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The New Proposed Safe Harbours for Certain Managed Care Plans and Risk-Sharing Arrangements: A History, Analysis, and Comparison with Existing Safe Harbors and Federal Regulations

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THE NEW PROPOSED SAFE HARBORS FOR CERTAIN MANAGED CARE PLANS AND RISK-SHARING ARRANGEMENTS: A HISTORY, ANALYSIS, AND COMPARISON WITH EXISTING SAFE HARBORS AND FEDERAL REGULATIONS

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I. INTRODUCTION

THE PURPOSE OF THIS ARTICLE is to present a brief history and analysis of the recently proposed safe harbors under the Anti-Kickback Statute[1] for managed care plans and risk-sharing arrangements. By proceeding chronologically through the official discussions and negotiations that culminated in the proposed safe harbors, the reader will develop an appreciation for the underlying policies upon which they are founded. After completing this historical overview, the safe harbors will then be analyzed in detail with special attention given to potential problems likely to develop if the rule is implemented as it now reads. In addition, where possible, comparisons will be made to existing regulations governing physician incentive plans and safe harbors which already exempt certain health plans from the Anti-Kickback Statute.

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[1] *See generally* 42 U.S.C. § 1320a-7b(b) (1994) (making it a felony to knowingly accept or solicit remuneration for referring individuals for services which may not be paid for by a state or federal health care program and making it a felony to make an offer of such payment).

II. HISTORY

The Anti-Kickback Statute, enacted in 1972, provides criminal penalties for individuals or entities who knowingly and willfully offer, pay, solicit, or receive bribes, kickbacks, or other remuneration in order to induce business reimbursed by Medicare, Medicaid, and other federal health care programs. The language of the statute is very broad and there has been much concern since its enactment that many innocuous and even beneficial arrangements are prohibited by the literal language of the statute. Consequently, in 1987, Congress enacted the Medicare and Medicaid Patient and Program Protection Act[2] which authorizes the Department of Health and Human Services (HHS) to promulgate regulations "specifying payment practices that shall not be treated as a criminal offense under [42 U.S.C. § 1320a-7b] and shall not serve as the basis for an exclusion under [42 U.S.C. § 1320a-7b(b)(7)]." These regulations are commonly referred to as "safe harbors." To date, HHS has promulgated two final rules, creating a total of thirteen safe harbors under the Anti-Kickback Statute.[3]

Section 216 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[4] amended the Anti-Kickback Statute to include additional exceptions to what would otherwise be prohibited "remuneration" under the statute. One of these exceptions was for certain types of managed care arrangements:

> [A]ny remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1395mm [of the Social Security Act] *or* if the written agreement, through a risk-sharing arrangement, places the individual

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[2] *See generally* Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93, 101 Stat. 680 (codified as amended in scattered sections of 42 U.S.C. (1994)) (amending the Social Security Act to provide greater protection for beneficiaries of the health care programs under that Act).

[3] *See* 56 Fed. Reg. 35,952 (1991) (implementing section 14 of Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987); 61 Fed. Reg. 2,122 (1996) (to be codified at 42 C.F.R. pt. 1001) (discussing the publication of two new safe harbors).

[4] Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 42 U.S.C. (1994)) (amending the Anti-Kickback Statute to add exceptions for acts which would otherwise be prohibited).

> or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide.[5]

Upon closer examination, it becomes apparent that there are actually two parts to this exception.[6] Each part focuses on a different type of conduct to be removed from the definition of "remuneration." The first part exempts remuneration between an "eligible organization" and an individual or entity providing items or services pursuant to a written agreement between the parties. In contrast, the second part exempts remuneration between an organization and an individual or entity if a written agreement places the individual or entity at substantial financial risk for the cost or utilization of items or services.

The Office of the Inspector General (OIG) of HHS was statutorily mandated by section 216 of HIPAA to establish a negotiated rulemaking committee under the Negotiated Rulemaking Act[7] and

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[5] 42 U.S.C. § 1320a-7b(b)(3)(F) (listing exceptions to the types of activities that will be considered felonious in terms of referring people for services in exchange for financial "kickbacks") (emphasis added).

[6] For the sake of adding clarity to an area of law where little exists, the statutory exception will be referred to as consisting of two "parts," whereas the proposed interim final rule (discussed *infra*) will be referred to as having two "prongs." Some sources use the terms interchangeably, causing confusion to the reader. Hopefully, that problem will be avoided by use of this convention.

[7] *See* Negotiated Rulemaking Act of 1990, 5 U.S.C. § 561-69 (1994). The Negotiated Rulemaking Act of 1990 provides a framework for conducting negotiated rulemaking and "encourages agencies to use negotiated rulemaking to enhance the informal rulemaking process." 62 Fed. Reg. 28,420 (1997) (to be codified at 42 C.F.R. pt. 1001). The Act requires the head of an agency to consider if:

1. There is a need for a rule;
2. There are a limited number of identifiable interests that will be significantly affected by the rule;
3. There is a reasonable likelihood that a committee can be convened with a balanced representation of persons who can adequately represent the identified interests and are willing to negotiate in good faith to reach a consensus;
4. There is a reasonable likelihood that the committee will reach a consensus on the rulemaking within a specific period of time;
5. The negotiated rulemaking process will not unreasonably interfere with the development and issuance of a final rule;
6. The agency has adequate resources and is willing to commit such resources, including technical assistance, to the committee; and
7. The agency, to the maximum extent possible consistent with the legal obligations of the agency, will use the consensus of the committee with respect to developing the rule proposed by the agency for notice and comment.

See 5 U.S.C. § 563 (a).

to follow the standards for formation and use of advisory committees pursuant to the Federal Advisory Committee Act (FACA).[8] The purpose of the committee would be to negotiate the development of an interim final rule interpreting these exceptions to the Anti-Kickback Statute. Specifically, the rule should create a safe harbor for:

> (1) arrangements in which the [federal] government makes a fixed payment to a Medicare health maintenance organization [(i.e., the first part of the exception)] and
>
> (2) arrangements in which providers of medical services are put at substantial financial risk for the items and services ordered and reimbursed by Medicare on a fee-for-service basis [(i.e., the second part of the exception)].[9]

In creating this rule, the Committee would need to consider the following factors:

> (1) the level of risk appropriate to the size and type of arrangement;
> (2) the frequency of assessment and distribution of incentives;
> (3) the level of capital contribution; and
> (3) the extent to which the risk-sharing arrangement provides incentives to control the cost and quality of health care services.[10]

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[8] 5 U.S.C. app. § 2 (1998) (establishing the Negotiated Rulemaking Committee in accordance with the Federal Advisory Committee Act). Negotiations are conducted by a committee chartered under the FACA. Federal agencies are required to comply with the FACA if they develop or use a group that includes non-federal members as a source of advice. The committee must include an agency representative and an impartial facilitator. Its purpose is to reach a consensus on the language or issues involved in a rule. If a consensus is reached, it is used as the basis for the interim final rule. The rulemaking process does not affect the procedural requirements of the FACA, the Administrative Procedure Act, or other statutes. *See* 62 Fed. Reg. 28,410 (to be codified at 42 C.F.R. pt. 1001) (citing the purpose and goals of the Negotiated Rulemaking Committee).

[9] Ursula Himali, *Advisory Group Gives Seal of Approval to Anti-Kickback Safe Harbor*, 2 HEALTH CARE FRAUD REP. (BNA) 69, 69 (Jan. 28, 1998) (discussing the Negotiated Rulemaking Committee's two-pronged proposal to expand safe harbor protection under the Anti-Kickback Statute).

[10] 62 Fed. Reg. at 28,411.

On May 23, 1997, HHS announced in the *Federal Register* its intent to form such a committee[11] which later became known as the Negotiated Rulemaking Committee for the Shared Risk Exception (the Committee).[12] HHS stated that the Committee would consist of persons representing interests likely to be substantially affected by the interim rule[13] and would be assisted by an impartial facili-

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[11] *See id.* at 28,410.

[12] The name of the Committee is somewhat of a misnomer because its purpose was to draft "safe harbors" – not "exceptions" – for managed care plans and risk-sharing arrangements. This distinction is important in that exceptions to the Anti-Kickback Statute are enacted only by Congress and are specified within the statute itself. Safe harbors, on the other hand, are rules promulgated by HCFA, published in the *Federal Register*, and subsequently codified in the *Code of Federal Regulations* as administrative regulations. Under the Anti-Kickback Statute, if an individual's or entity's conduct on its face is prohibited, and that conduct does not come within the scope of a safe harbor, the most that can be said is that the individual or entity *may* have violated the statute. Safe harbors only guarantee protection to individuals or entities that satisfy their criteria. One cannot infer that conduct which fails to satisfy the requirements of any safe harbor necessarily violates the Anti-Kickback Statute. Contrast this with the physician self-referral statutes ("Stark laws"), for which there are no safe harbors, only exceptions which can be implemented either legislatively by Congress or administratively by HCFA. *See* Omnibus Budget Reconciliation Act of 1989, § 6204, 42 U.S.C.A. § 1395nn (West Supp. 1998). If a physician's conduct on its face is prohibited by the Stark laws, and that conduct does not come within an exception (as contained within either the statute or regulations), he or she has violated the statute.

[13] HHS specified that the following organizations would be represented in the Committee:

American Association of Health Plans
American Association of Retired Persons
American Health Care Association
American Hospital Association
American Medical Association
American Medical Group Association
Blue Cross Blue Shield Association
Consumer Coalition on Quality in Health Care
Coordinated Care Coalition
Department of Justice
Federation of American Health Systems
Health Industry Manufacturers Association
Health Insurance Association of America
National Association of Community Health Centers
Independent Insurance Agents of America/National Association of Health Underwriters
National Association of Medicaid Fraud Control Units
National Association of State Medicaid Directors
National Rural Health Association
Pharmaceutical Research and Manufacturers Association
The IPA Association of America

62 Fed. Reg. at 28,411-12.

tator.[14] Although the list of participants is limited, "[t]he intent in establishing the negotiating committee is that all interests are represented, not necessarily all parties."[15] HHS set a deadline for the Committee to reach a consensus[16] on part or all of the interim final rule within six months after the Committee's first meeting.[17] The Committee is then to recommend through the OIG, that the Secretary of Health and Human Services adopt the Committee's consensus.[18] Subsequently, the interim final rule by HHS will be published in the *Federal Register*, followed by a sixty-day comment period.[19] The Committee may later recommend specific changes to the interim final rule in response to comments received by HHS.[20]

As a guideline, HHS initially identified for the Committee several terms in the exception that required clarification:

1. "Written agreement"
   a. What should it contain?
   b. Should it be of a minimum duration?
   c. Should unwritten side agreements be prohibited?
2. "Eligible organization"
   a. Is this term limited to Medicare risk contractors and arrangements for services provided under Medicare contracts, or is it broader?
   b. Does the exception apply to remuneration only if it is part of an agreement where an "eligible organization" is a party, or does it also apply to

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[14] *Id.* at 28,410 (stating that the Committee will include an agency representative from the Department of Health and Human Services in addition to being assisted by an impartial facilitator).

[15] *Id.* at 28,412.

[16] "Consensus," according to the Negotiated Rulemaking Act, consists of each represented interest concurring in the result, unless the term is defined otherwise by the Committee. The Committee subsequently defined "consensus" as "unanimous concurrence of those present." *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *Minutes* (Negotiation Session, July 28-30, 1997) (last modified Sept. 3, 1998) <http://www.dhhs.gov/progorg/oig/negrule/index.htm> at 1.

[17] *See* 62 Fed. Reg. at 28412. The Committee failed to meet this deadline by more than a month.

[18] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *Charter* (last modified Sept. 3, 1998) (visited Nov. 16, 1998) <http://www.dhhs.gov/progorg/oig/negrule/index.htm> (setting forth purpose, authority, functions, structure, meetings, compensation, cost estimates, reports, and termination date of the Committee).

[19] *See* Himali, *supra* note 9, at 71 (explaining the process by which the general outline for expanding safe harbor protection will become an interim final rule).

[20] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 18.

"downstream" agreements, such as between a physician and a physician group that has an agreement with a health maintenance organization?

c. Are "organization," as it is implicitly used in the second part of the exception, and "eligible organization" synonymous?

3. "Individual or entity providing items or services or a combination thereof"

a. Would this include entities such as pharmaceutical companies or device manufacturers providing combinations of items and services?

b. When would these combinations constitute "bundling" that could be harmful to the federal health care programs without further protection?

c. Would "services" be limited to health care services, or could they include such things as marketing services?

4. "Substantial financial risk"

a. What factors should be considered in determining if substantial financial risk exists?

b. Should special treatment be given to encourage providers to assume risk where they usually do not, or where risk is difficult to measure?[21]

In the months that followed, the Committee discussed all of these issues, as well as many others, in an effort to create a comprehensible framework within which to apply the statutory exception fairly to health care providers. Each of the seven meetings will be discussed in chronological order to give the reader an appreciation for the types of difficulties faced by members of the Committee in dealing with this task. Not every detail of these meetings will be recounted — only those which help to explain the basis for the provisions contained in the proposed interim final rule.

1. June Meeting

The first organizational meeting of the Committee was held in June 1997. At this meeting, the Committee decided that "remuneration" is adequately defined by the statute and would not need

[21] *See* 62 Fed. Reg. at 28,411 (describing specific issues for discussion).

to be defined any further in the interim final rule.[22] The members also noted that "eligible organization" is defined by the Social Security Act though there is no corresponding definition for what is simply meant by an "organization."[23] However, none of the members believed that "organization" should be limited to only health maintenance organizations (HMOs).[24] Although the members agreed that the statutory exception consisted of the two parts discussed previously,[25] they nonetheless realized that other various terms in the statutory exception required clarification in the interim final rule and that these issues would be discussed in subsequent meetings.[26]

2. July Meeting

At the Committee's negotiation session in July 1997, members identified what they considered to be the purposes of the shared risk exception: (1) reduce compliance costs; (2) avoid interference with developing risk-sharing arrangements that benefit the market; (3) protect patients against underutilization; (4) provide clarity because of the possibility of criminal prosecution; (5) prevent "sham" arrangements; and, (6) define legitimate risk-sharing arrangements.[27] The second and sixth purposes were designated as the most important.[28] Most of this meeting was spent discussing "substantial financial risk." One member suggested using the twenty-five percent standard applied to physician incentive plans by the Physician Incentive Plan (PIP) Regulations.[29] (See discussion in Part III.B.4.c.) However, the Committee predicted that there would be numerous potential problems with copying this standard. First, it would be difficult to apply the twenty-five per-

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[22] Negotiated Rulemaking Comm. for the Shared Risk Exception, *Minutes* (Organizational Meeting, June 17-18, 1997) (last modified Sept. 3, 1998) <http://www.dhhs.gov/progorg/oig/negrule/index.htm> at 10 (declining to define "remuneration").

[23] *Id.* (discussing the need to define "organization").

[24] *Id.* (noting that Committee members indicated that such a limit would not apply to the definition of "organization").

[25] *Id.* at 11 (defining the two parts of the statutory exception).

[26] *Id.* (identifying terms to be clarified in subsequent meetings).

[27] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 16, at 3-4.

[28] *Id.* at 4 (emphasizing two priority goals while noting Committee disagreement on other goals).

[29] *Id.* at 7 (stating that the member acknowledged that applying this standard to providers other than physicians was still questionable due to different payment methods).

cent rule to providers other than physicians where the method of payment is different.[30] Second, based on the Health Care Financing Administration's (HCFA) rationale for setting the standard at twenty-five percent, this percentage arguably would not be set high enough because of changes in the marketplace since the PIP Regulations were promulgated.[31] Third, there is a "reasonable middle" (an area below the threshold where there is still an incentive not to overutilize) not addressed in the PIP Regulations.[32] Fourth, the PIP Regulations are different because they only cover referrals and physicians.[33] Fifth, the PIP Regulations are based only on theory, and not on performance because there is no information to indicate a nexus between incentives and quality of care.[34] Sixth, Congress recognized that one percentage measure would not necessarily be appropriate for all types of providers.[35]

The Committee did, however, reach a consensus on two issues: (1) "or a combination thereof" in the second part of the exception means that the risk could be for items, services, or both; and, (2) "obligated to provide" refers to those items or services which the provider is obligated to provide according to the written agreement between it and the beneficiary rather than by statute.[36] (This definition of "obligated to provide" is in conformity with the comments to the PIP Regulations.) The Committee left open a third issue of whether the exception covers anything other than what the provider furnishes directly, including if a referral is itself a service.[37] Two options were considered for resolving this issue. Under the first option, only services which the provider furnishes directly or for which the provider is financially responsible (i.e., subcontracts) would be covered;[38] the exception would not cover a PIP that takes into account what a physician orders from a laboratory or hospital.[39] On the other hand, the second option would

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[30] *Id.*

[31] *Id.* (indicating a member's concerns about the 25% standard).

[32] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 16, at 7.

[33] *Id.* at 7-8.

[34] *Id.* at 8.

[35] *Id.* (stating the last of four main objections other members of the Committee had to the proposed 25% standard).

[36] *Id.* at 14-15 (noting that the facilitators indicated that the consensus was on broad concepts and on principle, rather than on exact language as presented).

[37] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 16, at 15.

[38] *Id.*

[39] *Id.*

cover the following: (1) what the provider furnishes directly; (2) items or services for which the provider is financially responsible; and, (3) items or services for which the physician could be financially rewarded.[40] For example, an incentive arrangement in which the incentive is tied to utilization of hospital services would be one in which the physician is financially rewarded.[41] The rationale for this second option is "that physician services such as referring a patient for laboratory services or admitting a patient to a hospital could be considered services that the physician is obligated to provide when they are medically necessary for the patient. A different interpretation . . . would put a chill on physician risk arrangements and lose the benefits from incentives that affect physician behavior."[42] Consequently, the Committee was faced with resolving how to treat subcontracting and other "downstream" arrangements under the statutory exception. Indeed, this would become one of the major issues debated by the Committee.

3. September Meeting

The Committee held its third meeting in September 1997. Members discussed a number of issues related to the second part of the exception. First, should it only apply to "first tier" contracts (i.e., incentive arrangements between the organization and the first level contractor), or should "downstream" arrangements also be protected?[43] Second, should "organization" be limited to "health plans" as that term is defined in other safe harbors?[44] The Committee noted a number of problems with placing these limitations on the exception: (1) it would exclude most existing risk-sharing arrangements; (2) the market might be better off if flexibility is permitted; (3) it would discourage subcontracting and encourage aggregation into one level; (4) the effect would be that no risk would be assumed at the provider level where the most opportunity exists to manage risk and control costs; (5) reserving protection for the first tier would not provide a safe harbor for individuals and entities at lower levels; (6) most health plans are already covered

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[40] *Id.*

[41] *Id.*

[42] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 16, at 15 (providing a rationale for the first option).

[43] Negotiated Rulemaking Comm. for the Shared Risk Exception, *Minutes* (Meeting, Sept. 9-10, 1997) (last modified Sept. 3, 1998) (visited Nov. 16, 1998) <http://www.dhhs.gov/progorg/oig/negrule/index.htm> at 6 (explaining the qualifications of the "top relationship between the MCO and first-level contractor").

[44] *Id.* at 6 (defining "organization" as a "health plan").

under the prepaid plan safe harbor;[45] (7) if lower levels do not have an incentive to manage risks, the effectiveness of the first tier arrangements will be undermined; and, (8) a majority of provider types would have arrangements that are unprotected.[46] Although the Committee did not resolve these issues at the September meeting, it ultimately determined that "downstream" contracts should be protected if certain requirements are met and "organization" should be defined more broadly than "health plan." (See discussion following in Part III.B.1.)

The third issue the Committee discussed was what items or services the individual or entity is "obligated to provide" under the second part of the exception. The Committee reached a consensus that this requirement would include two categories of items or services.[47] The first category includes items or services that are provided *directly* by the individual or entity or its employees.[48] The second category includes items or services for which the individual or entity is *financially responsible.*[49] This second category includes subcontracts if: (1) the individual or entity pays the subcontractor, (2) the organization pays the subcontractor on behalf of the individual or entity, or (3) the subcontractor is paid by reinsurance obtained by the individual or entity.[50] The possibility that the individual or entity would also be "obligated to provide" those items or services for which it does not receive payment but for which it may be rewarded was discussed as well.[51] This last category would include two subcategories. The first subcategory includes arrangements in which there is a close relationship between the compensation received by the individual or entity and specific items or services.[52] The second subcategory includes arrangements in which compensation is tied collectively to efficiencies.[53] The

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[45] *See* 42 C.F.R. § 1001.952 (l) (1997) (defining "health plan" very broadly); *see also* 42 C.F.R. § 1001.952 (m) (describing another safe harbor for price reductions offered in such health plans).

[46] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 43, at 6-7 (explaining the needs and concerns of those who did not concur with the Committee).

[47] *Id.* at 15 (explaining that of the three categories discussed by the Committee, the first two are covered by the phrase "obligated to provide").

[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 43, at 15 (explaining that the committee spoke of a third category).

[52] *Id.*

[53] *Id.*

Committee distinguished the two subcategories in a later meeting by considering an HMO physician incentive plan. In this situation, there would be a "close relationship between the compensation" and "particular items or services" if the panel of doctors whose risk is collectively considered is small (such as a group of ten doctors).[54] As the number of doctors who share in the risk increases, dilution will occur.[55] The second subcategory would begin "at the undefined point where there is a diminished effect on utilization."[56] Ultimately, the Committee included this last category of items or services in its proposed interim final rule as a matter to be adopted by the "HHS Regulatory Authority."[57]

The fourth issue addressed by the Committee concerned the term "substantial financial risk" in the second part of the exception. First, the Committee discussed what effect "pooling" of risk would have on "substantial financial risk." As discussed previously, this concept is also integral to the PIP Regulations. One member summarized "pooling" as follows: "If you aggregate lives across plans or product lines, the amount of risk is reduced. This is recognized in the PIP [Regulations], which allow . . . for less comprehensive stop-loss protection if more lives are involved. The more you aggregate, the more risk can be assumed because the risk becomes more predictable."[58] However, this same individual pointed out that the problem with pooling is that "to promote efficient delivery, you want the risk to have an impact. If you have ten doctors' groups, one of which is doing poorly, there is less incentive for them to improve if there is pooling of risk and the others do well."[59] Another problem is "that if you make the exception broader, to encompass pooling, the arrangement might include one risky deal (that seemed to be substantial financial risk) and one 'sweetheart' deal that meant the risk was not real."[60] Consequently,

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[54] Negotiated Rulemaking Comm. for the Shared Risk Exception, *Minutes* (Meeting Oct. 8-10, 1997) (last modified Sept. 3, 1998) <http://www.dhhs.gov/progorg/oig/negrule/index.htm> at 15 (meeting to resolve issues of September 1997 Committee meeting).

[55] *Id.* (providing a discussion of options for issues on what items and services are covered).

[56] *Id.* at 15-16.

[57] *See* discussion *infra*, Part III.A.1.

[58] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 43, at 17-18 (indicating the effect of pooling risk on whether it is "substantial financial risk").

[59] *Id.* at 18 (providing an example showing how there is less incentive).

[60] *Id.*

no consensus was reached as to this issue during the September meeting.

A second aspect of "substantial financial risk" discussed by the Committee was whether this concept should be defined in numerical or non-numerical terms. Members advanced a number of arguments favoring one over the other.[61] However, the primary arguments for numerical and non-numerical definitions are that the former would provide a bright line test and the latter would provide a flexible test that allows for variations in the market.[62] Likewise, the primary arguments against numerical and non-numerical definitions are that the former would not take into account differences among providers and the latter would create a "gray area," consequently failing to satisfy the amount of clarity that is required for a criminal statute.[63] As a result, the Committee was unable to achieve a consensus as to this aspect of "substantial financial risk," as well.

The fifth issue addressed (and resolved) by the Committee was that for risk-sharing arrangements between an organization and an individual or an entity, there is no functional difference between "withhold" and "bonus" because one could be made to look like the other.[64] The Committee did, however, later define "bonus" as an arrangement in which "there is no withhold of a portion of provider fees, but where a pool is created that providers can access when they meet a predetermined utilization budget or quality measure . . .[it] might be an aggregate amount, tied to performance of the whole network, not just individual performance."[65]

4. October Meeting

At this meeting, the Committee considered how to define a numerical standard for calculating "substantial financial risk" and the concept of "swapping." Three alternatives for a numerical standard were presented. Only the second alternative will be discussed to avoid confusion and because it provided the rudimentary basis for the standard which the Committee ultimately adopted. Under this alternative, the percent of risk is determined by divid-

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[61] *Id.* at 19-20 (discussing the needs and concerns of both definitions).

[62] *Id.* at 19 (explaining what might happen if a bright line is drawn).

[63] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 43, at 19-20 (explaining the major criticism in the anti-kickback area).

[64] *Id.* at 39.

[65] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 54, at 12 (defining, in contrast, a substantial fee withhold as a fee withhold that is large enough to influence the practice pattern of the provider).

ing the "potential upside gain" estimated on a reasonable basis by the "base payment rate" which is the amount received during the contract period.[66] The "potential upside gain" would include only incentives tied to utilization.[67] With some modifications, these two terms would later be referred to in the proposed safe harbor as the "target payment" and "minimum payment," respectively. (See discussion following in Part III.B.4.b.) Furthermore, the Committee placed two additional requirements on the percent of risk. First, it must satisfy a specified standard, such as ten percent.[68] This "specified standard" later became twenty percent for non-institutional individuals or entities and ten percent for institutional individuals or entities. (See discussion below in Part III.B.4.b.) Second, the Committee determined that the percent of risk cannot be the result of a "sham."[69] The Committee offered the following illustration of this rule:

> If a physician is entitled to receive 100 units of payment, but 10 units are withheld until the end of the year, the base pay is 90 units. Even if there is an opportunity for a bonus at the end of the year, the base pay is still 90 units. If there is a possibility that the physician might have to pay money at the end of the year to cover a risk pool deficit, this potential obligation is not calculated into the base pay. In identifying the potential upside gain, all dollars based on utilization or costs would be estimated, using a reasonable analysis based on projected cost, utilization, and distribution. If it is expected that the 10-unit withhold would be returned plus a bonus of 5 units gained, the potential upside gain would be 15. The percent of risk would be calculated by dividing 15 (the potential upside gain) by 90 (the base payment amount), which equals about 16%.[70]

There are three differences between this percent of risk formula and the analogous calculation under the PIP Regulations.

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[66] *Id.*, attachment B, at 7 (adding that this second element/alternative was discussed in the context of physicians/physician groups but could apply to others as well).

[67] *Id.* at 7-8 (allowing that there might be a provision requiring that the arrangement include quality incentives).

[68] *Id.* at 7 (adding that the Committee had not reached a consensus on this issue).

[69] *Id.* (postponing defining this term until a later meeting).

[70] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 54, at 8.

First, the PIP Regulations measure risk by theoretical gain or loss.[71] If the physician is entitled to a bonus that is not limited by the contract, theoretically the physician could triple his or her income if there was no hospital utilization.[72] The HCFA would consider the potential gain to be the triple income figure.[73] Consequently, the concern is that the PIP Regulations "make it [easier] for providers to 'game' the system by artificially inflating the amount of risk."[74] In contrast, the Committee believed that "potential upside gain" should be based on a reasonable projection.[75]

Second, the denominator, or minimum payment, in the PIP Regulations is based on total compensation as opposed to base payment; the latter essentially being a "guaranteed amount."[76] The Committee believed using a base payment would be simpler.[77]

Third, base payment does not factor in unquantifiable downside risk amounts because those amounts are subjective.[78]

The Committee also discussed the issue of "swapping." This term refers to payments under a written agreement that are "calculated with reference to compensation between the organization and the individual or entity that result in increased payments being claimed from a Federal health care program."[79] The Committee questioned whether the concern should be a "swap" deal ("you give me this for that") increasing costs to a federal health care program, or if it should be any express or implied agreement that one deal is contingent upon another.[80] An option proposed was to include language that parallels the following OIG regulation:

> [T]he contract health care provider must not claim payment in any form from the Department or the State agency for items or services furnished in accordance with the agreement except as approved by HCFA or the state health care program, or otherwise shift the burden of such an

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[71] *Id.*

[72] *See id.*

[73] *See id.*

[74] *See id.*

[75] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 54, at 8.

[76] *Id.*, Attachment B, at 8.

[77] *Id.* at 8-9.

[78] *Id.* at 9.

[79] *Id.* at 10.

[80] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 54, at 10 (indicating that the Committee would not support any deal that used government patents as a "bargaining tool" and that a "swap" should be judged by intent).

> agreement to the extent that increased payments are claimed from Medicare or a State health care program.[81]

The Committee did not reach a consensus on this issue at the October meeting;[82] however, the wording of the OIG regulation was essentially adopted as part of the proposed safe harbor.

5. November Meeting

At this meeting, the Committee first presented an outline of its interim final rule. In addition to previous issues upon which the members reached a consensus, the Committee agreed that the first prong of the safe harbor would include more "covered entities" than simply "eligible organizations" and that some "downstream" arrangements would be protected as well.[83] The Committee placed four requirements on downstream contracts to be protected,[84] subject to the "HHS Regulatory Authority."[85] If a downstream arrangement satisfies these four requirements, it will be protected regardless of whether or not it involves substantial financial risk.[86] The Committee later retained these four requirements in the final interim rule — although with a few modifications and additional criteria.

Members then discussed how "items or services" should be defined for purposes of the first prong. Two alternatives proposed were to limit the definition to "medical services" or to adopt an existing statutory definition.[87] However, both alternatives had inherent problems. Equating "items or services" to "medical services" would exclude transportation that might be covered under

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[81] *Id.* at 11 (citing 42 C.F.R. § 1001.952(m)(1)(i) (1997).

[82] *Id.*

[83] Negotiated Rulemaking Comm. for the Shared Risk Exception, *Minutes* (Meeting, Nov. 19-21, 1997) (last modified Feb. 12, 1998). <http://www.dhhs.gov/progorg/oig/negrule/index.htm> at 4 (explaining how the proposal would extend to "safe harbor protection" beyond section 216 of HIPAA).

[84] *Id.*, Attachment B, at 2. (statting that "a downstream provider must have a contract which:

(A) is set out in writing and signed by the parties to the contract;
(B) specifies the items and services covered by the agreement;
(C) lasts at least one year; and
(D) specifies that the provider cannot claim payment in any form from Medicare except as approved by HCFA.

Id.

[85] *See* discussion *infra* Part III.A.1.

[86] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 83, at 5 (noting protection of downstream arrangements).

[87] *Id.* at 9 (outlining alternatives proposed to limit definition).

Medicare or Medicaid.[88] Likewise, a statutory definition would also present several difficulties. First, the civil monetary provisions already define this term but in a manner that is not appropriate for this exception because "that definition covers some administrative services that the IG does not want covered."[89] Second, an existing definition might not cover all managed care services, such as disease management.[90] The Committee then considered a third option: defining "items or services" in terms of "health services" which would include disease management though would exclude "marketing services."[91] Ultimately, the Committee adopted a definition in conformity with this last alternative.

Concerning the second prong of the exception, the members agreed that it addresses situations in which a federal health care program is paying on a fee-for-service basis.[92] They then discussed possible definitions for "organization" as well as standards for determining substantial financial risk (SFR) and permissible "downstream" arrangements. Some Committee members proposed that an "organization" should be defined as a "health plan."[93] Otherwise, if there is not a sufficient managed care context, "free floaters" could easily "play with target levels to disguise an arrangement as substantial financial risk."[94] In other words, the second prong should only protect legitimate managed care arrangements; not "shams."[95] The proposed interim final rule modified the rudimentary definition of "organization" developed at this meeting. One of the most notable modifications was to link the definition of "health plan" to that provided in the existing safe harbor for these arrangements codified at 42 C.F.R. 1001.952(l)(2).[96]

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[88] *Id.* (discussing difficulties associated with limiting the definition to "medical services").

[89] *Id.* (noting the reasons why the Committee did not adopt a statutory definintion).

[90] *Id.*

[91] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 83, at 9 (noting the option developed at the September meeting that services be required to be health services or reasonably related to such services).

[92] *Id.* at 10.

[93] *Id.* at 10-11. (outlining the federal proposal's definition).

[94] *Id.* (indicating that the federal agencies see the second prong as addressing legitimate arrangements).

[95] *Id.* at 11.

[96] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *Minutes* (Meeting, Jan. 21-22, 1998) (last modified Sept. 3, 1998) (visited Nov. 10, 1998) <http://www.dhhs.gov/progorg/oig/negrule/index.htm> at 17 (interpreting exceptions to the Anti-Kickback Statute).

Next, the Committee discussed two possible coexisting standards for determining "substantial financial risk" — a payment methodology standard and a numeric standard. The proposed payment methodology standard read in part as follows:

> Payment Methodology Standard – a provider is at SFR if payments are made under any of the following:
>
> (i) full capitation;
> (ii) percentage of premium;
> (iii) inpatient case rate; or
> (iv) per diem (when the length of stay is not in the control of the provider).[97]

The Committee retained (i) and (ii) in the proposed interim final rule. However, "inpatient case rate" was defined at this meeting as "a hospital inpatient case rate like an inpatient DRG, where there is less risk of overutilization because of the magnitude of the services furnished."[98] Subsequently, the Committee rewrote the third possibility to read as follows: "inpatient Federal health care program DRGs, except those for psychiatric services."[99] Per diem payments were eliminated altogether, the rationale being "that there are insufficient controls over the number of days of service provided when payment is on [a fee-for-service] basis."[100] However, some members disagreed, arguing that utilization review and copayment requirements would provide disincentives for overutilization where payment is based on a *prospective* per diem basis.[101]

In contrast, the numeric standard proposed at this meeting is essentially the same as the one included in the proposed interim final rule. The Committee believed that this standard addressed the kickback concern of overutilization because it was constructed to include risk arrangements in which providers are penalized for

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[97] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 83, Attachment B, at 4.

[98] *Id.* at 13.

[99] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 20.

[100] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *Minutes* (Meeting, Dec. 16-18, 1997) (last modified Sept. 3, 1998) <http://www.dhhs.gov/progorg/oig/negrule/index.htm> at 9 (arguing that per diem payments were eliminated because there is a lack of control over the length of services when payment is on an FFS basis).

[101] *See id.* (indicating additionally that the Committee would propose specific language to identify such situations).

overutilization.[102] Additionally, it would potentially protect withholds and bonuses as well as some case rates and per diems.[103] The only significant change in the proposed interim final rule is a bifurcation of the percentage requirement. Originally, this figure had been twenty percent for all providers (i.e., target payments had to be twenty percent greater than minimum payments). [104] This percentage was retained for non-institutional providers though was lowered to ten percent for institutional providers.[105] Although the possibility of creating this distinction was first raised at the November meeting, it was not finally resolved until the subsequent meeting in December.[106]

Lastly, the Committee determined that, for the second prong, "downstream" arrangements would only be protected if both the parties are at substantial financial risk.[107] (See discussion following in Part III.B.5.) It is important to note that this requirement for downstream arrangements is different from the corresponding requirement for the first prong. Recall that the first prong does not require downstream providers to be at SFR as long as the financial arrangement between the organization and the first tier provider places the latter at SFR.

6. December Meeting

The December meeting primarily involved discussion of changes to the proposed interim final rule outlined at the November meeting. Also, the Committee decided that a number of additional topics should be addressed in the preamble to the safe harbor. Changes to the first prong were primarily to clarify certain terms in the December proposal. Concerning the second prong, some members pointed out that the scope of this provision is in-

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[102] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 83, at 14 (noting, in addition, the exception that some performance bonuses are added into the calculation of risk percentage).

[103] *Id.* (identifying types of reimbursement that the standard would potentially protect).

[104] *Id.* (noting that the figure was chosen based on antitrust policy).

[105] *Compare id.*, Attachment B, at 4 (explaining the target payment in terms of earnings by an individual provider) *with* Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 20-21 (setting a numeric standard target payment for when an individual or entity is at substantial financial risk).

[106] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 83, at 15 (discussing concerns raised by Committee members regarding the 20% figure, which included the suggestion that the distinction might address these concerns).

[107] *Id.* at 18 (indicating that such an arrangement is illustrated by the Committee in an example on page 5 of Attachment B).

tended to cover primarily "arrangements where Medicare is primary payor on [a fee-for-service] basis for retirees in an employer plan . . . [and] would also apply to section 1115 Medicaid waivers that do not fit under Prong 1."[108] Furthermore, they argued, the intent "was to limit protection under Prong 2 to situations where the Federal health care program enrollees would be treated the same from the perspective of the providers as other enrollees, in spite of the [fee-for-service] payment."[109] Members also reaffirmed that self-funded ERISA plans and third party administrators (TPAs) are excluded from the definition of "organization" under the second prong.[110] The rationale is that employers and TPAs, if included within the definition, would have no incentive to reduce fee-for-service claims to federal health care programs.[111] With respect to the enumerated requirements for an "organization," the Committee clarified that the fifty percent requirement in (G)(ii)(a) (see discussion following in Part III.B.1.) only applies to the agreement between the organization and the first tier provider; it does not extend to downstream arrangements.[112] The Committee also disclosed that after the November meeting it decided to include a third standard for determining substantial financial risk (in addition to the payment methodology and numeric standards) — one for physician incentive plans.[113] (See discussion below in Part III.B.4.c.)

III. THE PROPOSED SAFE HARBORS FOR CERTAIN MANAGED CARE PLANS AND RISK-SHARING ARRANGEMENTS

On January 22, 1998, the Committee unveiled its proposed interim final rule for certain managed care plans and risk-sharing arrangements.[114] After seven months of meetings and deliberations, the Committee reached an agreement upon what terms and re-

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[108] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 100, at 6.

[109] *Id.*

[110] *Id.* (expressing continued concerns as to the definition of "organizations").

[111] *Id.* at 7.

[112] *Id.* (noting, additionally, that one Committee member questioned the need for this 50% requirement at the first-tier level).

[113] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 100, at 11 (stating that the Committee members were willing to accept the physician incentive plan calculations even though those calculations include some theoretical bonuses).

[114] *See* Himali, *supra* note 9, at 69 (discussing the Negotiated Rulemaking Committee's approval of the proposed expansion of safe harbor protections).

quirements should be included in the safe harbor. The Committee's proposal really consists of two safe harbors (referred to as "prongs"). The first prong (Prong I) protects arrangements in which the federal government makes a *fixed payment* to certain types of managed care organizations (MCOs). It also covers "downstream" contracts by these MCOs if certain requirements are met. In contrast, the second prong (Prong II) protects arrangements in which providers of medical services are placed at SFR for items and services ordered and reimbursed by a federal health care program on a *fee-for-service* basis. If "downstream" arrangements place both the upstream and downstream provider at SFR, they too are protected by Prong II. Again, it should be emphasized that these two safe harbors will not become effective until the interim final rule is published in the *Federal Register*.[115]

Before proceeding, it is worth mentioning two other principles that should be kept in mind when trying to determine if a proposed arrangement will fit within the language of these safe harbors. First,

> The fact that an arrangement does not comply with a safe harbor does *not* mean that an arrangement is illegal. It is not correct to assume that arrangements outside of a safe harbor are [prohibited] due to that fact alone . . . . It means only that the arrangement does not have guaranteed protection . . . . Numerous managed care arrangements that exist in the market place [sic] today neither fall within this safe harbor, nor are they illegal.[116]

Therefore, just because a contractual arrangement in the health care sector does not come within the scope of these two safe harbors (or any of the others, for that matter) does not mean that the arrangement is *per se* unlawful under the Anti-Kickback Statute. Of course, at the same time, this does not imply that such arrangements are not possibly prohibited by some other statute or regulation.[117]

Second, an arrangement that potentially comes within the scope of multiple safe harbors need only satisfy the requirements

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[115] *See id.* (describing the two prongs of the proposed interim final rule for safe harbor expansion).

[116] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 26. *See also supra* note 12.

[117] *See id.* (noting that if an arrangement does not meet either of the two safe harbors, it only means that the arrangement does not have guaranteed protection). *See also supra* note 12.

of one.[118] Consequently, in reviewing a prospective arrangement, it is advisable to determine which, if any, safe harbor requirements could be most easily satisfied. If slight modification to the arrangement is all that is necessary for protection, the organization or provider can then be assured that it is not in violation of the Anti-Kickback Statute.

A. Prong I: Safe Harbor for Managed Care Organizations Under Federal Health Care Programs

The first safe harbor (Prong I) covers arrangements in which the federal government makes a fixed payment to "covered entities." It also protects certain "downstream" contractual arrangements. Prong I reads as follows:

> (n) Price reductions offered to covered entities.
>
> "Remuneration" under the Anti-Kickback Statute does not include any remuneration between a "covered entity" (see below) and an individual or entity or between an upstream individual or entity and its subcontractors, subject to the standards below.

1. "Covered Entities"

The first prong provides a definition for "covered entities" that covers more providers than merely "eligible organizations under section 1876." Recall that the second part of the statutory exception only protected the latter. Although Prong I includes "eligible organizations" within the definition of "covered entities," it also seeks to protect many other providers as well. However, issuing rules on these matters is outside the scope of section 216 of HIPAA and, therefore, must be promulgated under the "HHS Regulatory Authority"[119] to establish rules constituting "safe harbors."[120] Rulemaking on these issues is governed by the Administrative Procedures Act (APA) notice and comment procedures, not the negotiated rulemaking procedures.[121] Nonetheless, HHS agreed that it will consider issuing a rule on matters designated as "HHS

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[118] *See id.*

[119] *See* Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93, 101 Stat. 680 (codified as amended in scattered sections of 42 U.S.C. (1994)) (outlining standards for anti-kickback provisions).

[120] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 10.

[121] *See id.* at 14 n. 2.

Regulatory Authority" by the Committee.[122] Specifically, the safe harbor lists six categories of "covered entities," all except the first of which are designated as HHS Regulatory Authority:

- Eligible organizations under section 1876 include: (1) risk-based HMOs and competitive medical plans (CMPs) with Medicare contracts; (2) for arrangements with "first tier" individuals or entities *only*, cost-based HMOs and CMPs with Medicare contracts; and, (3) for arrangements with "first tier" individuals or entities *only*, federally qualified HMOs (without regard to Medicare contracts) for their capitated enrollees, including where a federal health care program is a secondary payor.[123]

- Any Medicare Part C health plan which receives a capitated payment from Medicare and which must have its total Medicare beneficiary cost sharing approved by HCFA under section 1854 of the Social Security Act [42 U.S.C. §1395w-24]. However, Medicare+Choice fee-for-service panels and medical savings account plans are excluded.[124]

- Medicaid MCOs as defined in section 1903(m)(1)(A) [42 U.S.C. §1396b(m)(1)(A)] (except for fee-for-service plans or medical savings accounts) which provide or arrange for services for Medicaid enrollees under a contract pursuant to section 1903(m) [42 U.S.C. §1396b(m)]. Also included are section 1915(b) [42 U.S.C. §1396n(b)] waivers, section 1115 [42 U.S.C. §1315] waivers that do *not* waive section 1903(m) [42 U.S.C. §1396b(m)] provisions, and Medicaid MCOs under section 1932 [42 U.S.C. §13964-2].[125]

- Medicaid MCOs that waive section 1903(m) [42 U.S.C. §1396b(m)] provisions, if they have risk-based

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[122] *See id.* at 10.
[123] *Id.* at 13.
[124] *Id.* at 13-14.
[125] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 14.

contracts with a state agency and provide or arrange for services for Medicaid enrollees and meet all of the requirements of section 1903(m) [42 U.S.C. §1396b(m)] except for section 1903(m)(2)(a)(vi) [42 U.S.C. §1396b(m)(2)(a)(vi)] as waived by the Secretary.[126]

- The Programs of All-Inclusive Care for the Elderly (PACE)[127] except the for-profit demonstrations under sections 4801(h) and 4802(h).[128]

- TRICARE.[129]

2. "First Tier" and "Downstream" Arrangements

The first prong then addresses "first tier" contracts and contracts between upstream and downstream individuals and entities. If a covered entity enters into a contract with an individual or entity (first tier) to provide "items or services"[130] to its members, the contract must:[131]

1. be written and signed by both parties;

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[126] *See id.* "The language for the safe harbor will also provide coverage for arrangements with the Arizona Health Care Cost Containment System." *Id.* at 14 n.3.

[127] 42 U.S.C. § 1395eee (1994) (describing payments to and coverage of benefits under the PACE program).

[128] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 14.

[129] *Id. See also* 32 C.F.R. § 199.17 (1997) (detailing the TRICARE program).

[130] For purposes of this safe harbor, "items or services only includes health items, devices, supplies, or services or those reasonably related to the provision of health care items, devices, supplies or services provided to enrollees, including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. Marketing services and services provided prior to enrollment are not covered." Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 16. "However, simply because such services are not included in the safe harbor does not mean that they are *per se* illegal. Nurse call-in lines for current enrollees of an organization are not marketing under this regulation. Marketing does include items such as 'value-added services.' The definition . . . includes services provided to individuals or entities that are reasonably related to the services being delivered to enrollees (i.e., disease management)." *Id.* at 28. According to the Chief Counsel for the OIG, the interim final rule will likely cover similar call-in services by other professional groups, such as pharmacies. *See also* Himali, *supra* note 9, at 71 (describing the types of "items or services" covered by the proposed safe harbor).

[131] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 15.

2. specify the items and services covered by the agreement;
3. be for a period of not less than one year; and
4. specify that the individual or entity cannot claim payment in any form from a federal health care program for items and services covered under the agreement (with one exception).[132]

Covered entities cannot claim payment from a federal health care program for items or services, other than the contractual amounts set forth in the covered entity's agreement with the federal health care program, unless they are within the exception to the fourth requirement.[133]

Although regulating contracts between upstream and downstream providers is under the "HHS Regulatory Authority," the Committee has proposed that these contracts generally fulfill the same requirements listed below for first tier contracts.[134]

Note also that there is no downstream protection for the following: federally qualified health centers (FQHCs) receiving supplemental payments; cost-based HMOs; and federally qualified HMOs.[135] However, first tier arrangements between a covered entity and an FQHC are covered.[136]

3. "Swapping" Under Prong I

Under the first prong, "swapping" is specifically prohibited. One party to a contract cannot provide or receive remuneration in return for or to induce the other party to provide or accept business (other than that covered by the contract) for which payment can be made by a federal health care program on a fee-for-service or cost

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[132] The exception is for "[f]ederally qualified HMOs or Medicare 1876 cost contractors where the Federally qualified HMO, Medicare section 1876 cost contractor, or its first tier provider is billing a Federal health care program, in which case, the billing arrangement must be set forth in the agreement." *Id.*

[133] *See id.*

[134] *See id.* (proposing that a contract between an upstream and a downstream individual entity: (a) be set out in writing and signed by the parties to the contract; (b) specify the items and services covered by the agreement; (c) be for a period of at least one year; and (d) specify that the individual or entity cannot claim payment in any form from a federal health care program).

[135] *See id.* (listing instances where no downstream protection is provided).

[136] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 15 (stating when downstream protection is provided).

basis.[137] In addition, the arrangement is not protected if it shifts the burden such that increased payments are claimed from a federal health care program.[138] "The language 'shifts the burden' . . . [refers to the fact] that the *financial* burden of an arrangement cannot be shifted to a Federal program. For example, an individual or entity cannot increase the number of claims submitted or increase the charges or costs for services in order to subsidize the costs of other less profitable lines of business."[139]

"The basic fear [of "swapping"] . . . is that those negotiating health insurance contracts are using their Medicare beneficiary population as a tool or bargaining chip to negotiate lower rates for the rest of the covered lives in the plan."[140] Whether "swapping" is a legitimate concern remains controversial among the Committee members. Some members argue that employers negotiating health insurance contracts are not trying to contrive ways to defraud the Medicare program.[141] According to these proponents, what is "driving the marketplace . . . is a sincere desire to reduce costs, and risk-sharing arrangements are one way to do that."[142] The possibility of swapping, the argument continues, is minimal and "designing a safe harbor [based] on the fear of swapping [is] tantamount to . . . 'the tail wagging the dog.'"[143]

B. Prong II: Safe Harbor for Managed Care Risk-Sharing Arrangements Where a Federal Program Pays on a Fee-For-Service Basis

Prong II establishes a safe harbor for both managed care risk-sharing arrangements in which a federal program pays on a fee-for-service basis and Medicaid section 1115 waivers that do not fit within Prong I.[144] It primarily applies to arrangements in which "Medicare is the primary payer on a fee-for-service basis for retir-

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[137] *See id.* at 15-16 (listing the instances when remuneration may be neither given nor received by either the upstream or downstream provider).

[138] *See id.* at 16 (explaining when an agreement between an upstream and a downstream provider is not protected).

[139] *Id.* at 30 (explaining when the burden is shifted in an arrangement between an upstream and a downstream provider).

[140] Ursula Himali, *Managed Care: Upcoming Medicare Anti-Kickback Safe Harbor to Offer Narrow Exception*, MEDICARE REP. (BNA) 1, 4 (Jan. 2, 1998).

[141] *See id.* (noting very few employers actually "scheme" to defraud the government in this manner).

[142] *Id.*

[143] *Id.*

[144] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 17 n. 4 (listing what is included in Prong II).

ees in an employer-sponsored plan."[145] Consequently, its scope is very narrow in contrast to Prong I which protects most Medicare health maintenance organizations.[146] As discussed previously, the reason that its applicability is limited is because placing providers at SFR is unusual in a fee-for-service health plan.[147] The safe harbor reads as follows:

> **Managed care organization risk-sharing arrangements**
>
> "Remuneration" under the anti-kickback statute does not include any remuneration between an organization and an individual or entity or between an upstream individual or entity and its subcontractors, where there is a risk-sharing arrangement (RSA) that puts the individual or entity at substantial financial risk (SFR) for the cost or utilization of items or services, if the requirements below are met.

The "requirements below" concern what must be contained in a written agreement; what qualifies as an "organization"; what constitutes a "risk-sharing arrangement"; what types of upstream and downstream arrangements are permissible; when "substantial financial risk" exists; and what "items or services"[148] the individual or entity is "obligated to provide."[149]

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[145] Himali, *supra* note 9, at 69 (explaining why the second prong of the proposed safe harbor is very narrow).

[146] *See id.* at 69-70 (noting that the first prong creates a safe harbor for arrangements in which the government makes a fixed payment to a Medicare HMO).

[147] *See id.* at 70 (noting that the Inspector General of the Department of Health and Human Services disputes the "narrow" characterization of Prong II).

[148] "Items or services" is limited to "health items, devices, supplies, or services or those reasonably related to the provision of health care items, devices, supplies or services provided to enrollees, including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. Marketing services and services provided prior to enrollment are not covered." Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 24.

[149] The items or services for which the individual or entity is "obligated to provide" include:

(A) services provided directly by the individual or entity and its employees;

(B) services for which the individual or entity is financially responsible but which are provided by subcontractors;

(C) services for which the individual or entity makes referrals or arrangements (HHS Regulatory Authority); and

1. "Organization"

An "organization" is any "health plan" as defined by 42 C.F.R. 101.952(l)(2)[150] that also provides a comprehensive range of health services. In addition, the health plan must provide for:

(A) reasonable utilization goals to avoid inappropriate utilization;
(B) an operational utilization review program;
(C) a quality assurance program that promotes the coordination of care, protects against underutilization, and specifies patient goals, including measurable outcomes where appropriate;
(D) grievance and hearing procedures;
(E) protection for members from incurring financial liability (except as to copayments and deductibles);
(F) no treatment for Federal health care program beneficiaries that is any different than other enrollees due to their status as Federal health care program beneficiaries; and
(G) either

(D) services for which individuals or entities receive incentives based on his or her own, group, or plan's performance. (HHS Regulatory Authority)

Id. at 22 (emphasis omitted).

[150] "Health plan" means an entity that furnishes or arranges under agreement with contract health care providers for the furnishing of items or services to enrollees, or furnishes insurance coverage for the provision of such items and services, in exchange for a premium or a fee, where such entity:

(i) Operates in accordance with a contract, agreement or statutory demonstration authority approved by HCFA or a State health care program;
(ii) Charges a premium and its premium structure is regulated under a State insurance statute or a State enabling statue governing health maintenance organizations or preferred provider organizations;
(iii) Is an employer, if the enrollees of the plan are current or retired employees, or is a union welfare fund, if the enrollees of the plan are union members; or
(iv) Is licensed in the State, is under contract with an employer, union welfare fund, or a company furnishing health insurance coverage as described in conditions (ii) and (iii) of this definition, and is paid a fee for the administration of the plan which reflects the fair market value of those services.

42 C.F.R. 1001.952(l)(2) (1997).

(i) no more than ten percent Medicare beneficiaries as enrollees where a Federal health care program is primary

or

(ii)(a) at least fifty percent non-Medicare beneficiaries as enrollees where a Federal health care program is not primary

and

(b) receipt of payments for premiums under the RSA on a periodic basis that does not take into account the dates services are provided, the frequency of services, or the extent or kind of services provided.[151]

Consequently, these additional requirements cause the second prong to be narrower than the existing safe harbor for health plans under 42 C.F.R. 100.952(l).

Because only MCOs (and even then, only *certain* MCOs) fit within the definition of "organization," it is likely that the policy underlying these requirements is HCFA's desire to ensure that the MCOs have in place measures to protect the rights of patients (quality assurance programs, grievance procedures, etc.) as well as ones to prevent unnecessary costs (utilization review, etc.).

The Committee also points out in this proposed safe harbor that an organization's written agreements which are protected do not lose protection simply because the organization has additional unprotected agreements.[152] Oddly enough, there is no similar provision under the first prong. The minutes from the Committee meetings do not indicate if this omission was intentional or merely an oversight.

2. Written Agreement

The risk-sharing arrangement, whether between an organization and a first tier provider or between downstream providers, must satisfy the following requirements:

(A) set out in writing and signed by the parties;

(B) specify the items and services covered by the agreement;

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[151] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 17-18 (listing the provisions each written agreement of the organization must contain in order to qualify for protection).

[152] *See id.* at 18 (explaining that an organization's written arguments remain protected despite other non-protected agreements).

(C) specify the intervals at which distributions will be paid;
(D) specify the formula for calculating incentives and penalties;
(E) set out that the arrangement is for a period of at least one year;
(F) specify the methodology for determining compensation which is commercially reasonable and which is set in advance in arms-length negotiations; and
(G) require participation in a quality assurance program that promotes the coordination of care, protects against underutilization, and specifies patient goals, including measurable outcomes where appropriate.[153]

3. "Risk-sharing Arrangement"

The safe harbor provides an elaborate definition of "risk-sharing arrangement." In general, for an arrangement to be considered an RSA, it must: (1) include items or services covered by a federal health care program; (2) require that the organization, rather than the entity or individual, bill the federal health care programs for these services; [154] and, (3) not set payment rates based on the source of payment or billing method.[155] The reason for the third requirement is to ensure "that, even if Medicare services are paid on [a fee-for-service] basis, Medicare beneficiaries will be treated the same as other enrollees in the health plan."[156] Historically, there has been a problem of "grouping the patients by payor source [which] could mean that over-65 Medicare beneficiaries would not be treated the same as any over-65 employees in the commercial plan, even if their

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[153] *Id.* at 24.

[154] "In the case of a self-funded employer plan that contracts with an organization to provide administrative services (i.e., a TPA or an ASO) the self-funded employer plan must bill." *Id.* at 18 n.5 (providing an example of an organization required to bill). These self-funded employer plans are governed by ERISA. *See* Himali, *supra* note 140, at 2-3 (discussing whether to include the ERISA-covered plans in the safe harbor plan).

[155] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 18 (explaining when arrangements do not qualify for protection as risk-sharing arrangements).

[156] *Id.* at 7.

health status [was] the same."[157] Consequently, the fee-for-service "population could be 'gamed' and therefore [the government needs] the assurance that this population is being treated the same as other enrollees and is subject to the same utilization targets."[158] A number of specific arrangements are also listed as qualifying for an RSA:

- An arrangement is deemed to be an RSA if the organization receives a fixed, periodic payment for its non-Federal health care program fee-for-service enrollees, and includes Federal health care program beneficiaries in its downstream RSAs.

- Inpatient services provided by hospitals will be deemed to be part of the RSA if the hospital is reimbursed by the Federal health care program directly on a DRG basis. Organizations must reimburse hospitals for inpatient hospital services provided to non-Medicare enrollees on a DRG basis, although payment amounts may be different.

- Part B services will be deemed included in the RSA if the Part B supplier receives a capitated or other risk payment from the organization (or the upstream individual or entity) and reassigns its rights to Federal health care program fee-for-service payments to the organization.[159]

However, "[t]he safe harbor does not protect any arrangement between a first tier individual or entity and an organization where the individual or entity has an investment interest in the organization, unless the investment interest [satisfies the "large entity" safe harbor of] 42 C.F.R. 1001.952(a)(1)."[160] Consequently, the second

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[157] *Id.* (explaining the problem created when patients are grouped by payor source).

[158] *Id.* (explaining that the federal agencies fear the fee-for-service population is being treated differently).

[159] *Id.* at 18-19 (detailing the specific arrangements which qualify as risk-sharing).

[160] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 19-20 (explaining when arrangements are not protected under the risk-sharing safe

prong does not protect provider-owned entities, such as physician hospital organizations (PHOs), management service organizations (MSOs), provider sponsored organizations (PSOs), and IPAs owned by physicians.[161] The rationale, according to the Chief Counsel for the OIG, is that if

> The providers own the plan, we could end up in a situation where money is just being transferred from one pocket to another and we wouldn't have substantial financial risk . . . [t]o the extent that the plan doesn't pay out money because they didn't meet their goals [but] keeps that money as profit and the profit then gets distributed to the same people . . . we're talking about taking money from one pocket and putting it in the other pocket. That's not real substantial financial risk.[162]

4. "Substantial Financial Risk"

An RSA must satisfy one of three standards for the provider to be at substantial financial risk (SFR): (1) payment methodology standard, (2) numeric standard, or (3) physician incentive plan standard. Each of these will be discussed in turn.

a. Payment Methodology Standard

Individuals or entities are at SFR if the payments they receive under an RSA are made according to one of the following: full capitation; percentage of premium; or inpatient federal health care program diagnosis related groups (DRGs), except those for psychiatric services.[163] The Committee has not defined "full capitation" and will seek comments as to the extent to which it is implicated by the purchase of stop-loss insurance[164] or contractual pro-

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harbor). The requirements of 42 C.F.R. 1001.952(a)(1) are generally considered difficult to satisfy.

[161] *See* Himali, *supra* note 9, at 71 (noting that provider-owned entities do not have the substantial financial risk that is required by Prong II because money merely changes pockets in this relationship).

[162] *Id.*

[163] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 20 (explaining what payment methods under a risk-sharing arrangement put an individual or entity at substantial financial risk).

[164] "Stop-loss insurance is an arrangement whereby a risk-bearing provider or other insurer buys coverage to limit undue losses. At issue is at what point is there no longer enough risk to satisfy the payment standard?" Himali, *supra* note 9, at 72.

visions concerning limitation of financial liability.[165] Nonetheless, the Committee did state during one of its earlier meetings that "full capitation" in this standard "would not preclude the use of reinsurance or taking capitation only for part of the services provided; if part of the services are 'carved out' and paid on [a fee-for-service] basis, however, . . . only the part that is capitated would be protected."[166] It should also be noted that "the reimbursement must be reasonable given the historical utilization patterns and costs for the same or comparable population in similar managed care arrangements."[167] Concerning DRGs, HHS has had past enforcement problems for psychiatric services and some members believed they should be excluded to protect patients seeking those medical services.[168] Specifically, they were concerned that psychiatric admissions could be "manipulated."[169]

b. Numeric Standard

This standard compares the provider's "target payment" and "minimum payment" to determine what percentage of income is at risk. "[T]arget payment is the fair market value payment established through arms [sic] length negotiations that will be earned" if target utilization is reached. It does not include any bonuses or fees for achieving utilization below the target level.[170] "[M]inimum payment," on the other hand, is "the guaranteed amount that an individual or entity is entitled to receive under the contract."[171] Both target payments and minimum payments include bonuses for performance (such as timely submission of paperwork and attending meetings) at a level which is achieved by seventy-five percent

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[165] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 29 (stating that the Committee will seek comments regarding the extent to which capitation is directly implicated by contractual provisions).

[166] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 93, at 13.

[167] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 20.

[168] *See id.* at 30 (stating that DRGs are not used in psychiatric services related to protection of the patient).

[169] *See* Negotiated Rulemaking Comm.for the Shared Risk Exception, *supra* note 100, at 10 (arguing that federal agencies do not have the same level of comfort when dealing with psychiatric admissions due to fear that they could be manipulated).

[170] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 21 (defining target payment).

[171] *Id.*

of participating providers that are paid a performance bonus based on the same structure.[172]

"Non-institutional" providers must have a target payment that is at least twenty percent greater than the minimum payment to be at SFR.[173] In contrast, "institutional" providers are only required to have a target payment that is at least ten percent greater than the minimum payment to be at SFR.[174] "Institutional" providers is limited to hospitals and nursing homes.[175] The Committee specifically stated that pooling of money by physicians and hospitals, such as by forming a joint venture PHO, would not qualify as an institution.[176] At the December meeting, the rationale given for this distinction "was that institutional providers have greater capital costs affecting what risk they can bear."[177] Additionally, the Chief Counsel for the OIG stated that it "is 'a reflection that their [hospitals' and nursing homes'] operating margins are much smaller than the typical [Medicare] Part B provider like a physician's office.'"[178] Moreover, the Committee emphasized that it "will request the submission of data on the appropriateness of different target payment percentages for institutional and non-institutional individuals or entities during the comment period."[179] Specifically, the Committee will inquire as to whether FQHCs should be categorized as institutions.[180]

The following provides an example of how to determine substantial financial risk for a non-institutional individual or entity:

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[172] *See id.* (comparing similar requirements for target and minimum payments).

[173] *See id.* at 20 (stating the numeric standard for SFR for non-institutional individuals or entities).

[174] *See id.* (stating the numeric standard for SFR for institutional individuals or entities).

[175] *See* Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 20.

[176] *See id.* at 6 (discussing which numeric standard for SFR should apply where hospital or physician money is pooled).

[177] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 100, at 10 (arguing that institutional providers have greater capital and should be able to bear more risks).

[178] Himali, *supra* note 9, at 71(discussing the reasons for requiring different target payments for different types of providers).

[179] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 28.

[180] *See id.* at 7 (noting that "the preamble topic on the appropriateness of payment percentages was modified to indicate that the preamble will inquire about" what numeric standard for SFR should apply to FQHCs).

> If the target payment is $80, the minimum payment is $60, and the $20 withheld goes into risk pools ($5 for specialty services and $15 for hospital services) and if the provider would get all of the $20 back by hitting the proper target (expected utilization based on [reasonable] principles), the ratio would be $20 over $60 (33.3%) and the 20% standard would be met. If performance bonuses (i.e., non-utilization based bonuses) totaling $100 are expected to be earned by 75% of providers, this amount would be added into both the target payment and the minimum payment, so the ratio would be $20 over $160 (12.5%). In this calculation, it would not matter if the $20 were a penalty that the provider had to pay back instead of a withhold.[181]

Prong II also includes the caveat that "the arrangement must ensure that the amount at risk, i.e., the bonus/withhold, is earned by an individual or entity in direct relation to the ratio of the actual to the target utilization. The minimum payment may not be set artificially low."[182] This rule will help to ensure that the policy basis for encouraging risk-sharing is not compromised by deceptive payment arrangements.

c. Physician Incentive Plan (PIP) Standard

Even before this proposed safe harbor, HHS promulgated rules governing physician incentive plans (i.e., the PIP Regulations)[183] and created a PIP exception under the Stark regulations.[184] The PIP standard under the proposed safe harbor reads as follows:

> Physician Incentive Plan Standard. [A] physician is at SFR if:
>
> (i) the upstream individual or entity has placed the physician at substantial financial risk for referral services in an amount that exceeds the substantial financial risk threshold under the Department's physician incentive plan regulations and the arrangement is in

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[181] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 83, at 14.

[182] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 20 n.6.

[183] *See* 42 C.F.R. § 417.479 (1997) (outlining requirements and defining terms for physician incentive plans).

[184] *See* 42 C.F.R. §§ 411.1-411.408 (1997).

compliance with the stop-loss and beneficiary survey requirements of those regulations.

(ii) notwithstanding the foregoing, an individual or entity will not be at substantial financial risk, for purposes of this standard, if the patient panel size is 25,000 covered lives or greater.[185]

The Committee essentially adopted these requirements from the PIP Regulations. Consequently, if a health plan is at substantial financial risk under the PIP Regulations, it will also be at SFR under Prong II.

5. "Downstream" Contractual Arrangements

This safe harbor, as with the PIP Regulations and Stark exception for physician incentive plans, provides protection for certain arrangements between upstream and downstream individuals or entities. However, "downstream individuals or entities are only protected if they are paid on an SFR basis by another individual or entity who is also paid on an SFR basis. In other words, contracts involving an individual or entity which is *not* paid on an SFR basis are *not* protected for *any* party."[186] This rule can best be understood by referring to the following diagram:

[185] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 21 (emphasis omitted).

[186] *Id.* at 22.

1. HMO (capitated)

arrangement between levels 1 and 2 protected

2. PHO (percentage of premium -- physician and hospital services)

arrangement between levels 2 and 3 not protected

3. IPA (fee-for-service) ("Non-SFR Individual or entity")

arrangement between levels 3 and 4 not protected

4. Physician group (capitated)

arrangement between levels 4 and 5 protected

5. Physician (capitated)[187]

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[187] *Id.* at 22-23.

In developing the proposed safe harbor, the Committee believed that this additional requirement was necessary "to prevent fee-for-service or cost-based kickbacks disguised as risk-sharing arrangements."[188] (Also referred to as "swapping.")[189] Although the Committee does not give much further explanation as to the basis for their concern, one can imagine the problems that might result if, for instance, the arrangement between Levels 3 and 4 were protected. The IPA at Level 3 is paid by the PHO at Level 2 on a fee-for-service basis. Consequently, the IPA has no incentive to control utilization of services; more services provided by the downstream providers means more money that the IPA will receive from the PHO. Therefore, even though the IPA is paying the physician group at Level 4 on a capitated basis, the IPA would have an incentive to encourage the physician groups to overutilize services (through such tactics as "kickbacks"). This result would be contrary to both the reasons for capitation and the reasons that justify exempting PIPs under the proposed safe harbor.

This requirement that both the upstream and downstream providers be paid on a basis which places them at SFR is more limiting than the corresponding requirements for subcontracting arrangements under the PIP Regulations. The PIP Regulations only focus on whether the subcontracting ("downstream") component of the contractual arrangement involves substantial financial risk. There is no requirement that the upstream provider under the subcontracting arrangement also be at SFR. If the subcontractor is placed at SFR under the terms of the subcontract, the inquiry ends. Because the Stark exception also adopts the PIP Regulations standards, it too is only concerned with substantial financial risk at the subcontract level.

This difference between Prong I, on the one hand, and the PIP Regulations and Stark exception, on the other hand, has already drawn sharp criticism. One commentator believes that this proposed safe harbor is so limited in applicability that it offers little protection for most managed care plans as they are currently structured.[190]

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[188] *Id.* at 22.

[189] "Swapping" refers to when a party provides or "receives remuneration in return for or to induce the other party to provide or accept business (other than that covered by the arrangement) for which payment may be made . . . by a Federal health care program on a fee-for-service or cost basis." *Id.* at 15-16.

[190] *See* Himali, *supra* note 9, at 70-71 (arguing that Prong II is too narrowly drafted to prevent some providers from creating sham risk-sharing arrangements).

6. "Swapping" Under Prong II

As with the first prong, "swapping" is also not permitted under Prong II. One party cannot provide or receive "remuneration in return for or to induce the other party to provide or accept business (other than that covered by [contract]) for which payment may be made . . . by a Federal health care program on a fee-for-service or cost basis."[191] In addition, the arrangement would not be protected if it shifts the burden of such an arrangement to the extent that increased payments are claimed from a federal health care program.[192]

IV. THE FUTURE OF THE PROPOSED SAFE HARBORS

The two new safe harbors contained in the proposed interim final rule will not become effective until they are published in the *Federal Register*. Although the Chief Counsel for the OIG at one point believed that the interim final rule would be published by the end of April 1998,[193] more recent opinions indicate that a better estimate is sometime toward the beginning of 1999. Ironically, it might actually be best if HHS delays publishing its interim final rule anytime soon. Based on the discussions throughout this Article, it is obvious that the complicated language of the proposed interim final rule requires serious revision in order to be understood by those individuals who are expected to interpret and apply the safe harbors. Regardless of whether or not the criticism that the safe harbors are too "narrow" is valid, one cannot ignore the fact that both safe harbors are worded in such a way as to generate numerous ambiguities and inconsistencies. Even the current names of the proposed safe harbors are misleading as to what types of arrangements they are aimed at protecting.[194] Consequently, it would

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[191] Negotiated Rulemaking Comm. for the Shared Risk Exception, *supra* note 96, at 24.

[192] *See id.* (stating, however, that this requirement does not "prevent parties from establishing different payment rates for different products").

[193] *See* Himali, *supra* note 9, at 69 (noting that, in a special report published in January of 1998, D. McCarty Thornton, Chief Counsel at the OIG, indicated that he expected an interim final rule to be published in the *Federal Register* "within the next three months").

[194] For example, Prong I is entitled "Price reductions offered to covered entities," which gives no indication that it primarily covers arrangements in which the provider receives a *fixed payment* from a federal health care program. Additionally, Prong II is designated as "Managed care organization risk-sharing arrangements," which seems almost directly contradictory to the fact that it mainly covers arrangements in which a

undoubtedly be wise for HHS to take the time to redraft the proposal to ensure that it precisely reflects the true intent of its authors. This task should be completed even if HHS does not wish to change any of the substantive provisions. After all, nowhere in the Committee's charter does it state that one of its goals would be to generate more work and frustration for lawyers and health care providers alike.

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provider receives payments from a federal health care program on a *fee-for-service basis.*