*—(1) Using the same method of service for each party, the presiding officer shall serve notice upon each party that the certified transcript, together with all hearing exhibits and exhibits introduced but not admitted into evidence at the hearing, has been filed with the presiding officer. Any party may file with the presiding officer proposed findings of fact, proposed conclusions of law and a proposed order within thirty (30) days after the parties have received notice that the transcript has been filed with the presiding officer, unless otherwise ordered by the presiding officer.

(2) Proposed findings and conclusions must be supported by citation to any relevant authorities and by page and line references to any relevant portions of the record. A post-hearing brief may be filed in support of proposed findings and conclusions, either as part of the same document or in a separate document.

(3) A party is deemed to have waived any issue not raised in proposed findings or conclusions timely filed by that party.

(b) *Reply briefs.* Reply briefs may be filed within fifteen (15) days after the date on which the parties' proposed findings and conclusions and proposed order are due. Reply briefs shall be limited strictly to responding to new matters, issues, or arguments raised by another party in papers filed in the proceeding. A party who has not filed proposed findings of fact and conclusions of law or a post-hearing brief may not file a reply brief.

(c) *Simultaneous filing required.* The presiding officer shall not order the filing by any party of any brief or reply brief supporting proposed findings and conclusions in advance of the other party's filing of its brief.

§ 1209.53 Recommended decision and filing of record.

(a) *Filing of recommended decision and record.* Within forty-five (45) days after expiration of the time allowed for filing reply briefs under § 1209.52(b), the presiding officer shall file with and certify to the Director, for decision, the record of the proceeding. The record must include the presiding officer's recommended decision, recommended findings of fact and conclusions of law, and proposed order; all pre-hearing and hearing transcripts, exhibits and rulings; and the motions, briefs, memoranda and other supporting papers filed in connection with the hearing. The presiding officer shall serve upon each party the recommended decision, recommended findings and conclusions, and proposed order.

(b) *Filing of index.* At the same time the presiding officer files with and certifies to the Director, for final determination, the record of the proceeding, the presiding officer shall furnish to the Director a certified index of the entire record of the proceeding. The certified index shall include, at a minimum, an entry for each paper, document or motion filed with the presiding officer in the proceeding, the date of the filing, and the identity of the filer. The certified index shall also include an exhibit index containing, at a minimum, an entry consisting of exhibit number and title or description for: Each exhibit introduced and admitted into evidence at the hearing; each exhibit introduced but not admitted into evidence at the hearing; each exhibit introduced and admitted into evidence after the completion of the hearing; and each exhibit introduced but not admitted into evidence after the completion of the hearing.

§ 1209.54 Exceptions to recommended decision.

(a) *Filing exceptions.* Within thirty (30) days after service of the recommended decision, recommended findings and conclusions, and proposed order under § 1209.53, a party may file with the Director written exceptions to the presiding officer's recommended decision, recommended findings and conclusions, and proposed order; to the admission or exclusion of evidence; or to the failure of the presiding officer to make a ruling proposed by a party. A supporting brief may be filed at the time the exceptions are filed, either as part of the same document or in a separate document.

(b) *Effect of failure to file or raise exceptions.*—(1) Failure of a party to file exceptions to those matters specified in paragraph (a) of this section within the time prescribed is deemed a waiver of objection thereto.

(2) No exception need be considered by the Director if the party taking exception had an opportunity to raise the same objection, issue, or argument before the presiding officer and failed to do so.

(c) *Contents.*—(1) All exceptions and briefs in support of such exceptions must be confined to the particular matters in or omissions from the presiding officer's recommendations to which that party takes exception.

(2) All exceptions and briefs in support of exceptions must set forth page or paragraph references to the specific parts of the presiding officer's recommendations to which exception is taken, the page or paragraph references to those portions of the record relied upon to support each exception and the legal authority relied upon to support each exception. Exceptions and briefs in support shall not exceed a total of 30 pages, except by leave of the Director on motion.

(3) One reply brief may be submitted by each party opposing the exceptions within ten (10) days of service of exceptions and briefs in support of exceptions. Reply briefs shall not exceed fifteen (15) pages, except by leave of the Director on motion.

§ 1209.55 Review by Director.

(a) *Notice of submission to the Director.* When the Director determines that the record in the proceeding is complete, the Director shall serve notice upon the parties that the case has been submitted to the Director for final decision.

(b) *Oral argument before the Director.* Upon the initiative of the Director or on the written request of any party filed with the Director within the time for filing exceptions, the Director may order and hear oral argument on the recommended findings, conclusions, decision and order of the presiding officer. A written request by a party must show good cause for oral argument and state reasons why arguments cannot be presented adequately in writing. A denial of a request for oral argument may be set forth in the Director's final decision. Oral argument before the Director must be transcribed.

(c) *Director's final decision.*—(1) Decisional employees may advise and assist the Director in the consideration and disposition of the case. The final decision of the Director will be based upon review of the entire record of the proceeding, except that the Director may limit the issues to be reviewed to those findings and conclusions to which opposing arguments or exceptions have been filed by the parties.

(2) The Director shall render a final decision and issue an appropriate order within ninety (90) days after notification to the parties that the case has been submitted for final decision, unless the Director orders that the action or any aspect thereof be remanded to the presiding officer for further proceedings. Copies of the final decision including findings of fact and an appropriate order of the Director shall be served upon each party to the proceeding and upon other persons as required by statute.

§ 1209.56 Exhaustion of administrative remedies.

To exhaust administrative remedies as to any issue on which a party disagrees with the presiding officer's recommendations, a party must file exceptions with the Director under § 1209.54. A party must exhaust administrative remedies as a precondition to seeking judicial review of any decision issued under subpart C of this part.

§ 1209.57 Stays pending judicial review.

The commencement of proceedings for judicial review of a final decision and order of the Director may not, unless specifically ordered by the Director or a reviewing court, operate as a stay of any order issued by the Director. The Director may, in his discretion and on such terms as he finds just, stay the effectiveness of all or any part of an order of the Director pending a final decision on a petition for review of that order.

§§ 1209.58 through 1209.69 [Reserved].

Subpart D—Parties and Representational Practice Before the Federal Housing Finance Agency; Standards of Conduct

§ 1209.70 Scope.

Subpart D contains rules governing practice by parties or their representatives before FHFA. This subpart addresses the imposition of sanctions by the presiding officer or the Director against parties or their representatives in an adjudicatory proceeding under this part. This subpart also covers other disciplinary sanctions—censure, suspension or disbarment—against individuals who appear before FHFA in a representational capacity either in an adjudicatory proceeding under this part or in any other matters connected with presentations to FHFA relating to a client's or other principal's rights, privileges, or liabilities. This representation includes, but is not limited to, the practice of attorneys and accountants. Employees of FHFA are not subject to disciplinary proceedings under this subpart.

§ 1209.71 Definitions.

Practice before FHFA for the purposes of subpart D of this part, includes, but is not limited to, transacting any business with FHFA as counsel, representative or agent for any other person, unless the Director orders otherwise. Practice before FHFA also includes the preparation of any statement, opinion, or other paper by a counsel, representative or agent that is filed with FHFA in any certification, notification, application, report, or other document, with the consent of such counsel, representative or agent. Practice before FHFA does not include work prepared for a regulated entity or entity-affiliated party solely at the request of such party for use in the ordinary course of its business.

§ 1209.72 Appearance and practice in adjudicatory proceedings.

(a) *Appearance before FHFA or a presiding officer.*—(1) *By attorneys.* A party may be represented by an attorney who is a member in good standing of the bar of the highest court of any State, commonwealth, possession, territory of the United States, or the District of Columbia and who is not currently suspended or disbarred from practice before FHFA.

(2) *By non-attorneys.* An individual may appear on his own behalf, *pro se.* A member of a partnership may represent the partnership and a duly authorized officer, director, employee, or other agent of any corporation or other entity not specifically listed herein may represent such corporation or other entity; provided that such officer, director, employee, or other agent is not currently suspended or disbarred from practice before FHFA. A duly authorized officer or employee of any Government unit, agency, or authority may represent that unit, agency, or authority.

(b) *Notice of appearance.* Any person appearing in a representative capacity on behalf of a party, including FHFA, shall execute and file a notice of appearance with the presiding officer at or before the time such person submits papers or otherwise appears on behalf of a party in the adjudicatory proceeding. Such notice of appearance shall include a written declaration that the individual is currently qualified as provided in paragraph (a)(1) or (a)(2) of this section and is authorized to represent the particular party. By filing a notice of appearance on behalf of a party in an adjudicatory proceeding, the representative thereby agrees and represents that he is authorized to accept service on behalf of the represented party and that, in the event of withdrawal from representation, he or she will, if required by the presiding officer, continue to accept service until a new representative has filed a notice of appearance or until the represented party indicates that he or she will proceed on a pro se basis. Unless the representative filing the notice is an attorney, the notice of appearance shall also be executed by the person represented or, if the person is not an individual, by the chief executive officer, or duly authorized officer of that person.

§ 1209.73 Conflicts of interest.

(a) *Conflict of interest in representation.* No representative shall represent another person in an adjudicatory proceeding if it reasonably appears that such representation may be limited materially by that representative's responsibilities to a third person or by that representative's own interests. The presiding officer may take corrective measures at any stage of a proceeding to cure a conflict of interest in representation, including the issuance of an order limiting the scope of representation or disqualifying an individual from appearing in a representative capacity for the duration of the proceeding.

(b) *Certification and waiver.* If any person appearing as counsel or other representative represents two or more parties to an adjudicatory proceeding, or also represents a nonparty on a matter

relevant to an issue in the proceeding, that representative must certify in writing at the time of filing the notice of appearance required by § 1209.72 as follows:

(1) That the representative has personally and fully discussed the possibility of conflicts of interest with each such party and nonparty; and

(2) That each such party and nonparty waives any right it might otherwise have had to assert any known conflicts of interest or to assert any non-material conflicts of interest during the course of the proceeding.

§ 1209.74 Sanctions.

(a) *General rule.* Appropriate sanctions may be imposed during the course of any proceeding when any party or representative of record has acted or failed to act in a manner required by applicable statute, regulation, or order, and that act or failure to act—

(1) Constitutes contemptuous conduct. Contemptuous conduct includes dilatory, obstructionist, egregious, contumacious, unethical, or other improper conduct at any phase of any proceeding, hearing, or appearance before a presiding officer or the Director;

(2) Has caused some other party material and substantive injury, including, but not limited to, incurring expenses including attorney's fees or experiencing prejudicial delay;

(3) Is a clear and unexcused violation of an applicable statute, regulation, or order; or

(4) Has delayed the proceeding unduly.

(b) *Sanctions.* Sanctions that may be imposed include, but are not limited to, any one or more of the following:

(1) Issuing an order against a party;

(2) Rejecting or striking any testimony or documentary evidence offered, or other papers filed, by the party;

(3) Precluding the party from contesting specific issues or findings;

(4) Precluding the party from offering certain evidence or from challenging or contesting certain evidence offered by another party;

(5) Precluding the party from making a late filing or conditioning a late filing on any terms that may be just; or

(6) Assessing reasonable expenses, including attorney's fees, incurred by any other party as a result of the improper action or failure to act.

(c) *Procedure for imposition of sanctions.*—(1) The presiding officer, on the motion of any party, or on his own motion, and after such notice and responses as may be directed by the presiding officer, may impose any sanction authorized by this section. The presiding officer shall submit to the Director for final ruling any sanction that would result in a final order that terminates the case on the merits or is otherwise dispositive of the case.

(2) Except as provided in paragraph (d) of this section, no sanction authorized by this section, other than refusing to accept late papers, shall be imposed without prior notice to all parties and an opportunity for any representative or party against whom sanctions may be imposed to be heard. The presiding officer shall determine and direct the appropriate notice and form for such opportunity to be heard. The opportunity to be heard may be limited to an opportunity to respond verbally immediately after the act or inaction in question is noted by the presiding officer.

(3) For purposes of interlocutory review, motions for the imposition of sanctions by any party and the imposition of sanctions shall be treated the same as motions for any other ruling by the presiding officer.

(4) Nothing in this section shall be read to preclude the presiding officer or the Director from taking any other action or imposing any other restriction or sanction authorized by any applicable statute or regulation.

(d) *Sanctions for contemptuous conduct.* If, during the course of any proceeding, a presiding officer finds any representative or any individual representing himself to have engaged in contemptuous conduct, the presiding officer may summarily suspend that individual from participating in that or any related proceeding or impose any other appropriate sanction.

§ 1209.75 Censure, suspension, disbarment, and reinstatement.

(a) *Discretionary censure, suspension and disbarment.*—(1) The Director may censure any individual who practices or attempts to practice before FHFA or suspend or revoke the privilege to appear or practice before FHFA of such individual if, after notice of and opportunity for hearing in the matter, that individual is found by the Director—

(i) Not to possess the requisite qualifications or competence to represent others;

(ii) To be seriously lacking in character or integrity or to have engaged in material unethical or improper professional conduct;

(iii) To have caused unfair and material injury or prejudice to another party, such as prejudicial delay or unnecessary expenses including attorney's fees;

(iv) To have engaged in, or aided and abetted, a material and knowing violation of the Safety and Soundness Act, the Federal Home Loan Mortgage Corporation Act, the Federal National Mortgage Association Charter Act, or the rules or regulations issued under those statutes, or any other applicable law or regulation;

(v) To have engaged in contemptuous conduct before FHFA;

(vi) With intent to defraud in any manner, to have willfully and knowingly deceived, misled, or threatened any client or prospective client; or

(vii) Within the last ten (10) years, to have been convicted of an offense involving moral turpitude, dishonesty or breach of trust, if the conviction has not been reversed on appeal. A conviction within the meaning of this paragraph shall be deemed to have occurred when the convicting court enters its judgment or order, regardless of whether an appeal is pending or could be taken and includes a judgment or an order on a plea of *nolo contendere* or on consent, regardless of whether a violation is admitted in the consent.

(2) Suspension or revocation on the grounds set forth in paragraphs (a)(1)(ii) through (vii) of this section shall only be ordered upon a further finding that the individual's conduct or character was sufficiently egregious as to justify suspension or revocation. Suspension or disbarment under this paragraph shall continue until the applicant has been reinstated by the Director for good cause shown or until, in the case of a suspension, the suspension period has expired.

(3) If the final order against the respondent is for censure, the individual may be permitted to practice before FHFA, but such individual's future representations may be subject to conditions designed to promote high standards of conduct. If a written letter of censure is issued, a copy will be maintained in FHFA's files.

(b) *Mandatory suspension and disbarment.*—(1) Any counsel who has been and remains suspended or disbarred by a court of the United States or of any State, commonwealth, possession, territory of the United States or the District of Columbia; any accountant or other licensed expert whose license to practice has been revoked in any State, commonwealth, possession, territory of the United States or the District of Columbia; any person who has been and remains suspended or barred from practice by or before the Department of Housing and Urban Development, the Office of the Comptroller of the Currency, the Board

of Governors of the Federal Reserve System, the Office of Thrift Supervision, the Federal Deposit Insurance Corporation, the National Credit Union Administration, the Federal Housing Finance Board, the Farm Credit Administration, the Securities and Exchange Commission, or the Commodity Futures Trading Commission is also suspended automatically from appearing or practicing before FHFA. A disbarment or suspension within the meaning of this paragraph shall be deemed to have occurred when the disbarring or suspending agency or tribunal enters its judgment or order, regardless of whether an appeal is pending or could be taken and regardless of whether a violation is admitted in the consent.

(2) A suspension or disbarment from practice before FHFA under paragraph (b)(1) of this section shall continue until the person suspended or disbarred is reinstated under paragraph (d)(2) of this section.

(c) *Notices to be filed.*—(1) Any individual appearing or practicing before FHFA who is the subject of an order, judgment, decree, or finding of the types set forth in paragraph (b)(1) of this section shall file promptly with the Director a copy thereof, together with any related opinion or statement of the agency or tribunal involved.

(2) Any individual appearing or practicing before FHFA who is or within the last 10 years has been convicted of a felony or of a misdemeanor that resulted in a sentence of prison term or in a fine or restitution order totaling more than $5,000 promptly shall file a notice with the Director. The notice shall include a copy of the order imposing the sentence or fine, together with any related opinion or statement of the court involved.

(d) *Reinstatement.*—(1) Unless otherwise ordered by the Director, an application for reinstatement for good cause may be made in writing by a person suspended or disbarred under paragraph (a)(1) of this section at any time more than three (3) years after the effective date of the suspension or disbarment and, thereafter, at any time more than one year after the person's most recent application for reinstatement. An applicant for reinstatement hereunder may, in the Director's sole discretion, be afforded a hearing.

(2) An application for reinstatement for good cause by any person suspended or disbarred under paragraph (b)(1) of this section may be filed at any time, but not less than one (1) year after the applicant's most recent application. An applicant for reinstatement for good cause hereunder may, in the Director's sole discretion, be afforded a hearing. If, however, all the grounds for suspension or disbarment under paragraph (b)(1) of this section have been removed by a reversal of the order of suspension or disbarment or by termination of the underlying suspension or disbarment, any person suspended or disbarred under paragraph (b)(1) of this section may apply immediately for reinstatement and shall be reinstated by FHFA upon written application notifying FHFA that the grounds have been removed.

(e) *Conferences.*—(1) *General.* Counsel for FHFA may confer with a proposed respondent concerning allegations of misconduct or other grounds for censure, disbarment or suspension, regardless of whether a proceeding for censure, disbarment or suspension has been commenced. If a conference results in a stipulation in connection with a proceeding in which the individual is the respondent, the stipulation may be entered in the record at the request of either party to the proceeding.

(2) *Resignation or voluntary suspension.* In order to avoid the institution of or a decision in a disbarment or suspension proceeding, a person who practices before FHFA may consent to censure, suspension or disbarment from practice. At the discretion of the Director, the individual may be censured, suspended or disbarred in accordance with the consent offered.

(f) *Hearings under this section.* Hearings conducted under this section shall be conducted in substantially the same manner as other hearings under this part, provided that in proceedings to terminate an existing FHFA suspension or disbarment order, the person seeking the termination of the order shall bear the burden of going forward with an application and with proof and that the Director may, in the Director's sole discretion, direct that any proceeding to terminate an existing suspension or disbarment by FHFA be limited to written submissions. All hearings held under this section shall be closed to the public unless the Director, on the Director's own motion or upon the request of a party, otherwise directs.

§§ 1209.76 through 1209.79 [Reserved].

Subpart E—Civil Money Penalty Inflation Adjustments

§ 1209.80 Inflation adjustments.

The maximum amount of each civil money penalty within FHFA's jurisdiction, as set by the Act and thereafter adjusted in accordance with the Inflation Adjustment Act, on a recurring four-year cycle, is as follows:

U.S. code citation	Description	Adjusted maximum penalty amount
12 U.S.C. 4636(b)(1)	First Tier	10,000
12 U.S.C. 4636(b)(2)	Second Tier	50,000
12 U.S.C. 4636(b)(4)	Third Tier (Entity-Affiliated party)	2,000,000
12 U.S.C. 4636(b)(4)	Third Tier (Regulated entity)	2,000,000

§ 1209.81 Applicability.

The inflation adjustments set out in § 1209.80 shall apply to civil money penalties assessed in accordance with the provisions of the Safety and Soundness Act, 12 U.S.C. 4636, and subparts B and C of this part, for violations occurring after the effective date of July 30, 2008.

§§ 1209.82 through 1209.99 [Reserved].

Subpart F—Suspension or Removal of an Entity-Affiliated Party Charged with Felony

§ 1209.100 Scope.

Subpart F of this part applies to informal hearings afforded to any entity-affiliated party who has been suspended, removed or prohibited from further participation in the business affairs of a regulated entity by a notice or order issued by the Director under section 1377(h) of the Safety and Soundness Act (12 U.S.C. 4636a(h)).

§ 1209.101 Suspension, removal, or prohibition.

(a) *Notice of suspension or prohibition.*—(1) As provided by section 1377(h)(1) of the Safety and Soundness

Act (12 U.S.C. 4636a(h)(1)), if an entity-affiliated party is charged in any information, indictment, or complaint, with the commission of or participation in a crime that involves dishonesty or breach of trust that is punishable by imprisonment for more than one (1) year under State or Federal law, the Director may, if continued service or participation by such party may pose a threat to the regulated entity or impair public confidence in the regulated entity, by written notice served upon such party, suspend such party from office or prohibit such party from further participation in any manner in the conduct of the affairs of any regulated entity.

(2) In accordance with section 1377(h)(1) of the Safety and Soundness Act (12 U.S.C. 4636a(h)(1)), the notice of suspension or prohibition is effective upon service. A copy of such notice will be served on the relevant regulated entity. The notice will state the basis for the suspension and the right of the party to request an informal hearing as provided in § 1209.102. The suspension or prohibition is to remain in effect until the information, indictment or complaint is finally disposed of, or until terminated by the Director, or otherwise as provided in paragraph (c) of this section.

(b) *Order of removal or prohibition.* As provided by section 1377(h)(2) of the Safety and Soundness Act (12 U.S.C. 4636a(h)(2)), at such time as a judgment of conviction is entered (or pretrial diversion or other plea bargain is agreed to) in connection with a crime as referred to above in paragraph (a) (the "conviction"), and the conviction is no longer subject to appellate review, the Director may, if continued service or participation by such party may pose a threat to the regulated entity or impair public confidence in the regulated entity, issue an order removing such party from office or prohibiting such party from further participation in any manner in the conduct of the affairs of the regulated entity without the prior written consent of the Director. A copy of such order will be served on the relevant regulated entity at which time the entity-affiliated party shall immediately cease to be director or officer of the regulated entity. The notice will state the basis for the removal or prohibition and the right of the party to request a hearing as provided in § 1209.102.

(c) *Effective period.* Unless terminated by the Director, a notice of suspension or order of removal issued under section 1377(h)(1) or (2) of the Safety and Soundness Act (12 U.S.C. 4636a(h)(1),(2)) shall remain effective and outstanding until the completion of any informal hearing or appeal provided under section 1377(h)(4) of the Safety and Soundness Act (12 U.S.C. 4636a(h)(4)). The pendency of an informal hearing, if any, does not stay any notice of suspension or prohibition or order of removal or prohibition under subpart F of this part.

(d) *Effect of acquittal.* As provided by section 1377(h)(2)(B)(ii) of the Safety and Soundness Act (12 U.S.C. 4636a(h)(2)(B)(ii)), a finding of not guilty or other disposition of the charge does not preclude the Director from instituting removal, suspension, or prohibition proceedings under section 1377(a) or (b) of the Safety and Soundness Act (12 U.S.C. 4636a(a),(b)).

(e) *Preservation of authority.* Action by the Director under section 1377(h) of the Safety and Soundness Act (12 U.S.C. 4636a(h)), shall not be deemed as a predicate or a bar to any other regulatory, supervisory, or enforcement action under the Safety and Soundness Act.

§ 1209.102 Hearing on removal or suspension.

(a) *Hearing requests.*—(1) *Deadline.* An entity-affiliated party served with a notice of suspension or prohibition or an order of removal or prohibition, within thirty (30) days of service of such notice or order, may submit to the Director a written request to appear before the Director to show that his or her continued service or participation in the affairs of the regulated entity will not pose a threat to the interests of, or threaten to impair public confidence in, the Enterprises or the Banks. The request must be addressed to the Director and sent to the Federal Housing Finance Agency at 1700 G Street, NW., Washington, DC 20552, by:

(i) Overnight U.S. Postal Service delivery or delivery by a reliable commercial delivery service for same day or overnight delivery to the address stated above; or

(ii) First class, registered, or certified mail via the U.S. Postal Service.

(2) *Waiver of appearance.* An entity-affiliated party may elect in writing to waive his right to appear to make a statement in person or through counsel and have the matter determined solely on the basis of his written submission.

(b) *Form and timing of hearing.*—(1) *Informal hearing.* Hearings under subpart F of this part are not subject to the formal adjudication provisions of the Administrative Procedure Act (5 U.S.C. 554 through 557), and are not conducted under subpart C of this part.

(2) *Setting of the hearing.* Upon receipt of a timely request for a hearing, the Director will give written notice and set a date within thirty (30) days for the entity-affiliated party to appear, personally or through counsel, before the Director or his designee(s) to submit written materials (or, at the discretion of the Director, oral testimony and oral argument) to make the necessary showing under paragraph (a) of this section. The entity-affiliated party may submit a written request for additional time for the hearing to commence, without undue delay, and the Director may extend the hearing date for a specified time.

(3) *Oral testimony.* The Director or his designee, in his discretion, may deny, permit, or limit oral testimony in the hearing.

(c) *Conduct of the hearing.*—(1) *Hearing officer.* A hearing under this section may be presided over by the Director or one or more designated FHFA employees, except that an officer designated by the Director (hearing officer) to conduct the hearing may not have been involved in an underlying criminal proceeding, a factually related proceeding, or an enforcement proceeding in a prosecutorial or investigative role. This provision does not preclude the Director otherwise from seeking information on the matters at issue from appropriate FHFA staff on an as needed basis consistent with § 1209.101(d)(2).

(2) *Submissions.* All submissions of the requestor and agency counsel must be received by the Director or his designee no later than ten (10) days prior to the date set for the hearing. FHFA may respond in writing to the requestor's submission and serve the requestor (and any other interested party such as the regulated entity) not later than the date fixed by the hearing officer for submissions or other time period as the hearing officer may require.

(3) *Procedures.*—(i) *Fact finding authority of the hearing officer.* The hearing officer shall determine all procedural matters under subpart F of this part, permit or limit the appearance of witnesses in accordance with paragraph (b)(3) of this section, and impose time limits as he or she deems reasonable. All oral statements, witness testimony, if permitted, and documents submitted that are found by the hearing officer to be materially relevant to the proceeding and not unduly repetitious may be considered. The hearing officer may question any person appearing in the proceeding, and may make any ruling reasonably necessary to ensure the full and fair presentation of evidence and to facilitate the efficient

and effective operation of the proceeding.

(ii) *Statements to an officer.* Any oral or written statement made to the Director, a hearing officer, or any FHFA employee under subpart F of this part is deemed to be a statement made to a Federal officer or agency within the meaning of 18 U.S.C. 1006.

(iii) *Oral testimony.* If either the requestor or agency counsel desires to present oral testimony to supplement the party's written submission he must make a request in writing to the hearing officer not later than ten (10) days prior to the hearing, as provided in paragraph (c)(2) of this section, or within a shorter time period as permitted by the hearing officer for good cause shown. The request should include the name of the individual(s), a statement generally descriptive of the expected testimony, and the reasons why such oral testimony is warranted. The hearing officer generally will not admit witnesses, absent a strong showing of specific and compelling need. Witnesses, if admitted, shall be sworn.

(iv) *Written materials.* Each party must file a copy of any affidavit, memorandum, or other written material to be presented at the hearing with the hearing officer and serve copies on any other interested party (such as the affected regulated entity) not later than ten (10) days prior to commencement of the informal hearing, as provided in paragraph (c)(2), or within a shorter time period as permitted by the hearing officer for good cause shown.

(v) *Relief.* The purpose of the hearing is to determine whether the suspension or prohibition from participation in any manner in the conduct of the affairs of the regulated entity will be continued, terminated or otherwise modified, or whether the order removing such party from office or prohibiting the party from further participation in any manner in the conduct of the affairs of the regulated entity will be rescinded or otherwise modified.

(vi) *Ultimate question.* In deciding on any request for relief from a notice of suspension or prohibition, the hearing officer shall not consider the ultimate question of guilt or innocence with respect to the outstanding criminal charge(s). In deciding on a request for relief from a removal order, the hearing officer shall not consider challenges to or efforts to impeach the validity of the conviction. In either case, the hearing officer may consider facts that show the nature of the events on which the conviction or charges were based.

(4) *Record.* If warranted under the circumstances of the matter, the hearing officer may require that a transcript of the proceedings be prepared at the expense of the requesting party. The hearing officer may order the record be kept open for a reasonable time following the hearing, not to exceed five (5) business days, to permit the filing of additional pertinent submissions for the record. Thereafter, no further submissions are to be admitted to the record, absent good cause shown.

§ 1209.103 Recommended and final decisions.

(a) *Recommended decision.*—(1) *Written recommended decision of the hearing officer.* Not later than twenty (20) days following the close of the hearing (or if the requestor waived a hearing, from the deadline for submission of the written materials), the hearing officer will serve a copy of the recommended decision on the parties to the proceeding. The recommended decision must include a summary of the findings, the parties' respective arguments, and support for the determination.

(2) *Five-day comment period.* Not later than five (5) business days after receipt of the recommended decision, the parties shall submit written comments in response to the recommended decision, if any, to the hearing officer. The hearing officer shall not grant any extension of the stated time for responses to a recommended decision.

(3) *Recommended decision to be transmitted to the Director.* The hearing officer shall promptly forward the recommended decision, and written comments, if any, and the record to the Director for final determination.

(b) *Decision of the Director.* Within sixty (60) days of the date of the hearing, or if the requestor waived a hearing the date fixed for the hearing, the Director will notify the entity-affiliated party in writing by registered mail of the disposition of his request for relief from the notice of suspension or prohibition or the order of removal or prohibition. The decision will state whether the suspension or prohibition will be continued, terminated or otherwise modified, or whether the order removing such party from any participation in the affairs of the regulated entity will be rescinded or otherwise modified. The decision will contain a brief statement of the basis for an adverse determination. The Director's decision is a final and non-appealable order.

(c) *Effect of notice or order.* A removal or prohibition by order shall remain in effect until terminated by the Director. A suspension or prohibition by notice remains in effect until the criminal charge is disposed of or until terminated by the Director.

(d) *Reconsideration.* A suspended or removed entity-affiliated party subsequently may petition the Director to reconsider the final decision any time after the expiration of a twelve (12) month period from the date of the decision, but no such request may be made within twelve (12) months of a previous petition for reconsideration. An entity-affiliated party must submit a petition for reconsideration in writing; the petition shall state the specific grounds for relief from the notice of suspension or order or removal and be supported by a memorandum and any other documentation materially relevant to the request for reconsideration. No hearing will be held on a petition for reconsideration, and the Director will inform the requestor of the disposition of the reconsideration request in a timely manner. A decision on a request for reconsideration shall not constitute an appealable order.

CHAPTER XVII—OFFICE OF FEDERAL HOUSING ENTERPRISE OVERSIGHT, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Subchapter D—Rules of Practice and Procedure

PART 1780—[REMOVED]

3. Remove 12 CFR Part 1780.

Dated: August 3, 2010.

Edward J. DeMarco,

Acting Director, Federal Housing Finance Agency.

[FR Doc. 2010–19567 Filed 8–11–10; 8:45 am]

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