ALERT:
FRAUD AND ABUSE SAFE HARBOR
FOR SHARED RISK ARRANGEMENTS

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Introduction

The Office of Inspector General of the U.S. Department of Health and Human Services ("OIG") recently published an Interim Final Rule regarding a safe harbor for risk sharing activities which could expose FQHCs to anti-kickback liability for their receipt of Medicaid supplemental (wrap-around) reimbursement when the FQHC does not contract directly with a managed care organization but instead contracts with an intermediary entity to provide health care services to enrollees of a federal health care program. Even though the FQHCs may have a legal right to claim such reimbursement, the OIG has determined that if the FQHC does not have a direct contract with the entity receiving risk payments from a federal health care program then the potential for increasing the federal health care program expenses exists. Therefore, according to the OIG, this type of subcontract should not automatically receive safe harbor protection.

I. Background

The federal Anti-Kickback Statute, which is codified at 42 U.S.C. § 1320(a)-7b(b), prohibits arrangements in which remuneration is exchanged for referrals or the purchasing or leasing of goods, services or equipment paid for in whole or in part by a federal health care program. Specifically, the statute prohibits any person or entity from knowingly or willfully soliciting or receiving (or offering or paying) remuneration directly or indirectly in cash or in kind in return for such referrals, purchases or leases. Violations of this statute occur even if the intent to induce referrals is only one of several reasons for the arrangement. Remuneration is interpreted expansively to encompass anything of value exchanged for referrals, including monetary savings through the use of discounts, rebates and free goods and/or services. The statute's broad language gives the OIG wide latitude in investigating and prosecuting practices which, on their face, may not appear to violate the statute. To combat the broad wording and interpretation of the statute and in recognition of the fact that not all financial arrangements between providers intentionally induce referrals, a series of "safe harbors" have been adopted to protect certain "benign" business practices.¹

Technically, all arrangements involving the transference of risk from a managed care entity to a provider theoretically are violations of the federal Anti-Kickback Statute because the capitation or other risk payment would constitute the provider giving a discount in exchange for the referral of the managed care entity’s enrollees to the provider.² Section 216 of the Health

¹ To qualify for protection under a safe harbor, the arrangement must meet all of the conditions of a safe harbor. Arrangements, which do not fit squarely within any safe harbor, may nevertheless still be permissible so long as the arrangement does not violate the statutory intent of the anti-kickback law. Consultation with legal counsel regarding an arrangement’s compliance with the requirements of a safe harbor is recommended.

² More specifically, prepayment of a fixed fee such as capitation constitutes the transference of risk because the entity accepting such payment does so with the understanding that it will be responsible for providing all the services necessary to treat the patient regardless of their cost. Consequently, if the services provided to the patient cost more than the payment received, each service’s cost to the federal health care program is reduced. In fraud and
Insurance Portability and Accountability Act of 1996 ("HIPAA") was enacted to address concerns raised about the propriety of managed care arrangements; this section created a new statutory exception (a safe harbor) for shared risk arrangements.

Pursuant to its statutory mandate, OIG convened a negotiated rule-making session with representatives of twenty-three health care organizations including NACHC. Two shared risk safe harbors were promulgated based upon the agreement of participants in the negotiated rule making: (1) a safe harbor protecting financial arrangements between managed care entities that receive a fixed or capitated amount from a federal health care program and providers, both individuals and entities, with whom the managed care entity contracts for the provision of health care goods or services; and, (2) a safe harbor protecting contractual relationships between managed care entities and their contractors and subcontractors which are at substantial financial risk for the cost or utilization of health care goods and services provided or ordered for enrollees of a federal health care program.  

II. The New Risk Sharing Safe Harbor for Federal Health Care Programs

The vast majority of arrangements will fall within the parameters of the first managed care/risk sharing safe harbor, which is codified at 42 C.F.R. § 1000.952(t), because it protects arrangements with an Eligible Managed Care Organization ("EMCO") which receives capitation or other fixed payments from a Federal health care program. 4 Direct contracts between the EMCO and a provider or intermediary entity, termed a “first-tier contractor” by the OIG, are always protected so long as they are in writing and signed by the parties, set forth the goods or services to be provided, have at least a one year term, and provide that the first-tier contractor does not claim additional payments from the Federal health care program.

The safe harbor provides a special exception for first-tier FQHC contracts. If an FQHC contracts directly with an EMCO, it will enjoy this safe harbor’s protection even if the FQHC seeks and receives supplemental (wrap-around) payments because the Interim Rule exempts first-tier FQHCs from the general prohibition that the safe harbor does not protect any entity which receives additional federal health program funds other than the EMCO risk payment. According to the OIG, FQHCs, as first-tier contractors, are protected because of their unique role in the health care delivery system in many medically underserved areas.

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abuse parlance, this would be a reduction in price and, therefore, remuneration to the managed care entity in exchange for the referral of a patient to the provider.

3 The second safe harbor is intended primarily for self-insured health care plans which cover individuals who are also enrolled in a federal health care program, such as those who qualify for Medicare and a retired-employees’ health benefit plan. This Issue Brief does not discuss this second risk sharing safe harbor because it will apply to only a limited number of arrangements.

4 CHAMPUS contractors, because they receive some cost-based reimbursement, do not qualify as EMCOs at this time. The OIG has asked for input as to whether CHAMPUS contractors should be included in the definition of an EMCO.
However, when an FQHC contracts with another entity which in turn contracts with the EMCO thereby making the FQHC a "downstream" contractor, the FQHC does not fall within the parameters of the safe harbor if it also claims supplemental (wrap-around) reimbursement. Thus, if an FQHC contracts with a network, Physician Hospital Organization ("PHO"), Independent Practice Association ("IPA") or other entity which accepts payment directly from the EMCO as a first tier contractor, then the downstream contractual arrangement, i.e. the provider (FQHC) contract with the first-tier contractor (intermediary entity), is not protected. The OIG believes that these arrangements may result in abuse inasmuch as the downstream contractor -- the FQHC -- is entitled to cost-based reimbursement. A possibility exists, according to the OIG, that the first tier contractor's (intermediary entity) remuneration paid to the downstream contractor, in this case the FQHC, might be too low and, therefore, the FQHC's claim for wrap-around would increase the costs of the federal health care program. This means that, except for FQHCs which are first-tier contractors, i.e. contracting directly with the EMCO, FQHCs are not protected under this safe harbor if they receive wrap-around payments.

If, however, the FQHC waives its right to wrap-around payments, then it appears that it would be entitled to protection so long as the safe harbor's other two limitations do not apply (see discussion below). Alternatively, the arrangement with the network, PHO, IPA or other intermediary entity might be restructured to allow the FQHC to obtain and maintain first-tier contracting status. Being a first-tier contractor allows the FQHC to not only have the safe harbor's protection but also to claim supplemental payments for rendering services to Medicaid patients.

To accomplish this goal of obtaining and maintaining first-tier contracting status, an evaluation of the FQHC's current arrangement(s) must be undertaken by the parties as well as counsel familiar with the statute, implementing regulations and OIG guidelines and opinions. In certain (but not all) instances, the FQHC must renegotiate its role with the intermediary entity so that the FQHC will be the first tier contractor. Or, depending upon the relative bargaining strength of the FQHC vis-à-vis the intermediary entity and the policies of the EMCO, both the FQHC and the intermediary entity may be first-tier contractors. All of the parties, the EMCO, the intermediary entity and the FQHC, must be involved as each has liability exposure under the Anti-Kickback Law. A comprehensive analysis of all relevant factors, including the priorities of the EMCO must occur before restructuring can begin.

The two other limitations to this managed care/risk sharing safe harbor concern the goods and services for which payment is made, and they apply to both first-tier and downstream contractors. Regardless of whether an entity is a first-tier or downstream contractor, this safe harbor does not protect the entity’s receipt of compensation for goods and services or remuneration not reasonably related to the provision of goods and services. As examples of non-related and, therefore, unprotected activities, the OIG cites marketing or other services provided prior to enrollment as activities not entitled to protection. Thus, if the EMCO pays the FQHC fifty cents per member per month for recruiting their patients to join the EMCO, such capitation

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5 Likewise, contracts between first-tier contractors and downstream contractors must be in writing, have a term of one year and cannot shift the financial burden of the contract so that Federal health program costs are increased.
payment would not be protected. The second limitation relates to arrangements which would fall within the safe harbor’s protection but for the arrangement being part of a larger scheme to steer fee-for-service business to the first-tier or downstream contractor or as, the OIG usually terms this practice, “swapping.”

III. NACHC’s Response to the OIG’s Interim Rule

NACHC has submitted comments to the OIG regarding its interim rule opposing the rule’s failure to protect, through this new safe harbor, arrangements between intermediary entities contracting with FQHCs for the provision of Medicaid services when those FQHCs seek supplemental payments from State Medicaid agencies. Essentially, NACHC continues to maintain that the same safe harbor protection the OIG has provided to agreements between EMCOs and FQHCs should be available to FQHCs which contract with intermediary entities which, in turn, contract with EMCOs for the provision of Medicaid services.

In this regard, NACHC has argued that federal Medicaid law pursuant to amendments enacted by the Balanced Budget Act of 1997, entitles FQHCs contracting with EMCOs to supplemental payments from State Medicaid agencies so as to assure receipt of their reasonable cost, and this protection should not be undermined because the FQHC is providing its services under contract to an intermediary entity. NACHC noted that in some State’s managed care programs, FQHCs have had no choice but to serve their Medicaid patients through IPAs, PHOs, networks or other intermediary entities, and in some instances FQHCs have formed their own networks so as to better adapt to State managed care programs.

NACHC has also contacted officials at the Health Care Financing Administration and requested that agency to make clear that it interprets federal Medicaid legislation as providing for State agency supplemental payments to FQHCs regardless of whether the FQHC has a direct contract with an EMCO or whether it provides services through an agreement with an intermediary entity that contracts with an EMCO. It is NACHC’s view that if HCFA states this position clearly, OIG would have to conform its safe harbor to reflect HCFA’s supplemental payment position.

Finally, in its comments to OIG, NACHC has requested that should OIG determine that it will not revise its new rule so as to safeguard EMCO/intermediary/FQHC arrangements, that it allow FQHCs affected by this rule a reasonable period of time in which to revise or terminate these arrangements. Note: While NACHC is hopeful that the OIG will respond to NACHC’s comment by revising its rule or, at a minimum, by providing FQHCs a period of time in which to revise or terminate current arrangements, there is no guarantee that the OIG will do so. Thus, FQHCs cannot rely on these efforts to safeguard them from the liability exposure that they currently incur in these arrangements.

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6 For example, if the EMCO sponsors a fee-for-service health benefit plan to commercial purchasers and the provider agrees to participate in the federal health care program plan so that it may also participate in the commercial plan program.
IV. Conclusion: Next Steps for FQHCs Contracting With Networks and Those Considering Such Arrangements

Compliance with the new risk sharing safe harbor must occur immediately as the Interim Final Rule became effective upon its promulgation in November 1999. Such an effort must begin with an examination of the FQHC’s contractual arrangements with EMCOs as well as networks, PHOs, IPAs and other intermediary entities. Based upon this evaluation, some restructuring of these relationships may be necessary in order to fit within the parameters of the new managed care/risk sharing safe harbor. In fact, such restructuring may be obligatory as there is likely to be a provision in the EMCO’s contract with the intermediary entity that requires both parties to remain compliant with applicable federal law. Such restructuring should permit FQHCs to retain their ability to submit claims for wrap-around payments from the Medicaid program. Of course, FQHCs currently considering a new arrangement with an intermediary entity should also consider the implications of the new safe harbor and consult counsel as to how they might be able to structure their new arrangements to avoid violation of the federal Anti-Kickback Law.
Part IV

Department of Health and Human Services

Office of Inspector General

42 CFR Part 1001
Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements; Final Rule
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991-AA91

Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements

AGENCY: Office of Inspector General (OIG), HHS

ACTION: Interim final rule

SUMMARY: In accordance with section 216 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, this interim final rule establishes two new safe harbors from the anti-kickback law (section 1128B(b) of the Social Security Act) to provide protection for certain managed care arrangements. The first safe harbor protects certain financial arrangements between managed care plans and individuals or entities with whom they contract for the provision of health care items and services, where Federal health care programs pay such plans on a capitated basis. The second safe harbor protects certain financial arrangements between managed care plans (including employer-sponsored group health plans) and individuals or entities with whom they contract for health care items and services with respect to services reimbursed on a fee-for-service basis by a Federal health care program provided that such individuals and entities are placed at substantial financial risk for the cost or utilization of items or services furnished to Federal health care program beneficiaries. Each of these safe harbors set forth standards that will result in the particular arrangement being protected from criminal prosecution and civil or administrative sanctions under the anti-kickback provisions.

DATES: Effective date: This rule is effective on November 19, 1999.

Comment period: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on January 18, 2000.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–54–IFC, Room 5246, Cohen Building 330 Independence Avenue, S.W., Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: Julie E. Kass, Senior Counsel, Office of Counsel to the Inspector General, (202) 205–9501; or Joel Schaer, Regulations Officer, Office of Counsel to the Inspector General, (202) 619–1306.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Anti-Kickback Statute

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a–7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a Federal health care program (including Medicare and Medicaid). The offense is a felony punishable by fines of up to $25,000 and imprisonment for up to 5 years. Section 2 of the Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA) authorizes the exclusion of an individual or entity from participation in the Medicare and State health care programs if it is determined that the party has violated the anti-kickback statute. In addition, the Balanced Budget Act of 1997, Public Law 105–33, amended section 1128A(a) of the Act to include an administrative civil money penalty provision for violating the anti-kickback statute. The administrative sanction is $50,000 for each act and an assessment of not more than 3 times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose. (See section 1128A(a)(7) of the Act; 42 U.S.C. 1320a–7a(a)(7)).

The anti-kickback statute contains five statutory exceptions from the statutory prohibitions. The exceptions are for certain discounts obtained by a provider and disclosed to the Federal health care program, compensation paid to a bona fide employee by an employer, amounts paid to a group purchasing organization by a vendor subject to certain conditions, waivers of coinsurance by Federally qualified health centers, and remuneration paid as part of a risk-sharing arrangement. The last exception is the subject of this rulemaking.

Section 14 of MMPPPA also required the OIG to promulgate regulations specifying those payment and business practices that, although potentially capable of inducing referrals of business under the Medicare and State health care programs, would not be subject to criminal prosecution under section 1128B of the Act and that will not provide a basis for administrative sanctions under sections 1128(b)(7) or 1128A(a)(7) of the Act. (See section 2 of Pub. L. 100–93.) Congress intended that the regulations setting forth various “safe harbors” would be periodically updated to reflect changing business practices and technologies in the health care industry.

The failure of an arrangement to fit inside a safe harbor or statutory exception does not mean that the arrangement is illegal. It is incorrect to assume that arrangements outside of a safe harbor are suspect due to that fact alone. That an arrangement does not meet a safe harbor only means that the arrangement does not have guaranteed protection and must be evaluated on a case-by-case basis.

The anti-kickback statute potentially applies to many managed care arrangements because a common strategy of these arrangements is to offer physicians, hospitals and other providers increased patient volume in return for substantial fee discounts. Because discounts to managed care plans can constitute “remuneration” within the meaning of the anti-kickback statute, a number of health care providers and managed care plans have expressed concern that many relatively innocuous, or even beneficial, commercial managed care arrangements implicate the statute and may subject them to criminal prosecution and administrative sanctions. In response to these concerns, we issued final safe harbor regulations for managed care arrangements on January 25, 1996 (61 FR 2122) to protect certain managed care arrangements that we did not believe posed any significant risk of fraud or abuse. (See 42 CFR 1001.952(m)). We are soliciting comments on whether the current managed care safe harbor should be removed in light of this rulemaking so as to avoid confusion.

We recognize that many managed care arrangements exist in the marketplace today that do not fall within a safe harbor, but are not illegal under the anti-kickback statute. Such arrangements must be analyzed on a case-by-case basis. Any individual or entity with questions regarding whether a specific arrangement violates the anti-kickback statute may submit an advisory opinion request to the OIG in accordance with regulations set forth in 42 CFR part 1008.
B. Section 216 of HIPAA

1. Summary of Statutory Provision

In section 216 of HIPAA, Congress created a new statutory exception to the anti-kickback statute that covers remuneration in accordance with two categories of risk-sharing arrangements. The first category is "any 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 1876 (of the Social Security Act) * * *". The second category is "any 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 written agreement, through a risk-sharing arrangement, places the individual 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." Congress directed the Department to develop regulations implementing the exceptions using a negotiated rulemaking process.

2. Negotiated Rulemaking Process

The negotiated rulemaking process began in the spring of 1997, and on March 7, 1997, a facilitator with the Department’s Departmental Appeals Board issued a convening report to the Inspector General, setting out findings and recommendations on the use of a negotiated rulemaking process for these regulations and identifying industry and consumer representatives who, based on their interests, should serve on the committee. On May 23, 1997, the OIG issued a notice of intent to form a Negotiated Rulemaking Committee, in accordance with the Negotiated Rulemaking Act of 1990, Public Law 101–648, as amended by Public Law 102–354 (5 U.S.C. 561 et seq.), and requested public comments on whether those interests affected by the key issues of the negotiated rulemaking had been identified (62 FR 28410). After review of the comments, the Secretary appointed a committee consisting of 23 parties representing all of the major groups identified as having a significant interest in these regulations. The negotiated rulemaking committee was comprised of the following groups:

- American Health Care Association
- American Medical Association
- American Medical Group Association
- Blue Cross Blue Shield Association
- Consumer Coalition for Quality Health Care
- Coordinated Care Coalition
- Department of Justice
- Federation of American Health Systems
- Health Insurance Association of America
- Health Insurance Manufacturers Association
- Independent Insurance Agents of America/National Association of Health Underwriters/National Association of Life Underwriters
- National Association of Chain Drug Stores
- National Association of Community Health Centers
- National Association of Insurance Commissioners
- National Association of Medicaid Fraud Control Units
- National Association of State Medicaid Directors
- National Rural Health Association
- Office of Inspector General, DHHS
- Pharmaceutical Research and Manufacturers of America
- The IPA Association of America
- American Health Care Association
- American Medical Association
- American Medical Group Association
- Blue Cross Blue Shield Association
- Consumer Coalition for Quality Health Care
- Coordinated Care Coalition
- Department of Justice
- Federation of American Health Systems
- Health Insurance Association of America
- Health Insurance Manufacturers Association
- Independent Insurance Agents of America/National Association of Health Underwriters/National Association of Life Underwriters
- National Association of Chain Drug Stores
- National Association of Community Health Centers
- National Association of Insurance Commissioners
- National Association of Medicaid Fraud Control Units
- National Association of State Medicaid Directors
- National Rural Health Association
- Office of Inspector General, DHHS
- Pharmaceutical Research and Manufacturers of America
- The IPA Association of America

The committee was charged with reaching consensus on the basic content of interim final regulations relating to section 216 of HIPAA. Committee consensus was defined as a unanimous concurrence of all committee members, provided that there was a quorum of two-thirds of the committee members present. Unanimous concurrence with respect to a committee decision meant only that the committee members "could live with" the particular decision.

The committee held seven multi-day negotiating sessions beginning in June 1997. During the sessions, the committee made significant progress in developing new regulations. On January 22, 1998, the committee unanimously concurred on the committee statement that formed the basis of this rulemaking when considered as a whole. A copy of the committee statement can be found on the OIG web site at http:// www.dhhs.gov/program/oig.

C. Basis for Interim Final Rulemaking

These interim final regulations will be effective upon publication. For a number of reasons, we find that good cause exists for an immediate effective date for these regulations. First, Congress specifically mandated that the regulations implementing section 216 of HIPAA should be published as interim final regulations. Second, those portions of the rule that are technically outside of the scope of section 216 of HIPAA were discussed in a public forum during the negotiated rulemaking sessions and are integral to the protections afforded under the portions of the regulation implementing section 216 of HIPAA. In addition, safe harbors do not create any affirmative obligation on any individuals or entities. They only exempt certain conduct from potential criminal and administrative sanctions. As a result, we find that the benefit conferred on the public by this rule’s immediate promulgation provides good cause for it to be effective upon publication.

II. Provisions of the Interim Final Rule

In this section, we discuss the purpose and scope of the safe harbors, summarize the provisions of this interim final rule, and describe general issues that arose during the negotiated rulemaking. We then describe the individual provisions of the rulemaking and related issues discussed by the committee.

A. Purpose

The rule is intended to implement section 216 of HIPAA by creating two new regulatory safe harbors that correspond to the two categories of managed care arrangements identified in that statutory provision. The first safe harbor, set forth in § 1001.952(t), protects various financial arrangements between managed care entities that receive a fixed or capitated amount from the Federal health care programs and individuals and entities with whom the managed care entity contracts for the provision of health care items or services.

The second safe harbor, set forth in § 1001.952(u), protects contractual relationships between managed care entities and their contractors and subcontractors where the contractors and subcontractors are at substantial financial risk for the cost or utilization of items or services they provide or order for Federal health care program beneficiaries. As explained in detail below, the negotiated rulemaking committee recognized that there are few existing managed care arrangements that would qualify under newly-established § 1001.952(u) that are not otherwise covered by the safe harbor in newly-established § 1001.952(t). In practice, most managed care arrangements, such as employer-sponsored health plans, do not place their contractors and subcontractors at substantial financial risk for the cost or utilization of items or services provided to Federal health care beneficiaries.
care program beneficiaries. Typically, the contractors and subcontractors to such health plans are reimbursed directly by the Federal payor on a fee-for-service basis. Notwithstanding the fee-for-service payment arrangements, §1001.952(u) identifies a category of arrangements that could qualify for protection.

B. Scope of the Safe Harbors

The safe harbors established in §§1001.952(t) and (u) protect remuneration between parties where the remuneration is a price reduction for the provision of health care items or services. Other remuneration, such as profit distributions from investment interests in an entity with a risk sharing arrangement, is not protected by these safe harbors. Individuals or entities seeking safe harbor protection for such arrangements may meet the requirements of another safe harbor, such as safe harbor for investment interests in small entities set forth in §1001.952(a)(2).

In addition, if an arrangement covers both remuneration that qualifies for protection under either §1001.952(t) or (u), and remuneration that is not qualified for protection, the former remuneration remains protected. For example, a managed care plan may “carve out” transplant services from its capitated payment methodology and pay for those services on a fee-for-service basis. The remuneration for the transplant services would not be protected under these safe harbors. However, payments for the items or services covered by the capitation, assuming all safe harbor conditions are otherwise met, would not be lost. Further, an arrangement that potentially falls within more than one safe harbor need only meet the requirements of one safe harbor. The remuneration for the transplant services may be protected under a separate safe harbor, such as the personal services safe harbor (§1001.952(d)).

Finally, compliance with a safe harbor only provides protection from the Federal anti-kickback criminal statute and related administrative sanction authorities. Safe harbors do not apply to other laws, such as State licensure laws, antitrust laws or other Federal and State health care fraud laws. Further, the terms and definitions in these safe harbors do not apply to other laws, including but not limited to the anti-trust laws.

C. General Issues Discussed By The Committee

The literal language of section 216 of HIPAA presented several threshold problems. First, the two categories of managed care arrangements identified by section 216 of HIPAA were narrow and did not provide protection for other managed care arrangements that the committee believed presented similar low risks of fraud or abuse. For example, section 216 was passed prior to the enactment of the Balanced Budget Act of 1997, which provides both for the phasing out of section 1876 managed care contracts, and the creation of Medicare+Choice programs under the new Medicare Part C. Many of the new Medicare+Choice organizations are similar to section 1876 organizations and deserve the same extensive protection. Nevertheless, while Congress in the Balanced Budget Act changed many of the references to section 1876 in the Act to the new Medicare Part C, it did not change the reference in section 216 of HIPAA.

A similar issue arose with respect to the second category of arrangements protected by section 216. The statutory language was limited to arrangements in which the provider or supplier is at substantial financial risk for items or services that it is obligated to provide. However, as a practical matter, many effective managed care systems place the physician at substantial risk, not for the physicians they provide directly, but for the ancillary and hospital services they order. Furthermore, the financial incentives in most managed care plans are based not on the individual performance of a physician, but on the aggregate performance of the physicians.

Given the shortcomings of the statutory language, the Department determined that it would exercise its authority under section 14 of the MMPPA to expand these safe harbors beyond the legal confines of section 216. Again, section 14 of MMPPA allows the Secretary to promulgate regulations to protect arrangements that the Department determines may technically violate the anti-kickback statute, but which pose a low risk of program fraud or abuse. Exercise of this authority permits protection of certain types of managed care arrangements that are not encompassed within the statutory language of section 216 of HIPAA. The committee statement includes these expanded provisions and specifically identifies them as areas outside of the scope of section 216.

A final conceptual issue was the definition of “substantial financial risk.” Some committee members wanted the rule to set forth clear “bright line” standards, so that both law enforcement officers and the industry would know whether a particular arrangement was protected or not. While bright line tests can potentially “chill” the development of some innovative managed care arrangements, any ambiguity in the scope of protection could be exploited by unscrupulous individuals or entities to engage in abusive or fraudulent activities, especially in light of the high burden of proof on the Government in criminal proceedings. Plans have the option of submitting advisory opinion requests for arrangements that do not fit within these safe harbors. Furthermore, the Department annually solicits suggestions for additions to the anti-kickback safe harbors (62 FR 65049; December 10, 1997). Moreover, we have agreed to review the target payment percentages of the numeric substantial financial risk test as more research and data become available.

D. Section 1001.952(t)—Price Reductions Offered to Eligible Managed Care Organizations

1. Overview

This safe harbor corresponds to the first category of arrangements identified in section 216 of HIPAA, which exempts certain arrangements involving “eligible organizations under section 1876” of the Act. Section 1876 of the Act provides for the Health Care Financing Administration (HCFA) to enter into managed care contracts with Federally-qualified health maintenance organizations (HMOs) and certain competitive medical plans that have characteristics similar to Federally-qualified HMOs. As used in section 1876 of the Act and the implementing regulations, an “eligible organization” encompasses both (i) Federally-qualified HMOs and competitive medical plans that have entered into either risk or cost-based managed care contracts with HCFA, and (ii) Federally-qualified HMOs that have not entered into risk or cost-based managed care contracts with HCFA.

This safe harbor recognized that eligible organizations with risk contracts under section 1876 of the Act presented little or no risk of overutilization or increased costs to the Federal health care programs, given applicable payment arrangements and regulatory oversight. When plans are paid a capitated amount for all of the services they provide regardless of the dates, frequency or type of services, there is no incentive to overutilize. In any event, even if overutilization occurs, the Federal health care programs are not at risk for these increased costs.

The safe harbor set forth in §1001.952(t) extends protection from the anti-kickback statute beyond the
managed care arrangements under section 1876 of the Act that are specifically protected by section 216 of HIPAA. The expansion includes other programs where the Federal health care programs pay on a capitated or fixed aggregate basis, such as certain Medicare Part C plans. Further, it extends safe harbor protection “downstream” to cover subcontractors with other providers and entities to provide items and services in accordance with a protected managed care arrangement. So long as the Federal health care programs’ aggregate financial exposure is fixed in accordance with its contract with the managed care organization, these subcontracting arrangements are protected regardless of the payment methodology, subject to the limitations set forth below.

2. Limitations

While §1001.952(t) broadens the statutory exception in important respects, there are some important limitations. First, the broad protection for arrangements with subcontractors is limited to risk-based managed care plans that do not claim any payment from a Federal health care program other than the capitated amount set forth in the managed care plan’s agreement with the Federal health care program. Where the managed care plan, its contractors or its subcontractors are permitted to seek additional payments from any of the Federal health care programs, the regulatory safe harbor protection is significantly more limited. For example, protection is not extended to arrangements with subcontractors when the contract under section 1876 of the Act is cost-based or where the prime contract is protected solely because the contracting entity is a Federally-qualified HMO. In the first instance, reimbursement from the Federal health care program is based on costs, and in the latter case, services for Medicare enrollees are reimbursed on a fee-for-service basis. In both instances, reimbursement will increase with utilization, thus providing the same incentive to overutilize as any fee-for-service payment methodology.

A second limitation on the regulatory safe harbor protection is that it only applies to remuneration for health care items and services and those items or services reasonably related to the provision of health care items and services. Section 1001.952(t) does not cover marketing services or any services provided prior to a beneficiary’s enrollment in a health plan. This limitation also applies to the other new safe harbor in §1001.952(u).

Another significant limitation is that there is no protection if the financial arrangements under the managed care agreement are implicitly or explicitly part of a broader agreement to steer fee-for-service Federal health care program business to the entity giving the discount to induce the referral of managed care business. Specifically, we understand that most managed care plans have multiple relationships with their contractors and subcontractors for the provision of services for various product lines, including non-Federal HMOs, preferred provider organizations (PPOs) and point of service networks. Consequently, although neither a managed care plan receiving a capitated payment from a Federal health care program nor its contractors or subcontractors has an incentive to overutilize items or services or pass additional costs back to the Federal health care programs under the capitated arrangement, we are concerned that a managed care plan or contractor may offer (or be offered) a reduced rate for its items or services in the Federal capitated arrangement in order to have the opportunity to participate in other product lines that do not have stringent payment or utilization constraints. This practice is a form of a practice that has become known as “swapping”; in the case of managed care arrangements low capitation rates could be traded for access to additional fee-for-service lines of business. We are concerned when these discounts are in exchange for access to fee-for-service lines of business, where there is an incentive to overutilize items provided to Federal health care program beneficiaries.

For example, we would have concerns where an HMO with a Medicare risk contract under Medicare Part C also has an employer-sponsored PPO that includes retirees and requires participating providers to accept a low capitation rate for the Medicare HMO risk patients in exchange for access to the Medicare fee-for-service patients in the PPO. Although in such circumstances the cost to the Medicare program for the risk based HMO beneficiaries will not be increased, there may be increased expenditures for Medicare beneficiaries in the PPO arrangement, since the providers may have an incentive to increase services to the Medicare enrollees in the PPO to offset the discounted rates to the Medicare HMO. Accordingly, such arrangements could violate the anti-kickback statute and should not be protected.

3. Analysis of §1001.952(t)

a. Arrangements between eligible managed care organizations and first tier contractors. Section 1001.952(0(1)(i) is divided into two parts and sets out the substantive standards that arrangements must meet in order to receive safe harbor protection. Paragraph (0)(1)(i) of this section sets out the standards for arrangements between the eligible managed care organization (EMCO) and any individual or entity that contracts directly with the EMCO. These direct or “first tier” contractors are the only parties that are protected by the literal language of section 216 of HIPAA. Accordingly, the regulation treats these first tier contractors differently than individuals or entities that provide health care items or services in accordance with subcontractors with these first tier entities. We refer to these subcontractors as “downstream” contractors or providers. Paragraph (0)(1)(iii) of this section sets out the standards which must be met in order for arrangements between first tier contractors and any downstream subcontractor or between successive tiers of downstream subcontractors to be protected.

Under §1001.952(0(1)(i)(A), the EMCO and any first tier contractor must have an agreement that is written and signed by the parties, specifies the items and services covered under the agreement, and has a term of at least one year. These requirements are similar to the requirements for written agreements in other safe harbor provisions. In paragraph (1)(i)(A)(IV) of this section, there is a requirement that neither party will receive any additional payment for covered services from the Federal health care programs. This requirement is intended to assure that there is an incentive to control costs by eliminating the ability on the part of the first tier contractor to offset losses incurred through the capitated methodology.

There are three exceptions to this general prohibition on the plan’s receipt of additional Federal health care payments. These exceptions, set out in §1001.952(0(1)(i)(A)(IV) are:

- HMOs and CMPs that have Medicare cost-based contracts under section 1876 of the Act;
- Federally-qualified HMOs without a HCFA contract; and
- Federally qualified health centers that claim supplemental payments from a Federal health care program.

For Federally-qualified HMOs and Medicare cost-based HMO/CMPs, the billing arrangement under which they receive additional Federal health program payments must be set forth in
the written agreement. With respect to
Federally-qualified HMOs and Medicare
cost-based HMOs/CMPs, the language of
section 216 of HIPAA expressly requires
this exception, since they are "eligible
organizations" in section 1876 of the
Act. The exception for Federally-
qualified health centers is beyond the
language of section 216. Nevertheless,
an exception for Federally-qualified
health centers recognizes the special
role they play in health care delivery
systems in many medically underserved
areas. We wish to make clear, however,
that the safe harbor protects only the
provision of health care items or
services by (1) individuals or entities
that contract directly with the HMOs
and CMPs with cost-based contracts
under section 1876 of the Act, or with
Federally-qualified HMOs that do not
have a risk-based contract with the
Medicare program, i.e., first tier
providers, or (2) in the case of a
Federally-qualified health center, by the
health center itself.

As part of this interim final rule, we
are soliciting comments concerning
coverage of arrangements where a
Medicaid managed care plan or an
individual or entity under such a plan
bills another Federal health care
program on a fee-for-service basis for
a person that is dually eligible for
Medicare and Medicaid. One possibility
would be to extend safe harbor
protection in instances where (1) the
Medicaid plan bills the Federal health
care program; (2) the individual or
entity is paid by the Medicaid plan in
the same amount and in the same way
as for those enrollees who are not
subject to the coordination of benefits;
and (3) neither the plan nor the
individual or entity otherwise shifts the
burden of such an arrangement to the
extent that increased payments are
claimed from Federal health care
programs.

b. Arrangements between first tier
contractors and downstream
contractors. Except as discussed below,
arrangements between a first tier
contractor and a downstream contractor,
or between successive tiers of
downstream contractors, are protected
as long as the arrangement is for the
provision of health care items or
services that are covered by the
arrangement between the first tier
contractor and the EMCO. In addition,
arrangements between the first tier
contractor and sub contractor, or
between such subcontractors and
subcontractors farther downstream,
must meet the same requirements as
apply to arrangements between EMCOs
and first tier contractors.

The one exception to the generally
broad safe harbor protection for
"downstream" providers is for
arrangements between providers for
health care items or services that are
downstream from (1) Federally-qualified
health centers receiving supplemental
payments, (2) HMOs or CMPs with cost-
based contracts under section 1876 of
the Act; or (3) Federally-qualified HMOs
(unless they are provided in accordance
with a risk-based contract under section
1876 of the Act or Medicare Part C).
Reimbursement to these entities is not
strictly risk-based and presents some
risk of overutilization and increased
Federal program costs. However, the
safe harbor does protect entities that are
providing items or services in
accordance with a contract or
subcontract with Federally-qualified
health centers if the health centers do
not receive any supplemental payments
from the State. In such situations, the
Federally-qualified health center has a
strong financial incentive to guard
against overutilization or excessive
costs.

c. Definitions. For purposes of
§1001.952(u)(1)(i), we have set forth
the definition for several terms. Rather
than discuss the definitions in alphabetical
order (as they appear in the regulation),
they are discussed below in logical
order, grouping the definitions that
to apply to various contracting parties
together.

Eligible Managed Care Organization—
Eligible managed care organizations are
Medicare risk-based or cost-based
contractors under section 1876 of the
Act. Medicare Part C health plans
(except for medical savings accounts
and fee-for-service plans), certain
Medicaid managed care organizations (as
described below), most Programs For
All Inclusive Care For The Elderly
(PACE) and Federally-qualified HMOs.

Section 1001.952(u)(2)(ii)(C)–(D)
identify the Medicaid managed care
organizations that fall within the
definition of eligible managed care
organization. Protected arrangements
are those defined in section
1903(m)(1)(A) of the Act that provide or
arrange for services for Medicaid
enrollees under a contract in accordance
with section 1903(m). These plans are
paid by the State Medicaid agency on a
capitated basis. In addition, the safe
harbor provision protects other plans
with risk-based contracts with a State
agency to provide or arrange for items
or services to Medicaid enrollees,
provided that contracts are subject to
the upper payment limit in 42 CFR
447.361 or any equivalent cap approved
by the Secretary.

The safe harbor also protects most
PACE programs. These programs
provide a capitated amount for medical
certain social services for the
elderly. The BBA changed not-for-profit
PACE programs from demonstration
status to covered services under
Medicare and Medicaid. PACE
programs that still have demonstration status (i.e.,
certain for-profit programs) are not
protected by this safe harbor.

We are soliciting comments on
whether the Department of Defense's
TriCare program should also be
included within the definition of
"eligible managed care organization" and,
if included, to what extent protection
should be granted. The committee
statement includes TriCare
within the types of organizations that
should receive protection through the
Department's regulatory authority.
However, TriCare is a relatively new
health care program for the active status
military and their dependents, and has
a more complex reimbursement
methodology than Medicare risk
contracts and retains important
elements of cost-based, retrospective
methodologies. Accordingly, it is
unclear whether there are financial
safeguards to control overutilization and
limit costs to the Federal Government
that are sufficient to warrant per se
protection from the anti-kickback
statute.

First Tier Contractors—A first tier
contractor is an individual or entity
that has a contract to provide or arrange for
items or services directly with an
eligible managed care organization.

Downstream Contractor—A
downstream contractor is an individual
or entity that provides or arranges for
items or services in accordance with a
subcontract with either (1) a party that
is contracting directly with an EMCO, or
(2) another party for the provision or
arrangement of items or services that are
covered in accordance with a contract between the parties in (1).

**Items and Services**—The term “items and services” is defined for purposes of this section to mean health care items, devices, supplies or services or those items or services that are reasonably related to such services, such as non-emergency transportation, patient education, attendant services, disease management, case management and utilization review and quality assurance. “Items and services” does not include marketing services or any similar pre-enrollment activities. The exclusion of marketing services is not meant to apply to nurse call-in lines or value-added services for current enrollees.

**E. Section 1001.952(u)—Price Reductions Offered to Qualified Managed Care Plans**

1. Overview

An overview of this new safe harbor, a summary of several major issues that arose during the committee’s discussions, and an outline of the new provisions of this safe harbor are set forth below.

While §1001.952(l) protects certain arrangements based upon the “status” of the parties, e.g., designation as an eligible organization for purposes of section 1876 of the Act or participation in the PACE program, §1001.952(u) provides safe harbor protection for arrangements that qualify under the functional test identified in section 216 of HIPAA, that is, risk-sharing arrangements that place a health care provider under substantial financial risk for the cost or utilization of health care services the provider is obligated to provide.

2. Limitations

Section 216 of HIPAA contains two important qualifications that substantially narrow the universe of arrangements that can potentially qualify for protection using the functional test. The most important constraint is that the provider has to be at substantial financial risk for items or services provided to Federal health care program beneficiaries. However, except for providers participating in the Medicare and Medicaid managed care plans that are already covered by the new safe harbor in §1001.952(l), almost all other providers are reimbursed by Federal health care programs on a fee-for-service basis.

Accordingly, in order to qualify under §1001.952(u), the risk sharing arrangement must be part of a comprehensive managed care plan. We use the term “qualified managed care plan” (QMCP) to describe such plans. These plans must be health plans, as defined in current safe harbor regulations (§1001.952(l)(2)), and provide a comprehensive range of health services. In addition, a QMCP must include certain elements in its arrangement with providers to assure that the health care services are managed, including utilization review, quality assurance and grievance procedure requirements. These requirements are derived from the current regulatory requirements for “eligible organizations” under section 1876 of the Act. Some of the representatives at the negotiating sessions expressed concern that while some of a QMCP’s arrangements with providers will meet the above requirements, others will not. The committee concluded that those

committee members believed the term “organization” could refer to any entity that provides health care services. However, other committee members were concerned that if the term “organization” meant any health care entity or individual, it would be easy for two parties to camouflage an illegal kickback arrangement as a risk sharing arrangement that could meet the requirements of the safe harbor. For example, the entity paying the kickback could agree to a capitation payment below fair market value for one service or group of patients, i.e., the “remuneration,” in exchange for referrals of fee-for-service patients. The scheme would be a variant of providing a deep discount on a good not reimbursable by Medicare to induce the purchase of other goods that are reimbursable by Medicare. We have previously stated that such arrangements potentially implicate the anti-kickback statute (61 FR 2139; January 25, 1996).

The committee members opposed to a broad reading of the term “organization” contended that the term in section 216 of HIPAA had to be read in context of the entirety of section 216. Under their reading, the term “organization” referred back to the term “eligible organization,” which preceded it in the same sentence, and should be construed consistent with that term. In other words, an “organization” in section 216 of HIPAA should have many of the characteristics of an “eligible organization” under section 1876 of the Act. The committee statement, as a whole, reflects this view.

Accordingly, in order to qualify under §1001.952(u), the risk sharing arrangement must be part of a comprehensive managed care plan. We use the term “qualified managed care plan” (QMCP) to describe such plans. These plans must be health plans, as defined in current safe harbor regulations (§1001.952(l)(2)), and provide a comprehensive range of health services. In addition, a QMCP must include certain elements in its arrangement with providers to assure that the health care services are managed, including utilization review, quality assurance and grievance procedure requirements. These requirements are derived from the current regulatory requirements for “eligible organizations” under section 1876 of the Act. Some of the representatives at the negotiating sessions expressed concern that while some of a QMCP’s arrangements with providers will meet the above requirements, others will not. The committee concluded that those
arrangements that meet the requirements could receive protection under the safe harbor, even though the other arrangements could not.

Further, the committee statement, which was adopted as a whole, reflects the view that the QMCP had to be at some financial risk for the cost or utilization of services provided to enrollees. This requirement was expected to protect against situations in which, for the reasons discussed above in section I.E.1 of this preamble, the providers generally are not at actual risk for the items or services being provided to Medicare enrollees. Accordingly, protection for such plans is premised on (1) the plans being at risk for services to their non-Medicare enrollees, and (2) the plans reimbursing providers for items or services to Medicare beneficiaries on the same basis as for other plan enrollees. Given the variety of employer arrangements, the regulations set out two alternative methods by which the QMCP must be at financial risk.

The first option is that the QMCP can receive a premium payment that is fixed in advance. This requirement would cover all insurance arrangements in which, by definition, the plan assumes risk. Under this option, 50 percent of the enrollees cannot have primary coverage under Medicare. Alternatively, even where the QMCP is not paid on a premium basis, it can qualify if less than ten percent of the plan's enrollees have primary coverage under Medicare. This alternative will permit many self-funded ERISA plans that provide health care items or services in accordance with arrangements with third party administrators (TPAs) or contracts with insurers for administrative services only (ASOs) to qualify. In these arrangements, an employer pays the TPA or ASO separately for administering the plan and retains responsibility for payments to the providers. In such arrangements, the TPA or ASO may not have a financial incentive to control utilization or costs. Moreover, because the rule requires the providers to reassign any proceeds from Federal health care programs to the employer, the employer may actually profit on services to Medicare beneficiaries. By limiting Federal health care beneficiaries to less than 10 percent of total enrollment, the regulations substantially limit the ability of the employer to offset costs for its employees with Medicare reassignment.

In addition to these requirements, the regulations also would not protect a QMCP that is receiving premiums from setting its premiums based on the number of Federal health care program beneficiaries in the health plan or the amount of services provided to such beneficiaries. Some committee members believed that such a requirement was necessary to prevent employers from receiving lower rates for non-federal health care program beneficiaries because the plan expects to make up the difference on utilization by the Federal health care program beneficiaries for whom they receive fee-for-service payments.

b. Substantial financial risk

Developing a definition for "substantial financial risk" was one of the most difficult and time consuming tasks for the committee. Several suggestions were offered, and two caucuses were held and developed options. One caucus discussed a numerical approach to the definition, while the other tried to find a non-numerical approach. Much of the discussion over the suggested definitions concerned whether a non-numerical definition could be clear and precise enough for individuals and entities to know definitively whether they met the safe harbor requirements. Suggestions that did not provide enough assurances were discarded, and after some joint discussion, the elements of each approach were combined. The committee statement and these regulations reflect that determination.

For purposes of the rule, the methods to determine substantial financial risk were grouped into three standards:

- The payment methodology standard protects certain payment methodologies that are commonly used to place an individual or entity at substantial financial risk, including the ratio, percentage of premium arrangements and payments based on certain diagnostic related groupings, so long as the reimbursement is reasonable and precise enough for individuals and entities to know definitively whether they met the safe harbor requirements. Suggestions that did not provide enough assurances were discarded, and after some joint discussion, the elements of each approach were combined. The committee statement and these regulations reflect that determination.

- The numeric standard includes bonuses and withhold arrangements that meet certain criteria.

- The numeric standard includes bonuses and withhold arrangements that meet certain criteria.

4. Analysis of § 1001.952(u)

a. Arrangements between QMCps and first tier contractors

In order to qualify for protection, a contractual arrangement must be directly between a QMCP and a first tier contractor. The definition of a QMCP is set forth in § 1001.952(a)(2)(vi). There are three standards that apply to the arrangements between the QMCP and first tier contractors. First, § 1001.952(a)(1)(f)(A) requires that the contracts must be set out in writing and contain certain information, including the payment methodology. These requirements facilitate verification of
compliance with the substantive requirements of the regulation.

Second, §1001.956(u)(2)(i)(B) makes clear that where a first tier contractor has an investment interest in the QMCP, the investment interest must meet the safe harbor requirements of §1001.952(a)(1). This condition addresses the concern that the contractor's substantial financial risk may be offset by returns on its ownership interest in the organization and therefore undermine protections against overutilization. We want to emphasize that, while arrangements in which providers have investment interests in a QMCP may not qualify for safe harbor protection, such arrangements do not necessarily violate the anti-kickback statute.

Third, §1001.952(u)(1)(i)(C) defines "substantial financial risk" by four alternative methodologies. The first three methods (paragraphs (u)(1)(ii)(C)(i)–(iii)) provides protection for several payment methodologies that historically have been used by plans and HMOs to transfer risk to providers: Capitation, percentage of premiums and inpatient reimbursement based on Federal health care program diagnostic related groupings (DRGs). Under any of these methods, the payment amounts must be reasonable given the historical utilization patterns and costs for the same or comparable populations in similar managed care arrangements. We are requesting comments on the extent to which the risk of full capitation is diminished by the purchase of commercial stop loss insurance or contractual provisions regarding the limitation of financial liability. The exception for DRGs is limited to Federal health care program DRGs, since these are the only DRG methodologies applicable to other enrollees. Because Medicare requires hospitals to claim payment directly, the rule is applicable where a hospital submits claims directly to a Federal health care program on a DRG basis and the plan pays the hospital for the plan’s other enrollees using the same methodology. Section 1001.952(u)(1)(i)(E) does not protect parties to a contract from trading discounted business for more remunerative fee-for-service business.

b. Arrangements with downstream contractors. Section 1001.952(u)(1)(ii) provides that subcontracting arrangements between first tier contractors and downstream contractors (and any arrangements with providers farther downstream) are protected if both parties are paid in accordance with one of the substantial financial risk methodologies identified in this section. This provides assurances that both parties have a financial incentive to control utilization. In addition, the individual or entity providing items or services in accordance with the contract must be paid for items and services to Federal health care program beneficiaries in the same manner as for other enrollees. Finally, as discussed above, the arrangement cannot involve remuneration in return for, or to include the provision or acceptance of other Federal health care program business and cannot shift the financial burden of the arrangement to the Federal health care programs.

c. Definitions. Most of the defined terms in §1001.952(u) have the same meaning as those set forth in §1001.952(d). The additional defined terms are discussed below.

Minimum Payment—The minimum payment is the guaranteed amount that an individual or entity is entitled to receive under a risk-sharing contract for purposes of calculating substantial financial risk on the remaining compensation. In year one of an arrangement, it is not necessary to include the performance bonus in the substantial financial risk calculation. Section 1001.952(u)(1)(i)(D) provides that the QMCP (or, in the case of a self-funded ERISA plan, the employer) must bill the Federal health care programs directly for covered services and compensate the provider for such services on the same basis as services to similar enrollees without primary coverage from a Federal health care program. Two examples of such arrangements are (1) staff model HMOs where the physicians are salaried, and (2) a plan that, in accordance with a reassignment agreement, bills Medicare for Part B services and pays the provider under the same bonus arrangement applicable to other enrollees. Because Medicare requires hospitals to claim payment directly, the rule is applicable where a hospital submits claims directly to a Federal health care program on a DRG basis and the plan pays the hospital for the plan’s other enrollees using the same methodology.
financial risk under the numeric standard. The minimum payment is the lowest amount a provider can reasonably be expected to receive based on past or expected performance.

Obligated To Provide—The statute requires individuals or entities to be placed at substantial financial risk for the cost or utilization of services they are "obligated to provide." A strict reading of the statutory language would not include many risk arrangements that are currently used to give incentives to physicians. Accordingly, for purposes of this regulation, the term is defined broadly and includes any items or services (as defined in this regulation) for which the individual or entity is financially responsible, makes referrals, or receives incentives based on the provider, group or health plan's performance.

Qualified Managed Care Plan—As discussed above, the committee statement, which was adopted as a whole, reflects the view that protection should apply to only those risk-sharing arrangements for the provision of health care items or services that were part of an comprehensive managed health care plan. For purposes of these regulations, we have defined such plans as "qualified managed care plans." Section 1001.952(u)(2)(v)(vi) requires that the terms and services be provided under agreement by an entity that qualifies as a health plan under § 1001.952(1)(2), and § 1001.952(u)(2)(vi)(A) requires that the QMCP provide a comprehensive range of health services. Section 1001.952(u)(2)(vi)(B) requires that the organization provide or arrange for (1) reasonable utilization goals and a utilization review program; (2) a quality assurance program that promotes the coordination of care, protects against underutilization and specifies patient goals, including measurable outcomes where appropriate; (3) grievance and hearing procedures; (4) protection for its members from incurring financial liability other than copayments and deductibles; and (5) assurances that treatment for Federal health care program beneficiaries is no different than for other enrollees due to their status as Federal health care program beneficiaries. These requirements are derived from current regulations under section 1876 of the Act and assure that basic indicia of a managed care plan exist. Finally, the requirement that there be at least 50 percent non-Federal health care program enrollees reduces the likelihood that Federal health care program beneficiaries will receive disparate treatment either in insured or ERISA plans as compared to other enrollees.

Target Payment—The target payment is defined as the fair market value payment consistent with arms-length negotiations that will be earned by an individual or entity depending on the individual or entity's meeting a utilization target or range of utilization targets that are consistent with historical utilization rates for the same or comparable populations in similar managed care arrangements. The utilization target may not be a precise number, but rather a range. In order to protect against undue incentives to underutilize, the rule provides that if a provider's utilization falls below or surpasses the utilization target (whether a fixed number or range), any payment amounts attributable to performance beyond (or below) the utilization target will not be included in the calculation of substantial financial risk.

Arrangements where the target payment is set at a level that is unrealistic would always produce the appearance of substantial financial risk and, accordingly, will not be protected.

III. Regulatory Impact Statement

Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act

The Office of Management and Budget (OMB) has reviewed this interim final rule in accordance with the provisions of Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), and has determined that it does not meet the criteria for a significant regulatory action. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety distributive and equity effects). The Unfunded Mandates Reform Act, Public Law 104-4, requires that agencies prepare an assessment of anticipated costs and benefits on any rulemaking that may result in an annual expenditure by State, local or tribal government, or by the private sector of $100 million or more. In doing so, these regulations impose no requirements on any party. Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement actions under the anti-kickback statute. We believe that any aggregate economic effect of these safe harbor regulations will be minimal and will impact only those limited few who engage in prohibited behavior in violation of the statute. As such, we believe that the aggregate economic impact of these regulations is minimal and will have no effect on the economy on Federal or State or local governments.

Additionally, in accordance with the Unfunded Mandates Reform Act of 1995, we have determined that there are no significant costs associated with these safe harbor guidelines that would impose any mandates on States, local or tribal governments, or the private sector, that will result in an annual expenditure of $100 million or more, and that a full analysis under the Act is not necessary. Further, in accordance with the Regulatory Flexibility Act (RFA) of 1980, and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, we are required to determine if this rule will have a significant economic effect on a substantial number of small entities and, if so, to identify regulatory options that could lessen the impact. While these safe harbor provisions may have an impact on small entities, we believe that the aggregate economic impact of this rulemaking should be minimal, since it is the nature of the violation and not the size of the entity that will result in a violation of the anti-kickback statute. Since the vast majority of individuals and entities potentially affected by these regulations do not engage in prohibited arrangements, schemes or practices in violation of the law, we have concluded that these interim final regulations should not have a significant economic impact on a number of small business entities, and that a regulatory flexibility analysis is not required for this rulemaking.

Paperwork Reduction Act

As indicated above, the provisions of these interim final regulations are voluntary and impose no new reporting or recordkeeping requirements on health care providers necessitating clearance by OMB.
IV. Public Inspection of Comments

Comments will be available for public inspection beginning December 10, 1999, in Room 5518 of the Office of Inspector General at 330 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m., (202) 619-0089.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare.

Accordingly, 42 CFR part 1001 is amended as follows:

PART 1001—[AMENDED]

1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(i), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E), and (F), and 1395hh; and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (41 U.S.C. 6101 note).

2. Section 1001.952 is amended by republishing the introductory text; by reserving paragraphs (n) through (s); and by adding new paragraphs (t) and (u) to read as follows:

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

1. Price reductions offered to eligible managed care organizations, as used in section 1128B of the Act, “remuneration” does not include any payment between:

(i) An eligible managed care organization and any first tier contractor for providing or arranging for items or services, as long as the following three standards are met—

(A) The eligible managed care organization and the first tier contractor have an agreement that:

(1) Is set out in writing and signed by both parties;

(2) Specifies the items and services covered by the agreement;

(3) Is for a period of at least one year; and

(4) Specifies that the first tier contractor cannot claim payment in any form directly or indirectly from a Federal health care program for items or services covered under the agreement, except for:

(i) HMOs and competitive medical plans with cost-based contracts under section 1876 of the Act where the agreement with the eligible managed care organization sets out the arrangements in accordance with which the first tier contractor is billing the Federal health care program;

(ii) Federally qualified HMOs without a contract under sections 1854 or 1876 of the Act, where the agreement with the eligible managed care organization sets out the arrangements in accordance with which the first tier contractor is billing the Federal health care program;

(iii) First tier contractors that are Federally qualified health centers that claim supplemental payments from a Federal health care program.

(B) In establishing the terms of the agreement, neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service basis.

(C) Neither party to the agreement shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program.

(ii) A first tier contractor and a downstream contractor or between two downstream contractors to provide or arrange for items or services, as long as the following four standards are met—

(A) The parties have an agreement that:

(1) Is set out in writing and signed by both parties;

(2) Specifies the items and services covered by the agreement;

(3) Is for a period of at least one year; and

(4) Specifies that the party providing the items or services cannot claim payment in any form from a Federal health care program for items or services covered under the agreement.

(B) In establishing the terms of the agreement, neither party gives or receives remuneration in return to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service basis.

(C) Neither party shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program.

(D) The agreement between the eligible managed care organization and first tier contractor covering the items or services that are covered by the agreement between the parties does not involve:

1. A Federally qualified health center receiving supplemental payments;

2. A HMO or CMP with a cost-based contract under section 1876 of the Act; or

3. A Federally qualified HMO, unless the items or services are covered by a risk based contract under sections 1854 or 1876 of the Act.

(ii) A downstream contractor means an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between an eligible managed care organization and the first tier contractor.

(iii) Eligible managed care organization means:

(A) A HMO or CMP with a risk or cost based contract in accordance with section 1876 of the Act;

(B) Any Medicare Part C health plan that receives a capped payment from Medicare and which must have its total Medicare beneficiary cost sharing approved by HCFA under section 1854 of the Act;

(C) Medicaid managed care organizations as defined in section 1001(m)(1)(A) that provide or arrange for items or services for Medicaid enrollees under a contract in accordance with section 1903(m) of the Act (except for fee-for-service plans or medical savings accounts);

(D) Any other health plans that provide or arrange for items and services for Medicaid enrollees in accordance with a risk-based contract with a State agency subject to the upper payment limits in § 447.301 of this title or an equivalent payment cap approved by the Secretary;

(E) Programs For All Inclusive Care For The Elderly (PACE) under sections 1894 and 1934 of the Act, except for for-profit demonstrations under sections 4801(h) and 4802(h) of Pub. L. 105–33; or

(F) A Federally qualified HMO.

(iii) First tier contractor means an individual or entity that has a contract directly with an eligible managed care organization to provide or arrange for items or services.

(iv) Items and services means health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency
transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. Marketing and other pre-enrollment activities are not "items or services" for purposes of this section.

(u) Price reductions offered by contractors with substantial financial risk to managed care organizations. (1) As used in section 1128(B) of the Act, "remuneration" does not include any payment between:

(i) A qualified managed care plan and a first tier contractor for providing or arranging for items or services, where the following five standards are met—

(A) The agreement between the qualified managed care plan and first tier contractor must:

(1) Be in writing and signed by the parties;

(2) Specify the items and services covered by the agreement;

(3) Be for a period of at least one year;

(4) Require participation in a quality assurance program that promotes the coordination of care, prevents against underutilization and specifies patient goals, including measurable outcomes where appropriate; and

(5) Specify a methodology for determining payment that is commercially reasonable and consistent with fair market value established in an arms-length transaction and includes the intervals at which payments will be made and the formula for calculating incentives and penalties, if any. 

(B) If a first tier contractor has an investment interest in a qualified managed care plan, the investment interest must meet the criteria of paragraph (a)(1) of this section.

(C) The first tier contractor must have substantial financial risk for the cost or utilization of services it is obligated to provide through one of the following four payment methodologies:

(1) A periodic fixed payment per patient that does not take into account the dates services are provided, the frequency of services, or the extent or kind of services provided;

(2) Percentage of premium;

(3) Inpatient Federal health care program diagnosis-related groups (DRGs) (other than those for psychiatric services);

(4) Bonus and withhold arrangements, provided—

(i) The target payment for first tier contractors that are individuals or non-institutional providers is at least 20 percent greater than the minimum payment, and for first tier contractors that are institutional providers, i.e., hospitals and nursing homes, is at least 10 percent greater than the minimum payment;

(ii) The amount at risk, i.e., the bonus or withhold, is earned by a first tier contractor in direct proportion to the ratio of the contractor's actual utilization to its target utilization;

(iii) In calculating the percentage in accordance with paragraph (u)(1)(i)(C)(4)(i) of this section, both the target payment amount and the minimum payment amount include any performance bonus, e.g., payments for timely submission of paperwork, continuing medical education, meeting attendance, etc., at a level achieved by 75 percent of the first tier contractors who are eligible for such payments;

(iv) Payment amounts, including any bonus or withhold amounts, are reasonable given the historical utilization patterns and costs for the same or comparable populations in similar managed care arrangements; and

(2) Neither party to the arrangement gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis; and

(2) Neither party to the arrangement shifts the financial burden of such arrangement to the extent that increased payments are claimed from a Federal health care program.

(ii) A first tier contractor and a downstream contractor, or between downstream contractors, to provide or arrange for items or services, as long as the following three standards are met—

(A) Both parties are being paid for the provision or arrangement of items or services in accordance with one of the payment methodologies set out in paragraph (u)(1)(i)(C) of this section;

(B) Payments for items and services reimbursable by a Federal health care program comply with paragraph (u)(1)(i)(D) of this section; and

(C) In establishing the terms of an arrangement—

(1) Neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the arrangement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis; and

(2) Neither party to the arrangement shifts the financial burden of the arrangement to the extent that increased payments are claimed from a Federal health care program.

(2) For purposes of this paragraph, the following terms are defined as follows:

(i) Downstream contractor means an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between a qualified managed care plan and the first tier contractor.

(ii) First tier contractor means an individual or entity that has a contract directly with a qualified managed care plan to provide or arrange for items or services.

(iii) Is obligated to provide means a contractor refers to items or services:

(A) Provided directly by an individual or entity and its employees;

(B) For which an individual or entity is financially responsible, but which are provided by downstream contractors;

(C) For which an individual or entity makes referrals or arrangements; or

(D) For which an individual or entity receives financial incentives based on
(iv) Items and services means health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. Marketing or other pre-enrollment activities are not "items or services" for purposes of this definition in this paragraph.

(v) Minimum payment is the guaranteed amount that a provider is entitled to receive under an agreement with a first tier or downstream contractor or a qualified managed care plan.

(vi) Qualified managed care plan means a health plan as defined in paragraph (1)(2) of this section that:

(1) Provides a comprehensive range of health services;
(2) Provides or arranges for—
   (A) Reasonable utilization goals to avoid inappropriate utilization;
   (B) An operational utilization review program;
(3) A quality assurance program that promotes the coordination of care, protects against underutilization, and specifies patient goals, including measurable outcomes where appropriate;
(4) Grievance and hearing procedures;
(5) Protection of enrollees from incurring financial liability other than copayments and deductibles; and
(6) Treatment for Federal health care program beneficiaries that is not different than treatment for other enrollees because of their status as Federal health care program beneficiaries; and
(7) Covers a beneficiary population of which either—
   (1) No more than 10 percent are Medicare beneficiaries, not including persons for whom a Federal health care program is the secondary payer; or
   (2) No more than 50 percent are Medicare beneficiaries (not including persons for whom a Federal health care program is the secondary payer). provided that payment of premiums is on a periodic basis that does not take into account the dates services are rendered, the frequency of services, or the extent or kind of services rendered, and provided further that such periodic payments for the non-Federal health care program beneficiaries do not take into account the number of Federal health care program fee-for-service beneficiaries covered by the agreement or the amount of services generated by such beneficiaries.

(vii) Target payment means the fair market value payment established through arms length negotiations that will be earned by an individual or entity that:

(A) Is dependent on the individual or entity's meeting a utilization target or range of utilization targets that are set consistent with historical utilization rates for the same or comparable populations in similar managed care arrangements, whether based on its own, its provider group's or the qualified managed care plan's utilization (or a combination thereof); and
(B) Does not include any bonus or fees that the individual or entity may earn from exceeding the utilization target.

June Gibbs Brown,
Inspector General.
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Donna E. Shalala,
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