Federal Register

Friday
November 19, 1999

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 with request for comment.

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 Association of Health Plans
- American Association of Retired Persons
- American Hospital Association
- 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/progorg/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 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 the 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, protection 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 physicians at substantial risk, not for the physician services 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 a group of physicians.

Given the shortcomings of the statutory language, the Department determined that it would exercise its authority under section 14 of the MMPPPA to expand these safe harbors beyond the legal confines of section 216. Again, section 14 of MMPPPA 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 subcontracts 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 services 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(t)(1) is divided into two parts and sets out the substantive standards that arrangements must meet in order to receive safe harbor protection. Paragraph (t)(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 subcontracts with these first tier entities. We refer to these subcontractors as ''downstream'' contractors or providers. Paragraph (t)(1)(ii) 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(t)(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 insure 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(t)(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 HMOs/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 a Federal health care program.

The last two standards in § 1001.952(t)(1)(i) insure that the discounts by the providers do not increase the risk of overutilization or increased costs in other Federal health care programs. As explained in the overview section, this safe harbor does not protect situations where one party gives or receives a discount or other remuneration in return for or to induce the provision or acceptance of business (other than that covered by the arrangement) for which payment may be made by the Federal health care programs on a fee-for-service basis. In addition, in accordance with paragraph (1)(i)(C) of this section, the arrangement cannot shift the financial burden 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 subcontractor, 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(t), 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 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(t)(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 and 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(t) 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(t), almost all other providers are reimbursed by Federal health care programs on a fee-for-service basis.

However, according to information presented to the committee, most managed care arrangements that cover Federal health care program beneficiaries and are not paid on a risk basis are employer-sponsored health plans that cover retirees who may also qualify for Medicare. In these managed care arrangements, the participating providers typically submit claims for services provided to enrollees who have primary coverage under Medicare directly to the Medicare carriers and intermediaries and receive reimbursement on a fee-for-service basis. In other words, services to Medicare beneficiaries typically are ''carved out'' of the risk-sharing arrangements these plans have with their participating providers. In accordance with section 216 of HIPAA, these providers are not at ''substantial financial risk'' for the cost or utilization of services they provide to Medicare patients. Therefore, such arrangements do not merit protection under the statutory criteria.

The second major limitation in section 216 is that the providers must be at risk for the cost or utilization of items or services they are ''obligated to provide.'' Many risk sharing arrangements with physicians are based on the cost or utilization of items and services they order but that are actually provided by other entities (e.g., physician bonuses based on the number of hospital admissions). Accordingly, this requirement also substantially narrows the universe of arrangements that could potentially qualify for protection under § 1001.952(u).

Working within these two constraints, the committee determined to protect financial arrangements that:

- Are part of a comprehensive managed care arrangement in which at least fifty percent of the enrollees do not have primary coverage under Medicare.
- Place providers at substantial financial risk for the cost or utilization of health care items and services for all enrollees.
- Use the identical risk and payment methodologies to reimburse providers for services provided to enrollees with primary coverage paid by Federal health care programs as is used for all other enrollees. In other words, payments from the plan to its providers must be the same for identical items or services provided to people with similar health status.
- Allow payment differentials only when they are related to utilization patterns and/or costs of providing items or services to the relevant population.

3. Major Issues

a. *Definition of an ''organization''.* The statutory language exempts ''remuneration between an organization and an individual or entity.'' Some 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 2130; 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 especially important because, for the reasons discussed above in section II.E.1 of this preamble, the providers generally are not actually at 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 can meet this risk requirement.

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 capitation, percentage of premium arrangements and payments based on certain diagnostic related groupings, so long as the reimbursement is reasonable given the historical utilization patterns and costs for the same or comparable population in similar managed care arrangements. Hybrid payment systems that combine a periodic fixed fee per patient with other incentives, such as withholds and bonuses, should be analyzed under the numeric standard.
- The *numeric standard* includes bonuses and withhold arrangements that meet certain criteria.
- The *physician incentive plan standard* protects arrangements that meet all of the requirements for HCFA's physician incentive plan rules under 42 CFR 417.479.

These provisions are discussed in greater detail in the section-by-section analysis that follows.

c. *Downstream arrangements.* The committee also discussed whether the rule would protect only arrangements between the QMCP and its direct or ''first tier'' contractors, or whether it would also protect arrangements between the first tier contractors and their downstream subcontractors and arrangements between those subcontractors and providers farther downstream. The committee statement, when taken as a whole, reflects the view that, with some exceptions, the rule should protect all written agreements between downstream subcontractors, as well as those between the QMCP and its first tier contractors. However, in order to prevent fee-for-service or cost-based kickbacks disguised as risk-sharing arrangements by contractors that are not at substantial financial risk, subcontractors are only protected if both parties to the subcontract are at substantial financial risk for the items or services covered by the agreement. In other words, if either party to an agreement is not paid on a substantial financial risk basis, the contract is not protected for either party.

Situations in which a subcontractor has an investment interest in its contractor raise other considerations. In such situations, the financial disincentive for overutilization created by a risk sharing arrangement might be offset by a return on the investment interest. Where both parties have to be at substantial financial risk in order to qualify for protection, the parties continue to have the necessary financial risk to protect against overutilization. However, where a first tier contractor has an investment interest in a QMCP, amounts received as a return on investment could offset the controls and safeguards of the risk-sharing arrangement. This result is possible because the QMCP may be receiving fee-for-service payments for services to Medicare enrollees on a reassignment basis. Therefore, the rule does not protect remuneration between a QMCP and a first tier contractor that has an investment interest in the QMCP, unless it qualifies under the large entity investment safe harbor (§ 1001.952(a)).

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(u)(2)(vi). There are three standards that apply to the arrangements between the QMCP and first tier contractors. First, § 1001.952(u)(1)(i)(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, § 1001.965(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)(i)(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 with which we have significant experience and data for Federal health care program beneficiaries. Inpatient psychiatric DRGs are not covered because, based on the experience of the Medicare and Medicaid programs, these groupings are not sufficient to deter unnecessary admissions or to protect patients seeking those services. We emphasize that, although the plan must reimburse providers for items and services to other enrollees using the same DRG system, the amount of payment may vary so long as it is based on adequate utilization and cost data for the covered population that justifies the difference.

The definition of substantial financial risk also includes a *numeric standard* for certain bonus and withhold arrangements (paragraph (u)(1)(i)(C)(IV)). In the case of a physician provider, the requirement for substantial financial risk will also be satisfied if the arrangement places the physician at risk for an amount that exceeds the substantial financial risk threshold of the *physician incentive payment* rule (42 CFR 417.479(f)), and the arrangement is in compliance with the stop-loss and beneficiary survey requirements of 42 CFR 417.479(g). Although the committee statement requires the patient panel size to be less than 25,000 covered lives to meet the substantial financial risk element, we determined that this requirement does not provide significant additional protection and, therefore, it is not included in this rule. A bonus or withhold arrangement can also qualify if the target payment is at least 20 percent greater than the minimum payment for individuals or non-institutional entities, or is at least ten percent greater than the minimum payment in the case of institutional entities, specifically, hospitals and nursing homes. We are requesting data on the appropriateness of different target payment percentages for institutional and non-institutional entities. In addition, we also seek comments on whether additional individuals and entities, such as pharmacy providers, manufacturers and federally qualified health centers, should be considered institutional entities for purposes of this paragraph.

The ''minimum payment'' is defined in § 1001.952(u)(2)(v). Generally, it represents the minimum amount a contractor will receive under a contract, regardless of utilization. In addition, the bonus or withhold must be earned in direct proportion to the ratio of the actual to the target utilization. For example, if the provider's utilization is only 80 percent of the target, the provider receives 80 percent of the difference between the target payment and the minimum payment. This requirement should protect against sham arrangements that provide a penalty or bonus conditioned entirely upon achieving a utilization level that is unreasonable. Finally, in calculating the substantial financial risk percentage, the target payment and the minimum payment must both include any bonus for performance (*e.g.*, timely submission of paperwork, continuing medical education, meeting attendance) that is given to at least 75 percent of the participating individuals or entities who are paid a performance bonus based on the same bonus structure under the arrangement. This requirement is necessary to prevent plans from reallocating their compensation to performance bonuses, thereby increasing the apparent percentage of 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.

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(t). 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 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)(vi) requires that the items 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 addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small businesses, the Secretary must specifically consider the economic effect of rule on small business entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity and available information. Regulations must meet certain standards, such as avoiding unnecessary burden. The safe harbor provisions set forth in this rulemaking are designed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy. 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 or on Federal or State expenditures.

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. 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(j), 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 (31 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:

* * * * *

(n)–(s) [Reserved]

(t) *Price reductions offered to eligible managed care organizations.* (1) As used in section 1128(B) 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; or

(*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.

(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 an eligible managed care organization and the first tier contractor.

(ii) *Eligible managed care organization*[1] *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 capitated 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 1903(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 § 447.361 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

[1] The eligible managed care organizations in paragraphs (u)(2)(ii)(A)–(F) of this section are only eligible with respect to items or services covered by the contracts specified in those paragraphs.

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 a least one year;

(*4*) 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; 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

(*v*) Alternatively, for a first tier contractor that is a physician, the qualified managed care plan has placed the physician at risk for referral services in an amount that exceeds the substantial financial risk threshold set forth in 42 CFR 417.479(f) and the arrangement is in compliance with the stop-loss and beneficiary survey requirements of 42 CFR 417.479(g).

(D) Payments for items and services reimbursable by Federal health care program must comply with the following two standards—

(*1*) The qualified managed care plan (or in the case of a self-funded employer plan that contracts with a qualified managed care plan to provide administrative services, the self-funded employer plan) must submit the claims directly to the Federal health care program, in accordance with a valid reassignment agreement, for items or services reimbursed by the Federal health care program. (Notwithstanding the foregoing, inpatient hospital services, other than psychiatric services, will be deemed to comply if the hospital is reimbursed by a Federal health care program under a DRG methodology.)

(*2*) Payments to first tier contractors and any downstream contractors for providing or arranging for items or services reimbursed by a Federal health care program must be identical to payment arrangements to or between such parties for the same items or services provided to other beneficiaries with similar health status, provided that such payments may be adjusted where the adjustments are related to utilization patterns or costs of providing items or services to the relevant population.

(E) 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 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) Payment arrangements 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* for 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

its own, its provider group's, or its qualified managed care plan's performance (or combination thereof).

(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 (l)(2) of this section that:

(A) Provides a comprehensive range of health services;

(B) Provides or arranges for—

(*1*) Reasonable utilization goals to avoid inappropriate utilization;

(*2*) 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

(C) 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.

Dated: February 11, 1999.

June Gibbs Brown,

Inspector General.

Approved: June 8, 1999.

Donna E. Shalala,

Secretary.

[FR Doc. 99–29988 Filed 11–18–99; 8:45 am]

BILLING CODE 4150–04–P