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Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

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RIN 0991–AA66 (Also incorporating RIN 0991–AA74)

Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Final rule.

SUMMARY: This final rule serves both to add new safe harbor provisions under the Federal and State health care programs' anti-kickback statute, as authorized under section 14 of Public Law 100–93, the Medicare and Medicaid Patient and Program Protection Act of 1987, and to clarify various aspects of the original safe harbor provisions now codified in 42 CFR part 1001 (originally proposed in RIN 0991–AA74). Specifically, this final rule modifies the original set of final safe harbor provisions codified in 42 CFR 1001.952 to give greater clarity to that rulemaking's original intent. In addition, this final rule sets forth an expanded set of safe harbor provisions designed to protect additional payment and business practices from criminal prosecution or civil sanctions under the anti-kickback provisions of the statute.

EFFECTIVE DATE: This rulemaking is effective November 19, 1999.

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SUPPLEMENTARY INFORMATION:

I. Background

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 in order to induce business reimbursable under the Federal or State health care programs. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to 5 years. Violations of the anti-kickback statute may also result in the imposition of a civil money penalty (CMP) under section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)) or program exclusion under section 1128 of the Act (42 U.S.C. 1320a–7).

The types of remuneration covered specifically include kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. In addition, prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration intended to induce the purchasing, leasing or ordering, or arranging of any good, facility, service, or item paid for by Federal or State health care programs.

Establishing the Original Safe Harbors

Since the statute on its face is so broad, concern had been expressed that some relatively innocuous commercial arrangements were technically covered by the statute and therefore were subject to criminal prosecution. As a response to the above concern, the Medicare and Medicaid Patient and Program Protection Act (MMPPPA) of 1987, section 14 of Public Law 100–93, specifically required the development and promulgation of regulations, the so-called ''safe harbor'' provisions, designed to specify various payment and business practices which, although potentially capable of inducing referrals of business under the Federal and State health care programs, would not be treated as criminal offenses under the anti-kickback statute. The OIG safe harbor provisions have been developed ''to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements.'' [1] 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 action under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks.

On July 29, 1991, we published in the **Federal Register** the 1991 final rule (56 FR 35952) setting forth various safe harbor provisions to the Medicare and Medicaid anti-kickback statute. The rulemaking was authorized under section 14 of Public Law 100–93, MMPPPA of 1987, and specified certain payment practices that will not be subject to criminal prosecution under section 1128B(b) of the Social Security Act (42 U.S.C. 1320a–7b(b)), and that will not provide a basis for exclusion from Medicare or the State health care programs under section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)). The initial final rulemaking established ''safe harbors'' in ten broad areas: investment interests, space rental, equipment rental, personal services and management contracts, sales of practices, referral services, warranties, discounts, employees, and group purchasing organizations. However, in giving the Department the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the regulations to be evolving rules that would be updated periodically to reflect changing business practices and technologies in the health care industry.

[1] 56 FR 35952; July 21, 1991.

Establishing Additional Safe Harbors

The public comments in response to the original proposed rule establishing the safe harbor provisions contained suggestions for the consideration and adoption of additional safe harbor provisions under 42 CFR 1001.952. As a result of those comments, on September 21, 1993, the OIG published a proposed rule (58 FR 49008) (the ''1993 proposed rule'') formally requesting public comments on seven new areas of safe harbor protection under the anti-kickback statute, as well as proposed modifications to the existing safe harbor for sales of practices. The proposals for new safe harbors addressed investment interests in rural areas; ambulatory surgical centers; group practices; practitioner recruitment; obstetrical malpractice insurance subsidies; referral agreements for specialty services; and cooperative hospital service organizations described in section 501(e) of the Internal Revenue Code.

Clarifying the Original Safe Harbor Provisions

After publication of the 1991 final rule, the OIG became aware of a limited number of issues that had created uncertainties for health care providers trying to comply with the original safe harbor provisions, and of certain instances where our intent, either to protect or preclude protection for particular business arrangements, was not fully reflected in the text of the regulation, even though it was reflected in the preamble. As a result, the OIG developed and published a new notice of proposed rulemaking on July 21, 1994 (59 FR 37202) (the ''1994 proposed clarifications'') intended to modify the text of 1991 final rule to conform to the rulemaking's original intent. The clarifications contained in the proposed rule did not represent an attempt to reevaluate the basic judgments that led to the original safe harbors, but rather were designed to protect business practices originally intended to be

protected by making the regulatory language more precise.

Annual Solicitations for Suggestions for Modified and New Safe Harbors

In accordance with section 205 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Pub. L. 104–191), the Department is now required to develop and publish an annual notice in the **Federal Register** formally soliciting proposals for modifying existing safe harbors and promulgating new safe harbors and OIG special fraud alerts. The Department will review the proposals and, in consultation with the Department of Justice (DoJ), consider issuing new or modified safe harbor regulations, where appropriate. On December 31, 1996, we published the first of these notices in the **Federal Register** (61 FR 69060), soliciting public comment regarding ''the development of proposed or modified safe harbor regulations,'' including the pending proposals for new and modified safe harbors (61 FR 69062). We published additional annual notices on December 10, 1997 (62 FR 65050) and December 10, 1998 (63 FR 68223). (These notices are referred to in this preamble collectively as the ''annual solicitations.'') Respondents to the annual solicitations suggested a number of areas for new or modified safe harbor protection; additionally, a number of respondents commented on the 1993 proposed rule and the 1994 proposed clarifications. This rulemaking is based on the comments received in response to the 1993 proposed rule, the 1994 proposed clarifications, and the annual solicitations insofar as the latter addressed the new and modified safe harbor proposals contained in the 1993 proposed rule and the 1994 proposed clarifications. Other suggestions for new and modified safe harbors are under review and will be the subject of annual reports to Congress made as part of the Inspector General's year-end semiannual report, as required by HIPAA.

Shared-Risk Exception

Section 216 of HIPAA created an exception to the anti-kickback statute for certain risk-sharing arrangements and directed the Department to use a negotiated rulemaking process to establish companion regulations. Specifically, section 216 of HIPAA created an exception for certain managed care arrangements, involving remuneration (i) between eligible organizations under section 1876 of the Social Security Act (certain health maintenance organizations and competitive medical plans) and individuals or entities providing items or services and (ii) between any organization and an individual or entity that has a risk-sharing arrangement, if a written agreement places the individual or entity at ''substantial financial risk'' for the cost or utilization of the items or services provided.

On January 22, 1998, the negotiated rulemaking committee comprised of 21 industry representatives, a representative from the DoJ, and an OIG representative representing the Department, reached consensus on a final proposal for two new safe harbors.[2] Issues raised in comments to the 1993 proposed rule and the 1994 proposed clarifications that pertain to matters covered by the two shared-risk exception safe harbors are not considered in this final rulemaking.

II. Summary of Proposed Rules, Response to Public Comments and Summary of Revisions

In response to the 1993 proposed rule and the 1994 proposed clarifications, we received a total of 313 timely-filed public comments on the additional safe harbors proposed rule and 28 timely-filed public comments on the safe harbor clarifications proposed rule from various provider groups, medical facilities, professional and business organizations and associations, medical societies, State and local government entities, private practitioners, and concerned citizens. We received 32 comments in response to the annual solicitations that were relevant to the issues addressed in this rulemaking. A summary of the comments and our responses to those comments follow.

A. General Comments

1. Conformity With Stark Law

Comment: Several commenters urged the OIG to conform existing and proposed safe harbors to the statutory exceptions to section 1877 of the Act, otherwise known as the ''Stark Law.'' These commenters believe that payment arrangements permitted under the Stark Law should be protected under the anti-kickback statute. They argue that it is confusing for the industry to be subject to two separate bodies of fraud and abuse law applicable to arrangements involving physician self-referrals. At minimum, these commenters urge that the safe harbors be made consistent with the Stark exceptions with respect to physician compliance with the anti-kickback statute.

Response: The Stark Law is a civil statute that generally (i) prohibits physicians from making referrals for clinical laboratory or other designated health services to entities in which the physicians have ownership or other financial interests and (ii) prohibits entities from presenting or causing to be presented claims or bills to any individual, third party payor, or other entity for designated health services furnished pursuant to a prohibited referral. (42 U.S.C. 1395nn(a)(1)). The anti-kickback statute, on the other hand, is a criminal statute that prohibits the knowing and willful offer, payment, solicitation, or receipt of remuneration to induce Federal health care program business. Both laws are directed at the problem of inappropriate financial incentives influencing medical decision-making. This similarity notwithstanding, the statutes are different in scope and structural approach. Under the Stark Law, physicians may not refer patients for certain designated health services to entities from which the physicians receive financial benefits, except as allowed in enumerated exceptions. A transaction must fall entirely within an exception to be lawful under the Stark Law. The anti-kickback statute, on the other hand, establishes an intent-based criminal prohibition with optional statutory and regulatory ''safe harbors'' that do not purport to define the full range of lawful activity. Rather, safe harbors provide a means of assuring that payment practices are not illegal. Payment practices that do not fully comply with a safe harbor may still be lawful if no purpose of the payment practice is to induce referrals of Federal health care program business. Because the two statutory schemes are fundamentally different, the conference report for the Stark Law included language clarifying that ''any prohibition, exemption, or exception authorized under this provision in no way alters (or reflects on) the scope and application of the anti-kickback provisions in section 1128B of the Social Security Act'' (H.R. Conf. Rep. 239, 101st Cong., 1st sess. 856 (1989)).

We are mindful that it may sometimes be burdensome for parties to review their arrangements under two separate statutory schemes. However, it would be inappropriate to adjust our safe harbor provisions in a manner that would prejudice enforcement of the anti-kickback statute merely to conform the safe harbors to an exception or prohibition under section 1877 of the Act. This is particularly the case in view of the clear legislative intent to keep

[2] The OIG's interim final rule addressing the safe harbors for shared-risk arrangements is published in today's edition of the **Federal Register.**

enforcement under the anti-kickback statute separate from enforcement under section 1877 of the Act. Moreover, variation between the Stark Law exceptions and anti-kickback safe harbors is reasonable in light of the schematic differences between the two statutes. To the extent the anti-kickback statute and the Stark Law address the same conduct, the Stark Law acts as a structural bar to arrangements that contain a *per se* conflict of interest. However, even if an arrangement passes muster under the Stark Law, it may still constitute a violation of the anti-kickback statute, if the requisite intent to induce referrals is present.

2. Integrated Delivery Systems and Managed Care

Comment: Several commenters urged the OIG to modify existing safe harbors and develop new safe harbors to protect and encourage the development of integrated health care delivery systems and managed care arrangements. For example, several commenters urged the OIG to provide specific safe harbor protection for payments between wholly-owned entities, including parent entities and their wholly-owned subsidiaries. Some commenters questioned whether the anti-kickback statute is an appropriate method of regulating business arrangements in the health care industry, particularly in the context of managed care.

Response: The anti-kickback statute is very broad and potentially covers many managed care arrangements that are common in the marketplace today. However, we have recognized that many of these arrangements do not create the potential for fraud or abuse under the anti-kickback statute and have created safe harbors aimed at those managed care arrangements. Currently, for example, a safe harbor protects certain price reductions offered to health plans (§ 1001.952(m)). In addition, Congress enacted in HIPAA a statutory shared-risk exception for certain managed care plans and arrangements that put individuals or entities at substantial financial risk.[3]

With respect to integrated delivery systems and payments between wholly-owned entities, we have stated previously that the anti-kickback statute is not implicated when payments are transferred within a single corporate entity, for example, from one division to another, and therefore no explicit safe harbor is needed for such payments (56 FR 35983). We recognize that there are many lawful integrated delivery system arrangements and arrangements between wholly-owned entities in the marketplace today and that many of these arrangements may be beneficial to the Federal health care programs and their beneficiaries. We are concerned, however, that integrated delivery systems, including arrangements involving wholly-owned subsidiaries, may present opportunities for the payment of improper financial incentives that result in overutilization of services and increased program costs and that may adversely affect quality of care and patient freedom of choice among providers. This is primarily of concern where payment by the Federal health care programs is on a fee-for-service basis, as may occur, for example, with a hospital's referrals to a wholly-owned home health care agency (see, for example, *Medicare Hospital Discharge Planning*, OEI–02–94–00320 (December 1997)). Accordingly, we do not anticipate providing safe harbor protection for integrated delivery systems and arrangements between wholly-owned entities at this time. The advisory opinion process (42 CFR part 1008) is available for parties wishing to obtain OIG review of their particular integrated delivery or wholly-owned arrangements.

3. Additional Safe Harbors

Comment: Several commenters urged the OIG to demonstrate renewed commitment to issuing clarifying interpretations of the anti-kickback statute in a regular and timely manner.

Response: The OIG recognizes the need to work closely with the industry to combat fraud and abuse in the Federal health care programs through meaningful industry guidance consistent with our law enforcement obligations. As part of HIPAA, the OIG received substantial additional funding for its fraud-fighting efforts. A portion of that funding has been used for a number of industry guidance purposes, including the creation of an Industry Guidance Branch in the Office of Counsel to the Inspector General, which is tasked with issuing advisory opinions and promulgating safe harbor regulations and special fraud alerts. As part of our mandate under HIPAA, we have canvassed the industry through annual notices in the **Federal Register** soliciting public suggestions for new and modified safe harbors and special fraud alerts. The suggestions received in response to those notices, as well as other suggestions received from the industry or generated internally, are under review, and we anticipate further rulemaking periodically in connection with some of these safe harbor suggestions. We have reported to Congress on the status of the suggestions in the OIG semiannual report to be issued shortly. In addition, the ongoing issuance of advisory opinions, model compliance guidance, special fraud alerts and special advisory bulletins is providing the industry with meaningful guidance on the scope and application of the anti-kickback statute in a regular and timely manner.

4. Transition Period

Comment: Several commenters urged the OIG to afford providers who entered into arrangements with a good faith belief that the arrangements did not violate the anti-kickback statute a reasonable grace period to restructure existing arrangements to conform to the final safe harbors contained in these regulations. In particular, several commenters expressed concern that the 1994 clarifications would be interpreted to be retroactive to the date of the original safe harbors, with no provision for ''grandfathering'' arrangements that providers believed in good faith complied with the safe harbors as set forth in the 1991 final rule. For example, these commenters note that it was not clear that only ''health care'' assets could be counted for purposes of qualifying for the large entity investment safe harbor (§ 1001.952(a)(i)). Specifically, one commenter proposed implementation of a one year grace period.

Response: We recognize that many providers have in good faith attempted to structure lawful arrangements under the anti-kickback statute that may not fit squarely within these final safe harbor rules. In this regard, we repeat our response to similar comments in our preamble to the 1991 final rule. There we stated:

> The failure of a particular business arrangement to comply with these provisions does not determine whether or not the arrangement violates the statute because * * * this regulation does not make conduct illegal. Any conduct that could be construed to be illegal after the promulgation of this rule would have been illegal at any time since the current law was enacted in 1977. Thus illegal arrangements entered into in the past were undertaken with a risk of prosecution. This regulation is intended to provide a formula for avoiding risk in the future.
>
> We also recognize, however, that many health care providers have structured their business arrangements based on the advice of an attorney and in good-faith belief that the arrangement was legal. In the event that they now find that the arrangement does not comply fully with a particular safe harbor provision and are working with diligence and good faith to restructure it so that it does comply, we will use our discretion to be fair

[3] See footnote 2.

to the parties to such arrangements. (56 FR 35955).

These same principles apply with respect to arrangements structured in good faith in accordance with the 1991 final rule. Thus, to the extent that parties reasonably believed that they complied with a safe harbor based on the 1991 final rule and work with diligence and good faith to restructure their arrangements so that they comply with the safe harbor as clarified in this final rule, we will exercise our discretion to be fair to the parties. We are not setting a specific ''grace period,'' as we believe that the reasonable time period for restructuring an arrangement will vary depending on the type and complexity of the arrangement.

5. Meaning of Safe Harbors

Comment: Several commenters asked the OIG to clarify that the failure to meet the conditions of a safe harbor does not mean that an arrangement is suspect under the anti-kickback statute. One commenter expressed concern that members of the public view arrangements that do not comply with a safe harbor as suspect arrangements.

Response: The issue of the scope and effect of the safe harbors is important and often misunderstood. We addressed this issue in our preamble to the 1991 final rule:

> This (safe harbor) regulation does not expand the scope of activities that the statute prohibits. The statute itself describes the scope of illegal activities. The legality of a particular business arrangement must be determined by comparing the particular facts to the proscriptions of the statute.
>
> The failure to comply with a safe harbor can mean one of three things. First * * * it may mean that the arrangement does not fall within the ambit of the statute. In other words, the arrangement is not intended to induce the referral of business reimbursable under (a Federal health care program); so there is no reason to comply with the safe harbor standards, and no risk of prosecution.
>
> Second, at the other end of the spectrum, the arrangement could be a clear statutory violation and also not qualify for safe harbor protection. In that case, assuming the arrangement is obviously abusive, prosecution would be very likely.
>
> Third, the arrangement may violate the statute in a less serious manner, although not be in compliance with a safe harbor provision. Here there is no way to predict the degree of risk. Rather, the degree of risk depends on an evaluation of the many factors which are part of the decision-making process regarding case selection for investigation and prosecution. Certainly, in many (but not necessarily all) instances, prosecutorial discretion would be exercised not to pursue cases where the participants appear to have acted in a genuine good-faith attempt to comply with the terms of a safe harbor, but for reasons beyond their control are not in compliance with the terms of the safe harbor. In other instances, there may not even be an applicable safe harbor, but the arrangement may appear innocuous. But in other instances, we will want to take appropriate action. (56 FR 35954)

Thus, it is not true that every arrangement that does not comply with a safe harbor is suspect under the anti-kickback statute, though such arrangements may be suspect in particular circumstances. Parties seeking guidance about their specific arrangements may request an OIG advisory opinion in accordance with the regulations set forth at 42 CFR part 1008.

B. 1994 Clarifications to Existing Safe Harbors

In general, the 1994 proposed clarifications were designed to clarify various aspects of the original safe harbor provisions. Set forth below are a summary of the proposed clarifications for each safe harbor provision, a summary of the final clarifications adopted in this rulemaking, summaries of the public comments received, and our responses to those comments.

1. Investment Interests

Summary of Proposed Clarifications: We proposed five clarifications to the investment interests safe harbor, as follows

- First, we proposed that only assets or revenues related to the furnishing of health care items or services will be counted for purposes of qualifying for either the $50,000,000 asset threshold for ''large entities'' (§ 1001.952(a)(1)) or the 60–40 gross revenue test for ''small entities'' (§ 1001.952(a)(2)(vi)). The purpose of this modification is to make clear our original intent that only assets and revenues derived from health care lines of business will be considered for purposes of qualifying for safe harbor protection.
- Second, we proposed revising the standards that prohibit an entity from loaning funds to an investor to be used to purchase the investor's investment interest in the entity. (§§ 1001.952(a)(1)(iv) and 952(a)(2)(vii)). The revised standard would make clear that the prohibition also includes any such loan from another investor or a person acting on behalf of the entity or any investor.
- Third, we proposed modifying the first investment interest standard to the small entity investment safe harbor (the 60–40 investor test) to allow an alternative to the existing requirement of class-by-class analysis. Under the current rule, ''each class of investments'' must meet the 60–40 investor test. Upon review, we found this class-by-class analysis unnecessarily restrictive. Accordingly, the proposed alternative would allow equivalent classes of equity investment interests to be combined together or equivalent classes of debt investment interests to be combined together (separate from the equity investments) in order to apportion investors into ''untainted'' and ''tainted'' pools for purposes of meeting the 60–40 investor test.
- Fourth, we proposed striking the language ''items or services furnished'' from the 60–40 revenue rule (§ 1001.952(a)(2)(vi)) in the small entity investment safe harbor to make clear that we did not intend for revenues that the joint venture derives from items or services furnished by an investor to the joint venture (such as management services) to be considered tainted for purposes of satisfying the 60–40 revenue test.
- Fifth, we proposed a clarification in the preamble to the 1994 proposed clarification to the effect that an interested investor must obtain his or her investment interest *in the same* way as members of the public (*i.e.*, directly off a registered national securities exchange through a broker) and the investment interest must be the same type of investment interest that is available to the public. In this regard, we stated that there cannot be any side agreements that require stock to be purchased or that restrict in any manner an investor's ability to dispose of the stock. We proposed no change in the language of the existing safe harbor, which states that the investment interest of an interested investor ''must be obtained on terms equally available to the public thorough trading on a registered national securities exchange * * * or on the National Association of Securities Dealers Automated Quotation Service'' (§ 1001.952(a)(1)(ii)).

Summary of the Final Rule: We are adopting the clarifications to the large and small entity investment safe harbors as proposed in the 1994 proposed clarifications and described above, with the following modifications in response to comments received (unless otherwise noted):

- We have added language to § 1001.952(a)(2)(vii) clarifying that, for purposes of the small entity investment safe harbor, loans to an investor may not be made by individuals or entities acting on behalf of the investment entity or any of its investors. This language is the same as language proposed to be added to § 1001.952(a)(1)(iv) in the large entity investment safe harbor in the 1994 proposed clarifications and was

described as applying to the small entity investment safe harbor in the preamble to the 1994 proposed clarifications. It was inadvertently omitted from the regulatory language published in the notice of proposed rulemaking.

- We have revisited the meaning of ''on terms equally available'' in the second standard of the large entity investment safe harbor and have concluded that an investment interest is obtained on equally available terms if it is obtained at the same price as is available to the general public trading on a registered securities exchange through a broker and is not subject to restrictions on transferability.

Comments and Responses

a. Large Entity Investments

Comment: In response to our clarification that only assets or revenues ''related to the furnishing of health care items or services'' will be counted for purposes of qualifying for either the $50,000,000 asset threshold for ''large entities'' or the 60–40 gross revenue test for ''small entities,'' several commenters sought guidance regarding what constitutes ''health care items or services.'' For example, some commenters wondered whether a managed care organization would be considered a health care business if it does not furnish health care services. Some commenters objected to the proposal, arguing that requiring items and services to be health care related would actually increase the incentives for improper referrals. They reason, for example, that a large entity entirely composed of health-care related businesses would be more susceptible to the lure of paying kickbacks for referrals than a diversified entity less dependent on health care derived profits.

Response: By using the term ''health care items or services,'' we mean (i) health care items, devices, supplies, and services and (ii) items or services reasonably related to the furnishing 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, quality assurance, and practice management services. Marketing services are not included. In this context, we believe that a managed care company would count as a health care related asset for purposes of the large entity investment threshold test and that revenue derived from a managed care company would count as ''tainted'' revenue for purposes of the 60–40 revenue test in the small entity investment safe harbor.

While we agree that diversified assets may, in some circumstances, indirectly minimize financial incentives for referrals from investor referral sources, we continue to believe that arrangements involving ventures between health care businesses and non-health care business pose an increased risk of program abuse. As we stated in the preamble to the 1994 clarifications, ''[i]t would be an obvious sham, inconsistent with our original intent, if a joint venture could merge with a non-health care business and have those non-health care assets, and the revenues derived from that non-health care line of business counted for the purposes of qualifying for safe harbor protection'' (59 FR 37203–37204).

Comment: Several commenters expressed concern about our clarification of the phrase ''on terms equally available to the public'' in the safe harbor condition that describes how interested investors must obtain their investment interests in order to receive safe harbor protection (§ 1001.952(a)(1)(ii)). We indicated that the phrase should be interpreted to mean that the interested investor must obtain his or her investment interest *in the same way* as investors from the general public. Several commenters urged that this interpretation was too narrow and imposed unwarranted limitations on investment in large entities. These commenters argued, for example, that a large entity should be permitted to purchase a physician's practice using stock in addition to cash, provided that the value of the stock plus all other consideration paid to the physician equals the fair market value for the practice. For example, one commenter asked why it would be acceptable for an entity to purchase a practice for $1 million in cash (assuming fair market value to be $1 million), but not to do so for $500,000 in cash and $500,000 worth of stock. These commenters suggest that the phrase ''on terms equally available'' should mean that the stock is not lettered, restricted, subject to side agreements, or otherwise subject to limited transferability. One commenter proposed an alternative safe harbor condition that would deny safe harbor protection to an interested investor's holding of publicly-traded stock that is subject to transfer restrictions that are not applicable to the stock when held by members of the public.

Response: We have two significant concerns regarding interested investors' investments in large entities that are in health care related businesses. First, we are concerned that limited transferability or other restrictions on the sale or disposition of stock may serve to ''lock'' interested investors into specific investments, thereby increasing the incentives for those investors to refer Federal health care program business to the investment entity. Second, we are concerned that interested investors who are potential referral sources for the investment entity not be permitted to obtain their investment interests at insider prices or at prices more favorable than those available to the general public when purchasing stock from a registered national securities exchange through a broker. Such favorable treatment could potentially be disguised remuneration for referrals. For example, we are aware of certain public offerings of health care companies that involve simultaneous acquisitions of physician practices in exchange for stock in the newly-public company, with the stock valued in a manner that results in the selling physician obtaining the stock at a lower price or on more advantageous terms than offered to the public. The economic benefit conferred on the physician in such an arrangement potentially violates the anti-kickback statute if one purpose of the benefit is to reward or induce referrals. The investment would not fall within the large entity investment safe harbor.

Notwithstanding, upon further consideration of this issue, we are persuaded that requiring stock acquired by interested investors to be obtained *in the same way* as the same stock acquired by members of the public imposes an unduly restrictive interpretation on the existing safe harbor language. Accordingly, we are adding language to make clear that an investment interest will not qualify for safe harbor protection as ''obtained on terms equally available to the public'' if (i) the investment interest is subject to restrictions or limited transferability (including side agreements) not applicable to the same investment interest when held by members of the public and/or (ii) the investment interest is not obtained for the same price that is available to the general public when trading on a registered national securities exchange through a broker. Thus, in the example cited by the commenter above, the investment interest would be protected if $1 million is the fair market value for the physician practice (not taking into account the value of any referrals) and the stock obtained by the physician is valued at $500,000 based on the price per share then available to the general public trading on a registered national

securities exchange through a broker. However, the public stock offering described in the preceding paragraph would not be protected.

b. Small Entity Investments

Comment: Some commenters asked that we clarify which investors constitute referral sources for purposes of the small entity safe harbor. One commenter recommended that we amend the small entity safe harbor to make clear that only physicians (using the Medicare program definition of that term) are capable of making referrals or influencing the flow of business. In this commenter's view, the current OIG position that referral source investors may include hospitals and other entities means that safe harbor protection is unavailable for various integrated delivery system models that involve joint ownership and investment. Another commenter requested that we clarify that manufacturers that invest in health care entities and sell products to those entities are rarely in a position to refer patients, and thus should not fall within the pool of ''tainted'' investors for purposes of the investment interests safe harbors.

Response: We continue to believe that the appropriate focus under this safe harbor is the status of the investors and the ability of the investors to make or influence the investment entity's referral stream or level of business activity. Investors that furnish items or services to the entity, as well as investors that refer patients or otherwise generate business for the entity, are ''tainted'' investors doing business with the entity for purposes of the 60–40 investor test. Thus, to iterate the example provided in the preamble to the 1991 final rule, if a durable medical equipment (DME) supplier and hospital enter into a joint venture to furnish DME to patients when they leave the hospital, both the DME supplier and the hospital fit within the category of investors doing business with the entity (56 FR 35968).

We are not persuaded that hospitals, nursing homes, skilled nursing facilities, or other institutions are incapable of influencing referrals of Federal health care program business. To the contrary, we are aware of instances of referrals that are in fact controlled by these institutions' employees or agents. (See, *e.g., Medicare Hospital Discharge Planning,* OEI–02–94–00320 (December 1997); *Special Fraud Alert: Fraud and Abuse in Nursing Home Arrangements with Hospices,* 63 FR 20415 (April 24, 1998)). Similarly, we believe that managed care companies and physician practice plans may control referrals in certain circumstances. We agree, however, that in many circumstances manufacturers that invest in health care entities and sell products to those entities may not be in a position to refer patients to, or generate business for, those entities for purposes of the 60–40 revenue test (§ 1001.952(a)(2)(vi)). However, in other circumstances, investor manufacturers may fall within the pool of ''tainted'' investors, and thus each arrangement must be evaluated on a case-by-case basis. In short, manufacturers may be ''tainted'' investors for purposes of the 60–40 investor test (§ 1001.952(a)(2)(i)), where they are in a position to furnish items or services to the investment entity or to influence the flow of referrals to the entity.

Comment: One commenter who supported our proposal to aggregate similar classes of investment interests sought clarification of the proposed condition that classes of investment interests be ''similar in all material respects'' for purposes of the 60–40 investor test, particularly as the condition applies to debt investment interests. For example, the commenter noted that the OIG is willing to treat general partners' and limited partners' interests as sufficiently similar for safe harbor purposes (56 FR 37204), even though general partner and limited partner interests are not similar in a number of arguably material respects, such as fiduciary obligations and assumption of liability. With respect to debt interests, the commenter questioned whether differing redemption rights would result in otherwise similar classes of debt being deemed too dissimilar to aggregate. Similarly, the commenter questioned whether debt instruments with different interest rates could be aggregated (especially if the different interest rates accurately reflect market rates at the time the instruments issued) and whether secured debt instruments could be aggregated with unsecured debt instruments.

Response: Our use of the phrase ''similar in all material respects'' was not intended to suggest that for purposes of aggregation, classes of investment interests must be similar in all respects that might be material to a partner or to a lender or a borrower, but only that classes of investment interests must be similar in all respects material to the purposes of the safe harbor. The focus is on the potential for remuneration to investors who are existing or potential referral sources; material investment terms are those terms that create, or relate to the creation of, potential value for investors. For example, classes of investment interests may be aggregated where the classes have similar rights with respect to the entity's income and assets, where investors receive equivalent returns in proportion to amounts invested, and, most importantly, where there is no preferential treatment of referral source investors, including, but not limited to, preferences that take effect in the event of a disposition of entity assets.

Comment: One commenter expressed concern about our treatment of general partners for purposes of the 60–40 investor rule. We have previously stated that general partners—who have fiduciary obligations to manage a partnership so as to make a profit and who are liable for losses incurred due to gross mismanagement—provide services to a partnership and are, therefore, ''tainted'' or ''interested'' investors for purposes of the 60–40 investor rule. The commenter observed that this interpretation serves to disqualify many partnerships from safe harbor protection and that our proposal to permit classes of investment interests to be aggregated for purposes of determining compliance with the 60–40 investor rule does not adequately address this issue. According to the commenter, even under our proposed aggregation test, safe harbor protection is only available if general partners hold a minority interest in the partnership, even if the partnership has no potential referral source investors. Thus, for example, a hospital owned entirely by a partnership composed of non-referral source investors would not qualify for safe harbor protection if the general partners owned more than 40 percent of any class of investment interest.

Response: As we explained in our preamble to the 1991 final rule, it would be inappropriate to grant safe harbor protection, for example, to a joint venture composed of a DME supplier and physicians, because all of the owners would be doing business with the joint venture by either furnishing items or services or making referrals (56 FR 35968). We recognize that there may be circumstances, such as those posited by the commenter, where the fact that an investor is furnishing items or services to the investment entity may not pose an increased risk of improper referrals comparable to the risk posed in our DME/physician joint venture example. However, we find that it is not feasible to craft a rule that would clearly distinguish among types of investors furnishing items or services, while excluding potentially abusive arrangements from safe harbor protection.

Distributions to investors in partnerships that have *no* existing or potential referral source investors may not implicate the anti-kickback statute at all, since the crux of the statute is a prohibition on remuneration to induce or reward referrals of Federal health care program business. To the extent the statute is implicated, partnerships that do not comply fully with all safe harbor conditions will have to be evaluated on a case-by-case basis. Our advisory opinion process is also available to parties contemplating such partnerships (42 CFR part 1008).

Comment: Several commenters supported our proposal to change the 60–40 revenue test by striking ''items or services furnished'' (§ 1001.952(a)(2)(vi)). However, these commenters asked for clarification of the term ''business otherwise generated'' as used in the safe harbor standard. We have previously explained that revenue is ''generated'' if it is ''*induced to come to* the joint venture for items or services *by an investor*'' (56 FR 37205) (emphasis in original). These commenters requested that we clarify that ''by an investor'' means by an investor who is a licensed professional with legal authority to order items and services, for instance, an investor with legal authority to refer or induce a person to obtain care from a participating provider.

Response: We disagree that the definition of an investor for these purposes should be as narrow as the commenters suggest. Certain investors that are arguably not ''licensed professionals,'' such as hospitals, long-term care facilities, home health agencies, managed care companies, and physician practice management companies, may be in a position to generate business for an entity in which they have an investment interest and to receive distributions that may be remuneration for that business. We recognize that there may be occasional instances where business is generated by investors who would not ordinarily be considered as potential referral sources. This might occur, for example, if an investor is not in a health care related line of business, but happens to refer friends or relatives to a joint venture entity in which he or she has invested. However, we think that these situations are likely to be infrequent and, in most circumstances, are not likely to generate appreciable revenue.

Comment: As described above, several commenters questioned our clarification that the term ''revenue'' for purposes of the 60–40 revenue test means revenue related to the furnishing of *health care* items or services. In addition, two commenters expressed concern about an example involving radiologists that we used to illustrate our discussion of the revenue rule in the preamble to the 1994 proposed clarifications. Specifically, the example stated that:

> If a radiologist holds an investment interest in an imaging center and reads all the films at the center, his or her reading of the film does not taint all the revenues from the referrals by non-investors. However, we have received a few questions from people who read the 60–40 revenue rule as making such referrals tainted because the investor furnished services at the joint venture.
>
> We emphasize that if a radiologist-investor is reading the film *and* making referrals or otherwise generating business, then the revenues the joint venture derives from that activity would become tainted. For example, revenues would be tainted when a radiologist-investor takes part in a consultation with a non-investor internist, and during that consultation the radiologist recommends a procedure which is performed at the joint venture. (59 FR 37205).

Commenters complained that in light of this example, a radiologist-investor seeking safe harbor protection would essentially be prohibited from practicing medicine, because he or she would be precluded from recommending follow-up procedures. Moreover, the commenters argued that compliance with the example would not be feasible because of the record keeping and administrative burden associated with tracking all recommendations to determine if recommended follow-up studies were later performed at the radiologist-investor's facility. These commenters asked that we clarify our position regarding radiologist-investors.

Response: We continue to be persuaded that it is appropriate and consistent with our original intent that only health care related revenues be counted for purposes of the 60–40 revenue test. The purpose of the test is to limit the number of investor referrals to a safe harbor protected joint venture, thereby minimizing the risk that profit distributions might be disguised payments for investor referrals.

Our use of the example in the preamble to the 1994 proposed clarifications was merely intended to illustrate the difference between providing items and services to an entity (which does not result in ''tainted'' revenue) and generating business for the entity (which does result in ''tainted'' revenue). In retrospect, our focus on radiologists in the example may have led to some confusion about the anti-kickback implications specifically for radiologists' practice of medicine. In the unique circumstances of radiologists, we wish to clarify that the occasional recommendation of additional testing by a radiologist to an attending physician with whom the radiologist has no financial arrangements and pursuant to a *bona fide* medical consultation is not prohibited under the anti-kickback statute. Accordingly, for purposes of the 60–40 revenue test, such consultative recommendations would not ''taint'' revenue derived from tests performed at the joint venture entity as a result of a subsequent referral of the patient by his or her attending physician for the recommended tests.

Comment: One commenter supported our proposed clarification regarding the prohibition on loans from entities or their investors that are used by investors to purchase their investment interests (§ 1001.952(a)(2)(vii)). Another commenter requested that we make clear that we do not intend to prohibit loans from banks or other unrelated parties.

Response: The seventh investment interest standard addressing loans is not intended to apply to loans from banks or other unrelated third parties that are not equity investors in the entity seeking safe harbor protection and that are not acting on behalf of the entity or any of its investors, even if the loan is used in whole or in part by a prospective investor to purchase an investment interest. On the other hand, the safe harbor condition is intended to preclude from protection loan guarantees, collateral assignments or other arrangements made by an investment entity or any of its investors, or by individuals or entities acting on their behalf, to secure a loan from a bank or other unrelated third party, if the loan is used in whole or in part by an investor to obtain an investment interest in the entity.

Comment: The remaining comments to the existing investment interest safe harbors addressed various aspects of the safe harbors not specifically covered by the proposed clarifications. Two commenters argued that the safe harbor's two 60–40 tests unnecessarily limit potential investors for, and referral sources to, legitimate, cost-effective, high-quality health care ventures. In one commenter's view, the 60–40 tests prevent potential joint ventures from attracting necessary capital and cause investors to refrain from using the venture's services, even when the venture offers higher quality, lower prices, or better patient convenience than competing providers. This commenter noted that the two 60–40 tests are particularly problematic in rural and underserved areas, where alternative sources of capital and

alternative providers are often in short supply.

Response: Except as otherwise noted above, we are adopting the proposed clarifications to the investment interests safe harbor as set forth in our 1994 proposed clarifications. Aside from clarifying that ''revenue'' refers to health care related revenue and deleting the phrase ''items or services furnished'' in § 1001.952(a)(2)(vi), we are not persuaded at this time that there is a need to revisit the two 60–40 tests for small entity investments. Elsewhere in this rulemaking, we address a new safe harbor for investments in rural and urban undeserved areas (§ 1001.952(a)(3)) that eliminates the 60–40 revenue test and incorporates a modified 60–40 investor test.

2. Space and Equipment Rental and Personal Services and Management Contracts Summary of Proposed Clarifications

We proposed 2 clarifications to the space and equipment rental and personal services and management contracts safe harbors (§§ 1001.952(b), (c), and (d)). First, we proposed revising these safe harbors expressly to preclude schemes involving the use of multiple overlapping contracts to circumvent the safe harbor requirement that space and equipment rental and personal services and management contracts be for terms of at least 1 year. This requirement was intended to prevent regular renegotiation of contracts based on the volume of referrals or business generated between the parties. Second, we proposed revising these safe harbors to preclude safe harbor protection for health care providers that rent more space or equipment or purchase more services than they actually need as a means of paying for referrals.

Summary of Final Rule: We are adopting the clarifications to the space and equipment rental and personal services and management contracts safe harbors as proposed in the 1994 proposed clarifications and described above, with the following modifications in response to comments received:

- We are substituting the word ''term'' for the word ''period'' in the second condition of each safe harbor to be more consistent with customary business terminology;
- We are replacing the phrase ''legitimate business purpose'' with the phrase ''commercially reasonable business purpose'' in each safe harbor to make clear that the test is not whether a business arrangement is lawful, but whether it serves a commercially reasonable business purpose, that is, whether the space and equipment leased or services purchased have intrinsic commercial value to the lessee or purchaser.

Comments and Responses

Comment: A commenter expressed concern that the safe harbor condition that a lease cover all equipment leased between parties and specify the equipment leased would jeopardize many common commercial equipment leasing transactions. This commenter asserted that manufacturers and lessors typically lease capital equipment to health care providers at different times, but under leases that cover the same time period, in whole or in part. The commenter opined that other safe harbor conditions, including those prescribing aggregate compensation, fair market value, and arms-length negotiations, are sufficient safeguards against abuse.

Response: We recognize that some lawful equipment contracts will not qualify for safe harbor protection and will need to be analyzed on a case-by-case basis. The existence of a safe harbor for a particular set of business arrangements does not jeopardize other types of arrangements under the anti-kickback statute. Many multiple contract arrangements are legitimate business arrangements that do not violate the statute; however, some multiple contract arrangements are essentially shams that operate to reward and encourage referrals. We are unable to provide safe harbor protection for such arrangements, in view of the potential abuse of multiple overlapping contracts described above. The advisory opinion process (42 CFR part 1008) is available to parties seeking individualized legal opinions regarding the legality of their leasing arrangements under the anti-kickback statute.

Comment: One commenter suggested that for purposes of clarity and consistency with customary business terminology we substitute the word ''term'' for the word ''period'' as used in §§ 1001.952(b)(2), (c)(2), and (d)(2).

Response: We agree that substituting the word ''term'' for ''period'' in §§ 1001.952(b)(2), (c)(2), and (d)(2) would provide clarity and consistency in the context of leases and service contracts.

Comment: One commenter approved of our proposal that the aggregate space, equipment, or services contracted for not exceed ''that which is reasonably necessary to accomplish the legitimate business purpose'' of the party renting the space or equipment or purchasing the services. This commenter believed that the clarification would inhibit lessors with greater bargaining power from coercing lessees into contracting for more space than needed to conduct business. However, several commenters suggested that the language of our proposed clarification is ambiguous, duplicative, and confusing, and, in the words of one commenter, would open a ''Pandora's Box of potentially conflicting interpretations.'' For example, one commenter observed that many arrangements in today's health care arena, such as cost-sharing or risk-sharing arrangements, joint research initiatives, and data collection arrangements, may not reflect ''traditional'' business purposes, but are legitimate and reasonable in responding to insurers' growing demands for cost-effectiveness. One commenter recommended replacing the word ''legitimate'' with the word ''reasonable.''

Response: We believe the proposed clarification further ensures that protected leases and personal services contracts will provide for fair market value compensation. However, we agree that the term ''legitimate'' may be misconstrued. Thus, in the final rule we are substituting the phrase ''commercially reasonable business purpose'' for ''legitimate business purpose'' to make clear that the test is not merely whether a business purpose is legal or illegal. The ''commercially reasonable business purpose'' test is intended to preclude safe harbor protection for health care providers that surreptitiously pay for referrals—whether because of coercion or by their own initiative—by renting more space or equipment or purchasing more services than they actually need from referral sources. By ''commercially reasonable business purpose,'' we mean that the purpose must be reasonably calculated to further the business of the lessee or purchaser. In other words, the rental or the purchase must be of space, equipment, or services that the lessee or purchaser needs, intends to utilize, and does utilize in furtherance of its commercially reasonable business objectives. Thus, for example, a space rental contract between a physician and a DME supplier for space in the physician's office that includes extra office space that the DME supplier neither occupies nor uses for its DME business would not be protected by this safe harbor. Nor would the safe harbor protect the lease of more space than would reasonably be rented by a similarly-situated DME supplier negotiating in an arms-length transaction with a non-referral source lessor. Cost-sharing or risk-sharing arrangements, joint research initiatives,

and data collection arrangements may qualify as commercially reasonable business purposes in many circumstances. However, we are aware of abusive arrangements involving contracts with referral sources for data collection services or research projects where the data to be collected or research to be performed have no value to the entity paying for them and are merely pretexts for payments for referrals. Such arrangements do not comply with the safe harbor and are highly suspect under the anti-kickback statute.

Comment: The remaining comments we received regarding clarification of this safe harbor addressed matters not covered by the proposed clarifications. Several commenters described difficulties in meeting the safe harbor for part-time arrangements—including time-share office leases, per use equipment leases, and personal services contracts with hourly compensation—caused by the requirement that the ''aggregate'' contract price be set in advance (§§ 1001.952(b)(5), (c)(5), and (d)(5)). One commenter noted that these types of arrangements typically contain compensation methods that are set in advance and that can be made consistent with fair market value and unrelated to the volume or value of referrals. Along these lines, one commenter suggested that the OIG permit ''aggregate'' payments that are not set in advance, if they are calculated in accordance with specific and predetermined formulas set forth in the written agreement. Similarly, several commenters expressed concern about the impracticality of the requirement that protected contracts specify the exact schedule of intervals for the use of space or equipment or the rendering of services for many part-time or as-needed arrangements.

Response: We continue to believe that both the ''aggregate'' and the ''specific schedule of intervals'' requirements are necessary to ensure that safe harbor protection is not afforded to arrangements that include payments that are adjusted periodically on the basis of the volume or value of referrals or business otherwise generated from a referral source. We recognize that these requirements may raise practical problems for certain providers seeking safe harbor protection for part-time or as-needed arrangements. Nevertheless, we are aware of many instances of abuse in these types of arrangements; therefore, for purposes of granting protection from prosecution, we believe it is appropriate to protect only those arrangements that can meet the safe harbor's strict standards. However, as we have stated numerous times, safe harbors do not define the scope of legal activities under the anti-kickback statute. Part-time, as-needed, and other similar arrangements that cannot fit within the safe harbor may be lawful, if no payments are made, directly or indirectly, to induce referrals of Federal health care program business.

Comment: One commenter sought clarification regarding the effect of a termination provision in a lease or contract in light of the safe harbor requirement that leases or contracts be for at least a 1-year term. This commenter specifically asked whether the 1-year term requirement is satisfied (i) if the lease or contract allows for ''for cause'' termination by either party, or (ii) if the lease or contract permits termination by either party with or without cause upon advance written notice, provided there is a concurrent contractual provision that restricts parties that terminate without cause from entering into any further relationships for the balance of the required 1-year period.

Response: The 1-year term requirement ensures that protected leases or contracts cannot be readjusted frequently based on the number of referrals between the parties. Although not specifically stated in the safe harbor regulation, a ''for cause'' termination clause that (i) specifies the conditions under which the contract may be terminated ''for cause,'' and (ii) operates in conjunction with an absolute prohibition on any renegotiation of the lease or contract or further financial arrangements between the parties for the duration of the original 1-year term would satisfy the 1-year term requirement. We remain concerned, however, that ''without cause'' termination provisions could be used by unscrupulous parties to create sham leases and contracts. This could occur, for example, where the parties enter into an agreement to pay a sum of money upfront for services to be performed over a period of time. Parties could disguise payments for referrals by terminating the agreement without cause after payment, but before performance of any services. A 1-year prohibition on renegotiation or further financial arrangements would be meaningless in such circumstances.

3. Referral Services

Summary of Proposed Clarifications: The referral services safe harbor requires that any fee a referral service charges a participant be ''based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated *by the participants* for the referral service * * *'' (§ 1001.952(f)(2)) (emphasis added). This language created an unintended ambiguity when a referral service tries to adjust its fee based on the volume of referrals *it makes to the participants.* We proposed clarifying that the safe harbor precludes protection for payments from participants to referral services that are based on the volume or value of referrals to, or business otherwise generated by, *either* party for the other party.

Summary of Final Rule: We received one comment in favor of our proposed clarification to the referral services safe harbor and none opposed. We are adopting the proposed clarification as set forth in the 1994 proposed clarifications.

4. Discounts

Summary of Proposed Clarifications: As a general rule, discounts for health care items and services are encouraged under the Federal health care programs so long as the Federal health care programs share in the discount where appropriate, and as appropriate, to the reimbursement methodology. Arrangements in accordance with which Federal programs get less than their proportional share of cost-savings on items or services payable by the programs are seriously abusive. Such arrangements result in the programs being overcharged and are not protected by either the statutory exception or regulatory safe harbor for discounts.

Because of expressed industry uncertainty over what obligations individuals or entities have to meet in order to receive protection under this safe harbor, we proposed clarifying the discount safe harbor by dividing the parties to a discount arrangement into three groups—buyers, sellers, and offerors of discounts—with descriptions of each party's obligations in separate paragraphs. In addition, we proposed clarifying the definition of ''rebate'' for purposes of this safe harbor. A rebate under our proposal would be defined as any discount not given at the time of sale. Consequently, a rebate transaction would not be covered by the safe harbor if it involves a buyer under § 1001.952(h)(1)(iii) that is neither a cost-reporter nor a HMO or CMP, because for such buyers, all discounts must be given at the time of sale.

We also proposed clarifying the scope of safe harbor protection for sellers in situations where buyers have not fully complied with their obligations under the safe harbor provisions. If a seller has done everything that it reasonably could under the circumstances to ensure that the buyer understands its obligation to

report the discount accurately, the seller is protected irrespective of the buyer's omissions. To receive such protection, however, the seller must report the discount to the buyer and inform the buyer of its obligation to report the discount. To emphasize that the seller's obligations require more than perfunctory compliance with the safe harbor, we proposed adding that the seller must inform the buyer ''in an effective manner.'' We also proposed adding a requirement that the seller ''refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.'' Thus, if the seller, in good faith, meets its obligations under the safe harbor and the buyer does not meet its obligations due to no fault of the seller, the seller would receive safe harbor protection. However, when a seller submits a claim or request for payment on behalf of the buyer, the seller must fully and accurately report the discount to the appropriate Federal or State health care program. An offeror of a discount would similarly receive safe harbor protection if it meets all of its safe harbor obligations, but its buyer or seller does not meet its obligations due to no fault of the offeror.

We further proposed clarifying whether any reduction in price offered to a beneficiary could be safe harbored under this regulation. To the extent that a discount is offered to a beneficiary and all other applicable standards in the safe harbor are met, such a discount would receive safe harbor protection. However, discounts to beneficiaries in the form of routine reductions or waivers of any coinsurance or deductible amount owned by the beneficiaries do not meet the safe harbor conditions and are not protected.

The preamble to the 1991 final rule stated that when reporting a discount, one only need report the actual purchase price and note that it is ''net discount.'' However, for purposes of submitting a claim or request for payment, we proposed clarifying that what is necessary is that the value of the discount be accurately reflected in the actual purchase price. It is not necessary to distinguish whether this price is the result of a discount or to state ''net discount.'' Consequently, parties who were uncertain about how or where to report on a particular form the fact that the price was due to a discount need not be concerned with reporting that fact, as long as the actual purchase price accurately reflects the discount.

Finally, we proposed some minor editorial changes that do not affect the substance of the provision, but hopefully make it easier to understand.

Summary of Final Rule: We are adopting the clarifications to the discount safe harbor as proposed in the 1994 proposed clarifications and described above, with the following modifications in response to comments received (unless otherwise noted):

- In paragraphs (h)(2) and (h)(5)(ii), we are changing the words ''furnishes'' to ''supplies'' and ''furnishing'' to ''supplying,'' respectively, to clarify the role of sellers under the discount safe harbor and to avoid confusion with other regulatory uses of the word ''furnishes.''
- We are modifying our proposal that sellers and offerors give buyers ''effective notice'' of their obligations to report discounts by requiring instead that sellers and offerors provide buyers with notice in a manner that is reasonably calculated to give the buyers notice of their reporting obligations, including their obligation to provide information to the Secretary upon request under § 1001.952(h)(1). The intent of this modification is to make clear that safe harbor protection for sellers and offerors who fully comply with the safe harbor conditions is conditioned on the actions of the sellers and offerors, and not on the buyers' compliance.
- We are modifying our proposed definition of a ''rebate'' to include any discount the terms of which are fixed at the time of the sale of the good or service and disclosed to the buyer, but which is not received at the time of the sale of the good or service. This modification will enable us to extend safe harbor protection to certain charge-based buyers and buyers reimbursed on the basis of fee schedules who obtain rebates. We are eliminating the requirement that charge-based buyers report discounts on claims submitted to the Federal programs; however, we are retaining the requirement that such buyers provide documentation of discounts to the Secretary upon request.
- We are clarifying that credits and coupons may qualify for safe harbor protection if they meet all of the safe harbor criteria; however, credits or coupons that are, in essence, cash equivalents are not discounts for safe harbor purposes.
- We are clarifying that, in certain circumstances described in more detail below, discounts on multiple items may qualify as a ''discount'' for safe harbor purposes where the reimbursement methodology for all discounted items or services is the same and where the discount can be fully disclosed to the Federal health care programs and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology.
- We are correcting a technical error in the proposed clarifications by changing the word ''include'' in § 1001.952(h)(5)(ii) to ''induce.''

Comment and Response

Comment: Many commenters questioned the relationship between the regulatory safe harbor for discounts and the statutory exception for discounts, which provides for protection for ''a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program, if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program'' (42 U.S.C. 1320a–7b(b)(3)(A)). In the preamble to the 1991 final rule, we stated that the regulatory safe harbor includes *all* discounts Congress intended to protect under the statutory exception (56 FR 37206). Commenters expressed concern that this statement means that failure to qualify under the discount safe harbor is a statutory violation if items or services payable by a Federal health care program are involved, since intent to induce business is always present in a discount arrangement. Under this interpretation, according to commenters, numerous forms of discount pricing, such as pricing one product dependent on the price of another, discount package pricing, and certain capitation arrangements, would be prohibited without the case-by-case analysis generally afforded other types of arrangements that do not fit squarely within a safe harbor. These commenters also urge that limiting permissible discounts to those that comply with the safe harbor ''freezes'' the health care industry into a particular way of doing business, thereby chilling innovations in discount pricing that could result in reductions in health care costs, especially as the market moves from fee-for-service arrangements to managed care. These commenters argue that Congress did not give the OIG authority to constrict the reach of the statutory exception. One commenter observed that Congress unequivocally stated that practices protected under the safe harbors were to be *in addition* to existing statutory protections (Pub. L. 100–93, section 14(a)), and therefore the regulatory discount safe harbor should create a class of protected practices *in addition* to practices protected under the statutory exception.

Response: As stated in the preamble to the 1994 proposed clarifications, it continues to be our position that the

regulatory safe harbor protects *all* discounts or reductions in price protected by Congress in the statutory exception (see 59 FR 37206). The Secretary is vested with the authority to make and publish rules, not inconsistent with the Social Security Act, necessary to the efficient administration of her functions under the Social Security Act (42 U.S.C. 1302). The anti-kickback statute, including all exceptions thereto, are codified as part of the Social Security Act. Moreover, the regulatory safe harbor expands upon the statutory safe harbor by defining additional discounting practices not included in the statutory exception that are not abusive, such as certain discounts to beneficiaries (other than routine waivers of cost-sharing amounts) that meet all applicable safe harbor standards. In sum, the regulatory safe harbor both incorporates and enlarges upon the statutory exception.

Comment: One commenter questioned the safe harbor exclusion of reductions in price that are available to one payer but not to Medicare or Medicaid (§ 1001.952(h)(3)(iii)), noting that it is unclear how failure to provide a discount to Medicare or Medicaid gives rise to a question under the anti-kickback statute, which prohibits remuneration to induce referrals of items or services payable by a Federal health care program. The commenter further argued that there is no basis in the statutory discount safe harbor for a requirement that Medicare and Medicaid patients receive the same prices as other patients.

Response: The safe harbor excludes from the definition of a protected ''discount'' price reductions that apply to one payer but not to the Federal health care programs. This exclusion is necessary to protect against abusive arrangements in which remuneration in the form of discounts on items or services for private pay patients is offered to a provider to induce referrals of Federal health care program patients. For example, as noted in the preamble to the 1991 final rule, we are aware of clinical laboratories that offer price reductions to physicians for laboratory work for private pay patients on the condition that the physicians refer all of their Medicare and Medicaid business to the laboratory. Such ''swapping'' arrangements, which essentially shift costs to the Federal health care programs, continue to be of concern to this office. We do not believe that Congress intended to except such schemes from the anti-kickback statute. Nor do we believe that Congress intended for the Federal health care programs to pay premium prices and thus serve as *de facto* subsidy programs for other reimbursement systems.

Comment: Several commenters generally supported the clarification of the discount safe harbor to recognize 3 groups: Buyers, sellers and offerors. However, a number of commenters requested further clarification regarding the meaning of ''offeror'' and how an ''offeror'' differs from a ''seller''. Specifically, commenters asked about the application of the ''offeror'' category to wholesalers and other brokers, as well as to managed care plans, group purchasing organizations and preferred provider organizations.

Response: An ''offeror'' may be any individual or entity that provides a discount on an item or service to a buyer, but that is not the seller of the item or service. For example, many pharmaceutical manufacturers sell some or all of their products through wholesalers, which, in turn, sell the products to hospitals, retail pharmacies, HMOs, and other providers. A manufacturer may offer a discount in the form of a rebate to the ultimate purchaser that is in addition to any discount from the wholesaler to the retailer. For purposes of this regulation, the manufacturer would be the ''offeror,'' the wholesaler the ''seller,'' and the retailer the ''buyer.'' While we believe that typically the wholesaler would be the ''seller'' and its retail customer the ''buyer,'' if a wholesaler offers a discount to a retail purchaser that has purchased the discounted product from another party, the wholesaler could qualify as an ''offeror.''

Nothing in these regulations precludes a managed care organization, including a preferred provider organization, from being eligible as an ''offeror'' in accordance with the safe harbor. However, in many situations, discounts offered by managed care organizations will not fit within the scope of the discount safe harbor, because the buyers who obtain the discounts will not be providers of services that claim payment for costs or charges associated with the discounted items or services under a Federal health care program. For example, the recipient of a preferred provider organization discount is typically an employer or other payer or patient. However, some discount arrangements offered by a managed care organization may be eligible for safe harbor protection under the discount safe harbor, provided all conditions of the safe harbor are satisfied. In addition, managed care ''discounts'' are potentially protected by the shared-risk exception (42 U.S.C. 1320a–7b(b)(3)(F)), and the existing safe harbors for managed care arrangements (§§ 1001.952(l) and (m)).

Comment: One commenter objected to the safe harbor's portrayal of the role of ''sellers.'' This commenter maintained that sellers do not generally ''furnish'' items or services, nor do they ''permit'' buyers to take discounts off the purchase price. Rather, sellers sell, lease, transfer, or otherwise arrange for the use of products, in some cases involving discounts or reductions in price. This commenter noted that other OIG regulations define ''furnish'' as referring to items and services provided directly by or under the direct supervision of, or ordered by, a practitioner or other individual, or ordered or prescribed by a physician (either as an employee or in his or her own capacity), a provider, or other supplier of services (see § 000.10). In addition, the preamble to the OIG final rule addressing amendments to the OIG's exclusion and CMP authorities resulting from Public Law 100–93 states that manufacturers who do not receive payment directly or indirectly from Medicare or Medicaid do not ''furnish'' items in the context of that definition (57 FR 3298 and 3300). For consistency and to avoid confusion, the commenter suggests that the term ''furnished'' should be replaced by the term ''supplies.''

Response: To avoid confusion with other regulatory definitions, we agree that the term ''supplies'' should be substituted for ''furnishes'' in §§ 1001.952(h)(2) and (h)(5)(ii).

Comment: Several commenters commented that the proposed language clarifying the seller's obligation to disclose the discount properly to the buyer is beyond the scope of the statutory exception and confuses rather than clarifies the seller's obligations. A number of commenters suggested that the requirement that sellers provide effective notice would lead to mistrust between buyers and sellers and disputes about whether ''effective notice'' was provided. One commenter suggested that the requirement inappropriately saddles a seller with the responsibility of being the buyer's ''brother's keeper.'' Some commenters requested clarification of what qualifies as ''notice.'' Others questioned the intention of the added language requiring sellers to ''refrain from impeding'' the buyer's performance of its obligations. One commenter objected that this requirement imposed an undue burden on sellers, because sellers would have to know all of an individual buyer's specific billing activities and possible obligations in order to be in a position to refrain from doing anything

that could impede the buyer in meeting its obligations.

Response: As we stated in the preamble to the 1991 final rule (56 FR 35958), we believe the statute permits us to interpret statutory terms used in the statutory exceptions, including the phrase ''appropriately reflect'' in the discount exception (also see 42 U.S.C. 1302). We note that the statutory exception does not protect any seller if the purchaser has not appropriately reflected the discount. Thus, the objection based on the statute is misplaced.

With respect to the substance of the comments, the proposed clarification would require that the seller inform the buyer ''in an effective manner'' of the buyer's obligation to report the discount and refrain from doing anything to impede the buyer from fulfilling its obligations. We agree that the phrase ''in an effective manner'' perhaps unintentionally focuses on the buyer's conduct and might inappropriately be interpreted to mean that a seller is only protected when the buyer, in fact, fulfills its obligation to report the discount. This was not our intention. Accordingly, we have decided to modify the language to require the seller to inform the buyer of its obligations ''in a manner that is reasonably calculated to give notice to the buyer.'' We believe this language provides the seller with an objective standard by which to measure the sufficiency of its notice. We are further clarifying that for safe harbor purposes one of the buyer's obligations is to provide information about discounts to the Secretary upon request in accordance with § 1001.952(h)(1).

We are not prescribing a specific form of notice. The form of notice appropriate in particular situations may vary. Our intention in adding the ''refrain from impeding'' standard is to make clear that a seller will only be protected by the safe harbor if it is not complicit in a buyer's noncompliance with its obligations to report discounts accurately to the Federal health care programs. We are not making any change to the requirement that the seller not impede the buyer's compliance because we believe the language is clear. The same standard applies to offerors; they will not be protected by the safe harbor if they are complicit in either buyer or seller noncompliance.

Comment: A number of commenters objected to our bar on safe harbor protection for rebates offered to charge-based providers. Our proposed definition of ''rebate'' defined a rebate as a discount not given at the time of sale. Under our proposed clarification, safe harbor protection would only be extended to charge-based providers for discounts made at the time of sale of a good or service. The commenters point out, for example, that the regulation precludes retail pharmacies and outpatient clinics from being eligible for price reductions on the same basis as hospitals (cost reporters) and other large purchasers (*e.g.*, HMOs). Moreover, the commenters note that there may be situations in which adjustments to previous billings or other errors could result in a rebate. The commenters also maintain that where payment is based on the lesser of actual charges or a fee schedule amount, fee schedules could be adjusted to reflect the availability of volume discounting. The commenters argue that excluding rebates for charge-based providers lacks a statutory basis, since the statutory exception refers to a ''reduction in price obtained by a provider,'' without any reference to *when* the reduction must be obtained. The commenters further argue that there is no sound basis for not protecting delayed discounts to physicians, since we are not requiring physicians to reduce their charges for the amount of a discount, even where there is a separately claimed item. Thus, the commenters urge that rebates be covered so long as the amount is fully disclosed to the Federal health care programs and the other safe harbor conditions are satisfied.

Response: The most important aspect of the discount safe harbor is that the Federal health care programs share in the discount in proportion to the percentage the programs pay of the total cost. Congress intended *only* to protect discounts that could fairly benefit the Federal health care programs. It is our intention in these regulations to ensure that the only discounts protected are those where the Federal programs receive such benefit.

Having considered the comments received about rebates, we have concluded that excluding safe harbor protection for all rebates to charge-based buyers or buyers that are reimbursed based on Federal program fee schedules is unnecessarily restrictive and may prevent the Federal health care programs from realizing indirect benefits that may accrue from rebates to charge-based providers.

Accordingly, we are defining a ''rebate'' for purposes of the safe harbor as a discount, the terms of which are fixed at the time of the sale and disclosed to the buyer at the time of sale, but which is not given at the time of sale. ''Terms'' refers to the methodology that will be used to calculate the rebate (*e.g.*, a percentage of sales or a fixed amount per item purchased during a given period of time). The terms of the rebate must be set at the time of the sale and disclosed to the buyer, even though the exact dollar amount of the rebate may not be known until the rebate is paid. In some circumstances, a rebate may be paid only after some number of successive purchases of particular goods or services; in such circumstances, the terms of the rebate must be fixed and disclosed to the buyer at the time of the first sale of a good or service to which the rebate applies. We are eliminating the safe harbor requirement that charge-based buyers (and sellers if submitting claims on behalf of charge-based buyers) disclose the amount of discounts on claims submitted to the Federal programs. We are retaining the existing requirement that buyers (and sellers submitting claims on their behalf) must provide information documenting the discount upon request of the Secretary.

Comment: The proposed clarifications eliminated a reference to credits and coupons in the definition of a ''discount'' (§ 1001.952(h)(3)). Two commenters expressed concern that this deletion indicated an intent to prohibit safe harbor protection for credits and coupons.

Response: To the contrary, our revised definition of ''discount'' applies to any reduction in the price a buyer who buys directly or through a wholesaler or group purchasing organization is charged for an item or service based on an arms-length transaction, except for certain forms of price reduction expressly not included in the definition (*e.g.*, no cash or cash equivalents, no routine waivers of copayments). If a coupon or credit fits within the definition of a discount, it is included within the safe harbor (assuming all safe harbor conditions are satisfied). However, we did not intend to protect credits or coupons that are merely surrogate cash payments, such as credits or coupons that can be used like cash to purchase unspecified goods or services from the seller or offeror. Thus, a coupon good for a reduced price on a designated item could be included in the definition, so long as it meets all of the other requirements of the regulation; however, a coupon good for a certain dollar amount off any goods sold by the seller is not included in the definition. We are, therefore, adding clarifying language to the definition of ''discount'' to make clear that cash equivalents are not discounts for purposes of the safe harbor.

Comment: One commenter objected to a ''discount'' for purposes of the safe harbor being limited to discounts offered to buyers who buy directly or

through wholesalers or group purchasing organizations. This commenter urged that this limitation fails to accommodate new distribution arrangements, many of which contribute to purchasing economies. For example, hospitals, physicians or ambulatory surgical centers may buy items and services through HMOs or other brokering-type suppliers.

Response: In general, if a discount is negotiated with a *bona fide* seller of the item or service, including an entity that aggregates provider demand to obtain access to volume discounts, in accordance with an arms-length transaction, and if the discount otherwise meets all safe harbor requirements, we believe that the discount would come within the safe harbor definition of discount. However, there may be arrangements that do not fit the definition where access to a seller's favorable discount rates is itself an inducement or reward for referrals, *e.g.*, providing certain physician practices access to a hospital's employee health benefits plan in order to reduce the physician's employee insurance costs.

Comment: Several commenters expressed concern about the exclusion from the definition of ''discount'' of price reductions furnished on one good or service without or at a reduced charge to induce the purchase of a different good or service. These commenters assert that this restriction was intended to preclude furnishing a good at a reduced price in exchange for any agreement to buy a good which was reimbursed under a different reimbursement methodology, in such a way that discounts would not be passed along to the Medicare program. For example, the safe harbor was not intended to protect a discount on hospital supplies covered by a Diagnostic Related Group (DRG) payment in exchange for the purchase at the full price of capital equipment separately reimbursed by Medicare on a reasonable cost basis in accordance with a hospital's cost report. Nor was it intended to protect a discount earned on products reimbursed by Medicare but applied to products reimbursed by non-Medicare payers. However, these commenters argue that the safe harbor should not exclude discounts on multiple products when the net value of the discounts could be properly reported to, and benefit, the Medicare program. For example, commenters believe that safe harbor protection should be available for a discount to a hospital for sterile gauze pads in exchange for the purchase of surgical tape, both of which are included in the hospital's DRG payment and recorded on the hospital's cost report as routine costs not separately reimbursable. These commenters expressed concern that the discount safe harbor's limitation on discounts for bundled or multiple items or services fails to recognize the diversity of cost controls inherent in such reimbursement methodologies as DRGs; physician payment under the RBRVS system; national limitation amounts for clinical laboratory tests; fee schedules for DME, prosthetics, orthotics, and other supplies; and fixed rates for ASCs. Finally, commenters noted that by restricting discounts on multiple items, the safe harbors may prevent the Federal health care programs from benefitting from purchasing economies that result from volume purchasing and group discounts.

Response: We agree that one purpose of the limitation on discounts for bundled items or services is to preclude protection for discounts that do not benefit the Federal health care programs, but which are used to induce purchases of other products for which the Federal health care programs pay the full price. These discounts are problematic, because they shift costs among reimbursement systems or distort the true costs of all items. As a result, it may be difficult for the Federal health care programs to determine proper reimbursement levels. (See 56 FR 35987, for example, citing the example of the development of accurate pricing data for intraocular lenses.)

However, we are persuaded that in certain circumstances, discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the programs through lower costs or charges achieved through volume purchasing and other economies of scale. Such circumstances exist where the goods and services are reimbursed by the same Federal health care program in the same manner, such as under a DRG payment.

Comment: Several commenters questioned our intent in changing certain language in the definition of discount from ''in exchange for any agreement to buy a different good or service'' to ''to include (induce) the purchase of a different good or service.'' (See § 1001.952(h)(5)(ii)).

Response: We changed this language to be consistent with the anti-kickback statute, which prohibits inducements to refer Federal health care program business, even if there is no actual referral made or agreement to refer. We are correcting an editorial error in the proposed rule, which incorrectly used the word ''include'' instead of ''induce'' in § 1001.952(h)(5)(ii).

5. Sham Transactions or Devices

Summary: We proposed a new provision to clarify that any arrangement entered into or employed for the purpose of appearing to fit within a safe harbor when the substance of the arrangement is not accurately reflected by its form will be disregarded, and the substance of the arrangement will determine whether safe harbor protection is warranted.

Comment: Although one commenter supported the proposed sham transactions rule, many commenters objected to it. These commenters argued that the proposed sham transactions rule was vague, lacked clear objective criteria, and did not provide any examples of sham transactions.

Response: Upon further consideration, we have decided to withdraw this proposal. We emphasize, however, that for purposes of determining compliance with the safe harbors, we will evaluate both the form and substance of arrangements. To be protected, the form must accurately reflect the substance. As we have explained in the context of space and equipment rentals:

> If a sham contract is entered into, which on paper looks like it complies with these provisions, but where there is no intent to have the space or equipment used or the services provided, then clearly we will look behind the contract and find that in reality payments are based on referrals. Thus, these contracts would not be protected under these provisions. (56 FR 35972)

This same general principle would apply in determining compliance with other safe harbors.

C. 1993 Proposed Safe Harbors

The 1993 proposed rule set forth new safe harbor regulations in the subject areas described below. Each description includes a summary of the proposed rule; a summary of the final rule, including a summary of significant changes between the proposed and final rules; and a summary of comments received and our responses.

1. Investment Interests in Underserved Areas

Summary of Proposed Rule: It had come to our attention that it is difficult for entities located in many rural areas to comply with the two 60–40 tests set forth in the ''small entity'' investment interest safe harbor. The first 60–40 rule (§ 1001.952(a)(2)(i)) requires that no more than 40 percent of the investment interests of the entity be held by

investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity (the ''60–40 investor rule''). The second 60–40 rule (§ 1001.952(a)(2)(vi)) requires that no more than 40 percent of the gross revenue of the entity may come from referrals or business otherwise generated from investors (the ''60–40 revenue rule''). Entities located in rural areas may have an especially difficult time complying with these two standards, because in many cases physicians may be the primary sources of capital in the area, and those physicians may have no alternative facility to which they can refer.

Consequently, we proposed an additional safe harbor for investments in entities located in rural areas that would have eliminated the two 60–40 rules. We proposed defining the rural areas included in the safe harbor in accordance with the standards set by the Office of Management and Budget (OMB) and used by the Bureau of the Census. We solicited comments on the appropriateness of this definition of rural area. We stressed that the method for designating rural areas must ensure that this safe harbor only protects entities that truly serve a rural population. We suggested that one alternative would be to adopt the definition of ''rural'' found at 42 CFR 412.62(f)(1)(ii), which is the definition used by HCFA in its DRG reimbursement rules. We proposed leaving in place the remaining six standards for small entity investments for purposes of the new safe harbor. These six standards provide substantial assurances against abuse, and we had not been apprised of any particular difficulty that rural entities were experiencing with these standards.

In place of the 60–40 tests, we proposed a more flexible standard that would still assure that referring sources, physicians in particular, were not inappropriately selected as investors. First, we proposed requiring the entity to make a *bona fide* offer of the investment interest to any individual or entity irrespective of whether such prospective investor is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. Thus, we proposed requiring that opportunities for investment be offered in a good faith, non-discriminatory manner to any individuals or entities that are potential sources of capital. Second, to exclude the possibility of sham business structures not intended to serve the rural areas in which they are located, we proposed incorporating a standard that would require that at least 85 percent of the dollar volume of the entity's business in the previous fiscal year or twelve month period be derived from items and services provided to persons residing in the rural area. For entities that have not been in business for 12 months, compliance with this standard would be determined by examining the composition of the entity's business over the entire period of its existence.

Methods of Classifying Geographic Areas: Depending on its purpose, the Government uses several methodologies to define whether certain geographic areas are ''urban'' or ''rural'' and whether certain geographic areas or populations have inadequate access to health care services. Among them, the following are relevant to this preamble discussion:

- *OMB Methodology:* The OMB defines a Metropolitan Statistical Area (MSA) as a group of counties (or, in New England, a group of townships) surrounding and related to an urban core area containing a large population nucleus. The core of an MSA is a city with a population of at least 50,000 people and/or an urbanized area with a total population of at least 100,000 (75,000 in New England). The OMB defines a county as part of the MSA if it contains the core city or contains part of a continuous urbanized area around the core city, even if outlying areas of the county are rural in character. Using this methodology, an area may be considered ''rural'' if it is not metropolitan, e.g., not part of an OMB-defined MSA (see 44 U.S.C. 3504).
- *HCFA DRG Definition:* For purposes of establishing DRG payments, HCFA defines ''rural'' areas as all areas outside the metropolitan areas (MSAs) defined by OMB (§ 412.62(f)(1)(ii)).
- *Medically Underserved Areas/Populations (MUA/MUPs):* The MUA/MUP system was developed in the 1970s in accordance with section 330(b)(3) of the Public Health Service (PHS) Act to identify areas and populations eligible to participate in the Community Health Center Program. MUAs and MUPs are designated by the Health Resources and Services Administration (HRSA). An MUA is either a rural or urban area designated by the Secretary as having a shortage of health care services; an MUP is a population group designated as having such a shortage, such as certain migrant farmworkers or homeless populations. Factors HRSA considers as part of the existing MUA/MUP designation process include population-to-primary care physician ratios, infant mortality rates, poverty rates, and the percentage of the population aged 65 or over. The regulations governing MUA/MUPs are currently set forth at 42 CFR part 51c.
- *Health Professional Shortage Areas (HPSAs):* HRSA developed HPSAs to meet the statutory requirement in section 332 of the PHS Act to designate areas, population groups and facilities with a shortage of health professionals eligible for placement of National Health Services Corps personnel. HPSA designations are currently based primarily on measurements of area population-to-provider ratios for specific geographic service areas (or population groups within those areas), together with indicators that provider resources in adjoining areas are overutilized, excessively distant (e.g., more than 30 minutes travel time away for primary care) or otherwise inaccessible (42 CFR part 5). A HPSA can be designated based on shortages of (1) providers in a geographic area; (2) providers willing to treat a specific population within a defined area; or (3) providers for a public or nonprofit facility serving a designated area or population group (which could include a hospital). HPSAs are identified for three types of provider shortages: primary care, dental care and mental health care. The current primary care HPSA criteria define a ''primary care physician'' as a physician in one of the following specialties: general practice, family practice, pediatrics, general internal medicine or obstetrics/gynecology. Mental health providers covered by mental health HPSA designations include psychiatrists, clinical psychologists, psychiatric nurses, psychiatric social workers and marriage counselors.
- *Notice of Proposed Rulemaking on MUA/MUPs and HPSAs.* HRSA has proposed revising the MUA/MUP and HPSA regulations to improve the current designation process by combining the two designation processes; automating the scoring process and simplifying it by maximizing the use of national data; expanding States' roles in identification of rational service areas for designation; and incorporating better measures or correlates of health status and lack of access, including measures of minorities and isolated rural areas (63 FR 46538). In response to public comments, HRSA has announced its intention to issue a second notice of proposed rulemaking following a period of evaluation of comments received, analysis of alternative approaches and impact testing (64 FR 28831). Following an additional public comment period, new regulations governing MUA/MUPs and

HPSAs are expected to be codified at 42 CFR part 5.

Summary of Final Rule: Paramount among OIG's concerns is that beneficiaries have adequate access to quality health care. We are aware that certain communities experience shortages of health care services that affect Federal program beneficiaries and others. This rule for investments in underserved areas is designed to balance the interests of those communities in facilitating the development of health care services with the anti-fraud interests that are the basis of the anti-kickback statute.

Health care joint ventures in underserved areas raise the same basic anti-kickback concerns as other joint ventures: First, is the joint venture a *bona fide* business enterprise? Second, are distributions from the joint venture really payments for referrals to the joint venture from investors? Third, are the distributions really payments for referrals from one investor to another? For this reason, it is important that any safe harbor contain adequate safeguards and conditions against fraud and abuse.

This new safe harbor for investments in joint ventures in underserved areas is designed to provide additional flexibility for investments in underserved areas that may experience a shortage of available capital from non-referral source investors. The safe harbor includes specific criteria that substantially reduce the risk of inappropriate payments for referrals and exclude from protection entities that do not serve the health care needs of people living in the underserved areas in which the entities are located. Because the safe harbor affords protection for a broader range of investments in joint ventures in underserved areas, we hope it will promote the development of needed health care ventures.

Based on our review of the comments received from, and concerns expressed by, various commenters, we have made several significant changes to the proposed safe harbor, all of which are described in more detail in the responses to comments section below.

- First, we have expanded safe harbor protection to include urban, as well as rural, underserved areas. We are persuaded that joint ventures in urban underserved areas often experience the same difficulties in qualifying for safe harbor protection as their rural counterparts. We are defining an underserved area as any defined geographic area that is designated as a MUA in accordance with the regulations at 42 CFR part 51c (or, if and when applicable, 42 CFR part 5).
- Second, we have reduced from 85 percent to 75 percent the volume of the investment entity's business that must be derived from residents of underserved areas.
- Third, we have provided a ''grace'' period for investment entities that qualify for safe harbor protection at the time of the initial investment, but subsequently find themselves located in areas that have ceased to meet the safe harbor definition of an underserved area.
- Fourth, we have incorporated a modified investor rule that requires that at least half of the investment interests in the entity be held by non-referral source investors. Here, we were in part persuaded by comments from health care entities that are currently located in underserved areas and that have no or few referral source investors. These entities expressed concern about unfair competition from new entities entirely composed of referral source investors (primarily physicians) in markets with few referral sources. We were also concerned about limiting inappropriate financial incentives.

Comments and Responses

Comment: We solicited comments regarding the appropriateness of our proposal to define ''rural'' with reference to the OMB standards for MSAs. In response, several commenters urged us to adopt our alternative proposal to use the rural definition employed by HCFA for purposes of reimbursing hospitals located in rural areas under DRG payment rates (42 CFR 412.62(f)(1)(iii)). A number of commenters urged us to extend the investment interest safe harbor for rural entities to equally qualified underserved urban areas.

Response: One of the important issues in designing this safe harbor is how to define geographically the scope of investments to which it applies. After consideration and examination of various approaches to defining ''rural'' for purposes of this safe harbor, we have decided to limit this safe harbor to investment interests in entities located in areas defined by HRSA as MUAs (that otherwise meet all safe harbor eligibility standards). This decision responds to requests for safe harbor protection to facilitate investment in areas demonstrably experiencing difficulty in attracting needed health care services. Unlike OMB's MSAs, which merely measure geographic distributions of population, MUAs identify areas experiencing health care shortages by accounting for such factors as poverty levels, infant mortality, and population age. Thus, we are amending the rule to substitute MUAs for the existing definition of ''rural'' to more closely tailor the safe harbor to protect investment interests in entities located in underserved areas.

In addition to more accurately targeting rural areas with shortages of health care services, protecting investments in MUAs offers a means of expanding safe harbor protection to urban underserved areas. We are persuaded that many urban underserved areas experience difficulties in attracting investments in health care services that are comparable to those experienced in rural areas. Because one of our objectives in creating this safe harbor is to foster the development of needed health care services, we believe it makes sense to protect qualified investments in defined shortage areas without regard to density of population.

At the time of publication of this rulemaking, HRSA's final regulations on the new process for designating MUAs are still pending. Although we anticipate that those regulations will be finalized, we are persuaded that, even in the absence of that rule, and notwithstanding certain concerns we have regarding the administration of the current program, our selection of MUAs as a basis for this safe harbor is sound and more consistent with the stated purpose of the safe harbor than either of our original proposals for identifying the covered areas.

We anticipate that, if finally promulgated, HRSA's new rule for evaluating and designating MUAs may result in some areas presently classified as MUAs losing their classifications. Moreover, HRSA has indicated its intent to review MUA classifications regularly, resulting in the possibility that some areas could periodically lose their classifications. Given this potential, it is incumbent on us to address the effect of the loss of a MUA designation on an entity protected by the safe harbor for investments in underserved areas. If an entity that meets all of the safe harbor standards were located in an area that loses its designation as a MUA after the entity has initially qualified for the safe harbor, the entity would technically no longer fit squarely within the safe harbor and would lose its protection. However, we are mindful of the need investors have for reasonable certainty in their arrangements and the significant effect a sudden loss of safe harbor protection resulting from circumstances outside their direct control may have on investors. Accordingly, we are including in this safe harbor a 3-year grace period during which such entities will be protected, provided they continue to meet all of the other safe harbor

conditions. This grace period will afford entities that wish to maintain safe harbor protection an opportunity to restructure so as to qualify for the small entity investment interest safe harbor at § 1001.952(a)(2). We wish to iterate that loss of safe harbor protection does not mean that a joint venture arrangement becomes unlawful.

Comment: Several commenters expressed concern about our proposal to eliminate the 60–40 tests of the small entity investment safe harbor for purposes of this safe harbor. One commenter advocated that the 60–40 rules should continue to apply to facilities located in rural areas to prevent a proliferation of unnecessary facilities, especially laboratories, that are dependent on referrals from investor-physicians. Another commenter supported restricting the safe harbor only to rural areas where alternative sources of a particular service are not otherwise available. These commenters argued that a proliferation of protected entities with large numbers of referral source investors could adversely affect existing entities in rural communities. One commenter suggested that we use a ''demonstrated community need'' standard instead of limiting safe harbor protection to defined geographic areas. This commenter further recommended that entities that meet such a ''demonstrated community need'' test be required to disclose to patients a referring physician's ownership interest and to conduct utilization review of an entity's services.

Response: Having considered these comments, we are persuaded that eliminating both 60–40 rules, and in particular the 60–40 investor rule, may lead to inappropriate financial incentives and unfair competition in some areas by allowing referral source investors, primarily physicians, to ''lock up'' the market for particular services in those areas. Ensuring fair competition in the health care marketplace is one of the goals of the anti-kickback statute. We are also concerned that an excessive proliferation of particular services in rural or urban underserved areas could lead to overutilization by entities competing for scarce revenue and could prompt protected entities to develop revenue streams from patients not residing in underserved areas, in contravention of the intent and spirit of the safe harbor.

MUA designations are not made on a service-specific basis; thus, an area may qualify as a MUA based on an overall shortage of health care services even if it has a sufficient supply of a particular heath care service. As we stated in the preamble to the 1993 proposed rule, one of the purposes of this safe harbor is to ensure adequate access to medical care for patients in underserved areas. Our intent was to design a safe harbor that would accomplish this purpose, while excluding ventures that do not serve the underserved areas in which they are located. We remain persuaded that there are many rural and urban underserved areas with legitimate shortages of health care services and limited sources of potential investors. However, while we believe that market competition should minimize the number of duplicative ventures in a particular underserved area, we are persuaded that safe harbor protection should be limited, to the extent practicable, to ventures that fill a genuine health care need of area residents.

In light of our intention to minimize safe harbor protection for redundant health care services owned by referral source investors in otherwise underserved areas, reduce inappropriate financial incentives, and maintain fair competition for providers that are not owned by referral source investors, we have revisited our original proposal to eliminate both of the 60–40 tests of the small entity investment safe harbor for purposes of this safe harbor. In this final rule, we are adopting our original proposal to eliminate the 60–40 revenue rule, but we are retaining a modified limitation on the number of interested investors. Specifically, we are requiring, as a condition for protection, that investors who make referrals or who are in a position to make referrals or furnish items or services to the entity not own more than 50 percent of the value of investment interests within each class of investments in the entity. As with the 60–40 investor rule in the small entity investment safe harbor, we are permitting equivalent classes of stock to be aggregated for purposes of determining safe harbor compliance.

We believe that eliminating the 60–40 revenue rule, thereby permitting entities to draw 100 percent of their revenue from referrals by investor-owners, should make investment in such entities sufficiently attractive to non-referral source investors so as to permit the entities to meet the new 50–50 investor test. We recognize that this safe harbor may not fully answer all of the concerns raised by the commenters and that there may be particular circumstances in which ventures with parties to existing health care entities can not qualify for safe harbor protection. Some of these ventures may be appropriate for protection through an advisory opinion (42 CFR part 1008). In addition, joint ventures in underserved areas may still qualify for protection under the small entity investment interest safe harbor at § 1001.951(a)(2).

We are not adopting the suggestion that we promulgate a ''demonstrated community need'' standard for this safe harbor. Such a standard would not create a sufficiently clear rule and would be unenforceable in practice. Moreover, the additional two standards suggested by one commenter—public disclosure of ownership interests and utilization review—while good practices, are not, in our experience, effective deterrents to fraud and abuse.

Comment: One commenter urged us to allow compliance with the rural investment safe harbor if an entity certified its inability to comply with the 60–40 rules in the small entity safe harbor despite its best efforts.

Response: A mere ''best efforts'' exception to the small entity investment interests safe harbor based on a certification from the investment entity would be insufficient to protect against abusive arrangements and would be impractical in application. Like all parties that cannot comply with a safe harbor, parties that are unable to comply with the 50–50 investor rule have recourse to the advisory opinion process for guidance about their specific arrangements.

Comment: One commenter requested that the OIG incorporate a ''fair market value'' principle more explicitly into the proposed rural investment safe harbor.

Response: The principle of ''fair market value'' is included in this investment safe harbor at § 1001.952(a)(3)(viii).

Comment: One commenter expressed concern that a rural referral center (RRC) that had been reclassified as located in an urban area by the Medicare Geographic Classification Review Board for purposes of Medicare payment (42 CFR 412.230) would not be eligible to receive protection under the rural investment interest safe harbor. RRCs are Medicare participating acute care hospitals that are located in rural areas and that qualify under HCFA rules as referral centers (see 42 CFR 412.96). Under certain circumstances, an individual hospital, including a referral center, may be redesignated from a rural area to an urban area for purposes of using the urban area's standardized amount for inpatient operating costs, wage index value, or both. (42 CFR 413.230).

Response: A RRC located in a MUA would be eligible for protection under the rural investment interest safe harbor, provided it meets all of the conditions of the safe harbor. Reclassification as

''urban'' for Medicare payment purposes would not bar safe harbor protection.

Comment: Several commenters asked us to further explain how facilities can comply with the requirement that an entity must offer equal and *bona fide* opportunities to acquire investment interests to individuals or entities irrespective of whether such prospective investors are in a position to make or influence referrals to, furnish item or services to, or otherwise generate business for the entity (§ 1001.952(a)(3)(i)). In the alternative, a commenter requested that this provision be deleted. One commenter expressed concern that the ''broad'' terms of the proposed safe harbor would make it difficult for parties to identify ''potential sources of capital'' and inquired whether satisfying the safe harbor required investment opportunities to be registered under Federal and State securities laws as public offerings. Another commenter expressed concern about publicizing investment opportunities in rural areas where investors often do not wish to be publicly identified.

Response: Our intent in proposing the ''equal and *bona fide* opportunities'' standard was to ensure that investment opportunities are offered in a good faith, nondiscriminatory manner to any individuals or entities that are potential sources of capital, so that referral source investors are not inappropriately selected as investors. In light of our decision to require that at least 50 percent of the investment interests be held by non-referral source investors, we have concluded that this standard is not necessary. Accordingly, we are not adopting it in the final rule.

Comment: The sixth standard of the proposed safe harbor required that at least 85 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period be derived from services provided to persons residing in the underserved area. One commenter asked us to lower the 85 percent dollar volume requirement to 40 percent in order to make the threshold more attainable and allow more investment interests to qualify for protection.

Response: As we explained in the preamble to the 1993 proposed rule, although we proposed eliminating the 60–40 revenue rule for investments for purposes of the proposed safe harbor, we remained concerned that a sham joint venture structure could be established that does not intend to serve the underserved area in which it is located. This safe harbor responds to requests for assistance in facilitating investment in underserved areas. It is not unreasonable to offer this safe harbor protection only to investments in entities that will primarily serve underserved populations by providing services needed in their communities. We are persuaded, however, that lowering the required percentage to 75 percent would adequately protect against abuses and further the purpose of this safe harbor. Accordingly, we are requiring that at least 75 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period be derived from services provided to persons residing in an underserved area or persons who are members of a MUP (as defined by HRSA).

2. Ambulatory Surgical Centers

Summary of Proposed Rule: We proposed a fourth investment interest safe harbor to protect payments to investors in ambulatory surgical centers (ASCs) who are surgeons who refer patients directly to the ASC and perform surgery themselves on these referred patients. What we intended to protect is often understood conceptually as an extension of the physician's office space. We further explained that a safe harbor for investment interests in ASCs was warranted because the professional fee generated by a referral from a physician-investor to the ASC is substantially greater than the facility fee generated by the referral, and therefore profit distributions to physician-investors, which are derived from the facility fee, do not constitute a significant improper inducement to make referrals. The rationale underlying the proposed safe harbor would not extend to investment interests held by physicians who are not in a position to refer patients directly to the ASC and perform surgery. We explained that the concern with investments by such physicians is the potential for indirect kickbacks, because they might receive a return, through the ASC's profit distribution, for referrals of patients to other investors who perform surgical procedures at the ASC. We solicited comments on whether the rationale underlying this safe harbor is applicable to entities other than ASCs. We also specifically solicited comments on what degree of disparity should exist between the professional fee and the facility fee generated by referrals to a type of entity for that type of entity to receive safe harbor protection.

The proposed safe harbor applied only to ASCs certified under 42 CFR part 416. We did not propose protecting ASCs located on the premises of a hospital that share operating or recovery room space with the hospital for treatment of the hospital's inpatients or outpatients. The proposed safe harbor contained the following 5 standards:

- The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished or the amount of business otherwise generated from that investor to the entity.
- There is no requirement that a passive investor, if any, make referrals to the entity as a condition for remaining an investor.
- Neither the entity nor any investor may loan funds to, or guarantee a loan for, an investor if the investor uses any part of such loan to obtain the investment interest.
- The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.
- Each investor must agree to treat patients receiving Medicare or Medicaid benefits.

In contrast to the other investment interest safe harbors that limit investment by individuals in a position to refer, the proposed ASC safe harbor would have only protected entities whose investment interests were held *entirely* by such individuals. With that distinction in mind, four of the five standards were adapted from the standards in the small entity safe harbor (§ 1001.952(a)(2)). We solicited comments on the extent to which other standards were appropriate to safeguard against potential abuse.

Summary of Final Rule: The OIG received nearly two hundred comments relating to the proposed safe harbor for investment interests in ASCs. As a result of these comments, we have significantly reworked this safe harbor to provide, in general, expanded safe harbor protection for investments in ASCs.

As an initial matter, our proposed placement of the ASC safe harbor with the investment interests safe harbor appears to have caused confusion as to the safe harbor's purpose and scope. Our proposed ASC safe harbor contemplated a joint venture composed entirely of referral source investors. Placing these regulations alongside the large entity safe harbor, which limits safe harbor protection to investments that are so small as to be, at most, tangentially related to referrals, and the small entity investment safe harbor, which limits safe harbor protection to ventures composed of no more than 40 percent referral source investors, led

some commenters to question why an ASC with 100 percent referral source investors would pose less risk of fraud and abuse than another type of investment entity with a smaller percentage of referral source investors. The answer is that ASC investments do not necessarily pose less risk. Rather, as described in more detail below, investments in ASCs raise concerns that are different from those addressed by the small entity investment safe harbor; therefore, investments in ASCs warrant different safe harbor criteria, including different safeguards, limitations and controls.

The new ASC safe harbor has four categories: Surgeon-Owned ASCs, Single-Specialty ASCs, Multi-Specialty ASCs, and Hospital/Physician ASCs. Safe harbor protection requires full compliance with all of the standards of any one category. All four categories have the following requirements in common: (i) The ASC must be certified under 42 CFR part 416; (ii) loans from the entity or other investors for the purpose of investing are prohibited; (iii) investment interests must be offered on terms not related to the volume or value of referrals; (iv) all ancillary services must be directly and integrally related to primary procedures performed at the ASC and none may be separately billed to Medicare or other Federal health care programs; and (v) neither the ASC nor physicians practicing at the ASC can discriminate against Federal health care program beneficiaries. Additional specific standards apply to particular categories. Moreover, in the interest of ensuring patient freedom of choice and promoting informed decision-making by patients, we have included a requirement in each category that patients referred to the ASC by an investor be fully informed of the investor's investment interest.

The four categories are summarized here and described in greater detail in the responses to comments below:

- *Surgeon-Owned ASCs.* The first category is designed to protect ASC investments where all of the physician investors are either general surgeons or surgeons engaged in the same surgical specialty. Specifically, category one protects certain investments in entities where all of the investors are either (i) general surgeons or surgeons engaged in the same surgical specialty, all of whom are in a position to refer patients directly to the ASC and perform procedures on such referred patients; (ii) group practices that are composed of such surgeons and that meet all of the requirements of the group practice safe harbor (§ 1001.952(p)); or (iii) investors who (a) do not provide items or services to the ASC or its investors, (b) are not employed by the ASC or any investor, and (c) are not in a position to refer patients directly or indirectly to, or generate business for, the ASC or any of its investors. A surgeon is considered to be in a position to refer patients directly and perform procedures if he or she derives at least one-third of his or her medical practice income from all sources for the previous fiscal year or previous 12-month period from his or her own performance of procedures that require an ASC or hospital surgical setting in accordance with Medicare reimbursement rules (the ''one-third practice income'' test).
- *Single-Specialty ASCs.* The second category is similar to the first category, except that it is designed to protect ASC investments where all of the physician investors are engaged in the same medical practice specialty (*e.g.*, gastroenterologists), provided that they perform ASC procedures as a significant part of their medical practices. The physicians that qualify under this category need not be traditional surgeons. Specifically, category two protects certain investments in entities where all of the investors are either (i) physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the ASC and perform procedures on such referred patients; (ii) group practices that are composed of such physicians and that meet all of the requirements of the group practice safe harbor (§ 1001.952(p)); or (iii) investors who (a) do not provide items or services to the ASC or its investors, (b) are not employed by the ASC or any investor, and (c) are not in a position to refer patients directly or indirectly to, or generate business for, the ASC or any of its investors. As with category one (Surgeon-Owned ASCs), physician investors must meet the ''one-third practice income'' test.
- *Multi-Specialty ASCs.* The third category is similar to the first two categories, but it allows a mix of the types of physicians addressed in those categories. Thus, the third category protects certain investments in entities where all of the investors are either (i) physicians (surgeons or non-surgeons) who are in a position to refer patients directly to the ASC and perform procedures on such referred patients; (ii) group practices that are composed of such physicians and that meet all of the requirements of the group practice safe harbor (§ 1001.952(p)); or (iii) investors who (a) do not provide items or services to the ASC or its investors, (b) are not employed by the ASC or any investor, and (c) are not in a position to refer patients directly or indirectly to, or generate business for, the ASC or any of its investors. The physicians must meet the ''one-third practice income'' test described in the preceding paragraphs. In addition, physicians in this category must meet a second standard related to practice income because of the increased risk of remuneration for referrals among physicians with different specialties. Specifically, the rule requires that at least one-third of the physician's procedures that require an ASC or hospital surgical setting (in accordance with Medicare reimbursement rules) be performed at the ASC in which he or she is investing. We believe that for physicians who meet the ''one-third/one-third'' test, an investment in an ASC truly qualifies as an extension of the physician's office. We believe such physician investors are unlikely to have significant incentives to generate referrals for other investors because of the minimal additional return on investment derived from such referrals.
- *Hospital/Physician ASCs.* The fourth category protects certain investments by hospitals in ASCs. To qualify for the safe harbor, at least one investor must be a hospital and the other investors must be (i) physicians or group practices that otherwise qualify under the safe harbor or (ii) non-referral source investors. The hospital must not be in a position to refer patients directly or indirectly to the ASC or any physician investor. The ASC space must be dedicated exclusively to the ASC and not used by the hospital for the treatment of the hospital's inpatients or outpatients. The ASC may lease space that is located in or owned by a hospital investor, if the space lease qualifies for protection under the space rental safe harbor. Equipment and personal services provided by the hospital must similarly meet safe harbor requirements.

In this final rule, we are expressly departing from the underlying rationale for our original safe harbor proposal, which was the professional fee/facility fee differential. The existence of a significant disparity between the facility fee and the professional fee, such that the facility fee is significantly smaller than the professional fee, minimizes the risk of improper incentives for referrals; however, we are aware that professional and facility fees have changed and may continue to change over time and that the ratio between them will not always, by itself, provide a clear basis for safe harbor protection. So although the fee differential was meaningful at the time, we will in the future look more broadly for indicia that an ASC investment represents the extension of a physician's

office space and not a means to profit from referrals.

The gravamen of an anti-kickback offense is payment of remuneration to induce the referral of Federal health care program business. In the context of an ASC, our chief concern is that a return on an investment in an ASC might be a disguised payment for referrals. Two examples illustrate the potential problem. First, primary care physicians could be offered an investment interest in an ASC for a nominal capital contribution as an incentive to refer patients to surgeon owners of the ASC. The primary care physicians would not perform any services at the ASC, but would profit from any referrals they make. Second, physicians in specialties that typically refer to one another could jointly invest in an ASC so that they are positioned to earn a profit from such referrals or so that one physician specialty provides the ASC services and the other provides the referrals. In such cases, medical decision-making may be corrupted by financial incentives offered to potential referral sources who stand to profit from services provided by another physician.

With the above concern in mind, we are still able to provide safe harbor protection for certain non-surgeon physicians, group practices and hospitals that meet certain requirements set forth in the safe harbor. These requirements are designed to preclude protection for investors who might have incentives to generate returns on their investments through referrals to other investors or to other physicians who perform procedures at the ASC. The safe harbor will also protect some investment interests held by persons who are not in a position to make or influence referrals either directly or indirectly to the ASC or to any of its investors.

However, except as otherwise described in the regulations, we are not protecting investment interests held by any party that provides items or services to, is in a position to influence the flow of referrals directly or indirectly to, or generates business for, the entity or any investor. Notwithstanding, investments by these parties are not necessarily unlawful, provided that payments made in return for the investment are not for the purpose of inducing or rewarding referrals.

Indeed, we recognize that some legitimate ASC arrangements may not fit precisely in the final ASC safe harbor. Those that do not fit may be eligible for safe harbor protection under the small entity investments safe harbor (§ 1001.952(a)(2)) or the new safe harbor for investments in underserved areas (§ 1001.952(a)(3)). Alternatively, current or potential investors may request an OIG advisory opinion in accordance with section 1128D(b) of the Act and the regulations at 42 CFR part 1008.

Our responses to public comments are summarized below.

Comments and Responses

Comment: Many commenters commended the OIG for proposing a safe harbor to shield ASCs from prosecution under the anti-kickback statute. Many commenters noted that ASCs have saved Medicare hundreds of millions of dollars, forcing hospitals to become more competitive, because ASC payment rates are typically lower than hospital payment rates for the same procedures. Several commenters stated that ASCs foster patient access to care, particularly in medically underserved regions. Moreover, many commenters observed that patients generally prefer outpatient surgical care at an ASC to hospital care.

Response: We agree that ASCs can significantly reduce costs for Federal health care programs, while simultaneously benefitting patients. The HCFA has promoted the use of ASCs as cost-effective alternatives to higher cost settings, such as hospital inpatient surgery. Where the ASC is functionally an extension of a physician's office, so that the physician personally performs services at the ASC on his or her own patients as a substantial part of his or her medical practice, we believe that the ASC serves a *bona fide* business purpose and that the risk of improper payments for referrals is relatively low. Where the criteria set forth in the safe harbor are satisfied, we do not consider investments in ASCs to be a likely source of overutilization of services payable by the Federal health care programs or increased program costs. We are concerned, however, that patient freedom of choice be protected and informed decision-making promoted in situations where a physician is required to refer to an entity that he or she owns in order to qualify for safe harbor protection. Accordingly, we are adding a requirement that the existence of the ownership interest be disclosed to patients. We note that such disclosure in and of itself does not provide sufficient assurance against fraud and abuse of the Federal health care programs. This conclusion derives from our observation that a disclosure of financial interest is often part of a testimonial, i.e., a reason why the patient should patronize that facility. Thus, often patients are not put on guard against the potential conflict of interest, *i.e.*, the possible effect of financial considerations on the physician's medical judgment.

Comment: Many commenters questioned our proposal to limit safe harbor protection to physicians who are ''surgeons'', given that many procedures or services performed in ASCs are performed by physicians not commonly called surgeons (*i.e.*, cardiologists, gastroenterologists, radiologists or pathologists). Many commenters argued that the ''extension of practice?'' rationale would apply to surgeons and such other physicians alike.

A number of commenters proposed that we adopt a definition of ''surgeon'' that would include any physician who performs procedures classified as surgical by HCFA regulations. For example, many kinds of endoscopy are classified as surgical procedures in accordance with 42 CFR 416.65 and various updates to the list of HCFA-approved ASC surgical procedures published in the **Federal Register** (see 42 CFR 416.65(c); 63 FR 32290 (1998) (to be codified at 42 CFR parts 416 and 488)). One commenter suggested that physicians who refer to an ASC, but do not perform services at the ASC, should be permitted in the safe harbor as long as they meet the safe harbor's five enumerated requirements.

Response: As discussed above, we agree that limiting the safe harbor to investors who are physicians traditionally termed ''surgeons'' is unnecessarily restrictive, especially in light of advancing technology and the scope of HCFA's approved list of ASC procedures. In light of the many comments received on this topic, we have revised the safe harbor to protect investments in ASCs certified under 42 CFR part 416 by non-surgeon physicians, group practices, hospitals and non-referral source investors that meet certain conditions. Investments by group practices and hospitals are discussed in responses to separate comments below.

With respect to physicians, we are promulgating three categories of safe harbor criteria, each designed to protect different types of physician investment. All of the categories protect combinations of qualifying physicians, which generally are those physicians who perform a substantial number of procedures listed on the HCFA ASC surgical procedures list as part of their medical practices. Specifically, at least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures that require an ASC or hospital surgical setting. In

addition, where there is a risk of referrals among physicians or surgeons in different specialties, we are requiring that each perform at least one third of his or her procedures that require an ASC or hospital surgical setting at the investment ASC. We believe these standards ensure that a physicians investment in an ASC will truly represent an extension of his or her office. Where physicians own an ASC in which they will personally perform a significant number of procedures, obvious and legitimate business and professional reasons exist for the ownership, including convenience, professional autonomy, accountability and quality control. Moreover, any risk of overutilization or unnecessary surgery is already present by reason of the opportunity for a surgeon to generate his professional fee; the additional financial return from the ASC is not likely to increase the risk of overutilization of procedures significantly. We believe that the ''one-third/one-third'' standards in the safe harbor ensure that physician investors will have no significant incentive beyond receipt of their professional fees to refer to the entity or any of its investors, because any return on investment will be attributable primarily to legitimate business and only tangentially to possible referrals of ASC business.

Because of the risk of remuneration for referrals, investments by other physicians, such as anesthesiologists, radiologists and pathologists, or by non-physician providers, such as certified registered nurse anesthetists, are not protected by the safe harbor if the physician or provider is in a position to provide items or services to, refer patients directly or indirectly to, or generate business for, the ASC or any of its investors. The determination whether an investor should be classified as a potential referral source is a factual question. As is the case for investments in small entities (56 FR 35964), we will accept a written stipulation that for the life of the investment the investor will not make referrals to, furnish items or services to, or otherwise generate business for, the entity or any of its investors, provided that, in fact, the investor's actions comport with the written stipulation. We wish to make clear that investments by these physicians and other providers do not necessarily implicate the anti-kickback statute. Finally, we note that we do not consider an investment by a physician's own wholly-owned professional corporation to be an excluded non-physician investment.

Comment: Many commenters also objected to our proposal to protect only ASCs owned entirely by surgeons who practice there. These commenters asserted that non-surgeons, and more specifically non-physicians, should be allowed safe harbor protection for investments in ASCs. Many commenters advocated a rule that would allow surgeon investors to transfer ownership to family members and other non-surgeons upon retirement or death without jeopardizing the ASC's safe harbor protection. Commenters also expressed concern that the safe harbor did not protect investments held by administrative staff at the ASC. Many commenters asserted that co-ownership with administrative staff would enable these individuals to make long-term commitments to providing better services in a cost-effective manner. Many commenters further expressed the view that anyone who is not in a position to refer patients to the ASC, including corporate entities such as for-profit management companies, should be eligible to invest in the ASC. Some commenters urged that investments held by a physician's retirement plan be protected.

Response: We are extending safe harbor protection to investors who are not in a position to provide items or services to the ASC or any of its investors and who are not in a position directly or indirectly to generate referrals for the entity or any of its investors. There is minimal risk that a payment made to such a non-referral source investor would implicate the anti-kickback statute, and accordingly investments by such investors do not taint the ASC investment. However, we believe that hospitals, skilled nursing facilities, home health agencies, managed care companies, physician practice management companies, and similar entities may be referral sources in some circumstances. By way of example only, a hospital may be in a position to influence referrals when it employs physicians who make referrals, when it owns surgical practices, or when it is affiliated with a ''friendly'' or ''captive'' professional corporation owned or controlled by its employees. We further believe that some employees, such as certain marketing and administrative staff, may be referral sources.

Comment: Many commenters argued that the scope of the safe harbor should be expanded to include facilities that are not traditionally considered ''surgical'' centers, such as lithotripsy facilities, end-stage renal disease (ESRD) facilities, comprehensive outpatient rehabilitation facilities (CORFs), radiation oncology facilities, cardiac catheterization centers and optical dispensing facilities. Many commenters argued that such facilities, like ASCs, are part of the physician's practice and are not simply vehicles for passive investment and self-referral. A number of commenters stated that such facilities would not encourage overutilization, would increase access to care, would reduce costs, and would maintain or improve quality of care. Several commenters averred that investments in such facilities offer little inducement because each investor makes very little profit from investments in such facilities, in part because in some facilities, each physician's investment is a small percentage of the whole. Other commenters stated that the cost of operating these facilities is so high that each investor's net revenues from the facility investment is marginal. Many commenters argued that existing regulation by Federal and State agencies and by physician associations creates sufficient checks on fraud and abuse.

Response: Our regulatory treatment of ASCs recognizes the Department's historical policy of promoting greater utilization of ASCs because of the substantial cost savings to Federal health care programs when procedures are performed in ASCs rather than in more costly hospital inpatient or outpatient facilities. Physician investment in ASCs was an important corollary to the Department's efforts to promote ASCs because physicians were natural sources of capital, since many hospitals were reluctant to open or invest in ASCs that competed with their own outpatient and inpatient surgery departments. Accordingly, many of the early ASCs were financed and owned by surgeons and other physicians who worked in them. Currently, HCFA's goal is to set payment rates that are consistent across different sites of service.[4] However, currently surgeries in ASCs generally continue to be reimbursed at lower rates.

Safe harbor protection for ASCs derives in large measure from this longstanding policy encouraging freestanding ASCs as a less costly alternative to hospitals for appropriate surgeries. In addition, Medicare's uniform, prospectively-established ASC payment methodology and the safe harbor's restriction on billing Medicare separately for ancillary services provide further assurance against abuse.

[4] *See e.g.*, Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998, 63 FR 32290, 32307 (to be codified at 42 CFR parts 416 and 488) (proposed June 12, 1998).

Investments by referring physicians or combinations of referring physicians and hospitals in non-ASC clinical joint ventures, including, but not limited to, cardiac catheterization laboratories, radiation oncology centers or ESRD facilities, do not share the same policy background and are not subject to the same reimbursement structure as investments by physicians in ASCs. Such clinical joint ventures may raise concerns not present with ASCs. In short, to qualify under this safe harbor, a facility must be a certified ASC under 42 CFR part 416. The existing small entity investment safe harbor (§ 1001.952(a)(2)) may be applicable for other joint ventures (assuming all safe harbor conditions are satisfied). In addition, we are not prepared at this time to extend safe harbor protection to non-HCFA-certified ASCs. Industry-promulgated standards, while welcome and often helpful in combating fraud and abuse, may not be sufficient to safeguard the Federal health care programs.

Comment: Several commenters asserted that hospitals with investment interests in ASCs should also be protected under the proposed ASC safe harbor. One commenter expressed the view that hospitals have no financial incentive to refer outpatient surgeries to ASCs because ASC net collections would be significantly lower than hospital net collections for the same procedures. By contrast, several other commenters suggested that hospitals would refer outpatient procedures to ASCs to enable the hospitals to focus resources on inpatient operations and treatments and the development of integrated delivery systems. Several commenters asserted that a hospital referral of a patient to an ASC would be an extension of the hospital's practice analogous to a surgeon's referral of a patient to an ASC. A number of commenters asserted that patients would benefit from using an ASC in close proximity to a hospital, and that creating an ASC would make efficient use of surplus hospital space.

Response: After reviewing the comments, we are persuaded that safe harbor protection should be extended to ASCs jointly owned by hospitals and physicians who qualify under the terms of this safe harbor. Although joint ventures between hospitals and physicians are often susceptible to fraud and abuse, precluding all safe harbor protection for hospital investors in ASCs may unnecessarily place hospitals at a competitive disadvantage if they are forced to compete with ASCs owned by physicians, who principally control referrals.

To be protected by the safe harbor, a hospital investment must meet all of the conditions set forth in the safe harbor. The hospital must not be in a position to make or influence referrals directly or indirectly to the ASC or to any of its physician investors. Whether this condition is met will depend on the facts and circumstances of particular arrangements. Any space used by the ASC that is located in, or owned by, the hospital must be leased in accordance with a lease arrangement that satisfies all of the criteria of the space rental safe harbor (§ 1001.952(b)). Similarly, any hospital equipment used by the ASC must be leased under an arrangement that satisfies the equipment rental safe harbor (§ 1001.952(c)), and any personal services provided by the hospital must be provided in accordance with a contract that complies with the personal services and management contracts safe harbor (§ 1001.952(d)). To further mitigate the risk of improper cost-shifting, in no event may operating or recovery room space be shared with the hospital for the treatment of the hospital's inpatients or outpatients, nor may the hospital reflect or include any costs associated with developing or operating the ASC on any Federal health care program claim or cost report (except such non-reimbursable costs as may be required by the programs).

Comment: Many commenters expressed the view that a safe harbor that protects an investment where 100 percent of the investors are physicians would be inconsistent with the 60–40 investor rule in the existing investment interest in small entities safe harbor. Several commenters argued that imposing a new 100 percent rule would be burdensome on those investors who diligently tried to comply with the 40 percent rule.

Response: We are not changing the rules for those ASCs that meet the criteria for the ''small entity'' safe harbor. However, many existing ASCs that are owned entirely or predominantly by the physicians who practice there cannot fit within the ''small entity'' safe harbor and thus are not currently afforded safe harbor protection. Depending on the circumstances, either this new safe harbor, the ''small entity'' safe harbor (§ 1001.952(a)(2)), or the new ''underserved areas'' safe harbor (§ 1001.952(a)(3)) may offer protection to investors in an ASC.

Comment: Several commenters requested clarification of the requirement that a participating practitioner ''must agree to treat'' Medicare and Medicaid patients. Some commenters noted that it was unclear what level of participation in these Federal health care programs would satisfy the requirement. One commenter questioned whether the safe harbor would require treating Medicare and Medicaid patients to the exclusion of other patients if capacity were limited. Two commenters questioned whether it was sufficient to ''agree to treat'' instead of actually treating Medicare and Medicaid patients. Another commenter wondered whether all investors in the facility must treat Medicare and Medicaid patients. One commenter suggested that the requirement be deleted from the safe harbor. Another suggested that each ASC maintain records, on an annual basis, to show that it actually provided services to Medicare and Medicaid patients in proportion to those patients in the community. Several commenters noted that the requirement to treat Medicare and Medicaid patients is unnecessary because the anti-kickback statute is implicated only when Federal health care program reimbursement is requested.

Response: The requirement that all protected investors agree to treat Medicare and Medicaid patients is intended to ensure Medicare and Medicaid patients access to care at ASCs on a non-discriminatory basis. Thus, decisions whether to accept and treat Federal health care program beneficiaries must be made on a nondiscriminatory basis. This requirement is further intended to promote cost savings for the programs by encouraging investors to provide services for Federal program beneficiaries in ASCs rather than hospitals in medically appropriate circumstances. We do not intend to exclude from protection physicians who are not accepting any new patients. We are not adopting the suggestion that ASCs demonstrate that they provide services to Medicare and Medicaid patients in proportion to the numbers of those patients in the community. We find that requirement to be too limiting. We are clarifying the language of the safe harbor to make clear its anti-discrimination purpose, and we are expanding it to require non-discriminatory treatment of all Federal health care program beneficiaries.

The commenter is correct that the anti-kickback statute would not be implicated, and no safe harbor protection required, if the investor physicians were not in a position to make referrals of or otherwise generate business payable in whole or in part under a Federal health care program. However, given the number of Federal health care programs, which include

Medicare, Medicaid, TRICARE, Veterans' Administration, Public Health Service, Indian Health Service, and children's health insurance under Title XXI of the Act, we think it likely that most investor physicians will potentially be in a position to refer Federal program business.

Comment: One commenter was concerned that States might interpret State self-referral prohibitions as also prohibiting surgeons in ASCs from referring patients to the ASC for related laboratory, radiology and other ancillary services, and asked that we clarify that, under this safe harbor, such ''self-referrals'' would be permissible.

Response: We are not in a position to comment on State self-referral prohibitions. The ASC safe harbor is not intended to protect payments derived from ancillary services performed at or by the ASC, unless such services are directly and integrally related to the primary procedure performed at the ASC. Thus, for example, payments in connection with invasive radiology (a procedure in which an imaging modality is used to guide a needle, probe, or catheter accurately) would be protected, while payments for diagnostic or therapeutic radiology would not be protected. To clarify the safe harbor on this point, we have added a requirement that all ancillary services for Federal health care program beneficiaries performed at or by the ASC be directly and integrally related to primary procedures performed at the ASC and that no ancillary services be separately billed to the programs. Simply stated, because of the risk of overutilization of ancillary services, this safe harbor does not protect ancillary services joint ventures married to ASCs. Payments to providers of ancillary services may be protected under the employee compensation or personal services contract safe harbors, if the arrangements meet all applicable criteria.

Comment: A number of commenters expressed the opinion that integrated multispecialty or single-specialty group practices, as well as HMOs, should be able to develop ASCs as part of the practice network or HMO. With respect to HMO ownership and operation of ASCs, one commenter requested that the safe harbor permit such ownership even if physicians own the HMO and would be referral sources for the ASC.

Response: We have revised the safe harbor to protect explicitly group practice investments in qualifying ASCs. To be protected, a group practice investor must meet the requirements for the group practices safe harbor at § 1001.952(p) and be composed entirely of physicians who meet all of the criteria for protection as individual investors under the ASC safe harbor. Nothing in these regulations is intended to preclude the development of ASCs by HMOs, provided such arrangements do not include impermissible payments of remuneration to induce or reward referrals of Federal program business. These rules merely describe a certain subset of lawful practices that are deemed protected from prosecution under the anti-kickback statute.

Comment: At least one commenter suggested that the safe harbor be expanded for ASCs in rural areas, so that any individual or entity who is financially able to invest may do so, on the ground that there is a great need for ASCs and limited ability to capitalize them in rural areas.

Response: We believe that the provisions of this safe harbor will permit most investors who are in a position to capitalize ASCs in rural areas to do so. No special exception is necessary. Investors in an ASC located in a rural area may qualify for safe harbor protection under the investment interests in ASCs safe harbor, the investment interests in small entities safe harbor, or the new investment interests in underserved areas safe harbor. Investors in ASCs need only satisfy one safe harbor to qualify returns on their investments for protection from prosecution under the anti-kickback statute.

3. Investment Interests In Group Practices

Summary of Proposed Rule: We proposed a new safe harbor to protect payments to investors in entities composed only of active investors in a group practice. This safe harbor would have protected the investment interests of members of group practices that met certain prerequisites and standards. We proposed adopting the definition of group practice contained in the Stark Law at section 1877(h)(4) of the Act. The Stark Law prohibits Medicare payment where physicians make referrals for designated health services to entities in which they have an ownership interest or with which they have a compensation arrangement, unless that interest or arrangement meets the strict terms of a statutory exception. In the proposed safe harbor, we intended principally to protect investors who are individuals who qualify as ''physicians'' under the Stark Law definition; however, our definition of group practice permitted a physician to invest as a professional corporation, if the corporation were exclusively owned by the physician. The proposed safe harbor was intended to protect any payment that is a return on an investment interest (such as a dividend or interest income) made to a physician member of a group practice who is an ''active investor'' in the investment entity, as long as all of the standards in the safe harbor were satisfied. For example, the safe harbor would have protected any payments resulting from the ownership of an interest in the group practice itself. It also could have been read—although it was not intended—to protect dividends from an investment in an MRI facility to which the physician-investors referred patients, if the investment met the terms of the safe harbor. The proposed safe harbor was not intended to protect other payments made by group practices, such as salary payments to employees of a group practice or payments to independent contractors.

We solicited comments on the appropriateness of our definition of group practice. We further solicited comments on the appropriateness of incorporating standards from the second investment interest safe harbor (§ 1001.952(a)(2)), including the prohibition on preferential terms of an investment interest being offered to certain physicians based on expected referrals; the prohibition on loans or loan guarantees from the entity or another investor used to obtain the investment interest; and the requirement that the amount of the return on an investor's investment must be directly proportional to the capital invested. In particular, we solicited information regarding the types of compensation arrangements that exist within group practices and the extent to which such compensation arrangements create inappropriate incentives that might distort the professional judgement of the members of the group. Lastly, we solicited comments on how we might expand the proposed safe harbor to other types of joint ventures composed exclusively of active investors.

We received over a dozen comments on this proposal. While some commenters supported the safe harbor and some opposed it, most questioned the need for the safe harbor and indicated that it would cause confusion among existing group practices. Moreover, it became apparent from reviewing the comments that the intended scope of the safe harbor was not clear. Some commenters understood the safe harbor to protect investments in group practices; others believed it protected investments by group practice members in other entities. A few commenters believed it covered both types of investments.

Summary of Final Rule: Because of the evident confusion caused by the proposed safe harbor, and for reasons more fully explained below, we have decided not to promulgate the safe harbor in the form it was originally proposed. Instead, we are adopting a simpler, although perhaps narrower, safe harbor that protects returns on investments in the group practice itself (i.e., not in separately owned health care services), if the group practice meets the Stark Law definition of a group practice (section 1877(h)(4) of the Act) and if the group practice investors are all licensed professionals who practice in the group. The safe harbor also protects investments in solo practices where the practice is conducted through the solo practitioner's professional corporation or other separate legal entity. The anti-kickback statute is not otherwise implicated for investments by solo practitioners in their practices. The safe harbor protects returns derived from in-office ancillary services that qualify for the exception for ''in-office ancillary services'' under the Stark Law (section 1877(b)(2) of the Act). This safe harbor does not protect investments made jointly by group members in separate entities. The general parameters of this new safe harbor were suggested in comments submitted by a group practice trade association as a less complicated alternative to our proposed safe harbor language.

Specifically, the new safe harbor imposes four criteria. First, the equity interests in the practice or group must be held by licensed professionals who practice in the practice or group. The equity interests may be held by an individual professional corporation if the corporation is exclusively owned by a single individual. Second, the equity interests must be in the practice or group itself, and not some subdivision of the practice or group. Third, the practice (unless a solo practice) must meet the definition of ''group practice'' in section 1877(h)(4) of the Act and implementing regulations. Fourth, profit distributions derived from in-office ancillary services are only protected if the services meet the definition of ''in-office ancillary services'' in section 1877(b)(2) of the Act and implementing regulations. We believe these conditions will offer reasonably broad safe harbor coverage for integrated medical practices, while at the same time minimizing financial incentives that could lead to inappropriate utilization and increased program costs.

Conceptually, this new safe harbor is consistent with the accommodation for referrals between group practice members contained in the safe harbor for specialty referral arrangements (§ 1001.952(s)). In our preamble to the 1993 proposed rule, we explained that revenues shared between members of a group practice as a result of a referral from one member of the group to another are an inherent part of belonging to a group practice. This safe harbor protects such payments, provided all safe harbor conditions are satisfied.

We want to emphasize our view that under section 1877(h)(4) of the Act, a group practice must consist of one legal entity and must be a unified business with centralized decision-making, pooling of expenses and revenues, and a distribution system that is not based on satellite offices operating as if they were separate enterprises or profit centers. This safe harbor is not intended to protect group practices that are not legally organized, but instead only hold themselves out as groups. Nor is this safe harbor intended to protect multiple groups of physicians that remain in many ways separate, but join together for selective purposes, such as taking advantage of the exceptions in section 1877 of the Act that apply to group practices. For purposes of these regulations, a group practice may be one legal entity if it is composed of owners who are individual professional corporations or is owned by physicians who are individually incorporated.

Comments and Responses

Comment: One commenter supported a safe harbor based on the definition of ''group practice'' contained in section 1877(h)(4) of the Act, but objected to the application of any other standards or conditions. This commenter argued that a *bona fide* group practice can be equated, for fraud and abuse purposes, with sole-practitioner medical practices in that any remuneration shared or exchanged among the members of the group and any investment made jointly by the group in an entity to which the members of the group practice may make referrals and which can be considered as ''extension'' of the group practice should be regarded as a self-referral. On the other hand, some commenters expressed concern regarding the anti-competitive effects of protecting group practice investments in ancillary services and the attendant increased risk of abusive practices, including overutilization. Commenters suggested that the safe harbor include a requirement for public notice of group practice investment in ancillary services entities and notices to patients identifying alternative service providers.

Response: We agree that, generally speaking, safe harbor protection is warranted for remuneration shared or exchanged among the members of a group practice that meets the definition of a group practice under the Stark Law (section 1877(h)(4) of the Act). However, we are persuaded that investments by group practice members in entities that provide ancillary services may have anti-competitive effects and may result in abusive arrangements and incentives to overutilize those ancillary services. Accordingly, we do not believe that safe harbor protection is warranted for group practice investments in ancillary services at this time. Of course, investments in ancillary services may be covered by the small entity investment safe harbor. This new safe harbor for investments in group practices protects remuneration derived from in-office ancillary services, as defined in section 1877(b)(2) of the Act and implementing regulations.

Comment: Some commenters questioned the need to protect physicians' investments in their own group practice, and suggested that the anti-kickback statute is not implicated by a physician's ownership of his or her own professional practice.

Response: The plain language of the anti-kickback statute is sufficiently broad so as potentially to include payments from a group practice to an investor in the practice, even if the investor is a physician member of the group practice. However, our promulgation of this safe harbor is not an indication that we view investments in group practices as suspect per se under the anti-kickback statute. Similarly, we do not view investments in solo practices as suspect per se.

Comment: Some commenters urged that the proposed safe harbor would have excluded from protection most existing group practices. First, the proposed safe harbor required all investment interests in the group to be held by physicians. ''Investment interests'' was broadly defined to include bonds, notes and other debt instruments. Thus, if a group practice borrowed from a bank or other entity, the bank or other entity would have had an investment interest that precluded safe harbor protection. Second, the proposed safe harbor required all investors to be ''active investors.'' One commenter noted that in most groups, the responsibility for the day-to-day management of the entity is given to one physician or to a practice manager operating under the supervision of a managing physician. This commenter stated that it is not possible or desirable for every physician partner to be responsible for the day-to-day operation of the practice. Another commenter

observed that many group practices are corporations in which the members are shareholders and thus not ''active investors'' in the corporation.

Response: We agree that inclusion of debt interests and the requirement that all investors be ''active investors'' as defined in our investment interests safe harbor unnecessarily limited the proposed group practice safe harbor. The new safe harbor, which applies only to investors who practice in a group practice that meets the group practice definition in the Stark Law, looks only to equity interests owned by physicians for purposes of measuring safe harbor compliance. Moreover, the new safe harbor does not require all group members be ''active investors'' as defined in the small entity investment interests safe harbor. Thus, the fact that all group members do not participate in the day-to-day management of the group practice will not disqualify a group practice from safe harbor protection.

Comment: One commenter expressed concern about the proposed restriction on investment terms being related to the previous or expected volume of referrals, noting that many physicians who previously practiced in solo or small groups have joined group practices or merged into large groups precisely because of the professional relationships between and among the physicians involved.

Response: We agree that a restriction on the terms of an investment interest being related to previous or expected volume of referrals is not necessary in the context of investments in group practices that meet the definition of a group practice under the Stark Law. Our revised safe harbor language does not contain such a requirement. However, the return on the investment interest must comply with the Stark Law, which limits compensation to physician investors that is based on the volume or value of referrals by the physician (section 1877(h)(4)(A)(iv) of the Act and implementing regulations).

Comment: One commenter expressed concern about the prohibition on group practices making loans to, or guaranteeing loans for, investors, if the loans are used to acquire an interest in the group. This commenter believed that this provision could create a problem for physicians who are given the opportunity to buy into an existing practice over time, if a deferred capital contribution were viewed as a loan.

Response: Our new safe harbor does not contain a prohibition on loans from group practices or group practice members used to acquire interests in the group practice.

Comment: One commenter suggested that the safe harbor should be expanded by adding protection for in-office ancillary services (such as a laboratory) shared by physicians who are not part of the same group practice, where the physicians sharing the in-office laboratory bill independently of one another and do not benefit from the volume or value of referrals made by their partners. According to the commenter, these arrangements are common, practical, and cost-effective.

Response: We agree that these arrangements are often practical and cost-effective for physicians. However, as indicated above, we are not prepared to provide safe harbor protection for investments in separately-owned ancillary services at this time, whether the ownership is by group practice members or others. We remain concerned that investments in ancillary services may create incentives for overutilization and lead to increased program costs. This is not to say that all such arrangements are unlawful under the anti-kickback statute. However, we do not believe that it would be possible to craft a sufficiently circumscribed safe harbor that would protect legitimate investments, while at the same time excluding from protection sham investments that are in reality vehicles for the payment of kickbacks.

Comment: One commenter recommended that the safe harbor apply to all practitioners within the reach of the anti-kickback statute, including nurse practitioners, certified nurse-midwives, clinical nurse specialists and certified registered nurse anesthesiologists.

Response: For now, we are limiting the safe harbor to group practices as defined in the Stark Law. The Stark Law definition of group practices applies only to physicians. We may consider an expansion to non-physician practitioners in future rulemaking.

4. Practitioner Recruitment

Summary of Proposed Rule: We proposed a safe harbor for certain payments or benefits offered by rural hospitals and entities in their efforts to recruit physicians and other practitioners. It had come to our attention that some hospitals located in rural areas encounter difficulties in attracting physicians to their communities. Our proposed safe harbor was designed to address this problem without protecting recruitment arrangements intended to channel Federal health care program beneficiaries to recruiting hospitals and entities.

We proposed limiting the practitioner recruitment safe harbor to entities located in rural areas as defined in our proposed safe harbor for investments in rural areas. However, we solicited comments on alternative geographic criteria. One alternative we suggested was limiting safe harbor protection to recruitment of practitioners located in areas that are health professional shortage areas (HPSAs) for the practitioner's specialty category.

To ensure that we did not protect arrangements designed to channel Federal program business to recruiting hospitals or entities, we proposed protecting recruitment of 2 types of practitioners: (1) Practitioners relocating at least 100 miles to a new geographic area and starting a new practice, and (2) new practitioners starting practices or specialties after completing an internship or residency program. We proposed seven standards that would have to be met to qualify for safe harbor protection. We also solicited comments about protecting payments designed to retain physicians already practicing in an area that has been designated as a HPSA for the physician's specialty category.

Summary of Final Rule: The intent of the practitioner recruitment safe harbor is to promote beneficiary access to quality health care by permitting communities that have difficulty attracting needed medical professionals to offer inducements to those professionals without running afoul of the anti-kickback statute. This safe harbor is intended to apply only to areas with a demonstrated need for practitioners and only to practitioners who actually serve the residents of such areas. We are adopting the proposed safe harbor with the following modifications:

- We are expanding the safe harbor to cover practitioner recruitment in urban, as well as rural, underserved areas. Specifically, the safe harbor applies to recruitment activities where the recruited practitioner's primary place of practice will be located in a HPSA for the practitioner's specialty area in accordance with 42 CFR part 5.
- We have eliminated the ''100 mile'' rule.
- We have reduced the required new patient revenues from 85 percent to 75 percent.
- At least 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA or a MUA or who are members of a MUP (as defined by HRSA).
- The benefits may be provided for a term of up to 3 years, provided there is a written agreement, and the benefits do

not directly or indirectly benefit other referral sources. If the HPSA ceases to be a HPSA during the term of the written agreement, the recruitment arrangement will not lose its safe harbor protection.

- The recruited practitioner must agree to treat Federal health care program patients in a non-discriminatory manner.
- We are not requiring the entity doing the recruiting to be located in the underserved area.
- We are not requiring new practitioners to establish staff privileges at the recruiting entity.

Comments and Responses

Comment: Commenters expressed a range of views regarding our proposed definition of ''rural'' for purposes of this safe harbor. Some urged us to adopt the definition of rural used by HCFA to reimburse hospitals located in rural areas under DRG payment rates (42 CFR 412.62(f)(1)(iii)). Others urged that an entity be protected under the safe harbor if it qualifies as a disproportionate share hospital (DSH) under Medicare payment policy. Some commenters suggested that we use HRSA's designations of HPSAs as a means of limiting protection afforded by the safe harbor. Several commenters recommended use of HRSA's designation of MUAs (42 CFR part 51c). One commenter suggested that we substitute a ''demonstrated community need'' standard for the geographic criteria. In addition, many commenters suggested that we extend the practitioner recruitment safe harbor to underserved urban areas. Several commenters proposed that we conform the safe harbor to the Stark Law exception for physician recruitment by eliminating geographic criteria.

Response: We are not prepared to expand this safe harbor by protecting practitioner recruitment wherever it occurs. In many areas, hospitals and other recruiting entities can attract sufficient numbers of qualified practitioners. In such areas, we see no need to protect additional payments or benefits that may in reality be disguised bonuses for high referrers. We recognize, however, that many hospitals in rural and urban underserved areas have legitimate problems attracting physicians and other practitioners and may need to offer additional financial incentives to acquire adequate staff. After carefully reviewing the suggested options, we have concluded that the most sensible approach—one that fairly balances the need to address practitioner shortages with the need to guard against abusive practices—is to extend safe harbor protection to recruitment payments and benefits provided to new and relocating practitioners who establish their primary place of practice in a HPSA in the practitioner's specialty area (see discussion of HPSAs above). The choice of HPSAs has the advantage of (i) including urban underserved areas, which we are persuaded often experience comparable difficulties attracting health care practitioners as rural areas, and (ii) targeting areas that have demonstrated a shortage of practitioners in particular specialties, and, consequently a need for additional recruitment.

We are not adopting the definition of ''rural'' used by HCFA for purposes of reimbursing rural hospitals under DRG payment rates. As discussed above, that definition is derived from the OMB definition of ''rural'' that is used by the Bureau of Census. The OMB methodology is not as closely tailored to the purpose of this safe harbor as is HRSA's HPSA methodology. Moreover, the OMB methodology would not identify underserved urban areas. We also concluded that the use of MUAs would create a broader safe harbor than is needed to facilitate the type of practitioner recruitment we intend to protect. Unlike HPSAs, which target practitioner shortages, MUAs measure shortages of health care services generally.

Similarly, we are not adopting the proposal to use DSH payments as a criterion for safe harbor protection. Although they are an indicator of the number of low-income patients a hospital treats, DSH payments do not necessarily indicate practitioner shortages. A ''demonstrated community need'' standard, while appealing in theory, presents too many difficulties in application to produce consistent and predictable safe harbor protection.

Comment: One commenter asked us to clarify whether the safe harbor protected payments made by recruiting entities that are not located in an rural area to practitioners who are practicing in a rural area. This commenter observed that some hospitals in ''non-rural'' areas serve patients who live in ''rural'' areas.

Response: The safe harbor provides that an entity will be protected if the practitioner's primary place of practice is located in a HPSA for the practitioner's specialty area. Consistent with our intent to facilitate recruitment of health care practitioners to serve the needs of underserved populations, we are not requiring that the recruiting entity also be located in a HPSA.

Comment: One commenter wondered whether a rural referral center (RRC) that had been reclassified by HCFA as urban for purposes of Medicare payment would be eligible for protection under the practitioner recruitment safe harbor.

Response: A RRC recruiting a practitioner whose primary place of practice will be located in a HPSA for the practitioner's specialty area would be eligible for protection under the rural investment interest safe harbor provided it met all of the conditions of the safe harbor.

Comment: The proposed safe harbor applies to new and relocating practitioners who derive 85 percent of their patient revenue from new patients not previously seen by the practitioner at his or her former place of practice. One commenter urged that the threshold be lowered to 50 percent to expand safe harbor protection. One commenter questioned the ability to measure compliance with the 85 percent revenue standard prospectively. Another commenter inquired whether a hospital would be required to audit a recruited physician's practice to ensure compliance with the 85 percent revenue test. One commenter suggested that the 85 percent revenue test be eliminated for urban providers.

Response: A dollar volume standard is necessary to ensure that safe harbor protection is granted only to new practitioners and those genuinely relocating and starting new practices. This safe harbor is intended to protect recruitment activities, not payments to retain physicians in existing practices. The safe harbor does not cover arrangements between hospitals and physicians that may be, in reality, payments to obtain the referrals of established practitioners. However, upon further consideration, we agree that the 85 percent standard we proposed is too high. We are, therefore, lowering the required percentage to 75 percent, which we believe will be sufficient to deter abuses. We recognize that determining compliance with the safe harbor may be problematic in some circumstances, such as during the first year of practice. However, we think that new and relocating practitioners should be able to achieve a reasonable degree of certainty that they have complied with the regulations. Parties to recruitment arrangements may use any reasonable method for establishing compliance, provided they use the same principles consistently over time, so as to avoid manipulating data to obscure noncompliance.

Comment: Several commenters suggested that we use a patient population test instead of a revenue test as a basis for ensuring that the practice is truly new or relocated.

Response: A revenue-based test more accurately measures whether services are, in fact, being provided to new patients than does a test based on the numbers of patients in a practitioner's practice. We do not intend to protect relocating practitioners who establish practices in HPSAs, but who continue primarily to treat patients from the practitioner's former practice.

Comment: The proposed safe harbor contained a requirement that a relocating practitioner's physical primary place of practice be at least 100 miles from his or her previous primary place of practice. Several commenters urged us to eliminate the 100 mile rule altogether or reduce the distance required. These commenters pointed out that the 100 mile requirement would produce arbitrary results in some circumstances and that some rural areas with practitioner shortages were located less than 100 miles from urban areas with pools of potential practitioners from which to recruit. Moreover, the 100 mile rule made it more difficult for urban undeserved areas to qualify for safe harbor protection. One commenter suggested using a travel distance of one and a half hours as a means of ensuring a majority of the practitioner's patients will be new. In the alternative, a commenter suggested making the 100 mile rule an alternative test to the 85 percent new patient revenue rule.

Response: The 100 mile rule was intended to ensure that the safe harbor protected recruitment of new or relocating practitioners only. However, we are persuaded that the proposed 100 mile rule would be impractical and lead to arbitrary results in some circumstances and would unnecessarily limit the protection afforded by this safe harbor. We also recognize that the 100 mile rule would make it difficult for entities in urban underserved areas to enter into recruitment arrangements that qualify for the safe harbor. Accordingly, we are eliminating the 100 mile rule, thereby enabling some recruitment arrangements to qualify for the safe harbor even if the practitioner relocates his or her primary place of practice only a short distance to a HPSA.

We are concerned, however, about the possibility of abuse by experienced practitioners, particularly in urban settings, who may ''relocate'' their offices short distances to underserved areas in order to qualify for the safe harbor and therefore receive recruitment payments that may, in fact, be rewards for referrals. The 75 percent new patient revenue test does not adequately guard against such abuse, because it measures whether patients are new to the practice and not whether patients are part of an underserved population. To ensure that safe harbor protection is not available for practitioners who relocate but do not serve the populations intended to benefit from this safe harbor, we are adding a requirement that 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA or a MUA or who are members of a MUP. The patients do not necessarily have to reside in the specific HPSA in which the practitioner's new practice is located, but may reside instead in a nearby MUA or HPSA. In sum, to qualify for the safe harbor, a new or relocating physician must substantially treat patients who are new to the physician's practice and who reside in underserved areas, or are members of medically-underserved populations designated by HRSA.

Comment: A number of commenters discussed the third proposed safe harbor standard, which would have imposed certain time limits on payments and benefits protected by the safe harbor. One commenter recommended extending the time limit for protected recruitment payments in non-HPSA rural areas from 3 years to 5 years. Several commenters urged us to allow protected recruitment payments for practitioners in HPSAs for as long as an area is designated as a HPSA. Some commenters questioned what would happen if a HPSA designation was revoked during the term of the recruitment contact. These commenters recommended that the contract continue to be protected for its term.

Response: Our original proposed safe harbor contemplated a 3 year limit on benefits, unless the practitioner was located in a HPSA, in which case recruitment benefits would be protected for the entire duration of the relationship between the practitioner and the recruiting entity. Given that we have limited the scope of this safe harbor to HPSAs, the 3 year limit for non-HPSA rural areas originally proposed no longer pertains.

However, our experience over the past few years has shown that practitioner recruitment is an area frequently subject to abusive practices. The risk of kickbacks is mitigated when payments are made to new or relocating physicians who do not have established referrals streams that can be locked up through inappropriate incentives and loyalties. Thus, we have concluded that protected payments under this safe harbor should not be of unlimited duration or subject to renegotiation that may be based on the volume or value of referrals. We believe that 3 years is a reasonable time period for recruitment benefits. Accordingly, we are amending the third standard to read as follows: ''the benefits are provided by the entity for a period not to exceed 3 years, and the terms of the agreement are not renegotiated during this 3 year period in any substantial aspect.'' By ''any substantial aspect,'' we mean in any manner that materially affects the payments and benefits to be made to the recruited practitioners under the written agreement. We have also revised the safe harbor to make clear that if the HPSA designation is revoked during the term of the contract, the payments will remain protected for the term of the contract (which term may not exceed 3 years), provided all other safe harbor conditions are satisfied.

We understand that limiting recruitment payments and benefits raises the question of incentives to retain physicians in HPSAs beyond an initial 3 year period. Because of the increased risk of kickbacks, payments for retention purposes require closer scrutiny than initial recruitment payments. We solicited comments regarding development of a physician retention safe harbor. We received several comments in support of such a safe harbor. A physician retention safe harbor may be the subject of future rulemaking.

Comment: Several commenters had concerns about the fourth proposed standard of the physician recruitment safe harbor, which would require that ''the entity providing the benefits cannot condition the agreement on the practitioner's referral of business to the entity.'' Specifically, one commenter inquired if this meant that the hospital could not condition the recruitment payments on the practitioner having and maintaining staff privileges at the recruiting entity.

Response: This requirement is derived from the small entity investment interests safe harbor at § 1001.952(a)(2)(iv) and is intended to ensure that the agreement is not conditioned on the referral of business from the practitioner to the entity. Consistent with this provision, hospitals may require a practitioner to have and maintain staff privileges; however, a hospital may not prohibit the practitioner from obtaining or maintaining staff privileges at other facilities. A hospital may not condition recruitment payments on aggregate admissions by the practitioner, nor may it require a recruited practitioner to admit a proportionate share of his or her patients to the hospital. A hospital may impose conditions intended to ensure quality of patient care, such as requiring that a physician have performed a minimum number of a particular type of

procedure before performing the procedure at the hospital.

Comment: Some commenters questioned the need for the requirement that practitioners agree to treat Medicare and Medicaid patients. One commenter suggested that the regulations require a recruited physician to treat all patients referred by the hospital, regardless of a patient's insurance status or ability to pay. A similar comment suggested that the regulations for physician recruitment require the physician to become a participating provider in the Medicare and Medicaid programs.

Response: We have generally addressed this issue in our discussion above. To impose a standard requiring a practitioner to treat all patients referred by a hospital would exceed our regulatory authority. Likewise, we are not requiring recruited practitioners to become participating providers in the Medicare and Medicaid programs. However, if they participate in any Federal health care program, they must treat all program beneficiaries in a nondiscriminatory manner.

Comment: A number of commenters requested that we further define the terms ''payment'' and ''benefit'' as used in §§ 1001.952(n)(1), (3), and (6) of the proposed physician recruitment safe harbor. Some commenters sought guidance regarding which specific payment practices are protected by the safe harbor.

Response: We decline to specify in these regulations any particular set of payment practices covered by this safe harbor. Recruitment practices necessarily vary depending on specific circumstances. Accordingly, whether payment practices are protected by this safe harbor must be evaluated on a case-by-case basis. In particular, the amount or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to, or business otherwise generated for, the recruiting entity by the practitioner for which payment may be made in whole or in part under a Federal health care program.

Comment: A commenter urged that the final regulations make clear that compliance with the recruitment safe harbor exempts parties from having to comply with other safe harbor regulations, including the personal services, space and equipment rental and obstetrical malpractice insurance safe harbors.

Response: This comment addresses a situation where a recruitment agreement may involve more than one safe harbor (*e.g.*, the space rental and obstetrical malpractice safe harbors). If the recruitment agreement as a whole meets the criteria of the recruitment safe harbor, then the agreement as a whole is exempt from criminal prosecution. If, however, the agreement does not fit within the recruitment safe harbor, certain payments made in accordance with it may still be protected under the other safe harbors, if the other individual safe harbor criteria are met.

Comment: Several commenters requested that we clarify whether the safe harbor protects joint recruitment efforts between hospitals and group practices or between hospitals and individual physicians who may employ new physicians in their practices. Along these same lines, one commenter asked us to protect the indirect recruitment activities of managed care organizations, which frequently conduct physician recruitment in conjunction with participating hospitals.

Response: We are aware that an increasing amount of physician recruitment is being conducted through joint arrangements between hospitals and group practices or solo practitioners. Typically, these arrangements involve payments from hospitals to group practices or solo practitioners to assist the group practice or solo practitioner in recruiting a new physician. Managed care organizations are also involved in joint practitioner recruitment activities with hospitals and physician practices. On the one hand, these arrangements can be efficient and cost effective means of recruiting needed practitioners to an underserved community. Moreover, many new practitioners prefer joining an existing group practice to starting a solo practice. On the other hand, these arrangements can be used to disguise payments for referrals from the group practice or solo practice to the hospital.

We are not persuaded that a safe harbor can be crafted that would protect legitimate joint recruiting arrangements of the type described above without sweeping in sham arrangements that are actually disguised payments for referrals. However, we want to make clear that joint recruitment arrangements are not necessarily illegal and must be evaluated on a case-by-case basis. Parties seeking further guidance about their joint recruitment activities may apply for an advisory opinion.

Comment: One commenter stated that the sixth standard of the proposed safe harbor for physician recruitment, which prohibits benefits that vary based on the volume or value of expected referrals, would eliminate income guarantees from safe harbor protection, since the amount of the funds advanced against the guarantee are generally not determined until the new physician has commenced his or her practice and the initial income from the practice has been determined. According to the commenter, income guarantees are among the most common recruitment incentives.

Response: The anti-kickback statute prohibits payment of any remuneration to induce referrals for which payment may be made in whole or in part by a Federal health care program. To this end, this safe harbor, like others, prohibits payments that are based on the volume or value of expected referrals. Recruitment incentives tied to volume or value of referrals generated are not immunized by this safe harbor. However, where the maximum amount of the income guarantee and the formula for determining payment under the guarantee are set in advance and not subject to renegotiation, the formula is not tied to volume or value of referrals, and the income guarantee otherwise meets the safe harbor requirements, the fact that the actual amount that will be paid to the practitioner under the guarantee is not known in advance will not disqualify the income guarantee from safe harbor protection.

Comment: One commenter requested clarification as to how the recruitment safe harbor would apply to physicians recruited to fill medical director positions where, in most cases, the physician is not an employee of the facility and is not generally perceived as a source of referrals.

Response: In many circumstances, medical directors are potential referral sources and medical director contracts serve as a means to reward referrals. There is no special protection for medical directors under the practitioner recruitment safe harbor. To be protected, a recruitment arrangement must meet all of the standards of the safe harbor, including the new patient and underserved patient revenue tests (§§ 1001.952(n)(2) and (8)). In the alternative, a contract for medical director services may qualify for protection under the employee compensation or personal services contract safe harbors (§§ 1001.952(i) and (d)).

Comment: Several commenters urged us to make the safe harbor consistent with IRS Revenue Ruling 97–21 on physician recruitment.

Response: The IRS Revenue Ruling 97–21 on physician recruitment by a tax-exempt hospital is intended to provide guidance on recruitment activities that are consistent with a hospital's operations as a tax-exempt entity. The revenue ruling sets forth standards for determining whether a

tax-exempt hospital's practitioner recruitment activities jeopardize its tax-exempt status. Under the revenue ruling, a hospital does not jeopardize its tax-exempt status if its recruitment payments are reasonably related to its tax-exempt purpose. However, this standard is an insufficient safeguard against improper payments for referrals. A payment that is reasonably related to a hospital's tax-exempt purpose, but is tied to the volume or value of expected referrals, will likely run afoul of the anti-kickback statute and is not appropriate for safe harbor protection.

Comment: One commenter asked us to reaffirm that not all physician recruitment activities necessarily violate the anti-kickback statute, and that recruitment programs not meeting the safe harbor criteria will be analyzed on a case-by-case basis.

Response: The failure of a particular arrangement to comply with the safe harbor does not determine whether or not the arrangement violates the anti-kickback statute. Neither does such failure determine whether an enforcement action is warranted. As a general rule, remuneration to physicians, including recruitment, should be consistent with fair market value for necessary services rendered by the physician. The practitioner recruitment safe harbor protects certain payment practices that may depart from this general rule if particular criteria established by the safe harbor are met. Arrangements that do not qualify for the safe harbor must be evaluated on a case-by-case basis to determine whether there has been a violation and whether an enforcement proceeding is warranted.

5. Obstetrical Malpractice Insurance Subsidies

Summary of Proposed Rule: We proposed a new safe harbor to permit a hospital or other entity to pay all or part of the malpractice insurance premiums for practitioners engaging in obstetrical practice in primary health care professional shortage areas. For purposes of this safe harbor, we included certified nurse midwives as defined in section 1861(gg) of the Act in the definition of ''practitioner.'' We limited this safe harbor to the provision of malpractice insurance regulated by State law. We explained that nothing in the safe harbor would authorize payment by the Federal health care programs to hospitals or other institutional providers for costs they may incur in providing malpractice insurance. Any allowable costs for such insurance are governed strictly by Federal health care program rules.

We solicited comments on specific, narrowly-drawn circumstances where this safe harbor provision could be expanded to help assure beneficiary access to services that may be significantly affected by the cost of malpractice insurance premiums. In addition, we solicited views regarding the feasibility of expanding this safe harbor to protect malpractice insurance programs that are not regulated under State law, but which are operated directly by providers.

Summary of Final Rule: This safe harbor is intended to facilitate access to obstetrical services for Federal health care program beneficiaries in primary care health professional shortage areas by protecting from the reach of the anti-kickback statute subsidized malpractice insurance for practitioners who are primarily engaged in obstetrical practices in those areas. We have adopted the proposed safe harbor with the following modifications:

- We are expanding the safe harbor to cover self-funded insurance plans.
- We are reducing from 85 percent to 75 percent the proportion of the practitioner's obstetrical patients who must be treated under the subsidized insurance coverage.
- We are eliminating the phrase ''be in a position to make or influence referrals'' from § 1001.952(o)(3), since most, if not all, insurers require practitioners to be in a position to perform obstetrical services as a condition of coverage.
- We are requiring that protected practitioners be engaged in obstetrics as a routine part of their practices. Full subsidies for obstetrical malpractice insurance may be paid for full-time obstetricians or nurse midwives; for part-time practitioners in obstetrics, the safe harbor protects only costs attributable to the obstetrical portion of their practices.

Comments and Responses

Comment: One commenter recommended expanding the phrase ''practitioners engaging in obstetrical practice'' to include explicitly family practitioners and other physicians who may deliver babies, in order to make clear that the safe harbor covers insurance subsidies for such individuals.

Response: We agree that limited safe harbor protection is appropriate for family practitioners and other physicians and certified nurse midwives who deliver babies as a routine part of their medical practices. Accordingly, we are amending the proposed regulation to provide for limited coverage for ''a practitioner who engages in obstetrical practice as a routine part of his or her medical practice.'' For purposes of this safe harbor, by ''routine'' we mean that the practitioner must provide substantial and regular obstetrical services; we do not intend to protect obstetrical insurance subsidies for practitioners who practice obstetrical medicine on only an occasional basis.

For practitioners who are not full-time obstetricians or certified nurse midwives, we will protect payments for *obstetrical* malpractice insurance only. We will not protect subsidies for other types of medical malpractice liability insurance. Thus, for these practitioners the protected subsidy will be the difference between the cost of malpractice insurance that includes obstetrical coverage and the cost of malpractice insurance that does not include such coverage. Similarly, the safe harbor will protect certain insurance subsidies paid on behalf of practitioners engaged in obstetrical practices part-time in a HPSA and part-time elsewhere. We have in mind, in particular, urban obstetricians who may practice several days in an inner-city clinic (in a HPSA) and several days in areas that are not underserved. For these practitioners, the safe harbor protects insurance subsidies for obstetrical malpractice insurance coverage related exclusively to services provided in the HPSA. If the practitioner is covered by a single insurance policy or program, the safe harbor covers subsidies for that portion of the insurance premium that is reasonably allocable to obstetrical services provided in a HPSA.

Comment: We solicited comments on specific, narrowly-drawn circumstances where this safe harbor provision could be expanded to help assure beneficiary access to services that may be significantly affected by the cost of malpractice insurance premiums. In response, one commenter recommended expanding this safe harbor to include neuro, cardiovascular and orthopedic surgeons. Two commenters recommended enlarging the safe harbor to cover malpractice insurance coverage for pediatricians. A commenter also recommended expanding the safe harbor to cover emergency room coverage by high risk medical specialists in situations where a hospital is able to certify that a viable panel of specialists is only possible if the hospital can provide this benefit. One hospital association expressed concern that a safe harbor only for insurance subsidies for obstetrical practitioners may create unnecessary concern in the industry that all other types of practitioner malpractice insurance subsidies may be suspect. The

association recommended greatly expanding the proposed safe harbor or deleting it as written.

Response: This safe harbor is intended to promote access to obstetrical services for Federal health care program beneficiaries and others in underserved areas. Although we solicited comments on expanding this safe harbor, we are not persuaded at this time that there are compelling reasons to expand it beyond malpractice insurance subsidies for practitioners engaging in obstetrical practices. This safe harbor does not call into question the legality of all other types of practitioner malpractice insurance subsidies. Such subsidies may qualify for protection under other safe harbors, such as practitioner recruitment, personal services contracts or employee compensation (§§ 1001.952(n), (d), and (i)). Moreover, as we have previously stated, the fact that a payment practice does not fall within the ambit of a safe harbor does not necessarily mean that the practice violates the anti-kickback statute. At the same time, we note that malpractice insurance subsidies paid to or on behalf of potential referral sources may be suspect under the anti-kickback statute. These arrangements are subject to a case-by-case evaluation. The advisory opinion process is available for parties seeking OIG guidance on the anti-kickback implications of particular insurance subsidy arrangements (See 42 CFR part 1008).

Comment: Several commenters offered views on the geographic scope of the safe harbor. One commenter recommended that we expand the scope of the safe harbor to protect subsidies in primary care HPSAs and in rural areas as defined in 42 CFR 412.62(f)(1)(iii). Another urged application of the safe harbor in urban areas. Some commenters noted that the HPSA designation process is a volatile, on-going process, and that the list of shortage areas is rarely an accurate reflection of actual need for health care professionals at a particular point in time. Moreover, these commenters believed that dependence on Federal designations fails to recognize the role of states in identifying and remedying health professional shortage areas. One commenter suggested focusing on emergency room admissions of obstetrics patients who have no designated primary care practitioner rather than on HPSA data to measure community need.

One commenter raised the question of what happens when the offer of subsidized malpractice insurance induces a physician to relocate to a HPSA, but the physician's relocation itself serves to remove the community's HPSA designation. This commenter proposed substituting a ''need'' standard, with the appropriate documentation of need for the subsidized practitioner left up to the entity providing the subsidy. This commenter observed that many current safe harbors use the concept of ''fair market value'' without requiring any particular fair market value standard to be met, and the health care community for the most part understands that documentation is critical to prove fair market value in the event a particular transaction is later scrutinized. Examples of documentation of ''need'' could include determinations by State legislatures, as well as any other appropriate indications of need for a particular type of health care professional.

Response: As described in greater detail above in our responses to comments on the practitioner recruitment safe harbor, primary care HPSAs may be located in rural or urban areas. We are limiting this safe harbor to primary care HPSAs so as to ensure as much as possible that the benefits protected by this safe harbor are extended to practitioners in areas where there is a well-founded, documented shortage of obstetrical practitioners. We are aware that there are and have been problems with the HPSA process. We expect that the Department's anticipated revision of the process should address many of those problems, including providing States with greater input in designating shortage areas. We believe that a general ''need'' standard could be manipulated in ways that would permit abusive payments in the guise of insurance subsidies. We note that nothing in this safe harbor prevents protection of malpractice insurance subsidies for practitioners engaged in practice outside primary care HPSAs as part of an arms-length, fair market value compensation package that meets the requirements of the personal services safe harbor or the employee compensation exception to the anti-kickback statute (§§ 1001.952(d) and (c); 42 U.S.C. 1320a–7b(b)(3)(B)).

Comment: One commenter questioned the feasibility of the requirement that 85 percent of the practitioner's obstetrical patients treated under the insurance coverage must come from certain defined underserved populations, noting that compliance with the standard can only be determined after the payment of the insurance premium subsidy. The commenter observed that obtaining liability coverage necessarily precedes treatment of any patients under that coverage. Documenting compliance with the standard is particularly problematic where insurance subsidies are used as recruiting devices for new or relocating practitioners who do not have established patient pools that can be measured. One commenter suggested that this problem could be solved by deeming the 85 percent test satisfied if the practitioner provides a written stipulation that the 85 percent test will be met.

Response: Upon further review, we believe that an 85 percent test is unnecessarily restrictive. Accordingly, we have amended the safe harbor to provide that 75 percent of the patients treated must come from underserved populations, that is, they must reside in a HPSA or a MUA or be part of a MUP, all as defined by HRSA and described above. Moreover, we agree that under the test as drafted in the proposed rule, it would not be possible for parties seeking safe harbor protection to determine whether a payment for an insurance subsidy satisfies the safe harbor prior to making the payment. However, we believe that a practitioner stipulation is insufficient by itself to ensure that appropriate populations are benefitting from the increased access to obstetrical care contemplated by this safe harbor. Accordingly, we have amended the safe harbor to provide that for the initial coverage period, which will be limited to one year, the practitioner must certify that he or she has a reasonable basis for believing that he or she will meet the 75 percent test for the duration of the coverage period. Thereafter, for payments of insurance premiums to be protected, the 75 percent standard must have been met for the period covered by the preceding insurance premium payment, which coverage period may not exceed one year.

Comment: One commenter recommended eliminating the requirement that the insurance subsidy be paid to the insurance provider, rather than the subsidized practitioner.

Response: The requirement that the subsidy be paid to the insurance provider is a reasonable means of ensuring that the payment is used for the purposes intended by this safe harbor. Permitting a direct cash payment to the subsidized practitioner increases the risk that the ''subsidy'' payment may in fact be a disguised payment for referrals. We are not persuaded that payment directly to insurance providers is impractical or unduly burdensome on subsidizing entities or subsidized practitioners.

Comment: One commenter believed that the requirement that practitioners

treat Medicaid patients is superfluous, because the anti-kickback statute is only implicated where Medicaid and Medicare referrals are in fact made. Another commenter recommended amending the requirement to provide that a physician may not discriminate against Medicaid patients to the extent the physician is able to see new patients in his or her practice. Otherwise, the safe harbor would preclude protection for physicians whose current practices may be full.

Response: These issues are addressed above with respect to the safe harbor regarding physician recruitment.

Comment: A commenter observed that some professional liability underwriters, especially in states with harsh liability climates, do not have the surpluses required to provide coverage beyond certain minimum limits, and suggested that the safe harbor should protect hospital underwriting of all physician liability above certain limits in order to protect physicians against large awards against them. The commenter suggested limits of $100,000 to $300,000.

Response: This proposal, which essentially would cover the entire range of practitioner services, does not meet our requirements for proposals of specific, narrowly-drawn circumstances where the safe harbor could be expanded to help assure beneficiary access to services significantly affected by the cost of malpractice insurance premiums.

Comment: Several commenters suggested the safe harbor be extended to protect payment of premiums or establishment of reserves in self-funded programs underwritten and operated by hospitals and other providers, including risk-retention groups. These commenters point out that many hospitals and other entities elect self-insurance programs for physicians on the medical staff, instead of purchasing commercial insurance from independent third parties. The commenters noted that self-insurance programs, including risk-retention groups, were established in response to the unavailability or unaffordability of malpractice insurance for certain areas or specialities. Commenters believed that these programs keep health care costs to a more reasonable level and ought to be encouraged and protected. They argued that the benefit to the physician is the same whether insurance is provided through a self-funded program or commercial third party insurance, and thus hospitals or other health care providers with self-funded programs should not be deprived of protection. Self-insured hospitals are not in a position to make payments to another entity that provides insurance. To assure that only *bona fide* programs are shielded, one commenter recommended that only programs that have been certified by a qualified actuary as adequate relative to the risk assumed should be afforded safe harbor protection. Finally, several commenters suggested expanding the safe harbor to include offshore insurance products.

Response: We solicited comments regarding the feasibility of expanding the safe harbor to protect subsidies for insurance under programs operated directly by providers. As indicated in the preamble to the 1993 proposed rule, our concern was that the subsidized insurance policies be *bona fide* to ensure that this safe harbor is not used as a mechanism to disguise improper inducements to practitioners. The requirement that the insurance be *bona fide* also protects practitioners and patients. We agree that from the practitioner's perspective, the benefit derived from an insurance subsidy is the same whether the insurance is provided by commercial third party insurance or a self-funded program. Accordingly, we have amended the safe harbor to extend protection to *bona fide* self-funded obstetrical malpractice insurance programs, including risk-retention groups that qualify under the Liability Risk Retention Act, 15 U.S.C. 3901, and to *bona fide* offshore insurance products. Although we are not defining the full scope of *bona fide* insurance products, we believe that certification by a qualified actuary that the program is adequate relative to the risk insured would be an indicator of a *bona fide* insurance program.

Comment: One commenter suggested that the prohibition on requiring a physician to ''be in a position to make or influence referrals'' limits the ability of facilities to require that physicians maintain medical licenses and be in a position to practice medicine and recommended that the prohibition be eliminated.

Response: Nothing in these safe harbor regulations is intended to prevent hospitals and other health care facilities from requiring that physicians and other practitioners who perform services at or for such facilities be fully licensed and able to practice medicine. In particular, we recognize that proper licensure and qualifications to practice medicine are prerequisites for obtaining malpractice insurance. We are persuaded that the language ''be in a position to make or influence referrals to'' is unnecessary in the context of a safe harbor for obstetrical malpractice insurance subsidies. Therefore, we have amended the third condition of the safe harbor to prohibit any requirement that practitioners ''make referrals to, or otherwise generate business for, the entity as a condition for receiving the benefits.''

Comment: One commenter expressed concern that the safe harbor does not adequately protect group practices.

Response: A group practice that provides obstetrical malpractice insurance subsidies may qualify as an ''entity'' for purposes of this safe harbor. Moreover, as indicated above, we have amended the safe harbor to permit entities to subsidize insurance through self-funded insurance programs. This safe harbor is not intended to protect group practices for any payment practice that does not satisfy all of the safe harbor criteria, including the requirements that the subsidized practitioner practice in a primary care HPSA and that 75 percent of the obstetrical patients treated reside in underserved areas.

6. Referral Agreements for Specialty Services

Summary of Proposed Rule: We proposed a new safe harbor for referral agreements for specialty services. This safe harbor would protect arrangements under which an individual or entity agrees to refer a patient to another individual or entity for specialty services in return for an agreement on the part of the party receiving the referral to refer the patient back at a certain time or under certain circumstances. For example, a primary care physician and a specialist (to whom the primary care physician has made a referral) may agree that, when their patient reaches a particular stage of recovery, the primary care physician should resume treatment of the patient.

We proposed three standards that such a referral arrangement would have to meet to fit within the safe harbor. First, the service for which the initial referral is made must not be within the medical expertise of the referring party and must be within the special expertise of the party receiving the referral. Second, the parties could receive no payment from each other for the referral. Third, the only exchange of value permitted between the parties would be the monetary remuneration each party would receive directly from third-party payers or the patient as compensation for professional services furnished by each party to the patient.

We proposed an accommodation in this safe harbor for members of the same group practice who refer to one another. Where the referring and receiving physicians belong to the same group practice, revenues are shared among

members of the group practice, and thus it appears that the referring physician receives remuneration for the referral. However, such financial benefits are an inherent part of belonging to a group practice, and therefore we proposed protecting such remuneration if the group practice met the definition of ''group practice'' in section 1877(h)(4) of the Act.

Summary of Final Rule: Because of the potential for abuse when the referring physician and the specialty physician receiving the referral split a global payment from a Federal health care program, we are revising the regulation specifically to exclude remuneration received in such circumstances from the safe harbor. We are also adding a requirement that the condition for the referral back to the originating referral source must be clinically appropriate. We are otherwise promulgating the safe harbor as proposed.

Comments and Responses

Comment: A number of commenters generally supported the approach of the proposed safe harbor, stating that it would adequately protect legitimate referral arrangements while sufficiently discouraging illegitimate ones. They suggested that the safe harbor would be useful because it would assure convenient access to follow-up care in communities where there are no specialists. However, several commenters suggested that insulating referrals for specialty services from the kickback statute would encourage arrangements that might compromise the quality of patient care, because arrangements between the primary physician and the referral specialist might require a patient to be referred back to the primary physician, regardless of whether it would be clinically appropriate. Further, specialty referral arrangements could deny patients the right to choose their providers.

Response: We share the commenters' concerns that patient referrals be made only under clinically appropriate circumstances. Indeed, clinical appropriateness should be the touchstone of all referrals, specialty or otherwise. To emphasize the importance of clinical appropriateness as a consideration, we are revising the safe harbor to reflect that the ''mutually agreed upon time or circumstance'' for the receiving specialist to return the patient must be clinically appropriate. We are not further defining ''clinically appropriate,'' however, because whether a referral is clinically appropriate will depend on the particular facts and circumstances. Depending on circumstances, an agreement to refer a patient back on a date certain, without regard to medical condition, would be questionable.

We also share the commenters' concerns regarding the preservation of patient freedom of choice. Patient freedom of choice may be compromised, however, if patients are not given access to needed specialty care. There is a legitimate concern if physicians are disinclined to refer patients to specialists because of fear of losing patients to those specialists permanently. Thus, for example, the safe harbor would protect an agreement between a general cardiologist and a cardiologist with special expertise on a particular medical condition whereby (i) the general cardiologist would refer a patient to the specialist for treatment of the particular medical condition about which the specialist has expertise, and (ii) the specialist—who also has a general cardiology practice—would refer the patient back to the originating cardiologist upon completion of the specialty treatment.

We want to make clear that protection under this safe harbor is limited to referral arrangements for patients of the physician making referrals to the specialist. The safe harbor does not protect generalized cross-referral arrangements of the ''you send me your patients and I'll send you mine'' variety. Rather, the safe harbor protects an agreement to refer patients to a specialist in return for an agreement or understanding that the specialist will refer those *same* patients back at the agreed upon time or circumstance (*e.g.*, completion of the specialist services for which the patient was referred). In other words, assuming all safe harbor conditions are satisfied (and there is no split of a global fee, as discussed below), the safe harbor will protect agreements along the lines of ''I'll send you my patients who need your specialist services if you agree to send them back to me upon completion of your services.''

On balance, we believe that a safe harbor under the anti-kickback statute for referrals for specialty services is appropriate and will protect many legitimate referral arrangements that benefit patients, including those living in remote areas. Where no payment is made between the referring and receiving parties (and there is no splitting of a Federal health care program global fee, as discussed below), we believe the specialty referral arrangements protected by the safe harbor pose no more than a minimal risk of illegal remuneration for referrals in violation of the anti-kickback statute.

Comment: Ophthalmology providers were especially concerned that the proposed safe harbor may encourage the development of potentially abusive referral arrangements with optometrists, who wish to receive the post-operative portion of the Medicare global fee for eye surgery. The ophthalmologists allege that many optometrists refer patients to ophthalmologists on the condition that patients be referred back to the optometrists for post-surgical care, often without regard to clinical appropriateness. Some ophthalmologists claimed that optometrists generally control referrals and therefore ophthalmologists, for whom surgical procedures are the mainstay of their practices, must acquiesce to these return referral arrangements in order to get patients. One commenter described a situation where an optometrist/ophthalmologist network referred patients for cataract surgery only to ophthalmologists who would agree to split the global surgical fee by referring the patient back to the optometrist for post-operative care. The optometrists referred their patients to an ophthalmologic surgery center 200 miles away when there were at least 50 available ophthalmologists from 7 to 35 miles away. In such circumstances, the ophthalmologists do not do any of the follow-up care for the patients and the post-operative portion of the global fee is paid to the optometrists. The commenter, an ophthalmologist, had provided some of the patients referred by the optometrist network with a second opinion and found that none required surgery.

Response: The serious issues raised by the ophthalmologists about apparently routine or blanket agreements to split global Medicare fees with referring optometrists (as well as other information that has come to our attention from industry and Government sources) has caused us to modify the scope of this safe harbor. We have revised the safe harbor regulation to preclude protection for arrangements between parties that share or split a global or bundled payment from a Federal health care program for the referred patient. Thus, for example, the safe harbor does not protect referral arrangements where the parties bill Medicare using the 54/55 modifiers to indicate an 80 percent-20 percent split of the surgical fee for cataract surgery.

By limiting the safe harbor, we do not mean to suggest that all specialty referral arrangements involving splitting of global fees are illegal under the anti-kickback statute. Whether a particular

referral arrangement for specialty services violates the anti-kickback statute depends on a case-by-case analysis of all of the facts and circumstances, including, but not limited to, whether the specialty services are medically necessary, whether the timing of the referrals is clinically appropriate, and whether the services performed are commensurate with the portion of the global fee received.

Comment: One commenter questioned whether the anti-kickback statute applies to specialty referral arrangements where no kickback, rebate or other consideration is made for the referral.

Response: As the United States Court of Appeals for the First Circuit has recognized, the opportunity to generate a fee may constitute the requisite remuneration under the statute, even if no payment or rebate is paid for a referral. For instance, the opportunity to split a global surgical fee, as in the hypothetical described in the previous comment, is an example of a circumstance in which an opportunity to generate a fee is something of value to a referring party apart from any payment for the referral. Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare patients toward a particular recipient. (See *United States* v. *Bay State Ambulance and Hospital Rental Service, Inc.,* 874 F.2d 20, 29 (1st Cir. 1989)).

Comment: A managed care organization trade association commented that managed care organization arrangements often require the referral of patients to other contracting providers as a condition of the provider's compensation and that the anti-kickback statute should not be construed so broadly as to encompass these types of managed care arrangements. In addition, a managed care plan commented that the safe harbor should be expanded to exempt expressly referrals made within an HMO, or that the OIG should establish a new safe harbor for referrals made by HMO-participating physicians.

Response: The anti-kickback statute is broad and technically may cover many managed care arrangements that are common in the marketplace today. However, we have recognized that most of these arrangements involving HMOs do not create the potential for fraud or abuse and have created safe harbors aimed at those arrangements. Currently, § 1001.952(m) protects certain price reductions offered to health plans. In addition, as part of HIPAA, Congress enacted a statutory exception for managed care arrangements that put individuals or entities at substantial financial risk (42 U.S.C. 1320a–7b(b)(3)(F)).[5] These safe harbors offer broad protection under the anti-kickback statute to HMOs.

Comment: One commenter urged that we clarify the safe harbor to make clear that it covers primary care practitioners in rural areas who do not belong to group practices.

Response: The safe harbor applies to solo practitioners, as well as members of group practices. To be protected by the safe harbor, solo practitioners may not give anything of value to a specialist in exchange for the referral back of his or her original patient, except for the opportunity to receive compensation for services directly from third parties or patients. Members of *bona fide* group practices who refer among themselves are not similarly restricted; they may share revenues from specialty services performed as a result of the intra-group referrals.

7. Cooperative Hospital Service Organizations

Summary of Proposed Rule: We proposed a new safe harbor to protect cooperative hospital service organizations (CHSOs) that qualify under section 501(e) of the Internal Revenue Code. These organizations are formed by two or more tax exempt hospitals (known as ''patron hospitals'') to provide specifically enumerated services, such as purchasing, billing, and clinical services solely for the benefit of patron hospitals. These entities are required by law to distribute all of their net earnings to patrons on the basis of services performed (26 U.S.C. 501(e)(2)).

The safe harbor would protect payments from a patron hospital to a CHSO to support the CHSO's operational costs and those payments from a CHSO to a patron hospital that are required by IRS rules. As a condition of protection, the CHSO must be wholly owned by its patron hospitals, in order to avoid potentially abusive joint venture arrangements formed under the guise of CHSOs. To the extent a CHSO acts as a group purchasing agent or a patron hospital obtains discounts as a result of the CHSO's activities, CHSOs and patron hospitals must comply with the respective safe harbor provisions applicable to group purchasing organization and discounts (§§ 1001.952(j) and (h)) to be fully protected. We solicited comments regarding the various types of payment formula (which comply with the IRS rules) that are used by CHSOs, but did not receive any comments on this issue.

Summary of Final Rule: We are adopting the rule as proposed, with some minor technical changes.

Comments and Responses

Comment: We requested comments on the extent to which we should expand this provision to protect other similar entities specifically organized under Federal or State laws. Four comments were submitted suggesting that the safe harbor be expanded to include other types of cooperative organizations that qualify under subchapter T of the Internal Revenue Code (sections 1381 to 1388). One commenter also requested that the safe harbor be expanded to include other types of hospital cooperative organizations.

Response: We decline to extend safe harbor protection to cooperative organizations that do not qualify under section 501(e). Unlike CHSOs complying with that section, there are few limitations applicable to cooperative organizations qualifying under subchapter T. There are no limits on the types of services that may be shared, nor are there restrictions on the identity of shareholders. The conditions and limitations imposed on tax-exempt entities, including the limits on private inurement, do not apply to subchapter T organizations. We believe the limitations imposed under section 501(e) are necessary to protect against potentially abusive joint ventures or referral arrangements. Additionally, in view of the small number of comments we received concerning non-hospital cooperatives and the fact that we received only a single comment requesting broader hospital coverage, we are not persuaded of the need to broaden the safe harbor to other types of hospital or non-hospital cooperatives. Accordingly, we are adopting the proposed safe harbor for CHSOs without modification.

8. Modification of Sale of Practice Safe Harbor

Summary of Proposed Rule: We solicited comments on the desirability of modifying the existing sale of practice safe harbor set forth in § 1001.952(e) to accommodate transactions involving the rural hospital purchase of a physician practice as part of a practitioner recruitment program that complies with the safe harbor we are establishing to protect practitioner recruitment. The existing sale of practice safe harbor did not protect such purchases. We had been informed that many rural hospitals buy and ''hold'' the practice of a retiring physician, often using *locum tenens*

[5] See footnote 2.

physicians until a new physician can be recruited to replace the retiring one.

Summary of Final Rule: We are modifying the existing sale of practice safe harbor to protect payments made to a practitioner by a hospital or other entity to purchase the practitioner's practice where the following conditions are satisfied:

- The sale is completed within 3 years.
- After completion of the sale, the practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing entity for which payment may be made by a Federal health care program.
- The practice being acquired must be located in a HPSA for the practitioner's specialty area.
- Commencing at the time of the sale, the purchasing entity must diligently and in good faith engage in recruitment activities that (i) may reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within 1 year of completion of the sale, and (ii) satisfy the conditions of the new practitioner recruitment safe harbor (§ 1001.952(n)).

Comments and Responses

Comment: Commenters generally supported our proposed modification to the sale of practice safe harbor. Some commenters urged that the safe harbor be extended to sales of practices in urban underserved areas. One commenter stated that the problem of preserving and maintaining a retiring physician's practice until a new physician can be recruited and established exists in both urban and rural HPSAs. Because of these difficulties, a hospital may find itself in the position of ''holding'' a practice for some time. One commenter suggested that in the case of small, rural hospitals with tight cash flow, the payment period under the safe harbor should be 3 to 5 years, rather than 1 year as set forth in the existing safe harbor.

Several commenters stated that the existing sale of practice safe harbor is too narrow. Some commenters suggested that the safe harbor be expanded to include entities other than hospitals, such as hospital systems and other health care organizations. These commenters urged the OIG to modify the safe harbor to protect, among other arrangements, sales of practices in accordance with fair market value transactions and sales of practices to entities in connection with the process of creating integrated health care delivery systems. One commenter urged the OIG to modify the safe harbor to provide that reasonable valuation of all assets, tangible and intangible, may be used to determine the market value of the practice.

Response: Based on the comments we received to our solicitation and after further consideration, we are persuaded that a need exists to protect certain practice acquisitions by hospitals and other entities located in rural and urban underserved areas that are engaged in practitioner recruitment programs, and that these arrangements can be protected without concurrently immunizing potentially fraudulent or abusive practices. Specifically, we are modifying the sale of practice safe harbor to protect acquisitions of the practices of physicians in underserved areas who are retiring or relocating a distance that would preclude them from being in a position to make referrals to the purchasing entity, if the acquisitions occur as part of a practitioner recruitment program that qualifies for protection under the safe harbor for practitioner recruitment contained in these regulations. We are requiring that the physician be retired from the practice of medicine or otherwise no longer in a position to generate referrals for the hospital. A purchase of a practice from a physician potentially still in a position to make referrals to the purchasing entity might result in abusive payments to induce referrals of business from the physician's new practice. Relocation a significant distance from the practice being sold is an indicator that a physician is no longer in a position to refer patients. We agree that a longer payment period is appropriate in the context of this safe harbor; accordingly, we are establishing a 3 year period for completion of the sale from the date of the first agreement pertaining to the sale.

As a result, to be protected, a sale of practice by a practitioner must meet all of the following conditions: (1) The period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than 3 years; (2) following the sale, the practitioner may not be in a position to make or influence referrals to, or otherwise generate business for, the purchasing entity for which payment may be made in whole or in part under a Federal health care program; (3) the practice being acquired must be located in a HPSA for the practitioner's specialty area; (4) commencing at the time of the first agreement pertaining to the sale, the purchasing entity must diligently and in good faith engage in commercially reasonable recruitment activities that (i) may reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within a 1 year period, and (ii) will satisfy the conditions of the practitioner recruitment safe harbor at § 1001.952(n).

We are not inclined at this time to modify the sale of practice safe harbor further. While we do not intend to stand in the way of integrated delivery system acquisitions of practices, we are concerned that many such arrangements may provide incentives for overutilization, increased billings to the Federal programs, and inappropriate steering of patients in circumstances where the Federal health care programs pay on a fee-for-service basis. Moreover, we remain of the opinion that payments for ''intangibles'' can easily be used to disguise payments for referrals of Federal health care program business, and therefore we are unwilling to provide safe harbor protection for any particular valuation methodology.

III. Regulatory Impact Statement

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

The Office of Management and Budget has reviewed this 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 an economically significant regulatory action. Executive Order 12866 direct 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 a 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. We believe that this final rule should have no significant economic impact. 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 State, 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 some of 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 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 final regulations are voluntary and impose no new reporting or recordkeeping requirements on health care providers necessitating clearance by OMB.

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 set forth below:

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 as follows:

a. By republishing the introductory text;

b. Revising paragraph (a), introductory text;

c. Republishing paragraph (a)(1), introductory text;

d. Revising paragraphs (a)(1)(ii) and (iv), (a)(2)(i), (vi) and (vii);

e. Adding a new paragraph (a)(3)

f. Redesignating the closing definitional paragraph in paragraph (a); as paragraph (a)(4) and revising it;

g. Revising paragraph (b), and introductory text, and paragraph (b)(2) and adding a new paragraph (b)(6);

h. Revising paragraph (c), and introductory text, and paragraph (c)(2) and adding a new paragraph (c)(6);

i. Revising paragraph (d), introductory text, and paragraph (d)(2) and adding a new paragraph (d)(7);

j. Revising paragraph (e);

k. Republishing paragraph (f), introductory text, and revising paragraph (f)(2);

l. Revising paragraph (h); and

m. Adding new paragraphs (n) through (s).

The additions and revisions to § 1001.952 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:

(a) *Investment interests.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as all of the applicable standards are met within one of the following three categories of entities:

(1) If, within the previous fiscal year or previous 12 month period, the entity possesses more than $50,000,000 in undepreciated net tangible assets (based on the net acquisition cost of purchasing such assets from an unrelated entity) related to the furnishing of health care items and services, all of the following five standards must be met—

* * * * *

(ii) The investment interest of an investor in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be obtained on terms (including any direct or indirect transferability restrictions) and at a price equally available to the public when trading on a registered securities exchange, such as the New York Stock Exchange or the American Stock Exchange, or in accordance with the National Association of Securities Dealers Automated Quotation System.

* * * * *

(iv) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

* * * * *

(2) * * *

(i) No more than 40 percent of the value of the investment interests of each class of investment interests may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. (For purposes of paragraph (a)(2)(i) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.)

* * * * *

(vi) No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors.

(vii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the

entity if the investor uses any part of such loan to obtain the investment interest.

* * * * *

(3)(i) If the entity possesses investment interests that are held by either active or passive investors and is located in an underserved area, all of the following eight standards must be met—

(A) No more than 50 percent of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous 12-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity. (For purposes of paragraph (a)(3)(i)(A) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.)

(B) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(C) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(D) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(E) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross-referral agreement) to passive investors differently than to non-investors.

(F) At least 75 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period must be derived from the service of persons who reside in an underserved area or are members of medically underserved populations.

(G) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(H) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(ii) If an entity that otherwise meets all of the above standards is located in an area that was an underserved area at the time of the initial investment, but subsequently ceases to be an underserved area, the entity will be deemed to comply with paragraph (a)(3)(i) of this section for a period equal to the lesser of:

(A) The current term of the investment remaining after the date upon which the area ceased to be an underserved area or

(B) Three years from the date the area ceased to be an underserved area.

(4) For purposes of paragraph (a) of this section, the following terms apply. *Active investor* means an investor either who is responsible for the day-to-day management of the entity and is a bona fide general partner in a partnership under the Uniform Partnership Act or who agrees in writing to undertake liability for the actions of the entity's agents acting within the scope of their agency. *Investment interest* means a security issued by an entity, and may include the following classes of investments: shares in a corporation, interests or units in a partnership or limited liability company, bonds, debentures, notes, or other debt instruments. *Investor* means an individual or entity either who directly holds an investment interest in an entity, or who holds such investment interest indirectly by, including but not limited to, such means as having a family member hold such investment interest or holding a legal or beneficial interest in another entity (such as a trust or holding company) that holds such investment interest. *Passive investor* means an investor who is not an active investor, such as a limited partner in a partnership under the Uniform Partnership Act, a shareholder in a corporation, or a holder of a debt security. *Underserved area* means any defined geographic area that is designated as a Medically Underserved Area (MUA) in accordance with regulations issued by the Department. *Medically underserved population* means a Medically Underserved Population (MUP) in accordance with regulations issued by the Department.

(b) *Space rental.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following six standards are met—

* * * * *

(2) The lease covers all of the premises leased between the parties for the term of the lease and specifies the premises covered by the lease.

* * * * *

(6) The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

* * * * *

(c) *Equipment rental.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following six standards are met—

* * * * *

(2) The lease covers all of the equipment leased between the parties for the term of the lease and specifies the equipment covered by the lease.

* * * * *

(6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

* * * * *

(d) *Personal services and management contracts.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met—

* * * * *

(2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

* * * * *

(7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

* * * * *

(e) *Sale of practice.* (1) As used in section 1128B of the Act, ''remuneration'' does not include any payment made to a practitioner by another practitioner where the former practitioner is selling his or her practice to the latter practitioner, as long as both of the following two standards are met—

(i) The period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than one year.

(ii) The practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in part under Medicare or a State health care program after one year from the date of the first agreement pertaining to the sale.

(2) As used in section 1128B of the Act, ''remuneration'' does not include any payment made to a practitioner by a hospital or other entity where the practitioner is selling his or her practice to the hospital or other entity, so long as the following four standards are met:

(i) The period from the date of the first agreement pertaining to the sale to the completion date of the sale is not more than three years.

(ii) The practitioner who is selling his or her practice will not be in a professional position after completion of the sale to make or influence referrals to, or otherwise generate business for, the purchasing hospital or entity for which payment may be made in whole or in part under Medicare or a State health care program.

(iii) The practice being acquired must be located in a Health Professional Shortage Area (HPSA), as defined in Departmental regulations, for the practitioner's specialty area.

(iv) Commencing at the time of the first agreement pertaining to the sale, the purchasing hospital or entity must diligently and in good faith engage in commercially reasonable recruitment activities that:

(A) May reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within a one year period and

(B) Will satisfy the conditions of the practitioner recruitment safe harbor in accordance with paragraph (n) of this section.

(f) *Referral services.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value between an individual or entity (''participant'') and another entity serving as a referral service (''referral service''), as long as all of the following four standards are met—

* * * * *

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by either party for the other party for which payment may be made in whole or in part under Medicare or a State health care program.

* * * * *

(h) *Discounts.* As used in section 1128B of the Act, ''remuneration'' does not include a discount, as defined in paragraph (h)(5) of this section, on an item or service for which payment may be made, in whole or in part, under Medicare or a State health care program for a *buyer* as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section; a *seller* as long as the seller complies with the applicable standards of paragraph (h)(2) of this section; and an *offeror* of a discount who is not a seller under paragraph (h)(2) of this section so long as such offeror complies with the applicable standards of paragraph (h)(3) of this section:

(1) With respect to the following three categories of buyers, *the buyer must comply with all of the applicable standards within one of the three following categories*—

(i) If the buyer is an entity which is a health maintenance organization (HMO) or a competitive medical plan (CMP) acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, it need not report the discount except as otherwise may be required under the risk contract.

(ii) If the buyer is an entity which reports its costs on a cost report required by the Department or a State health care program, it must comply with all of the following four standards—

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;

(B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(C) The buyer must fully and accurately report the discount in the applicable cost report; and

(D) the buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section, or information provided by the offeror as specified in paragraph (h)(3)(ii) of this section.

(iii) If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare or a State health care program (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the buyer must comply with both of the following standards—

(A) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and

(B) the buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(iii)(B) of this section, or information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section.

(2) The seller is an individual or entity that supplies an item or service for which payment may be made, in whole or in part, under Medicare or a State health care program to the buyer and who permits a discount to be taken off the buyer's purchase price. The seller must comply with all of the applicable standards within the following three categories—

(i) If the buyer is an entity which is an HMO a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the seller must comply with either of the following two standards—

(A) Where a discount is required to be reported to Medicare or a State health care program under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph; or

(B) Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; when the value of the discount becomes

known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and refrain from doing anything which would impede the buyer from meeting its obligations under this paragraph.

(iii) If the buyer is an individual or entity not included in paragraph (h)(2)(i) or (h)(2)(ii) of this section, the seller must comply with either of the following two standards—

(A) Where the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed, the seller must provide, upon request by the Secretary or a State agency, information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section; or

(B) Where the buyer submits a claim, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.

(3) The offeror of a discount is an individual or entity who is not a seller under paragraph (h)(2) of this section, but promotes the purchase of an item or service by a buyer under paragraph (h)(1) of this section at a reduced price for which payment may be made, in whole or in part, under Medicare or a State health care program. The offeror must comply with all of the applicable standards within the following three categories—

(i) If the buyer is an entity which is an HMO or a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the offeror need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the offeror must comply with the following two standards—

(A) The offeror must inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such a discount and to provide information upon request under paragraph (h)(1) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's ability to meet its obligations under this paragraph.

(iii) If the buyer is an individual or entity in whose name a request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare or a State health care program (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the offeror must comply with the following two standards—

(A) The offeror must inform the individual or entity submitting the claim or request for payment in a manner reasonably calculated to give notice to the individual or entity of its obligations to report such a discount and to provide information upon request under paragraphs (h)(1) and (h)(2) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's or seller's ability to meet its obligations under this paragraph.

(4) For purposes of this paragraph, a *rebate* is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.

(5) For purposes of this paragraph, the term *discount* means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction. The term *discount* does not include—

(i) Cash payment or cash equivalents (except that rebates as defined in paragraph (h)(4) of this section may be in the form of a check);

(ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;

(iii) A reduction in price applicable to one payer but not to Medicare or a State health care program;

(iv) A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;

(v) Warranties;

(vi) Services provided in accordance with a personal or management services contract; or

(vii) Other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section.

(n) *Practitioner recruitment.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value by an entity in order to induce a practitioner who has been practicing within his or her current specialty for less than one year to locate, or to induce any other practitioner to relocate, his or her primary place of practice into a HPSA for his or her specialty area, as defined in Departmental regulations, that is served by the entity, as long as all of the following nine standards are met—

(1) The arrangement is set forth in a written agreement signed by the parties that specifies the benefits provided by the entity, the terms under which the benefits are to be provided, and the obligations of each party.

(2) If a practitioner is leaving an established practice, at least 75 percent of the revenues of the new practice must be generated from new patients not previously seen by the practitioner at his or her former practice.

(3) The benefits are provided by the entity for a period not in excess of 3 years, and the terms of the agreement are not renegotiated during this 3-year period in any substantial aspect; provided, however, that if the HPSA to which the practitioner was recruited ceases to be a HPSA during the term of the written agreement, the payments made under the written agreement will continue to satisfy this paragraph for the duration of the written agreement (not to exceed 3 years).

(4) There is no requirement that the practitioner make referrals to, be in a position to make or influence referrals to, or otherwise generate business for the entity as a condition for receiving the benefits; provided, however, that for purposes of this paragraph, the entity may require as a condition for receiving benefits that the practitioner maintain staff privileges at the entity.

(5) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

(6) The amount or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare or a State health care program.

(7) The practitioner agrees to treat patients receiving medical benefits or assistance under any Federal health care

program in a nondiscriminatory manner.

(8) At least 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA or a Medically Underserved Area (MUA) or who are part of a Medically Underserved Population (MUP), all as defined in paragraph (a) of this section.

(9) The payment or exchange of anything of value may not directly or indirectly benefit any person (other than the practitioner being recruited) or entity in a position to make or influence referrals to the entity providing the recruitment payments or benefits of items or services payable by a Federal health care program.

(o) *Obstetrical malpractice insurance subsidies.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a hospital or other entity to another entity that is providing malpractice insurance (including a self-funded entity), where such payment is used to pay for some or all of the costs of malpractice insurance premiums for a practitioner (including a certified nurse-midwife as defined in section 1861(gg) of the Act) who engages in obstetrical practice as a routine part of his or her medical practice in a primary care HPSA, as long as all of the following seven standards are met—

(1) The payment is made in accordance with a written agreement between the entity paying the premiums and the practitioner, which sets out the payments to be made by the entity, and the terms under which the payments are to be provided.

(2)(i) The practitioner must certify that for the initial coverage period (not to exceed one year) the practitioner has a reasonable basis for believing that at least 75 percent of the practitioner's obstetrical patients treated under the coverage of the malpractice insurance will either—

(A) Reside in a HPSA or MUA, as defined in paragraph (a) of this section; or

(B) Be part of a MUP, as defined in paragraph (a) of this section.

(ii) Thereafter, for each additional coverage period (not to exceed one year), at least 75 percent of the practitioner's obstetrical patients treated under the prior coverage period (not to exceed one year) must have—

(A) Resided in a HPSA or MUA, as defined in paragraph (a) of this section; or

(B) Been part of a MUP, as defined in paragraph (a) of this section.

(3) There is no requirement that the practitioner make referrals to, or otherwise generate business for, the entity as a condition for receiving the benefits.

(4) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

(5) The amount of payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare or a State health care program.

(6) The practitioner must treat obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(7) The insurance is a bona fide malpractice insurance policy or program, and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance. For purposes of paragraph (o) of this section, *costs of malpractice insurance premiums* means:

(i) For practitioners who engage in obstetrical practice full-time, any costs attributable to malpractice insurance; or

(ii) For practitioners who engage in obstetrical practice on a part-time or sporadic basis, the costs:

(A) Attributable exclusively to the obstetrical portion of the practitioner's malpractice insurance and

(B) Related exclusively to obstetrical services provided in a primary care HPSA.

(p) *Investments in group practices.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to a solo or group practitioner investing in his or her own practice or group practice if the following four standards are met—

(1) The equity interests in the practice or group must be held by licensed health care professionals who practice in the practice or group.

(2) The equity interests must be in the practice or group itself, and not some subdivision of the practice or group.

(3) In the case of group practices, the practice must:

(i) Meet the definition of ''group practice'' in section 1877(h)(4) of the Social Security Act and implementing regulations; and

(ii) Be a unified business with centralized decision-making, pooling of expenses and revenues, and a compensation/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers.

(4) Revenues from ancillary services, if any, must be derived from ''in-office ancillary services'' that meet the definition of such term in section 1877(b)(2) of the Act and implementing regulations.

(q) *Cooperative hospital service organizations.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made between a cooperative hospital service organization (CHSO) and its patron-hospital, both of which are described in section 501(e) of the Internal Revenue Code of 1986 and are tax-exempt under section 501(c)(3) of the Internal Revenue Code, where the CHSO is wholly owned by two or more patron-hospitals, as long as the following standards are met—

(1) If the patron-hospital makes a payment to the CHSO, the payment must be for the purpose of paying for the bona fide operating expenses of the CHSO, or

(2) If the CHSO makes a payment to the patron-hospital, the payment must be for the purpose of paying a distribution of net earnings required to be made under section 501(e)(2) of the Internal Revenue Code of 1986.

(r) *Ambulatory surgical centers.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor, as long as the investment entity is a certified ambulatory surgical center (ASC) under part 416 of this title, whose operating and recovery room space is dedicated exclusively to the ASC, patients referred to the investment entity by an investor are fully informed of the investor's investment interest, and all of the applicable standards are met within one of the following four categories—

(1) *Surgeon-owned ASCs*—If all of the investors are general surgeons or surgeons engaged in the same surgical specialty, who are in a position to refer patients directly to the entity and perform surgery on such referred patients; surgical group practices (as defined in this paragraph) composed exclusively of such surgeons; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or

expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each surgeon investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures (as defined in this paragraph).

(iii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(v) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vi) The entity and any surgeon investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(2) *Single-Specialty ASCs*—If all of the investors are physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices (as defined in this paragraph) composed exclusively of such physicians; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures (as defined in this paragraph).

(iii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(v) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vi) The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(3) *Multi-Specialty ASCs*—If all of the investors are physicians who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices, as defined in this paragraph, composed exclusively of such physicians; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following seven standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures (as defined in this paragraph).

(iii) At least one-third of the procedures (as defined in this paragraph) performed by each physician investor for the previous fiscal year or previous 12-month period must be performed at the investment entity.

(iv) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(vi) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vii) The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(4) *Hospital/Physician ASCs*—If at least one investor is a hospital, and all of the remaining investors are physicians who meet the requirements of paragraphs (r)(1), (r)(2) or (r)(3) of this section; group practices (as defined in this paragraph) composed of such physicians; surgical group practices (as defined in this paragraph); or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to refer patients directly or indirectly to the entity or any of its investors, all of the following eight standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iii) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(iv) The entity and any hospital or physician investor must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(v) The entity may not use space, including, but not limited to, operating and recovery room space, located in or owned by any hospital investor, unless

such space is leased from the hospital in accordance with a lease that complies with all the standards of the space rental safe harbor set forth in paragraph (b) of this section; nor may it use equipment owned by or services provided by the hospital unless such equipment is leased in accordance with a lease that complies with the equipment rental safe harbor set forth in paragraph (c) of this section, and such services are provided in accordance with a contract that complies with the personal services and management contracts safe harbor set forth in paragraph (d) of this section.

(vi) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vii) The hospital may not include on its cost report or any claim for payment from a Federal health care program any costs associated with the ASC (unless such costs are required to be included by a Federal health care program).

(viii) The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity.

(5) For purposes of paragraph (r) of this section, *procedures* means any procedure or procedures on the list of Medicare-covered procedures for ambulatory surgical centers in accordance with regulations issued by the Department and *group practice* means a group practice that meets all of the standards of paragraph (p) of this section. *Surgical group practice* means a group practice that meets all of the standards of paragraph (p) of this section and is composed exclusively of surgeons who meet the requirements of paragraph (r)(1) of this section.

(s) *Referral agreements for specialty services.* As used in section 1128B of the Act, *remuneration* does not include any exchange of value among individuals and entities where one party agrees to refer a patient to the other party for the provision of a specialty service payable in whole or in part under Medicare or a State health care program in return for an agreement on the part of the other party to refer that patient back at a mutually agreed upon time or circumstance as long as the following four standards are met—

(1) The mutually agreed upon time or circumstance for referring the patient back to the originating individual or entity is clinically appropriate.

(2) The service for which the referral is made is not within the medical expertise of the referring individual or entity, but is within the special expertise of the other party receiving the referral.

(3) The parties receive no payment from each other for the referral and do not share or split a global fee from any Federal health care program in connection with the referred patient.

(4) Unless both parties belong to the same group practice as defined in paragraph (p) of this section, the only exchange of value between the parties is the remuneration the parties receive directly from third-party payors or the patient compensating the parties for the services they each have furnished to the patient.

Dated: February 4, 1999.

June Gibbs Brown,

Inspector General.

Approved: June 9, 1999.

Donna E. Shalala,

Secretary.

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