

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991-AA49

Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions

Monday, July 29, 1991 (56 FR 35952)

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

ACTION: Final rule.

SUMMARY: This final rule implements section 14 of Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987, by specifying various payment practices which, although potentially capable of inducing referrals of business under Medicare or a State health care program, will be protected from criminal prosecution or civil sanctions under the anti-kickback provisions of the statute.

EFFECTIVE DATE: This regulation is effective on July 29, 1991.

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SUPPLEMENTARY INFORMATION:

I. Background

A. The Medicare Anti-Kickback Statute

Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)), previously codified at sections 1877 and 1909 of the Act, provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the Medicare 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.

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

Since the statute on its face is so broad, concern has arisen among a number of health care providers that many relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution.

B. Public Law 100-93

Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987, added two new provisions addressing the anti-kickback statute. Section 2 specifically provided new authority to the Office of Inspector General (OIG) to exclude an individual or entity from participation in the Medicare and State health care programs if it is determined that the party has engaged in a prohibited remuneration scheme. (Section 1128(b)(7) of the Act, 42 U.S.C. 1320a-7(b)(7)) This new sanction authority is intended to provide an alternative civil remedy, short of criminal prosecution, that will be a more effective way of regulating abusive business practices than is the case under criminal law.

In addition, section 14 of Public Law 100-93 requires the promulgation of regulations specifying those payment practices that will not be subject to criminal prosecution under section 1128B of the Act and that will not provide a basis for exclusion from the Medicare program or from the State health care programs under section 1128(b)(7) of the Act.

C. Notice of Intent

The legislative history of section 14 of Public Law 100-93 indicates that Congress expected the Department of Health and Human Services to consult with affected provider, practitioner, supplier and beneficiary representatives before promulgating regulations. In order to most effectively address issues related to this provision, we published a notice of intent to develop regulations (52 FR 38794, October 19, 1987) soliciting comments from interested parties prior to developing a proposed regulation. As a result of that notice, the OIG received a number of public comments, recommendations and suggestions on generic criteria that can be applied to particular types of business arrangements in order to determine if such arrangements are inappropriate for civil or criminal sanctions.

D. Notice of Proposed Rulemaking

The proposed regulation designed to implement section 14 of Public Law 100-93 was developed by the OIG and published in the Federal Register on January 23, 1989 (54 FR 3088). The regulation sets forth various proposed business and payment practices, or "safe harbors," that would not be treated as criminal offenses under section 1128B(b) of the Act and would not serve as a basis for a program exclusion under section 1128(b)(7) of the Act. As a result of that proposed rulemaking, we received a total of 754 public comments for consideration.

II. Summary of the Proposed Rule

A. Business Arrangements Not Exempt

The proposed regulation indicated that in order for a business arrangement to comply with one of the ten safe harbors, each standard of that safe harbor provision would have to be met. The proposed rule stated that if the business arrangement involves payments for different purposes (for example a single payment for personal services and for equipment rental) then each payment purpose would be analyzed to determine if all the standards of each applicable safe harbor provision have been fulfilled. The proposed rule further specified that where individuals and entities have entered into arrangements that are covered by the statute and where they have chosen not to fully comply with one of the exemptions proposed in these regulations, they would risk scrutiny by the OIG and may be subject to civil or criminal

enforcement action.

B. Need for Continuing Guidance

Since there may be a need for the Department to respond to changes in health care delivery or business arrangements more quickly and informally than through the regulatory process to keep the industry abreast of our enforcement policy, the proposed rule invited public comment on how we can best achieve the dual goals of keeping the industry aware of our views of particular business practices, and assuring that our regulations remain current with new developments.

C. Notice to Beneficiaries

While we considered including in several of the proposed safe harbor provisions a requirement that a person notify each Medicare or Medicaid patient he or she refers to a related entity of the financial relationship that exists, we indicated that such notice requirements may be unduly burdensome compared with the potential benefits and, therefore, did not include the requirement in the safe harbors in the proposed regulation. Instead, we invited public comments on this issue.

D. Preferred Provider Organizations

We cited the increasing variety of arrangements among entities grouped under the generic headings "preferred provider organizations" (PPOs) or "managed care," and that unlike HMOs, there is often no single entity that is recognized as the "health care provider." The proposed regulations did not specifically delineate a safe harbor provision for these arrangements since we believed that one or more of the other proposed safe harbors would often cover relationships in preferred provider and managed care networks. We invited comments from the public, however, on the idea of adding additional safe harbors that would provide further protection to HMOs, PPOs, and other managed care plans.

E. Waiver of Coinsurance and Deductible Amounts for Inpatient Hospital Care

We noted that with the advent in 1983 of the prospective payment system for paying hospitals for inpatient care, some hospitals have advertised the routine waiver of Medicare coinsurance and deductible amounts as a means of attracting patients to their facilities. We solicited comments on defining a safe harbor for waiving coinsurance and deductible amounts that would be limited to inpatient hospital care, be available to all Medicare beneficiaries without regard to diagnosis or length of stay, and assure that any costs to the hospital of waiving the coinsurance and deductible amounts would not be passed on to any Federal program as a bad debt or in any other way.

F. Proposed Safe Harbors

The regulation published on January 23, 1989, proposing to amend 42 CFR part 1001 by adding a new § 1001.952, set forth "safe harbors" in ten broad areas:

1. Investment Interests

To reflect the view that Congress did not intend to bar all investments by physicians in other health care entities to which they refer patients, a safe harbor provision was proposed for investment interests in large public corporations where such investments are available to the general public. This safe harbor described a minimum number of shareholders and a minimum number of assets the company must have in order to qualify under this provision.

Safe harbors for limited and managing partnerships were considered under the proposed regulation, but were not included. These areas were discussed in the preamble of the proposed rule, and we specifically requested public comments on adopting these practices as safe harbors.

2. Space Rental

While many rental arrangements are legitimate, many situations exist where rental payments are simply a device used to mask illegal payments intended to induce referrals. Accordingly, a safe harbor provision was proposed for rental arrangements if: (a) Access to the space is for periodic intervals and such intervals are set in advance in the lease, rather than based on the number of referred patients; (b) the lease is for at least one year so it cannot be readjusted on too frequent a basis to reflect prior referrals; and (c) the charges reflect fair market value.

3. Equipment Rental

With the understanding that the payment for the use of diagnostic and other medical equipment may simply be a vehicle to provide reimbursement for referrals, a safe harbor was proposed for certain situations involving equipment rentals similar to those applied to real estate rentals cited above.

4. Personal Services and Management Contracts

While health care providers often have arrangements to perform services for each other on a mutually beneficial basis, some of these arrangements may vary the payment with the volume of referrals. The proposed regulation set forth a safe harbor provision for joint ventures and other arrangements involving payments for personal services or management contracts, but only if certain standards are met that limit the opportunity to provide financial incentives in exchange for referrals. This proposed provision required the services to be paid at fair market value, and was predicated on requirements similar to those set forth in the provisions for space and equipment rental.

5. Sale of Practice

Unlike the traditional sale of a practice by a retiring physician, a physician may sell, or appear to sell, a practice to a hospital while continuing to practice on its staff. A safe harbor provision was proposed for the sale of physician practices when occurring as the result of retirement or some other event that removes the physician from the practice of medicine or from the service area in which he or she was practicing, but not when the sale is for the purpose of obtaining an ongoing source of patient referrals.

6. Referral Services

Professional societies and other consumer-oriented groups often operate referral services for a fee. Because such a service fee could be construed as a payment in order to obtain a referral, we concluded that it was appropriate to establish a specific safe harbor for this type of practice. In order to safeguard against abuse, however, the provision is only available when several standards are met.

7. Warranties

It is in the public interest to have companies offer warranties as an inducement to the consumer to purchase a product. A safe harbor was proposed for such purposes.

8. Discounts

Safe harbors relating to discounts, employees and group purchasing organizations are specifically required by statute. The discount exception was intended to encourage price competition that benefits the Medicare and Medicaid programs. The proposed discount provision was limited in application to reductions in the amount a seller charges for a good or service to the buyer. The discount could take the form of a specified price break, or the inclusion of an extra quantity of the item purchased "at no extra charge." We did not propose to protect many kinds of marketing incentive programs such as cash rebates, free goods or services, redeemable coupons, or credits.

9. Employees

The proposed exception for employees permitted an employer to pay an employee in whatever manner he or she chose for having that employee assist in the solicitation of program business and applied only to bona fide employee- employer relationships.

10. Group Purchasing Organizations

The proposed group purchasing organization (GPO) exception was designed to apply to payments from vendors to entities authorized to act as a GPO for individuals or entities who are furnishing Medicare or Medicaid services. The proposed exception required a written agreement between the GPO and the individual or entity that specifies the amounts vendors will pay the GPO.

III. Response to Comments and Summary of Revisions

As indicated above, in response to the proposed rulemaking we received 754 public comments from various provider groups, medical facilities, professional and business organizations and associations, medical societies, State and local government entities, private (35954) practitioners and concerned citizens. The comments included both general and broadreaching concerns regarding the impact of this regulation, and specific comments on those areas and safe harbor provisions about which we requested public input. A summary of the comments received and our responses to those comments follows.

A. General Comments

Comment: A large number of commenters expressed concern about the implication of engaging in a business arrangement that does not comply fully with a provision of this regulation. Some of these commenters expressed the view that the safe harbor provisions are narrowly drawn and leave many lawful business arrangements unprotected. Moreover, the preamble to the proposed rule warns: "[W]here individuals and entities have entered into arrangements that are covered by the statute, where they have chosen not to comply fully with one of the exemptions in these regulations, they would risk scrutiny by the OIG * * *." These commenters urged the OIG to make clear that the failure to comply fully with a safe harbor provision is not per se illegal, and does not mean that prosecution will automatically follow. In addition, they requested safe harbor protection for business arrangements where there has only been a "technical violation" of the statute, where there has been "substantial compliance" with this regulation, or where the remuneration in question is "de minimis."

Response: This regulation covers many categories of business arrangements, providing standards to be met within each safe harbor provision. If a person participates in an arrangement that fully complies with a given provision, he or she will be assured of not being prosecuted criminally or civilly for the arrangement that is the subject of that provision.

This 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, as we stated in the preamble to the proposed rule, 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 Medicare or Medicaid; 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 the 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 that 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.

We do not believe the Medicare and Medicaid programs would be properly served if we assured protection in all instances of "substantial compliance," "technical violations," or "de minimis" payments. Unfortunately, these are vague concepts, subject to differing interpretations. In this regulation, we have attempted to provide bright lines, to the extent possible, for safe harbors in order to provide clarity and predictability as to what conduct is immune from government action. Our endorsement of the concepts mentioned above would only serve to blur these lines and produce litigation as to what "substantial," "technical" and "de minimis" really mean. The OIG therefore declines to adopt these concepts.

A recent decision of the United States Court of Appeals for the First Circuit provides an indication of the litigation problems that could arise if "substantial compliance" with a safe harbor provision was all that was required. *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F.2d 20 (1st Cir., 1989) involved an arrangement between an employee of a city owned hospital (Felci) and an ambulance company (Bay State). Felci was involved in the administration of the city's ambulance service contract. During this period, Bay State retained Felci as a consultant, provided him with two automobiles, and paid Felci's consulting company several thousand dollars. When it came time for renewal of the ambulance contract, Felci used his position and influence at the city hospital to assist Bay State in securing the new contract. Felci was prosecuted and convicted under the statute.

In affirming Felci's conviction (as well as that of Bay State's president, Kotzen), the First Circuit rejected Felci's contention that he had substantially complied with this regulation as published as a notice of proposed rulemaking, and thus should not be prosecuted. The court found: "The proposed regulation does not exempt every transaction in which the amount paid for services is an amount consistent with fair market value; rather it exempts only a small subset of such transactions * * *. [U]nder the circumstances such as the present case where the consulting arrangement is not full-time, * * * stringent requirements are necessary to meet the exemption from criminal liability. HHS has thus decided not to create a safe harbor for transactions such as the present case." (Emphasis in original; footnote omitted) *Id.* 874 F.2d at 31.

Comment: Several commenters described business arrangements that technically may violate the statute,

but do not increase costs to the Medicare or Medicaid programs, or otherwise injure beneficiaries. They requested safe harbor protection for these arrangements because of concern of their risk of being scrutinized.

Response: Increased cost to the Medicare and Medicaid programs and harm to beneficiaries are not the only criteria we look at in determining whether a particular business arrangement is abusive. As the court in *United States v. Ruttenberg*, 625 F.2d 173, 177, n.9 (7th Cir. 1980) noted:

[T]he law does not make increased cost to the government the sole criterion of corruption. In prohibiting "kickbacks," Congress need not have spelled out the obvious truisms that, while unnecessary expenditure of money earned and contributed by taxpaying fellow citizens may exacerbate the result of the crime, kickback schemes can freeze competing suppliers from the system, can mask the possibility of government price reductions, can misdirect program funds, and, when proportional, can erect strong temptations to order more drugs and supplies than needed.

Furthermore, it is unfortunately not possible to provide safe harbor protections for all business arrangements that are not abusive. There are certain arrangements that, although themselves legitimate, are structurally so similar to abusive arrangements that protection by way of new safe harbor provisions will inevitably also protect abusive practices as well. For example, equipment rental arrangements made between parties in a position to make and accept referrals do not receive safe harbor protection if the payments are based on utilization (sometimes known as a "wear and tear" clause). We recognize that equipment becomes less valuable the more it is used, and that its owner deserves compensation for such wear and tear. However, it is also a relatively easy matter to disguise such a wear and tear payment as a payment for referrals. Thus, we need to examine the intent of the parties on a case-by-case basis even though a large majority of such payments may represent only legitimate compensation to the owner of the equipment.

The recent case, *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, discussed above, emphasizes that the gravamen of a violation of the statute is "inducement" and not necessarily the structure of the arrangement. *Id.* 874 F.2d at 29. Thus, such case by case inquiries must necessarily focus on the intent of the parties.

The *Bay State Ambulance* case also illustrates the risk health care providers engage in when they enter into a business arrangement that violates the statute, but try to argue that the arrangement does not increase program costs or result in overutilization. The First Circuit rejected the defendants' arguments that there would have been no fiscal drain on public programs because ambulance services and Medicare reimbursement would have been required no matter which ambulance service company had received the contract. The court noted that it was unclear whether Medicare paid Bay State more for these services than it would have paid to the losing bidder even though that bidder's charges were lower. The court observed: "Although the reason for enacting the statute was to prevent drains on the public fisc, the statute does not require that there be a drain on the public fisc in order for payments to be illegal." *Id.* n.21, 874 F.2d at 32.

Comment: Numerous commenters expressed concern about the difficulty in revising a business arrangement that they entered into with a good-faith belief that the arrangement did not violate the statute, but which they now find does not qualify under one of the safe harbor provisions. They suggested that the OIG either "grandfather" these arrangements or provide a reasonable period of time before initiating enforcement action to enable health care providers to restructure their arrangements to meet the safe harbor provisions.

Response: The failure of a particular business arrangement to comply with these provisions does not

determine whether or not the arrangement violates the statute because, as we stated above, 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 believed 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 to the parties to such arrangements.

Nonetheless, we believe that it would be inappropriate for us to provide a blanket protection, even for a limited period of time, for all business arrangements that do not qualify for a safe harbor. As we stated above, certain business arrangements that do not qualify may warrant immediate enforcement action.

Comment: Many commenters discussed the interrelationships between these safe harbor provisions and reimbursement rules promulgated by the Health Care Financing Administration (HCFA). A few of these commenters appeared to suggest that if a health care provider complied with a particular safe harbor provision, then its reimbursement may be affected.

Response: We wish to emphasize that nothing in this regulation changes reimbursement rules promulgated by HCFA or a State health care program. Clearly if a provider chooses to engage in one course of conduct in order to comply with these safe harbor provisions, such action may very well have reimbursement implications. However, such reimbursement is governed exclusively by HCFA or State regulations, and not by this regulation.

Comment: Several commenters requested that the OIG publish this regulation with an additional comment period because of the complexity of the issues involved and the revisions or additions of new safe harbor provisions created as a result of the comments.

Response: We believe that the disadvantages of providing an additional comment period outweigh the benefits. As we stated above, we received extensive comments in response to this proposed rule. In addition, due to the novelty and complexity of these issues, we started this process with a special notice of intent to develop regulations, (52 FR 38794, October 19, 1987) and received over 150 comments, which we used to develop the proposed rule.

Also weighing against any benefit of receiving additional comments on this rule is the desirability of providing the level of certainty that accompanies a final rule. This will permit individuals and entities to structure business arrangements under the provisions of this rule with the assurance that it will not change in the near future. Such assurance is delayed somewhat by providing an additional comment period.

We acknowledge the congressional expectation that we should "formally re- evaluate the anti-kickback regulations on a periodic basis, and, in so doing, * * * solicit public comment at the outset of the review process." H.R. Rep. No. 85, part 2, 100th Cong. 1st Sess. 27 (1987). We believe it is most appropriate to allow all parties time to obtain experience with these safe harbor provisions in their final form before we solicit additional public comments to start our formal re-evaluation process.

Nonetheless, we received many comments requesting safe harbor protection for a number of business arrangements, many of which deserve safe harbor protection. As discussed in more detail below in section III.B.3. of this preamble, the comments we received on HMOs, PPOs, and other managed care

plans warrant the creation of two new safe harbor provisions. Because of the lack of specificity in those comments, we expect to publish these provisions as a separate interim final regulation at a later date. While this provision will be effective upon publication, the public will have an opportunity to submit their specific comments and concerns regarding this new safe harbor.

In addition, as discussed in more detail below in section III.B. of this preamble, many other arrangements brought to our attention were for arrangements on which we did not solicit comments. Because some of these arrangements may deserve safe harbor (35956) protection, we anticipate publishing additional safe harbor provisions in a separate notice of proposed rulemaking. Any discussion below indicating that we are considering a new safe harbor provision should in no way be construed as legalizing the business arrangement at this time.

Comment: Numerous commenters suggested that the OIG should employ a cease and desist mechanism. Some suggested that the OIG should be required to employ such a mechanism before it initiates a criminal prosecution or program exclusion. Others supported the use of this mechanism because they believed that many business arrangements that violate the statute do not warrant prosecution but should be stopped.

Response: We do not have the authority to seek or issue a legally enforceable order directing a person to cease and desist from a particular unlawful kickback activity. We recognize that there may be situations where it may be appropriate to inform a person that he or she is violating the statute, and request that the unlawful activity be stopped. Where the person takes immediate action to conform his activity to the law, we may decide that no further action is warranted. However, there may be other situations where criminal prosecution is appropriate even though the person has stopped the illegal activity. Since we lack the power to issue or seek a legally enforceable cease and desist order, we cannot rely on that mechanism as a significant enforcement tool.

Comment: Three commenters suggested that because many business arrangements will not meet the safe harbor provisions, the regulation was of limited value. They suggested that health care providers would be better aided if the OIG would provide examples of arrangements that violate the statute.

Response: As we stated above, the purpose of this regulation is not to describe illegal conduct, but rather to set forth standards for certain safe harbors. If an individual or entity engages in a business arrangement that is the subject of a safe harbor provision and complies with all of its provisions, that individual will be assured that he or she will not be prosecuted. However, we recognize the desirability of communicating to the public the existence of other business practices and arrangements that we believe are subject to serious abuse. Accordingly, we issued a special OIG Fraud Alert on joint venture arrangements that described various suspect features of these business ventures that may result in a violation of the statute. As the need arises, we intend to issue other fraud alerts that will provide guidance to the public on other types of arrangements.

Comment: In seeking guidance with respect to transactions or practices not covered by any specific safe harbor provision, many commenters requested the OIG to include within this regulation a list of generic criteria it would consider in evaluating business arrangements under the statute. These commenters cite a variety of positive and negative factors as relevant generic criteria, including on the positive side whether the arrangement has "a legitimate business purpose" or promotes the delivery of needed services, particularly to indigent, elderly, or rural populations; and on the negative side whether the arrangement promotes overutilization, interferes with patient freedom of choice, diminishes the quality of care provided, or increases costs to beneficiaries or to the government. Some commenters pointed out that the legislative history of Public Law 100-93 directs the Department to include in the rules "any generic criteria that might apply to business arrangements generally." H.R. Rep. No. 85, part 2, 100th Cong., 1st

Sess. 27 (1987).

Response: We believe the same generic criteria applicable to all business arrangements would not provide useful guidance to the extent that they are based on value judgments regarding the relative advantages (e.g., lower cost or improved accessibility) and disadvantages (e.g., higher cost or overutilization) of the arrangement. It would be virtually impossible to set forth rules describing how we intend to apply them. For example, the determination of whether a joint venture has a legitimate business purpose, is a matter of subjective judgment, and we believe the use of such criteria would invite litigation because health care providers will not be sure if they are complying with them.

An example of the problems in using these types of generic criteria can be seen if we attempted to provide safe harbor protection for business arrangements that have a "legitimate business purpose." The statute proscribes the giving of rebates as a form of remuneration to induce referrals. Yet rebates are legitimate and common business practices outside the health care services business sector. For the numerous people who engage in both health care and non-health care lines of business, they may have become accustomed to providing various inducements to others in their non-health care activities. They may now start to provide similar inducements in their health care lines of business in a manner that violates the statute. To them, these inducements have a "legitimate business purpose," that is, to gain referrals and thereby make money, yet the practice is expressly prohibited by the statute.

We believe that Congress did not require us to specify such generic criteria. The House Committee Report so often cited by commenters directs us to promulgate rules that, "to the extent practical, contain * * * any generic criteria that might apply to business arrangements generally." *Id.* We believe that we have done so. It was only practical to include generic criteria for specific categories of arrangements, such as "fair market value" in the "space rental" safe harbor. We have concluded, however, that a single set of standards for all business arrangements would be of extremely limited value because the subjectivity or arbitrariness in applying the standards to individual fact situations would make such standards of extremely limited value.

We recognize that some of the factors cited by commenters are useful in determining the extent to which a particular arrangement is abusive, and therefore likely to be prosecuted. For example, the more an arrangement involving remuneration offered to induce referrals increases Medicare or Medicaid program costs or results in unnecessary utilization, the more likely it would be that we would have an interest in prosecuting the offense. It must be emphasized that these are not the only factors upon which a determination regarding prosecution is based, and as we have noted "the statute does not require that there be a drain on the public fisc in order for payments to be illegal." *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, *supra*, 874 F.2d at 32, n. 21.

Comment: Several commenters objected to the regulation because they believed that the OIG had exceeded its statutory authority. In particular, they commented that the OIG does not have authority under section 14 of Public Law 100-93 to narrow the scope of the statutory exceptions, particularly the "discount" exception of section 1128B(b)(3)(A) of the Act. They cited the last sentence of section 14(a) which states, "Any practices specified in regulations pursuant to [sec. 14 of Pub. L. 100-93] shall be in addition to the practices described in subparagraphs (A) through (C) of section 1128B(b)(3)." This sentence led some commenters to conclude that our regulatory authority does not permit us to refine or clarify the statutory exceptions.

Response: We believe that these commenters have misconstrued the intent of this sentence. The plain language of the first sentence of section 14(a) of Public Law 100-93 requires the Secretary to promulgate regulations "specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) of the Social Security Act and shall not serve as the basis for an exclusion under section 1128

(b)(7) of such Act." We believe that the second sentence, which was quoted by many commenters, requires us to add to the exceptions provided in section 1128B(b)(3) of the Act. But we do not believe the intent of this sentence is to prohibit us from interpreting statutory terms used in these exceptions. The clear congressional intent behind the development of these safe harbor provisions is to define innocuous arrangements that should not be prosecuted, including the statutory exceptions. We believe it is in the public interest to provide the health care community with our interpretation of the meaning of certain important statutory terms, for example, "appropriately reflect" in the discount exception or "bona fide employment relationship" in the employee-employer exception.

Comment: One commenter asked the OIG to clarify how it expects health care providers to comply with this regulation when it engages in a business arrangement that may be covered by two or more of the provisions of this regulation.

Response: This comment addresses two potential situations. The first situation arises where a payment practice serves a single purpose (e.g., compensation for personal services), but potentially fits into more than one safe harbor (e.g., the employer-employee safe harbor and the personal services and management contracts safe harbor). In this situation, if the payment practice fits into either one of the safe harbors, it is exempt from criminal prosecution and program exclusion. In the example given, if the payment practice does not qualify as a bona fide employment relationship, it still may receive safe harbor protection under the personal services and management contract safe harbor.

The second situation arises where a payment practice serves multiple purposes (e.g., a payment to recompensate another party for personal services and equipment rental). Under these circumstances, it will be necessary to examine each aspect of the payment practice to determine compliance with each respective safe harbor provision. A person engaged in a "multi-purpose" payment practice who seeks protection will need to document separately his or her compliance with the safe harbor applicable to each purpose being served by the payment practice. Compliance with one provision (for one of the purposes of the payment practice) would not insulate the entire payment practice from criminal prosecution or program exclusion, where another purpose of the payment practice is implemented in a manner which violates the statute.

In the provision-by-provision analysis in section III.C. below, we will discuss specific comments and our responses to other special issues regarding the interrelationships of these provisions.

Comment: Two commenters requested that the OIG clarify the relationship between the statute and various State laws.

Response: Issues of state law are completely independent of the federal anti-kickback statute and these regulations. There is no federal preemption provision under the statute. Thus, conduct that is lawful under the federal anti-kickback statute or this regulation may still be illegal under State law. Conversely, conduct that is lawful under State law may still be illegal under the federal anti-kickback statute.

Comment: We received many comments on the proposed "Ethics in Patient Referrals Act" then pending in Congress aimed at restricting physicians from referring patients to entities in which they have a financial interest, the so-called "Stark Bill." Many of these commenters asked the OIG to either support or oppose this legislation. Others asked the OIG to clarify the relationship of this legislation to the anti-kickback statute and this regulation.

Response: This legislation was enacted as section 6204 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101-239, adding a new section 1877 to the Act. With numerous exceptions, it generally restricts physicians from making referrals for clinical laboratory services to entities in which they have an

ownership or other compensation arrangement. These referral restrictions become effective on January 1, 1992.

The legislation, although in many respects aimed at the same problems as we are addressing in this regulation, requires different elements of proof and has different remedies than under the anti-kickback statute. Generally, section 1877 is violated when a "financial relationship" exists between an entity furnishing clinical laboratory services and a physician, and a referral is made or a claim or bill is presented. For the anti-kickback statute to be violated, it must be shown that the remuneration between the two parties was intended to induce the referral of business payable under Medicare or Medicaid. Whereas the anti-kickback statute contains criminal penalties, violations under section 1877 will result in a denial of payment and may result in the imposition of civil money penalties and program exclusions under section 1128A of the Act.

Because of these differences between the two provisions, the conference report includes the following clarification:

The conferees wish to clarify 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. The conferees do not intend that this provision should be construed as affecting, or in any way interfering, with the efforts of the Inspector General to enforce current law, such as cases described in the recent Fraud Alert issued by the Inspector General. In particular, entities which would be eligible for a specific exemption would be subject to all of the provisions of current law.

H.R. Conf. Rep. 239, 101st Cong., 1st sess. 856 (1989).

This clear expression of legislative intent to keep enforcement under the anti-kickback statute separate from enforcement under section 1877 makes it inappropriate to adjust our safe harbor provisions to take into account any exception or prohibition under section 1877.

Comment: Thirty-three commenters reacted to our comments in the preamble of the proposed rule regarding the breadth and scope of the statute. Fourteen commenters suggested that these regulations should in no way undermine the scope or strength of the statute. These commenters believe that by adding the civil exclusion remedy for the kickback violations as part of Public Law 100- 93, Congress sent a clear and appropriate message to the health care community not to place financial considerations above beneficiaries' interests. Two commenters requested that the statute's term "to refer" should be defined. Other commenters were concerned that diminishing the reach of the statute would create conflicts of interest between health care providers and their patients, and impugn the professional image of physicians. A few commenters opposed the implementation of any safe harbor provisions whatsoever.

Response: Our charge from Congress under section 14 of Public Law 100-93 is to clarify what payment practices will not subject a person to criminal prosecution or exclusion from the Medicare or State health care programs. The process involves both a determination of the scope of the statute and decisions as to how to draft the safe harbor provisions so that they protect only non-abusive relationships.

With respect to the scope of the statute, we do not believe that it is necessary to define any of the statute's terms in the regulation itself. However, the meaning of two of its terms deserve comment (1) "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind;" and (2) "to induce." These terms demonstrate congressional intent to create a very broadly worded prohibition. Our comments in the preamble to the proposed rule reflected our belief that Congress ratified this intent in their mandate to create these safe harbor provisions.

Congress's intent in placing the term "remuneration" in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever. The statute's language makes clear that illegal payments are prohibited beyond merely "bribes," "kickbacks," and "rebates," which were the three terms used in the original 1972 statute. The language "directly or indirectly, overtly or covertly, in cash or in kind" makes clear that the form or manner of the payment includes indirect, covert, and in kind transactions. Moreover, the statutory exception for discounts demonstrates that Congress prohibited transactions where there is no direct payment at all from the party receiving the referrals.

The remuneration in a discount is merely a lowered price that a purchaser would otherwise obtain from a seller, which is made as an inducement to purchase larger quantities.

The statute's legislative history supports this reading of the term "remuneration," and makes clear that the fundamental analysis required of a trier of fact is "to recognize that the substance rather than simply the form of a transaction should be controlling" (123 Cong. Rec. 30,280 (1977), Statement of Chairman of the House Committee on Ways and Means and principal author of H.R. 3, Representative Rostenkowski). Also see H.R. Rep. No. 393, part II, 95th Cong., 1st Sess. 53; reprinted in (1977) U.S. Code Cong. & Ad. News 3056; S.Rep. No. 453, 95th Cong., 1st Sess. 12 (1977).

The meaning of the term "to induce," which describes the intent of those who offer or pay remuneration in paragraph (2) of the statute, is found in the ordinary dictionary definition: "to lead or move by influence or persuasion" (The American Heritage Dictionary (2d College Ed. 1982)).

The OIG's interpretation of the statute is fully supported by its case law. At the time that the proposed rule was issued, the leading case interpreting the breadth of the statute was *United States v. Greber*, 760 F.2d 68 (3d Cir.) *cert. denied*, 474 U.S. 988 (1985). Since publication of the notice of proposed rulemaking on January 23, 1989, two other circuit courts have lent further support to a broad reading of the statute: *Bay State Ambulance*, which was discussed above, and *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989).

Kats involved an arrangement between physician offices or clinics, a phlebotomy service ("THC"), and a clinical diagnostic laboratory ("Tech-Lab"). Under the arrangement, THC collected blood and urine samples from physician offices and medical clinics, and forwarded these laboratory specimens to Tech-Lab. Tech-Lab performed the laboratory tests and billed the respective insurance programs, including Medicare and Medicaid. Tech-Lab kicked back 50 percent of its proceeds to THC, which in turn kicked back part of its proceeds to the various physician offices and clinics, including a clinic owned by Yan Kats. Kats and others were prosecuted and convicted under the statute.

In upholding Kats's conviction, the United States Court of Appeals for the Ninth Circuit became the first court specifically to adopt the holding in *Gerber* that "if one purpose of the payment is to induce future referrals, the [M]edicare statute has been violated." 760 F.2d at 69. The *Kats* court held that the statute is violated unless the payments are "wholly and not incidentally attributable to the delivery of goods or services." *Id.* 871 F.2d at 108. The court upheld a jury instruction that read, in part, "It is not a defense that there might have been other reasons for the solicitation of a remuneration by the defendants, if you find that one of the material purposes for the solicitation was to obtain money for the referral of services." *Id.* 871 F.2d at 108, n.1.

Because the statute is broad, the payment practices described in these safe harbor provisions would be prohibited by the statute but for their inclusion here. In mandating this regulation, Congress directed us to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements. We believe that we have accomplished this task in a manner that will not restrict our ability to prosecute, either criminally or civilly, abusive schemes that

violate the statute. However, these safe harbor provisions do not constitute a guarantee that a health care provider whose practice conforms to a particular safe harbor will not engage in abusive practices. For this reason, we intend to monitor business arrangements that comply with the terms of these safe harbor provisions, particularly investment interests (see section III.C.1.b.ii. below), to determine whether abusive arrangements exist within the parameter of a particular safe harbor. If abusive arrangements are found to exist, we will entirely withdraw or modify any provision as appropriate.

Comment: A small number of commenters requested clarification as to whether the statute prohibits remuneration in return for referrals or other arrangements to induce services or items reimbursed under Medicare alone, or whether the conduct prohibited by the statute includes referrals or other arrangements to induce services or items reimbursed by Medicaid and other State health care programs.

Response: We agree that clarification is needed, and have amended the final rule to make clear that the statute, and hence these safe harbor provisions, apply to items or services which may be paid in whole or in part under Medicare or a federally funded State health care program, such as Medicaid. However, because commenters have expressed particular concern about the applicability of these provisions to items and services payable under the Medicare and Medicaid programs, our discussion of comments and responses often refer solely to these two programs.

B. Comments on Areas That the OIG Invited Comments

In this section, we discuss four issues on which we specifically invited public comments: continuing guidance, notice to beneficiaries, preferred provider organizations (PPOs), and waiver of coinsurance and deductible amounts for inpatient hospital care. We also requested comments on suggested standards for two additional investment interest provisions that would protect investors, such as limited and general partners, investing in small entities. Our discussion of those comments and our responses are contained in the provision-by-provision analysis of investment interests (see section III.C.1. below).

1. Continuing Guidance

Comment: We received a large number of responses to our invitation for comments on how the OIG can best inform health care providers about fraudulent practices, and can best ensure that the safe harbor regulation remains current as new health care business practices develop. Many of these commenters suggested that the Department issue advisory opinions about the legality of proposed business arrangements under the statute. Some commenters requested that the Department implement a mechanism for informing health care providers about business practices that raise problems under the statute.

Proponents of advisory opinions argued that such a mechanism would provide guidance concerning activities unaddressed by the safe harbor regulation, curb illegal payment practices, and keep the Department informed of industry developments. These commenters asserted that the Department has authority to issue advisory opinions pursuant to its general statutory authority to promulgate regulations, and pursuant to the specific authority under Public Law 100-93 to promulgate this regulation. The commenters contended that advisory opinion rulings would not hamper the Department of Justice's prosecutorial discretion under the statute, because the immunizing effects of advice given would be limited to the facts disclosed. The commenters also claimed that several other agencies employ advisory opinion procedures in administering laws under their respective jurisdictions.

Response: We understand and appreciate providers' desire for legal security in their business relations. Consistent with our mandate under Public Law 100-93, we will continue to make efforts to inform health care providers about business practices that may subject them to criminal prosecution or program

exclusion.

We have concluded that we will not provide a mechanism responding to individual requests for advisory opinions about the legality of a particular business arrangement under the statute. The statute is primarily a criminal statute, and the Department of Justice is vested with exclusive authority to enforce all criminal laws of the United States. See sections 516, 519 and 547 of title 28 of the United States Code. A plethora of case law holds that this exclusive authority extends to all decisions to initiate, or to decline to initiate, criminal prosecutions. See *Smith v. United States*, 375 F.2d 243, 247 (4th Cir. 1967), *cert. denied* 389 U.S. 841; *Powell v. Katzenbach*, 359 F.2d 234 (D.C. Cir. 1965), *cert. denied* 384 U.S. 906; *United States v. Wong Kim Bo*, 466 F.2d 1298 (5th Cir. 1972); *United States v. Kysar*, 459 F. 2d 422 (10th Cir. 1972). For these reasons, this Department cannot, through advisory opinions, immunize health care providers from criminal prosecution under the statute.

The general or specific statutory authorizations cited by commenters do not supersede the case law cited above. The Department's general authority as an executive agency to promulgate regulations governing conduct within the Department's jurisdiction does not, implicitly or explicitly, include authority to make judgments that are within the exclusive domain of another agency. Neither does our mandate, under Public Law 100-93, to promulgate this regulation provide such authority. Our charge to immunize, by regulation, conduct and arrangements potentially falling under the statute does not include judging whether the conduct of particular individuals violates the statute.

Aside from these legal impediments, it is impossible as a practical matter to give meaningful advice with respect to liability under the statute in the context of a letter ruling. The statute requires proof of a knowing and willful intent to induce or arrange for referrals or for other business reimbursable under the Medicare or Medicaid programs. See *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, *supra*, 874 F.2d at 29 ("The gravamen of Medicare Fraud is inducement"); *United States v. Greber*, 760 F. 2d 68 at 71 ("The statute is aimed at the inducement factor"). Thus, the extent to which conduct is motivated by inducing or arranging for referrals will, in large part, determine liability under the statute. The types of factual summaries that typically accompany requests for advisory opinions--descriptions of proposed management contracts or lease agreements, or prospectuses of joint ventures--are likely, however, to be insufficient for purposes of understanding the motives of the parties.

In our experience, assessing whether parties to a particular scheme intend to induce referrals requires substantial investigation resources. Requests for advice typically do not furnish complete and objective accounts of all the facts necessary to determine the subjective intent of the parties. In addition, requests for advice involving business arrangements not yet consummated are especially difficult to analyze because the motives of the parties to induce referrals often become apparent only when the arrangement is operational.

Furthermore, we do not believe that an advisory opinion process is a necessary or appropriate mechanism for keeping the Department aware of new developments in industry business practices, and ensuring that the regulation remains current. As we have discussed above, the legislative history of Public Law 100-93 clearly directs the Secretary to "formally re-evaluate the anti-kickback regulations on a periodic basis and, in so doing, * * * solicit public comment at the outset of the review process." H.R. Rep. No. 85, *supra*, at 27. We believe that periodic updating of this regulation, with the opportunity for public input, is the best way to ensure that these regulations remain practical and relevant in the face of changes in health care delivery and payment arrangements. The need to clarify, interpret, fine tune, expand, or otherwise alter this regulation in response to public and industry input will provide an occasion for us to respond to unanticipated, newly developing, or other beneficial arrangements.

Despite commenters' arguments that other Federal agencies offer the public mechanisms for obtaining

advisory opinions, only one other agency of which we are aware, the Federal Elections Commission (FEC), provides any advice with respect to a statutory provision that prohibits "knowing and willful" conduct. The FEC issues such advice under specific statutory authority (2 U.S.C. 437d(a)(7)). It is our understanding, however, that the FEC's advisory opinions do not inquire into whether any conduct is knowing and willful. Thus, the FEC's practice follows the general rule that agencies will refrain from rendering prospective advice on issues of intent. For example, the IRS has stated that it will not issue advice as to the "due diligence" or "good-faith" of parties. See Rev. Proc. 88-3, 1988-1 IRB 29.

As an alternative, we believe that OIG fraud alerts are the best mechanism for imparting practical and continuing guidance to individuals and entities seeking to avoid violations of the statute. The fraud alert program, implemented in March of 1984, was designed to increase our effectiveness in preventing fraud in this Department's programs by highlighting conduct likely to be illegal. Since 1984, we have issued over 100 fraud alerts on subjects unrelated to the anti-kickback statute. On April 24, 1989, we initiated distribution of a Special Fraud Alert on Joint Venture Arrangements to all individuals and entities participating in Medicare, which gave examples of specific characteristics of provider-owned entities that, in our view, might result in abusive or unlawful business arrangements. By identifying what we consider to be suspect features of limited partnerships and other joint ventures (including potentially abusive practices for selecting and retaining investors, for structuring the legal entity or entities involved, and for distributing profits), the Special Fraud Alert communicated our views about the legitimacy of potential or existing ownership arrangements. We believe that fraud alerts can be equally as educational about other areas of enforcement of the statute, and plan to distribute similar information as the need arises.

Comment: A few commenters inquired about the binding effect of advisory letters written by HCFA in the 1970s, when that agency was responsible for enforcing the statute. The commenters suggested that these letters may serve to protect health care providers who engage in a particular business arrangement that was approved by HCFA at that time even though the OIG has not now proposed a safe harbor for that arrangement.

Response: No person in the Department or with the fiscal intermediaries or carriers is, or ever has been, authorized to permit a practice that the statute makes illegal. The Department's lack of authority to provide legal advice on the application of the statute to specific factual situations has been consistently communicated to the public for years. Consequently, no person may reasonably rely on any such advice, especially when that advice is a letter written to a third party about a business arrangement different from the one in which the party is engaging. In sum, the so-called advisory letters may not be regarded in any way as authoritative.

The only authority to legalize conduct is this safe harbor regulation. This regulation supersedes any prior communications from the Department regarding business practices considered not subject to prosecution, and is the only formal mechanism to set forth business arrangements or payment practices that will not be prosecuted under the statute.

Comment: Two commenters requested the OIG to issue selective opinions on issues affecting a class of providers that arise under the statute and safe harbor regulations, even if we decline to provide advice about specific business arrangements or activities.

Response: As we have said, we plan to provide guidance on generic issues through fraud alerts distributed to the provider community. In addition, we remain open to examining the usefulness of other mechanisms for informing the public and health care provider groups about the types of new business arrangements to which the OIG will give investigative priority.

2. Notice to Beneficiaries

Comment: Commenters overwhelmingly supported requiring health care providers to disclose to patients any financial relationships with sources of referral. They argued that such disclosure would not be burdensome, and that many codes of professional ethics, as well as many state statutes, already mandate such disclosure.

Response: With one exception, we have decided not to require such disclosure to qualify under a particular safe harbor provision. First, the activities covered under each safe harbor provision are by definition activities that we deem have a low potential for abuse. Second, disclosure in and of itself would not provide a significant additional assurance that abuse would not occur, even though disclosure may reduce the potential for abuse somewhat by increasing consumer awareness of the relationship between health care providers. Finally, it is possible for a health care provider to cast a disclosure to fit that provider's promotional objective, which is exactly the opposite result from that which we would want to achieve.

The one provision in which we condition safe harbor protection on disclosure is that of referral services. Referral services help beneficiaries make their initial contact with the health care system before a relationship of trust is established with a particular health care provider. Without disclosure of the manner in which a provider of services was selected or rejected by a referral service and the relationship between the service and health care providers, a consumer has very little information upon which to base his or her trust in the practitioner to whom the consumer is being referred. For example, a consumer may well decide to put more trust in a surgeon referred by the referral service if the consumer knew that the referral service only uses board certified physicians. On the other hand, a consumer may feel less confidence in a referral if any physician, no matter what his or her disciplinary record, were one of the referral service's members. Consequently, we are confident that, in this instance, disclosure represents a meaningful added protection.

Although we are not requiring disclosure of financial interests under the other safe harbor provisions, we consider disclosure of financial interests in entities to which health care providers refer patients an ethical duty (See, for example, rule 8.03 of the Current Opinions of the Council on Ethical and Judicial Affairs of the American Medical Association, Chicago, Ill. 1989). Also, to the extent that disclosure affects a patient's freedom of choice and quality of care, it may be necessary to enable a patient to give informed consent.

3. Health Maintenance Organizations, Preferred Provider Organizations and Other Managed Care Plans

We received a number of responses to our invitation to comment on how to protect health maintenance organizations (HMOs), preferred provider organizations (PPOs), and other managed care plans. In addition, we received many other comments regarding HMOs that waive coinsurance and deductible amounts, and price reduction agreements negotiated by these and other types of health benefit plans. We are including these comments in this section.

Comment: Two commenters requested safe harbor protection for HMOs that waive the beneficiary's obligation to pay coinsurance and deductible amounts. They believed that this was a common practice among HMOs. In addition, a few commenters pointed out that some PPOs negotiate agreements with contract health care providers for those providers not to charge the health plan or enrollee for some or all of the coinsurance and deductible amounts they are owed for furnishing services to enrollees. Under such an agreement, when the contract provider bills the Medicare program directly (and not the health plan) and agrees to waive all coinsurance and deductibles, the commenters typically phrased the agreement as one "to accept Medicare payment as payment in full." One commenter specifically objected to this

practice.

Response: We agree that protection should be given to prepaid plans with contracts and agreements with HCFA and State agencies for waiver of beneficiary obligations to pay coinsurance and deductible amounts. However, as will be discussed below, we do not agree that such protection is warranted at this time for PPOs and prepaid plans that do not have contracts or agreements with HCFA or State agencies.

Health plans offer a variety of incentives to attract beneficiaries to become enrollees. In many instances, HCFA permits such HMOs and competitive medical plans (CMPs) to waive the premiums attributable to the coinsurance and deductible amounts. Further, HMOs and CMPs under a risk contract with HCFA are required under certain circumstances to reduce coinsurance and deductible amounts or offer additional benefit options.

The routine waiver by a prepaid health plan of beneficiaries' obligation to pay coinsurance and deductible amounts is clearly distinguishable from such routine waiver by other health care providers, such as hospital outpatient departments, physicians, or durable medical equipment suppliers. Two principal characteristics distinguish a health plan's routine waiver of cost-sharing amounts from that of other health care providers. First, a health plan's routine waiver program is inextricably intertwined with the offering of a comprehensive package of covered benefits, and is not offered for the purchase of an individual item or service. Quite often, in the case of prepaid plans, the routine waiver of cost-sharing amounts is made in the form of a reduction or waiver of the beneficiary's premium and may also be combined with the offering of increased covered benefits. Thus, the routine waiver of cost-sharing amounts is generally not an incentive to use a particular item or service at the time it is furnished.

Second, although cost-sharing requirements can serve to control utilization, HMOs and other health plans under contract with HCFA or a State agency have built-in incentives to control unnecessary utilization, or have their utilization and costs monitored by HCFA or the State agency. Thus, the issue of potential overutilization (with increased costs to the programs) is adequately dealt with without resort to imposing the obligation on beneficiaries to pay coinsurance and deductible amounts.

Therefore, we expect to publish at a later date an additional safe harbor provision to protect prepaid health plans that have a contract or agreement with HCFA or a State agency where the health plan offers beneficiaries increased benefits coverage, reduced cost-sharing amounts (coinsurance, deductibles, or copayments), or reduced premiums where certain standards are met. Because of the limited scope of the comments we received on HMOs, PPOs and managed care plans, we expect to publish at a later date an interim final rule in order to solicit additional comments from the public on this new safe harbor provision.

This new safe harbor provision will not protect incentives offered to beneficiaries by health plans, such as PPOs, that are not operating under a contract or agreement with HCFA or a State agency. Unlike health plans with such contracts or agreements, we are not confident that all PPOs that engage in these negotiated waiver agreements properly protect the Medicare and Medicaid programs against overutilization. And we did not receive sufficient comments on the different types of PPOs for us to distinguish the characteristics of a PPO engaging in these negotiated waiver agreements where the Medicare and Medicaid programs are properly protected.

Comment: Several commenters requested the OIG to protect a variety of arrangements between HMOs, PPOs, competitive medical plans (CMPs), managed care plans, and other health plans on the one hand, and medical groups and other health care providers who furnish items and services to the health plans at a reduced price on the other hand. A few of these commenters observed the benefits that can be achieved when a health care provider offers discounts to these organizations. Several commenters recommended

special treatment for relationships between HMOs and health care providers, such as physicians and hospitals, involving the leasing of space and equipment and contracting for personal services. One commenter requested special safe harbor protection for "[a]ll transactions between an HMO and contracting medical groups * * * if the medical group provides over 90 percent of its services to HMO members."

Response: We agree that there is a need to provide safe harbor protection for certain practices between managed care plans and health care providers. Thus, we are expecting to publish a rule that will protect many of these price reduction arrangements where certain standards are met. For the same reasons as stated above, we are expecting to publish this safe harbor provision as an interim final rule with an opportunity for additional comments from the public.

The safe harbor provision we are expecting to publish will only protect agreements between health plans and contract health care providers for the sole purpose of furnishing items and services covered by the health plan, Medicare, or Medicaid. In other words, for the reasons explained below, we are not protecting in this provision the contracts between health plans and contract health care providers for these providers to furnish services other than covered benefits, such as peer review and management services.

As with all safe harbor provisions, where two parties engage in a multi-faceted payment arrangement where protection is sought from more than one safe harbor, we expect separate justifications to be clearly set forth for each provision for which protection is sought. Where HMOs contract with physicians and other health care providers for the furnishing of services other than covered health care services, we believe that HMOs, PPOs and other prepaid health plans will be able to conform their arrangements to the appropriate safe harbor provisions. For example, many contract health care providers furnish peer review, marketing services, or pre-enrollment screening for HMOs. For the remuneration attributable to the furnishing of such services to be protected, it must comply with the personal service/management contracts safe harbor provision. Also for example, the remuneration attributable to the lease of space or equipment must comply with those respective safe harbor provisions.

We are not convinced that merely because a medical group has a large majority of its business with an HMO that a special across-the-board exemption for all transactions is warranted. HMOs operate under a variety of payment mechanisms, both with respect to the Medicare and Medicaid payments they receive and the payments they make to physicians. Although in many cases the incentive structure in which HMOs operate is designed to protect against overutilization of service, this incentive structure may not extend to fee-for-service arrangements.

Further, even though many HMOs have generally operated largely free of fraud and abuse problems, we are aware of some HMOs that have abused their contractual relationships with medical groups, where individuals in the groups have engaged in abusive activities on behalf of the HMO, or where the medical group has compromised the interest of beneficiaries in order to keep the vital HMO contract. In at least one case, a criminal conviction was obtained for such a practice. Although safe harbor protection is warranted for certain contractual relationships between health plans and contract health care providers, we also intend to use our authorities aggressively to monitor closely and, where appropriate, penalize any abusive relationships between these parties to assure that medically necessary services of a high quality are available and accessible to all enrollees.

4. Waiver of Beneficiary Deductible and Coinsurance Amounts

Comment: The OIG received numerous comments on the establishment of a safe harbor for waiver of hospital inpatient coinsurance and deductible (copayment) amounts owed by program beneficiaries. Many commenters requested the OIG to provide safe harbor protection for routine hospital waiver or

partial reduction of inpatient fees not subsequently claimed as bad debts because the practice would benefit hospital inpatients without increasing program costs. Some commenters urged the OIG to protect the submission of bad debt claims where copayments were routinely waived for limited categories of patients, such as seniors. On the other hand, several commenters were concerned that permitting hospital waiver of inpatient copayments would encourage overutilization of hospital services and promote cost-shifting to patients with nongovernmental insurance policies.

Response: Since October 1, 1983, when the prospective payment system (PPS) for reimbursing hospital inpatient services was implemented, we have been aware of hospitals that routinely waive Medicare beneficiary deductibles and coinsurance charges for inpatient hospital services in order to attract patients. Because the waiver of patient charges constitutes an inducement to use services in exchange for something of value (the forgiveness of financial obligation), this practice violates the statute. However, assuming the waived amounts are not later claimed as bad debt, the practice appears to cause no direct financial harm to the Medicare program because hospitals receive a pre-determined payment amount under PPS regardless of their costs or charges. Moreover, due to hospital peer review requirements and the relatively fixed level of patient demand for hospital inpatient services, waiver of inpatient beneficiary fees is not likely to increase utilization significantly. Furthermore, if hospital waiver policies do not discriminate on the basis of length of stay or type of disease, the potential for program abuse appears minimal.

In addition, we know of no data, nor have commenters produced or referred us to any, indicating that routine hospital waivers of inpatient copayments owed by program beneficiaries will shift the costs of care to non-Medicare patients. Rather, we assume that most hospitals that choose to waive these amounts do so because the hospital more than makes up in increased volume for any initial "loss" resulting from not collecting the full amount to which it is entitled. Although we believe there is little risk of "cost-shifting" to the non-Medicare population, the first standard in this provision makes clear that any such cost-shifting is not protected.

We do not agree, however, that health care providers who choose to waive copayment amounts routinely for some or all of their patients should be permitted to claim such amounts as bad debt. Such a rule would muddle two very distinct Medicare policies. Traditionally, Medicare health care providers are reimbursed for uncollectible payments owed by beneficiaries. See 42 CFR 413.80. This rule requires, among other things, that health care providers make an indigence determination on a case-by-case basis, or reasonable collection efforts, prior to recouping bad debt losses from the program. See also Provider Reimbursement Manual, sections 310, 312, HCFA Pub. No. 15-1. Thus, payment of Medicare bad debts, unlike routine waivers of Medicare cost sharing amounts protected under this safe harbor regulation, are only authorized under certain conditions pertaining to the uncollectability of payments and the indigence of beneficiaries. Health care providers who routinely waive beneficiary copayments in accordance with this safe harbor regulation, and do not make case-by-case indigence determinations or otherwise prove uncollectability under 42 CFR 413.80, cannot deduct expenses as bad debt. Where such an unlawful expense is claimed, the hospital may be subject to civil or criminal prosecution.

Comment: Many commenters requested the OIG to extend safe harbor protection to waiver of patient fees imposed for a wide array of provider services. Several commenters sought protection for waiver of beneficiary copayments for part A services furnished by other cost-based health care providers, such as skilled nursing facilities and home health agencies. These commenters argued that where services are paid on a reasonable cost basis, just as where services are reimbursed under PPS, waiver of beneficiary copayments causes no financial harm to the program. Other commenters sought still broader protection under the safe harbor for copayments for services under part B, arguing that the limited protection granted for inpatient hospital copayments was discriminatory.

Response: We believe that protection is uniquely appropriate for waiver of patient charges related to hospital inpatient services. A routine waiver program will not likely increase patient demand for these services, since beneficiaries cannot admit themselves, and hospital overnight stays are inherently undesirable from a patient's perspective. Thus, it is unlikely that a routine waiver program will affect utilization. By contrast, cost-based fee-for-service health care providers, such as home health agencies and nursing homes, may be able to offset their losses resulting from their waiver of copayments by increasing their Medicare allowable costs. Such manipulation of reimbursement amounts would be virtually impossible to prevent. Thus, we do not believe that the protection offered under this safe harbor provision should be extended to routine waiver of beneficiary copayments by cost-based fee-for-service health care providers.

Routine waiver of beneficiary copayments by individuals or entities reimbursed on the basis of reasonable charges even more clearly affects program costs. When charge-based health care providers routinely fail to collect all or part of beneficiary copayments authorized by law, and then submit actual charges to Medicare as if copayment amounts were collected, these charges increase customary and prevailing rates which, in turn, inflate program costs. The Medicare Carriers Manual makes clear that in these situations, a health care provider is required to reduce his or her actual charge. See section 5220, HCFA Pub. No. 14. Thus, we believe that individuals and entities who fail to reduce actual charges submitted to Medicare are misrepresenting their charges, and may be subject to civil and criminal liability for submitting false claims.

We are aware that some local government health care providers, including county hospital outpatient departments, routinely reduce beneficiary payments at the time of service for the extremely indigent populations they serve. For these health care providers, offering patients the option of reduced payment at time of service may be a more successful collection strategy than subsequently billing patients for the entire copayment. This practice, while not protected by this safe harbor regulation, would not likely violate the statute so long as the partial forgiveness of the copayment obligation was strictly a pragmatic financial decision and not an inducement to patients to purchase medical services. We see no purpose in interfering in the mission of local governments or other hospitals that serve primarily indigent populations when they reduce beneficiary fees for those unable to pay. Such health care providers, typically, have no need to engage in sophisticated marketing strategies to induce more business.

Comment: One commenter advised the OIG that in accordance with 42 U.S.C. 254b(f)(3)(F) and 254c(e)(3)(F), federally qualified migrant and community health care centers are required to develop a sliding fee schedule for patients based upon ability to pay, which could result in waiver of part or all of the Medicare coinsurance and deductible amounts. These commenters argued that such waivers, although mandated under Public Health Service Act grant programs, could be deemed a violation of the statute.

Response: In section 4161(a)(4) of Public Law 101-508, the Omnibus Budget Reconciliation Act of 1990, Congress enacted a fourth statutory exception to the statute, which exempts a waiver of any Medicare Part B coinsurance by a Federally qualified health care center to any individual who qualifies for subsidized services under the Public Health Services Act. Thus, we are providing a safe harbor provision for this exception. In addition, we are making this safe harbor applicable to similarly situated individuals who receive services under the Maternal and Child Health Service Block Grant program (see section 505(2)(D) of the Act; 42 U.S.C. 705(2)(D), or who are Medicaid beneficiaries.

Comment: Six commenters argued that protecting routine waiver of beneficiary payments for inpatient hospital services would discourage competition from ambulatory surgical centers (ASCs).

Response: Although the granting of safe harbor protection for the waiver of inpatient copayments gives practitioners or their patients an incentive to choose inpatient hospital settings over outpatient settings, we

believe that the activities of the PROs reasonably ensure that services are furnished in outpatient settings where appropriate. Therefore, we believe that the granting of safe harbor protection only for inpatient services is unlikely to draw patients away from ASCs and other outpatient settings.

Comment: A few commenters requested the OIG to protect waiver or discounts of inpatient copayments where hospitals and physicians offer this benefit not to patients directly, but to insurance companies, HMOs, or employer or union medical service plans, that have assumed liability for the beneficiary portion of payment under the terms of their insurance policies. Insurers offering these insurance benefits may attempt to negotiate with hospitals to reduce or eliminate the beneficiary portion of reimbursement in exchange for endorsing the hospital as a preferred provider or offering other tangible benefits.

Response: This safe harbor provision protects the waiver by hospitals of inpatient copayment amounts only where these amounts would otherwise be paid by Medicare beneficiaries themselves. In paragraph (k)(1)(iii), we have expressly made this provision inapplicable to negotiated price reduction agreements between health care providers and third-party payers, even where the reduction involves beneficiary copayments for which the third party payor has assumed liability as part of a Medigap policy. As we discussed in the section immediately above, we are expecting to publish an additional safe harbor provision to protect HMOs, CMPs and HCPPs under contract with HCFA or a State agency that waive coinsurance and deductible amounts owed by beneficiaries where certain standards are met.

Comment: Two commenters sought protection for the waiver of patient copayment amounts for the first eight days of care in a skilled nursing facility (SNF) after discharge from a hospital under the same ownership. These commenters stated that protection was needed to enable the smooth transfer of patients who were ill, and to allow hospital beds to be vacated for sicker patients.

Response: We understand that health care providers operating both hospitals and SNFs may, for entirely legitimate reasons, wish to continue waiving SNF copayment amounts when transferring hospital patients into the SNF for a brief period. In section III.D. below, we discuss in more detail the special considerations that exist where the hospital and SNF are wholly owned by a single "parent" entity, or where one of the facilities is the sole owner of the other.

Comment: One commenter requested the OIG to expand the safe harbor provision for waiver of hospital inpatient copayments to cover the provision of free items or services such as meals or presurgical overnight stays, samples of products from manufacturers, or blood screening and other testing services. The commenter suggested that such free gifts benefit patients without causing harm to the program, so long as there is no obligation to purchase additional items or services upon receipt of the free gifts.

Response: We decline to protect the offer of free gifts to beneficiaries within this safe harbor provision, as we have declined to protect this practice within the safe harbor provision governing discounts. The statute clearly contemplates that illicit remuneration may involve payments "in cash or in kind." The practice of offering free gifts may well induce beneficiaries to purchase additional or unnecessary items or services. Such inducements could easily become excessive, and there is no distinct financial or other cut-off point below which we could be sure that gifts remained non-abusive. Because we understand that such inducements are an area of significant abuse, we believe that protection of this practice would be unwarranted.

C. Provision-by-Provision Analysis of Safe Harbors

1. Investment Interests--s 1001.952(a)

The OIG received close to three hundred comments on the issue of providing safe harbor protection for

payments from investment interests. These comments are divided into three broad categories: (a) Comments on the proposed safe harbor provision for payments from investments in large publicly traded entities; (b) suggestions for safe harbors for payments from investments in small entities such as limited partnerships, about which we solicited comments, and (c) proposals for protecting payments from other investment interests. For convenience, we are discussing all of these comments in this section. Before discussing the comments and responses for these three broad categories of investment interests, we will discuss general issues raised with respect to investment interests.

Comment: We received a number of comments asking the OIG to clarify the types of investors and investment interests to be protected. In particular, we received many comments urging the OIG to protect indirect investment interests held by family members and to protect debt as well as equity investments.

Response: We are adding a definition of the terms "investor" and "investment interests" to this safe harbor provision. We are defining an "investor" to include both individuals and entities who either directly or indirectly hold an investment interest in an entity. Our definition includes examples, which are not intended to be an exhaustive list, of ways that investment interests may be indirectly held. For example, a family member of a referring physician may hold the investment interest in the joint venture entity, or a referring physician may have a legal or beneficial interest in an entity, such as his or her group practice, a trust or a holding company, where that entity directly holds the investment interest in the joint venture entity. In both cases, we view the physician as having the ownership interest in the joint venture entity.

In many cases we distinguish investors who do business with the entity in which they have invested from other investors who are exclusively seeking a return on their investment. We call an investor who does business with the entity as "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." This classification is meant to include all investors who do business in any manner with the entity. Except as noted below, we do not limit this category to investors who actually make referrals. Rather, our focus is on the status of the investor and the ability to make or influence the referral stream or level of business activity for the entity. Such investors include not only physicians, but hospitals and other entities capable of influencing referrals.

We note that this category of investor doing business with the entity also includes those investors who furnish items and services to the entity as well as those investors who otherwise generate business for the entity. Thus for example, if a durable medical equipment (DME) supplier and hospital both enter into a joint venture to furnish DME to patients when they leave the hospital, both the DME supplier and the hospital fit within this category of investor doing business with the entity.

There are some very limited situations where, because of the special status or location of the investor, he or she does not fit within this category of investor doing business with the entity. For example, for the most part, retired physicians no longer make or influence referrals. In addition, typically a physician who resides and practices in a separate service area from the entity is similarly not "in a position to make or influence referrals." Or an investor could simply make an agreement barring him or her from actually making or influencing referrals to the entity. In all three examples, the determination whether an investor should be classified as doing business with the entity in which he or she has invested is a factual question. However, we will accept a written stipulation that for the life of the investment the investor will not make referrals to, furnish items or services for, or otherwise generate business for the entity. We emphasize that, because of the potential for abuse of this stipulation agreement, the investor must be bound to this agreement for the life of the investment as long as he or she remains an investor.

Finally, our definition of the term "investment interest" makes clear that debt as well as equity investments are protected.

a. Large Publicly Traded Entities. Comment: Several commenters questioned the relationship of this proposed safe harbor provision to the rules of the Securities and Exchange Commission (SEC) for the registration of securities. For example, some suggested that the OIG should exempt all investment interests that are traded on a publicly regulated exchange, while another suggested that public trading be an additional condition for protection. In addition, a variety of comments were received regarding the standards adopted from the SEC rules that, in order for payments from investment interests in an entity to be protected, the assets of the entity must exceed \$5 million and the number of shareholders must exceed 500 persons (the so-called "\$5 million asset/500 investor rule"). While some suggested the \$5 million test was too high, one suggested that it was too low. One commenter suggested that the 500 shareholder test was too high, and another suggested that the OIG require either \$5 million in assets or 500 shareholders, but not both. Finally, another commenter suggested that the OIG protect an investment in an entity any time the asset level was greater than \$5 million.

Response: We intended to protect profit distributions made to referring investors in large publicly traded corporations where the investment interest was obtained at fair market value through trading on a publicly regulated exchange. The remuneration received by these investors is so tangentially related to their referrals that the potential for abuse is minimal.

As we stated in the preamble of the proposed rule, we adopted the SEC registration rules from 15 U.S.C. 78l(g) and 17 CFR 240.12g-1, which generally require entities with more than \$5 million in assets and more than 500 investors to register with the SEC. At the time, we had believed that such a test would protect payments from only those entities that are actively traded on a national securities exchange.

Based on the comments we received and our experience in enforcing the statute, we believe that in many respects the SEC rules are not applicable for the purposes of protecting against abuse. In particular, the \$5 million threshold is too low. An entity that owns two magnetic resonance imaging (MRI) machines may well meet this test. Thus, we are changing the asset threshold level from \$5 million to \$50 million. Publicly traded entities of this size are sufficiently large to assure that abuse is minimal.

In addition, the SEC's other criteria of 500 investors does not provide meaningful protection against abuse. We recognize that in many cases a large number of investors can dilute the influence of one investor's referral patterns on the level of payments that he or she receives. However, it has been our experience that many sham joint ventures try to obtain many investors, each of whom contribute nominal investments, as a mechanism to lock-in the loyalties of as many physicians as possible. Thus, depending on the factual circumstances of a particular joint venture, a large number of investors could either be abusive or minimize abuse.

We are making other revisions to this first investment interest safe harbor provision to provide greater clarity consistent with our original intent. Thus, this safe harbor as revised contains two definitional prerequisites in paragraph (a)(1) for the type of entity we are protecting, and is followed by five standards, all of which must be met to the extent they apply to the investment interest in question.

For an entity to be protected under this safe harbor, it must meet two definitional prerequisites. The first prerequisite to qualify for protection is that the assets of the entity must be measured any time within the previous fiscal year or the previous 12 month period. This time period is different from the SEC rule, which we believe to be overly restrictive for the purposes of this safe harbor. The time period for measuring compliance which we are adopting will mean for all practical purposes that growing entities will be protected as soon as they reach compliance with all the preconditions and standards in this safe harbor, rather than having to wait for the next fiscal year as the SEC requires. In addition, the time period we are specifying permits an entity to retain safe harbor protection for a limited time period even though it is no longer in compliance with the \$50 million asset threshold in this rule. During this time period, an

entity will have the opportunity to bring itself back into compliance.

The second definitional prerequisite is that the entity must possess \$50 million in the form of undepreciated net tangible assets. This clarification of what we mean by \$50 million in assets removes many assets which we never intended to include within the scope of protection. We are excluding all intangible assets such as the company's valuation of its name recognition and stock and other forms of goodwill. We are excluding such assets because their valuation is too subject to "creative" accounting or appraisal techniques. The assets must also be reduced by any liabilities. Thus, a corporation only has \$1 million of net tangible assets when it buys a \$5 million piece of equipment with a \$4 million loan. However, we are excluding from the calculation of assets any reductions in the value of assets due to depreciation. We believe it is inappropriate for an entity to lose safe harbor protection as a result of the aging of its assets. Further, we do not want to create incentives to replace equipment unnecessarily merely for the entity to regain safe harbor protection based on the value of new equipment. We are also clarifying that the reporting of net tangible assets must be based on net acquisition costs of purchasing such assets from an unrelated entity. The use of net acquisition costs in this rule is a generally accepted accounting principle, and makes clear that, for the purposes of this rule, we will not accept a company's use of current market valuations of assets. Further, we intend to use the Medicare related party rule, 42 CFR 413.17, to assure that the acquisition costs from the purchase of an asset is only based on a bona fide purchase through an arm's length transaction. Our final clarification in how to apply the \$50 million asset test is that assets unrelated to a company's health care line of business cannot be used in the calculation of assets. For example, a nursing home corporation could be a subsidiary of a hotel chain. The hotel assets cannot be used for purposes of qualifying for the \$50 million asset test. However, with the exception of the related party rule, it is not our intent to require corporations to be familiar with cost reimbursement rules of 42 CFR part 413. Tangible assets used in furnishing items and services may be counted even though they may not be allowable costs under part 413. The information necessary to determine compliance with this \$50 million asset test is readily available in the accounting books of entities, and the accounting methods for determining compliance are fully consistent with generally accepted accounting principles. Thus, an independent certified public accountant should have little trouble certifying an entity's compliance with these requirements.

This safe harbor contains five standards, not all of which may be applicable in every instance. The first two standards, paragraphs (a)(1) (i)- (ii), which will be discussed here, focus on the nature of the investment interest. (The three remaining standards are being added in response to other comments which will be discussed below.)

The first standard (see paragraph (a)(1)(i)) applies only to an investment interest in an equity security, and requires such a security to be registered with the SEC under 15 U.S.C. 78l (b) or (g). We had considered but are rejecting an alternative standard that the investment interest must merely meet the SEC registration qualifications. This requirement of actual registration provides a clear bright-line rule, and is an indication of good-faith entry into the public securities markets, which is a significant factor underlying the rationale for this safe harbor. In addition, we are requiring the investment interest actually to be registered with the SEC because many exemptions exist to the SEC's \$5 million asset/500 investor rule, which permit many entities to be actively traded but not to be registered with the SEC, and thus not under its oversight. See 15 U.S.C. 78l(g)(2). However, the SEC's reasons for granting an exception may not be consistent with the purposes of this rule, and thus we see no particular reason to protect securities simply because they qualify for an SEC exemption. We note that one such exemption under 15 U.S.C. 78l(g)(2) is for securities listed and registered on a national securities exchange. Such securities must comply with 15 U.S.C. 78l(b), and for the purposes of this rule we are requiring such securities to be registered with the SEC.

We are not applying the registration requirement to investment interests that involve debt securities

because we believe that the extra safeguard of SEC registration is unnecessary. Publicly traded debt instruments, although protected under this safe harbor, are not the type of investment interests that are the focal point of this rule. Although the potential for abuse is present, we have not been apprised of the actual occurrence of abuse relating to these investment interests, and believe that their usefulness as instruments for inducing investors' referrals is more limited than equity investment interests.

The second standard (see paragraph (a)(1)(ii)) responds to the commenters' suggestions regarding public trading. We are adding a standard to this provision requiring the investment interest of an investor in a position to make or influence referrals to, furnish items and services to, or otherwise generate business for the entity to be obtained on terms equally available to the public through a registered national securities exchange, such as the New York Stock Exchange or the American Stock Exchange, or through the National Association of Securities Dealers Automated Quotation (NASDAQ) system. We note that we specifically intend to preclude safe harbor protection for securities traded through the so-called "pink sheets" or those "non-NASDAQ" securities that are traded through the OTC Bulletin Board Service. See, Securities Exchange Act Release No. 34-27975, May 1, 1990. This standard follows our original intent to assure that the investment interests of physicians or others in a position to influence referrals must be obtained through the kind of arms length trading that is normally associated with actively traded public securities at the fair market value through a publicly regulated exchange. Such public trading assures that the entity does not obtain capital by self-selecting investors based on their status as sources of referrals.

Although we are not requiring investment interests of other investors to be obtained through public trading, physicians and others in a position to influence referrals must strictly comply with this standard. We plan to closely scrutinize attempts to circumvent this standard. For example, any investment interest obtained before an entity becomes publicly traded is not protected under this provision. In addition, an investor is not protected by exchanging a limited partnership interest for shares in a newly formed entity that is publicly traded. Further, this standard precludes protection of payments from securities where physicians are afforded the opportunity to buy the available shares of an entity before other members of the public have the opportunity to invest in that entity. Such an entity would have only physicians as investors, and it is not our intent to protect payments from such entities. We expect the public to be afforded a genuine opportunity to invest in these publicly traded entities. Where referring sources (or their immediate families) hold a large proportion of the shares, we will presume that this standard has not been met.

Comment: A number of commenters suggested that the OIG expand this provision in a variety of ways to protect remuneration from debt as well as equity instruments and from entities other than corporations, such as partnerships.

Response: As discussed above, this safe harbor protects debt as well as equity instruments. We recognize that an ambiguity existed in our proposed rule in that our 500 investor test applied only to "a class of equity security" and thus appeared to prohibit debt instruments from qualifying under this safe harbor provision. However, this ambiguity is resolved by eliminating the 500 investor test. In addition as discussed above, we are exempting debt instruments from the SEC registration requirement contained in the first standard.

We also agree that investments in partnerships should be protected, and we are revising this provision accordingly, by adding a definition of investment interest.

Comment: A few commenters expressed concern that entities meeting the requirements contained in the proposed safe harbor provision could still be engaging in abusive relationships with individuals in a position to make referrals. One commenter suggested that we specifically protect against fraudulent cross-referral arrangements whereby investors in entity "A" are explicitly or implicitly encouraged to

refer to entity "B" in return for entity "A" receiving the referrals from the investors of entity "B."

Response: We agree with the thrust of these comments, and are adding three standards (see paragraphs (a)(1) (iii)-(v)) to clarify our original intent and assure that investment interests are not used as inducements for referrals. One, the entity or any investor must not market or furnish the entity's items or services to passive investors in any manner differently than to non- investors. In other words, although an entity may seek referrals or other business from passive investors, it must promote and furnish its items or services to investors and non-investors in the same manner. An entity may not use a separate marketing approach or provide a different level of service to passive investors as opposed to non-investors. For example, in its promotional efforts, the entity may not in any manner appeal to or refer to such investor's position as an investor, and in serving customers it may not offer special arrangements to investors that are not available or are offered on different terms to non-investors. Any distribution to passive investors of individual or aggregate investor referral patterns would also not be protected under this provision. In addition, the entity or any investor must not promote the items or services of other entities as part of a cross referral agreement. One type of cross referral arrangement we are not protecting is the sham transaction described in the above comment.

Two, the entity must not loan funds to or guarantee a loan for an investor to use for the purpose of obtaining the investment interest. We do not believe protection should be afforded where an investor is loaned money from the entity, or from a parent or subsidiary corporation (or is guaranteed a loan by the entity or a related organization), and the investor makes an investment based on that loan. In such a situation, the investor is adding no real capital to the entity. We note, however, that safe harbor protection is available where the investor borrows from other sources, such as from his or her broker or a bank.

And three, the amount of payment in return for the investment interest must be directly proportional to the amount of the capital investment. Such payments are consistent with the type of corporate dividend payment that we are trying to protect.

We believe that these minor revisions, which are fully consistent with our original intent, should offer reasonable protection against the possibility of significant abuses without unduly restricting the types of entities that may qualify under this provision.

b. Small Entities. In the notice of proposed rulemaking we solicited comments on expanding the proposed investment interest safe harbor to protect payments from investments in small entities, particularly limited and general partnership interests. For limited partnership interests we suggested four standards for protection: (1) A bona fide opportunity to invest is made on an equal basis without regard to the investor's ability to make referrals, (2) no requirement is imposed on the investor to make referrals, (3) disclosure is made to the referred patient, and (4) payments are not related to referrals. As conditions for protection of payments from investments in general partnership interests, we suggested that disclosure of the investment interest be made to a referred patient and payments not be related to referrals.

Comment: A large number of people commented that, in view of the OIG's interpretation of the statute as not prohibiting all referrals to entities in which a physician has an investment interest, safe harbor protection should be provided for legitimate arrangements. While some commenters suggested that the OIG adopt generic criteria for analyzing these arrangements, others commented more directly on the proposed standards we suggested in the proposed rule. A few commenters suggested that any safe harbor protections should treat indirect ownership interests held by family members in the same manner as direct ownership interests to assure that investors who make referrals to that entity do not circumvent the intent of these requirements by having investments held in the name of family members instead of their own names.

The enormous response to this invitation for comment reflected the polarization of the health care community on this issue. Those supporting safe harbor protection emphasized that physician-investor joint ventures promote competition, provide quality services, promote patient convenience, bring needed services to communities, are cost effective, do not lead to over- utilization, do not compromise ethics, and enable services to be provided outside hospitals and physician offices. Those urging no safe harbor protection or expressing a need for stringent safeguards argued that these joint ventures hurt competition, compromise quality of care, are not in patients' best interests, increase costs, lead to over-utilization, and create conflict of interests between health care providers and patients.

A large number of commenters generally supported safe harbor protection for payments to those with managing partnership interests and agreed with the OIG's two suggested conditions for protection. However, a few commenters opposed such protection. In addition, a few commenters suggested that the OIG define which individuals would be protected under this provision.

Response: Because of the significant business investment activity in these small entities--typically joint ventures--and the advantages of permitting them in certain situations, we believe that safe harbor protection is warranted. However, we have also observed widespread abuses in many of these joint ventures. In particular, we believe that a large number of these newly formed entities are designed to have physicians as investors specifically to induce them to use the entity in which they have invested. Therefore, any safe harbor protection must include significant safeguards to minimize any corrupting influence the investment interest may have on the physician-investor's decision where to refer a patient. We are including a second **(35967)** investment interest provision (paragraph (a)(2)) that protects payments to investors who are limited and general partners, shareholders, or holders of debt securities where eight standards are met. We will discuss some of the definitional categories of persons who are protected under this provision, our response to comments recommending special protection for managing partnership interests, and our three categories that provide structure for the eight standards in this safe harbor.

We have classified "investors" as either "passive" or "active" because some of the standards apply only to those defined as "passive" investors. The definition of an "active" investor includes two categories of persons. The first category is modeled after a bona fide general partner in a partnership under the Uniform Partnership Act who is responsible for the day-to-day management of the entity.

We are including a second way to qualify as an "active" investor: the individual or entity must agree in writing to undertake the liability for the partnership, including the acts of its agents acting within the scope of their agency. We believe that such an affirmative act will assure that the individual or entity performs many of the same functions that general partners do who actively manage the day-to-day operations of the joint venture entity. For example, these active investors undertake the business risk that a typical general partner does, and will be interested in assuring that the day-to-day managers of the entity engage in sound business practices and not run afoul of the statute as well as other Federal and State laws and regulations.

"Passive" investors are those investors who are not active investors, such as limited partners in a partnership or shareholders in a corporation.

This second investment interest safe harbor provision includes some standards that must be met by both passive and active investors, and some standards that need only be met by passive investors, to the extent any exist in the joint venture. If an entity contains only active investors, the standards applicable only to passive investors would, of course, not apply. It must be emphasized, however, that the standards for this safe harbor must be met by all the investors in the entity. To the extent that one class of investors, such as active investors, qualifies, but the passive investors do not meet one of the standards, safe harbor

protection is not given to payments to any investors in the entity.

In this regard, special attention must be paid to cases involving ownership interests held indirectly through other entities. Take a situation, for example, where a group of individuals are passive investors in entity "A", which in turn is the active investor in entity "B." For entity "B" to qualify under this safe harbor provision, entity "A" must meet all the requirements for active investor in entity "B," and the individual investors of entity "A" must meet all the requirements as passive investors in entity "B."

We believe that this provision will protect investment interests of those with managing partnership interests who establish limited partnerships that meet the standards of this provision. We have decided not to include a third investment interest provision at this time that would place fewer requirements on business structures composed entirely of active investors. We recognize that there are many legitimate small businesses structured in this manner where a group of individuals come together and all of them participate as hands-on managers in the day-to-day operations of the business and undertake personal liability for the entity. Historically, many hospitals were formed in this manner. And currently many group practices and other innovative health care delivery systems are being formed on a bona fide basis in this same manner. However, there are many new entities that have the same business structure, but that may be subject to abuse under the statute. Consequently, we have determined that it is inappropriate to implement a safe harbor provision at this time for entities composed exclusively of active investors that would not have to meet the standards we are implementing in this second investment interest provision. However, we are considering a new safe harbor provision for such investment interests which we anticipate publishing as a separate regulation.

The safe harbor provision we are including in this rule for investment interests in small entities was developed based on the standards we suggested in the proposed rule, the comments we received on our proposals and our continuing experience in enforcing the statute. This experience includes investigations of abusive joint venture arrangements, our Fraud Alert describing suspect features of these arrangements, and our Report to Congress entitled "Financial Arrangements Between Physicians and Health Care Businesses" (OIG, Office of Analysis and Inspections, May 1989). The Report to Congress disclosed in detail both the extensive ownership of joint ventures by physicians, and the additional services received by patients of these physicians as compared to all Medicare patients in general.

The standards for this provision are structured into three categories that we have identified as being of concern to us in joint venture arrangements: (1) The manner in which investors are selected and retained, (2) the nature of their business structure, and (3) the financing and profit distributions. To the extent possible, we have adopted bright line rules. We believe that this approach will facilitate compliance because investors will be able to determine easily whether they meet the conditions of safe harbor protection. As discussed in section III.A. above, we are not accepting commenters' suggestions for generic criteria. We believe that such criteria do not provide sufficient protection against abusive arrangements, nor do they provide meaningful guidance to delineate when a provider has complied with them.

The following discussion will be structured along the lines of the three problem areas we have identified.

(i) Manner in which investors are selected and retained. In this section we discuss the comments and our responses regarding the problem of the manner in which investors are selected and retained. The first five standards of this investment interest provision protecting small entities (paragraphs (a)(2)(i)-(v)) relate to this problem area.

Comment: The OIG received mixed comments on the first standard suggested in the proposed rule, that a bona fide opportunity to invest be provided on an equal basis to all investors without regard to their

ability to make referrals. A large number of commenters expressed concern about the meaning and workability of this standard, particularly that it is vague and would be difficult to police. Several commenters construed this first suggested standard as a results-oriented test requirement, in other words, that joint ventures must be owned partly by individuals not in a position to make referrals. Some suggested that the OIG place a limit on the percentage of ownership of an entity that can be held by such referring investors. The percentages ranged from 5 percent to 85 percent ownership by referring investors. Others suggested that the OIG should not require these entities to have some amount of non-referring investors. One commenter specifically objected to a requirement that a joint venture have a majority of the ownership interests held by non-referring investors. Five commenters expressed concern that any requirement that investment interests be offered to non-referring individuals may be construed as requiring a public offering, thus triggering the necessity of complying with SEC rules (such as Regulation D governing the limited offering and sale of securities without registration under the Securities Act of 1933, 17 CFR 230.501 *et seq.*) or State "blue sky" laws which require public securities registration.

Response: We agree with the concerns expressed by most of the commenters about our first suggested standard. Thus, we are replacing it with three standards (paragraphs (a)(2)(i)-(iii)) in order to better address problems concerning the manner in which investors are selected. To comply with our first standard, investors who make referrals or who are in a position to make referrals or furnish items or services cannot own more than 40 percent of the value of investment interests within each class of investments in the entity. This standard requires not only that a bona fide opportunity to invest has been afforded to people not in a position to make referrals, but that these individuals hold at least 60 percent of the value of the investment interests in each class of investments.

In essence, we are switching a process measure with an outcome measure. As several commenters observed, our proposed standard of equal opportunity to invest contemplated that an equal number of referring and non-referring individuals would be given an opportunity to invest. Such a process-orientated test would have been virtually impossible to monitor. For example, such a standard would have required a joint venture to monitor all marketing solicitations, and determine the referral status of everyone who was solicited to make sure that an equal number of referring and non-referring potential investors were given the opportunity to invest. The alternative outcome measure we are adopting will provide a bright line test which will assist all the parties to the joint venture and the Department in determining whether compliance with this first standard has been achieved.

Although compliance with this "60-40 percent investment" standard will necessitate some monitoring data, we want to minimize the burden. Therefore, the joint venture is free to use any internal accounting principles it chooses to adopt so long as it uses such principles consistently over time so that it is not manipulating the data to obscure its noncompliance. In addition, we are establishing two alternative time periods in which compliance is to be measured. The measurement period can either be a joint venture's prior fiscal year or the previous 12 month period. For example, if a joint venture uses a calendar year as its fiscal year and wants to know in April 1990 whether it is in compliance with this standard, it may either look at the number and status of investors in 1989, or it may use its investor data from March 1989 through March 1990.

We expect that the parties to a joint venture will find it far preferable to use its prior fiscal year data because if that year's data shows compliance with this standard then the joint venture is in compliance for the entire current fiscal year. The alternative approach of a rolling 12 month average will enable a joint venture to reach compliance sometime within the current fiscal year so that it does not have to remain out of compliance for a full year. However, we also recognize that a joint venture using this rolling 12 month average that is being operated close to this 40 percent line may find itself in compliance one month and then out of compliance the next month. We emphasize that it is highly unlikely we will pursue an

investigation of a joint venture where it complies with all the other standards in this safe harbor, is out of compliance with this 60-40 percent investment standard based on its prior fiscal year data, but is making a good-faith effort to reach compliance with this standard based on data showing compliance on a monthly basis for the most recent months of operation.

As previously discussed, for the purposes of complying with this 60-40 percent investment standard, we are classifying investors who provide items and services together with investors who make or influence referrals to the entity. This classification is necessary to preclude a supplier, such as a DME company, from forming a joint venture with referring physicians, giving them a 39 percent interest in the entity. It would be inappropriate to grant safe harbor protection to such an entity because all of the owners would be doing business with the joint venture by either furnishing items or making referrals. In order to remedy this problem, the DME supplier is classified with the referring physicians for the purposes of this 60-40 percent investment standard. Thus, for example, if a DME supplier and its referral sources want to be investors in an entity with which they will do business, to comply with this first standard, at least 60 percent of the value of the investment interests must be held by investors who will neither make referrals nor engage in business activity with the entity.

The second and third standards of this provision address the problems of discriminatory marketing strategies that result in the offer of better deals, for example, more shares or a better price, to individuals who will refer a high volume of patients. The second standard focuses on the status of investor and bars safe harbor protection where the terms of investment opportunities depend on whether a passive investor is in a position to influence referrals, furnish items or services, or otherwise generate business for the entity. The entity can offer investments to such investors only on the same terms as those offered to other passive investors not in a position to influence the flow of business to the entity. We are not imposing this standard on active investors because we recognize that it is precisely because of a physician's familiarity with the health care field that he or she may be chosen as a general partner and offered different investment terms from those offered to passive investors.

The third standard assumes that an investment interest is being offered to a person in a position to make referrals, but bars the offering of favorable terms based on his or her past or expected referrals or amount of business otherwise generated for the entity. This standard applies both to active and passive investors because we believe it is inappropriate to protect all investment interests where any investor, even general partners, can obtain more shares because they can be expected to generate more business for the entity. We recognize that there may be situations where it is not abusive to offer more shares based on this consideration, but we also believe that such a practice can have a serious potential for abuse.

With respect to the potential triggering of a public registration requirement under SEC rules or State "blue sky" laws, we believe that there is nothing in this provision that would compel such a result. Thus, we see no need to modify this provision.

Comment: In response to the OIG's proposal that no requirement be imposed on the investor to make referrals, many comments dealt with the issue of how investors are retained. Specifically, many commenters objected to requirements, which entities commonly place on investors, that investors must divest their interest if they no longer are able to make referrals to that entity. One commenter suggested that the OIG prohibit entities from distributing any information to investors about their referral patterns to that entity.

Response: We generally agree with these comments and have addressed them in the fourth and fifth standards of this safe harbor provision. (Paragraphs (a) (2) (iv) and (v)). The fourth standard bars the entity from requiring passive investors to make referrals or remain in a position to make referrals as a condition for retaining their investment. The fifth standard parallels the new standard for publicly traded

entities and requires the entity and investors not to market or furnish items or services to passive investors in any manner differently than to non-investors. Some examples of practices that would not be protected are provided in the discussion above on the parallel provision for publicly traded entities. These two standards apply only to passive investors because, as we stated, we recognize that active investors are often sought out because they will help generate business for the joint venture.

This fifth standard also requires the entity and any investor not to promote the services of other entities as part of a cross referral agreement. As we noted in the previous section on publicly traded entities, an example of a cross referral arrangement that would not comply with this standard exists when investors in entity "A" are explicitly or implicitly encouraged to refer to entity "B" in return for entity "A" receiving the referrals from the investors of entity "B."

Comment: A large number of commenters supported the OIG's third proposal that disclosure of the investment interest be made to individuals for which a referral is made. However, some were opposed to such a requirement.

Response: For the reasons discussed in section III.B.2. above, we decline to adopt a disclosure requirement.

(ii) Business structure. In this section we discuss the comments and our responses regarding the problem of the nature of the business structure of joint ventures. The sixth standard (paragraph (a)(2)(vi)) relates to this problem area.

Comment: The OIG received a large number of comments relating to the business structure of joint ventures, and particularly on the problem that many abusive joint ventures exist primarily on the referrals from their investors. Many of these commenters alleged that such joint ventures are unable to compete for business in the open market on the basis of cost, quality and convenience. These commenters alleged that such joint ventures thereby hurt competition by unfairly "locking in" referrals from investors. However, one trade association reported from a survey of its members that, on average, 47 percent of the referrals to entities operated by its members came from non-investors. Many commenters also expressed concern that abusive joint ventures have no real business purpose, and that the four standards we suggested will not prevent abuse. Four commenters suggested that safe harbor protection be provided where the costs to Medicare and Medicaid are not increased. One commenter observed that, in many cases, the apparent lower costs of joint ventures are illusory because their hours of operation are shorter than those of hospitals. To assure that joint ventures do not raise costs or operate in an abusive manner, a large number of commenters suggested that the OIG require utilization review.

Response: We agree with the concern that entities protected under this safe harbor provision should not exist by relying on their business coming from referrals from investing physicians. In our experience, a large number of joint ventures are formed with the intent to encourage investors to refer patients to the joint venture. In many cases, the referrals from investing physicians dominate the joint venture's business so that it does not have to compete for outside business and that it cannot survive without such referrals from its investing physicians. At that point, the business purpose of the joint venture becomes suspect.

We also agree with commenters who believed that the standards we suggested in the proposed rule will not sufficiently protect against abuse. Although some protection is afforded by the fifth standard we are promulgating which is discussed immediately above (that the entity may not treat a passive investor differently than non-investors), we believe that an additional bright line rule is necessary as a condition of safe harbor protection.

Therefore, the sixth standard in this provision requires that no more than 40 percent of an entity's gross

revenue comes from referrals from, or items or services furnished by, investors. This "60-40 percent revenue" standard is reasonable, and, at least according to one commenter's survey of its members, appears to be achievable for many joint ventures.

This standard, as well as the first standard in this safe harbor provision, provide clear rules which assure that no protection is afforded to joint ventures that operate primarily on the referrals of physician investors. By requiring that no more than 40 percent of the joint venture's revenue come from investors' referrals, we help assure that revenues of these joint ventures come from a wider group than referrals from physician investors. And by limiting the number of investors who make referrals, we help assure that the profits from these entities are distributed to a wider group than referring physician investors. Thus, these two standards will help assure that joint ventures are not dependent on the capital and referrals of physician-investors.

As part of the Department's program to monitor business arrangements' compliance with these safe harbor provisions (see section III.A. above), we will report to the Secretary on the compliance with these two 60-40 rules (see § 1001.953). This report, which will be issued within 180 days of the publication of this rule, will evaluate whether compliance with these two 60-40 rules adequately controls abusive arrangements or whether more stringent requirements are needed.

As with the first 60-40 percent standard, we are permitting a joint venture to use any internal accounting principles it chooses to adopt so long as it uses such principles consistently over time so that it is not manipulating the data to obscure its non-compliance. In addition, we are establishing the same two alternative time periods in which compliance is to be measured. The measurement period can either be a joint venture's prior fiscal year or the previous 12 month period. Again, as with the first 60-40 percent standard, it is highly unlikely we will pursue an investigation of a joint venture where it complies with all the other standards in this safe harbor, is out of compliance with this 60-40 percent standard based on its prior fiscal year data, but is making a good-faith effort to reach compliance with this standard based on data showing compliance on a monthly basis for the most recent months of operation.

As noted above in the discussion of our definition of the term "investor," in applying these two 60-40 rules in situations where the joint venture entity is owned by other entities, we will examine the ownership structure of these other entities to determine whether they are owned by physicians who are referring to the joint venture entity. In such a situation, these physicians are considered to be investors of the joint venture entity, and their ownership interest must be offset by non-referring owners and the revenue they generate for the joint venture must be offset by referrals from non-investors.

We believe the suggestion that we require protected joint ventures to provide services at lower costs to Medicare and Medicaid is unworkable. Although such a feature is obviously a desirable goal, we believe that any analysis of the relative costs of services can only be accomplished meaningfully on a case-by-case basis. Examples of some of the areas such an analysis must examine include: (1) The reimbursement methodology of the service, (2) the patient population being served, (3) the hours of operation, (4) the bad debt and free care policies, and (5) the impact on costs and charges of depreciation of new equipment. These factors must be analyzed for both the joint venture entity and other competing entities to which a comparison is being drawn.

We believe that utilization review should be encouraged. However, there are many variables that distinguish a successful utilization review program from a sham. For example, utilization review may be conducted under contract by a Peer Review Organization or another independent contractor, or it may be conducted in-house. A critical feature of utilization review is that follow-up or corrective action occurs when a determination is made that a particular practitioner who is under review is engaging in aberrant or substandard behavior. Obviously this action can take many forms, ranging from barring the practitioner

from further practice to taking no action at all. Because there are so many variables to an effective utilization review program, we believe it would be overly prescriptive and largely unproductive to impose such a requirement. Thus, we decline to include a utilization review requirement as part of this safe harbor.

(iii) Financing and profit distributions. In this section we discuss the comments and our responses regarding the problem of the financing and profit distribution of joint ventures. The last two standards (paragraphs (a)(2) (vii) and (viii)) relate to this problem area.

Comment: As discussed above, a large number of commenters argued that physician involvement in joint ventures is necessary because physicians provide needed capital. Several commenters, however, questioned whether investors are really generating capital for the joint ventures in which they invest. Many suggested that the OIG only protect an investor's capital in cases where the capital was genuinely at risk. In other words, if the investor's interest is obtained through a no-interest loan paid off through deductions from future dividend distributions, there was never really any capital placed in risk. Some suggested that the OIG protect investment interests even where the entity loans the investor funds which are then used to make the capital investment. One commenter reported results from a survey of its members that, on average, 60 percent of the investment from referring physician owners came in the form of non-cash investments (including debt guarantees).

Response: We agree that a new condition of safe harbor protection is needed to assure that the investments are bona fide, i.e., that investors' funds are genuinely at risk. Thus, the seventh standard of this provision parallels the new standard for the provision dealing with investments in large publicly traded entities: These entities cannot lend the funds or guarantee loans used to make the investment. Consistent with our first investment interest provision, other debt relationships are permitted. For example, the entity may borrow from the investor, and investors may borrow from other sources to obtain funds to use for the capital investment. But as we discussed above, where investors make their investment with money loaned from the entity, they are adding no real capital to it. Thus, this standard will help assure that physicians and other investors in fact provide new needed capital and that the joint venture is not in reality a sham to facilitate the distribution of payments for referrals.

Comment: The OIG received a large number of comments suggesting other protections to assure non-abusive financing arrangements and, in particular, urging the OIG to protect "nominal" investments. Many suggested that the OIG specify an upper limit on the amount an individual may invest, either in terms of a dollar amount or a percentage interest in the entity. Some specifically suggested a 5 percent limit. Three commenters took another approach and suggested a minimum capitalization amount, pointing out that many of the more abusive arrangements have minimal capital needs.

Response: We believe that individuals with a small investment in an entity may be just as likely as those with a large investment stake to be influenced to make referrals to the entity. Many of the more abusive joint venture arrangements of which we are aware offer only nominal investments to physicians. We believe that, in many cases, these nominal investment interests are designed to induce referrals or encourage the investor to otherwise generate business for the entity. In addition, by distributing the benefits of ownership to as wide a base of physician investors as possible, these joint ventures seek to lock-up their market, and thus operate in an insulated business environment largely free from normal competitive pressures such as pricing constraints.

We believe that it is not useful to impose a minimum capitalization requirement. Because each joint venture has different capital needs, it is not possible to specify one level of capitalization that would represent a reasonable floor for all joint ventures. For example, requiring at least \$500,000 in capitalization would obviously be viewed very differently by a laboratory joint venture than by a

magnetic resonance imaging joint venture. We do believe, however, that it is useful to analyze joint ventures on a case-by-case basis to determine what the real capital needs of the project are, and whether the capital that has been invested is merely a sham to pay investors for referrals.

Comment: We received a large number of comments on one of the standards suggested in the preamble to the proposed rule, that payments not be related to referrals. We also received other comments relating to the general problem of the manner in which profits are distributed. Many commenters suggested that the OIG limit the return on investment which will be subject to protection. Some suggested merely that the return be "reasonable," while another commenter stressed that there is no realistic way to determine an appropriate cut-off for a return on investment that would still be classified as "reasonable." One commenter suggested that, because there is less potential for abuse with repayments on debt instruments, the OIG should treat these payments differently from profit distributions.

Response: The eighth standard in this provision is that the amount of payment to each investor must be directly proportional to his or her capital investment. In other words, to receive protection, dividend payments can only be tied to the number of shares owned by an investor, and not to his or her referrals. Where investors, such as general partners, contribute capital in the form of pre-operational services or sweat equity, their dividend payments may reflect the fair market value of those services rendered.

This standard in no way protects payments to active investors for operational services they provide to the joint venture. By its very terms, this provision only protects payments that represent a return on investment. Safe harbor protection for the personal services that an active investor renders would be governed by the "personal services and management contracts" provisions (paragraph (d)).

With respect to limiting the return on investment, we believe that it would be arbitrary to specify a limitation applicable for all joint ventures, and that it would be meaningless to merely specify as a general criterion that the return "be reasonable." As many commenters pointed out, a reasonable return can be appropriately measured only in light of the risk of the investment. An investor would surely expect a much higher return from an investment in an expensive piece of diagnostic equipment that might soon become obsolete than from an investment in a relatively inexpensive piece of equipment that can be expected to generate a steady profit stream for the foreseeable future.

With respect to repayments on debt instruments, we believe that it is unnecessary to create a separate provision for debt instruments, but, as discussed in section III.C.1.a. above, this provision is written to protect a variety of payments in securities, including debt instruments.

c. Proposals for New Safe Harbor Provisions

A large number of comments were received urging the OIG to provide special protection for investments in certain special circumstances which would not qualify under the safe harbor provisions suggested in the proposed rule.

Note: Any discussion below indicating that we are considering a new safe harbor provision should in no way be construed as legalizing the business arrangement at this time.

Comment: A large majority of these commenters requested protection for ambulatory surgical centers (ASCs). Many of these commenters believed that the OIG was attempting to eliminate ASCs. In presenting the benefits of ASCs, these commenters made many of the same arguments discussed in section III.C1.b. above, regarding the positive features of joint ventures in general. In addition, many commenters emphasized the unique features of ASCs: (1) They are subject to peer review; (2) they provide services at lower prices than hospitals; (3) they were formed to a very large extent by physicians,

and (4) in many cases, they are really an extension of a physician's practice. Several other commenters suggested protection for payments from other types of entities based on a rationale similar to this latter "extension of practice" argument. For example, commenters wanted protection for physicians providing inpatient services for their patients, nephrologists performing services at renal dialysis facilities, pathologists examining test results in laboratories, and radiation therapy oncologists performing radiation therapy services at outpatient centers.

Response: We understand that a special situation may exist when a physician sees a patient in his or her office, makes a referral to an entity in which he or she has an ownership interest and performs the service for which the referral is made. In such a situation, Medicare makes payment to the facility for the service it furnishes, which may result in a profit distribution to the physician. And the physician may also receive reimbursement from the program for performing the professional service.

We believe that, with respect to the physician's own fee, such a referral is simply a referral to oneself. It should not matter whether the patient is first seen at the office or at the facility. Consequently, we believe that, in this situation, both the professional service fee and the profit distribution from the associated facility fee that are generated from this referral may warrant protection. However, we remain concerned about the investing physician's ability to profit from any diagnostic testing that is generated from the services he or she performs. We are also concerned about the extent to which we should modify this second investment interest safe harbor to protect a physician-investor's profit in other joint venture entities where he or she both makes a referral and performs some level of service for the referred patient at the entity. Therefore, we are considering a safe harbor provision, that we anticipate publishing as a separate regulation to protect these payments where there is no likelihood of abuse.

We believe that a broader exemption at this time for payments from ASCs and similar entities is not appropriate. We recognize that many of these entities, and ASCs in particular, have operated under the Medicare and Medicaid programs largely without abuse and have saved these programs money when compared to some alternative treatment settings, particularly inpatient hospital care. We also recognize that one of the fundamental purposes of the statute is to prevent abusive business arrangements that increase cost to the Medicare and Medicaid programs. However, our approach is one of providing standards that define categories of business arrangements and business practices that will be given safe harbor protection. Our approach is not one of providing protection to particular categories of health care providers who earn it by being lawful or cost-effective.

We remain concerned about the widespread apprehension expressed by those commenters with an ownership interest in ASCs. Many commenters did not understand that the investment interest safe harbor provisions upon which we invited comment would protect many of the situations about which the commenters claimed no protection was being offered. In addition, as we made clear in section III.A. above, when an investment interest does not qualify under one of the safe harbor provisions, it does not mean that prosecution is imminent. The business arrangement may not even violate the statute, or, after examination on a case-by-case basis, we may conclude that prosecution is not warranted. Our disinclination to provide blanket protection for all investment interests in ASCs does not mean that we hold them in disfavor.

2. Space and Equipment Rental and Personal Services and Management Contracts--

§§ 1001.952 (b), (c), and (d)

Comment: An overwhelming number of commenters criticized the restrictive definition of fair market value in the safe harbor provision for space rental. Many expressed concern that the safe harbor does not exempt rental payments that take into account added value attributable to a rental property's intended use

as a facility for furnishing medical, laboratory, or other health services. Some were disappointed that this safe harbor provision does not appear to allow adjustments in rental charges for special construction or renovation costs incurred by the lessor to make the space suitable for furnishing medical services. Other commenters argued that the added value to providers of locating in a building or area proximate and convenient to other health care providers is a legitimate factor in calculating rent and may bear no relationship to prospective referrals of Medicare or Medicaid program business. They contended that the close proximity of rental property to other health care providers justifies elevated rent because both providers and their patients view such location as a convenience.

Response: The safe harbor provision for space rental does not contemplate a single figure for fair market value. Rather, it contemplates a rental fee falling within a reasonable commercial range, but not taking into account any value attached by either party based upon the property's proximity or convenience to referral sources. To the extent there is a nexus between the location of property and the opportunity to engage in business reimbursable under Medicare or Medicaid, rental charges that take location into account may impermissibly generate referrals or other health care business. For example, we believe that a fair inference may be drawn that impermissible payments are being made when a group of doctors owns a medical arts building and rents space in that building to a diagnostic laboratory, and the rent is substantially above the laboratory's cost of renting the same sized space at a nearby location.

Consequently, we decline to extend safe harbor protection to space rental charges that take into account any value attached to property due to the proximity of referral sources. We have modified the definition of fair market value in this provision to clarify that protection does not extend to rental charges reflecting the value attributed by either party to the proximity or convenience of property to potential sources of referrals or other business from the other party. However, we would note that where the lessor is a real estate developer or other entity not involved in the delivery of health care services, any arrangements that encourage referrals between the lessee and other third parties would not likely be scrutinized by the OIG.

However, we recognize that there may be instances where rental fees for medical, laboratory or other health related office space are justifiably higher than the market price for comparable commercial property. For example, we agree with commenters who stated that the cost of leasehold improvements needed to make space suitable for the furnishing of medical services (such as extra plumbing or electrical costs) should be considered within the provision's definition of fair market value. Accordingly, we have further amended this safe harbor's definition of fair market value to delete the requirement that fair market value not take into account the intended use of rental space. However, we have retained the requirement that rental payments be commensurate with the fair market value of equivalent commercial property, and decline to extend blanket safe harbor protection to rental arrangements that reflect the added value a hospital places on having referring physicians located in a medical building the hospital owns on its property. We recognize that this requirement will preclude safe harbor protection for many health care providers who lease space to physicians or suppliers at a reduced rate due to the favorable location of the property. In particular, hospitals that give rent concessions to staff physicians leasing private office space may not fall within the safe harbor. For a discussion of how such payments may qualify as part of a physician recruitment effort, see section III.D. below.

Comment: A few commenters inquired whether rental arrangements involving both the use of office space and the furnishing of personal or management services must meet the requirements of both safe harbor provisions in order to be protected from liability under the statute.

Response: In section III.A. above, we addressed generally the circumstances under which the requirements of two relevant safe harbor provisions must be met in order to be protected under this regulation. However, because several commenters specifically requested guidance about contracts involving the rental of space and the furnishing of personal services, we are responding to their comments

here.

To the extent that office rental payments include the value of other personal services furnished as part of a business arrangement, the payments must reflect the fair market value of the rent and these personal services in order to qualify under the safe harbor regulation. To be exempt from kickback liability, arrangements involving remuneration for rental and personal services must meet the conditions of each provision. For example, where a mobile business provides diagnostic services to patients in physicians' offices, and contracts for diagnostic equipment or for cleaning, billing or other services in addition to renting office space from these physicians, the arrangement must qualify under the provisions for space and equipment rental and personal services and management contracts.

Comment: Several commenters, expressing support for a strong and effective anti-kickback statute, stated that sham office leases in which the space is not actually used are among the most common and abusive kickback schemes. Examples of such abusive schemes cited by commenters included physicians who entered into office rental contracts with other referring physicians, solely in order to obtain the referrals, and diagnostic services companies and clinical laboratories that lease space from physicians which the laboratories in reality do not use, as kickbacks for the physicians' patient referrals.

Response: We agree that sham contracts in which remuneration is exchanged for property that does not exist or space which is not used are among the most egregious kickback arrangements. We have become aware of office rental arrangements in which the "space" rented may not be large enough or otherwise suitable to perform any services for which rent could legitimately be paid. For example, a physician may rent office space to a clinical laboratory, allegedly in order to provide space to furnish laboratory services, when the space (often a closet or anteroom not useable for such purposes) is not actually occupied by laboratory personnel at any time. If the physician refers most or all laboratory work to this lessee, the "rent" is simply remuneration for referring laboratory work.

We believe, however, that these safe harbor provisions are sufficient to protect against this abuse. These provisions require that the amount of payments for rent, equipment or personal services contracts not take into account the volume or value of referrals or other business generated between the parties. 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.

Comment: Two commenters stated that the safe harbor requirements for determining fair market value of rental space should be the same requirements of section 501(c)(3) of title 26 of the United States Code, the Internal Revenue Code section governing tax exemptions for nonprofit institutions. Under this section, fair market value assessments are necessary to determine whether hospital/physician arrangements result in the prohibited inurement of private benefit to individuals.

Response: We do not believe that procedures for assessing the fair market value of hospital/physician arrangements under the Internal Revenue Code are relevant to safe harbor requirements under the anti-kickback statute. The anti-kickback statute is concerned with prohibiting fraud and abuse by individuals and entities participating in the Medicare and Medicaid programs; a statute providing tax exemptions to nonprofit institutions under specified conditions does not share this focus. The requirements we have set forth for determining fair market value under the safe harbor regulation are not undermined by the fact that they do not replicate the requirements under the Internal Revenue Code. Moreover, we cannot see, nor has any commenter adequately explained, how these regulations impede health care providers' ability to obtain tax exempt status under the Internal Revenue Code.

Comment: Commenters requested clarification as to whether these safe harbor provisions protect any types of percentage, "per use" or "per procedure" leases or contracts in which the amount of compensation fluctuates in accordance with the actual use of premises or equipment, or the frequency of services performed. A few commenters inquired whether percentage leases between parties in a position to refer Medicare or Medicaid business were a per se violation of the statute. Many commenters urged the OIG to extend safe harbor protection to per use equipment leases, and to percentage contracts for personal services, in which total business, in contrast to referral business, is the basis for payment. With regard to equipment leases, several commenters argued that these provisions should protect equipment lessors who receive higher rent based on increased use, because the useful life and value of equipment depreciates with use.

Response: As we explained in section III.A. above, in discussing wear and tear clauses, percentage or per use agreements between health care providers in a position to refer Medicare or Medicaid business threaten to violate the statute because the payments in these arrangements are directly tied to the volume of business or amount of revenue generated, providing an improper incentive to refer. Moreover, historically, percentage leases and contracts have been rife with abuse.

These sorts of arrangements need to be examined on a case-by-case basis. For example, a lease to a hospital of major medical equipment, such as a magnetic resonance imaging scanner, may specify that higher rent is to be paid when more than a predetermined number of procedures is performed. Such an arrangement can be troublesome if the lessor is a partnership of radiologists on the hospital's medical staff, because the incentive for overutilization is clear. It is the nature of the relationship, if any, between overall volume of use and referrals, that triggers the statute. Thus, if the owner of equipment were not in a position to make referrals to the lessee, the agreement would not violate the statute.

For these reasons, we specifically decline to protect rental charges or compensation for personal services where the aggregate amounts of payments are not set out in advance. This does not mean, however, that percentage or per use leases and contracts that are based on overall volume (including business from referral sources with no financial interest to motivate them), are per se violations of the statute. We recognize that legitimate considerations, such as the depreciation of equipment, could result in some part of the payment to be based on a percentage or "per use" payment arrangement without these payments influencing or being influenced by Medicare or Medicaid referrals. However, the more the payments appear to reflect the volume of referrals from the financially-interested party, the more suspect the arrangement becomes and the more likely we will need to examine it carefully.

Comment: Many commenters were opposed to the condition that space and equipment leases and personal services and management contracts run for periods of not less than one year. They argued that the one year condition was superfluous, given additional restrictions relating to fair market value and referral relationships between the parties. They also argued that the one year rule would preclude many legitimate short-term arrangements, such as leases of state-of-the-art imaging equipment by health care providers who could not afford a full year's lease. Some health care providers claimed that the rule would cause them to forsake good business judgment in order to obtain needed equipment or services.

Commenters were most concerned about the one year requirement in the context of personal services and management contracts. Several commenters argued that many professional services typically contracted for by health care providers, from medical or surgical consulting services to peer review functions, involve projects or activities that require less than one year to complete. They argued that it is inefficient and wasteful for health care providers to enter into contracts for periods of one year under these circumstances. Additionally, a few commenters sought clarification as to the effect of the one year rule on leases terminated for cause prior to the expiration of a contract extending one year or longer. In particular, there was concern that the conditions of the space rental safe harbor not conflict with Internal

Revenue Service guidelines governing advance determinations of tax exempt status. These guidelines require tax exempt facilities to be able to terminate, within 90 days notice, contracts with non-exempt persons where compensation is based on fees charged for services furnished by the non-exempt persons.

Response: We have retained the one year contract requirement as a condition for safe harbor protection under the space rental, equipment rental, and personal services and management contracts safe harbor provisions. We included the one year rule limitation in these provisions because we are concerned about abuse resulting from periodic renegotiation of ostensibly short term agreements, in response to changes in referral patterns. For example, if a health care provider rents office space to another individual or entity with whom he or she is in an ongoing referral relationship, and these providers alter their rental terms with frequency, the volume or value of referrals can influence the size of renegotiated rental payments. When rental charges are constantly subject to modification, the threat to the lessor of receiving reduced rent, or the threat to the lessee of paying higher rent, may improperly induce increased referrals. However, we recognize that health care providers may enter into short-term leases or services contracts for legitimate business reasons and not on account of referral opportunities. For example, an academic physician who spends one semester or school year visiting at another medical university may need to rent office space from the medical university for less than a year.

Several commenters expressed concern that contracts for the performance of activities or services that, by their very nature, take less than one year, would necessarily fall outside the safe harbor provision for personal services and management contracts. However, the one year contract requirement restricts the period within which contract terms may not be changed, and not the time within which services under a contract may be performed. So long as contract terms are not altered within a one year period, an agreement that is performed in less than one year's time will meet the one year requirement in the safe harbor provision.

With regard to the comments we received concerning early termination clauses in leases or contracts extending not less than one year, we acknowledge the customary use of such provisions for tax and other legitimate business purposes. The legitimacy of an early termination clause in a lease or contract which otherwise meets the conditions of these three provisions depends on the parties' intent. Termination "for cause" clauses drafted in compliance with Internal Revenue Service or other legal or regulatory requirements should not jeopardize safe harbor status, if the purpose of the termination clause is to comply with those requirements, and not to facilitate renegotiation of contract terms. If a contract is terminated in accordance with a legally enforceable termination clause, the failure to renew the contract would provide evidence that the termination was effectuated for a legitimate purpose.

Comment: The safe harbor provisions governing space and equipment rental and personal services and management contracts provide that when the property or service is to be provided on a periodic, sporadic or part-time basis, the agreement must specify precisely the timing and duration of rental periods and compensation charged for each period. Numerous commenters were troubled by these requirements. They argued that furnishing professional services and leasing space and equipment on an "as needed" basis are commercially acceptable, cost-effective business practices that should be protected so long as the rate of compensation is commercially reasonable. They also stated that under many periodic lease and contract arrangements, precise intervals of activity or use, and the exact compensation for these intervals, cannot feasibly be specified in advance. In addition, there was concern that requiring specificity of time intervals and compensation as conditions for safe harbor protection would interfere with the flexibility necessary to accommodate changing demand, and would increase costs in situations where the demand proved lower than expected at the time the contract was made. Finally, a few commenters asked for clarification of the meaning of the word "periodicity" in these three provisions when the space or equipment lease or personal services agreement is not on a full-time basis.

Response: Part-time contractual arrangements and periodic access leases between health care providers are especially vulnerable to abuse because they are subject to modification based on changing referral patterns between the parties. For example, an optometrist who pays ad hoc "rent" to an ophthalmologist for the time spent in the physician's office examining only referred patients, is impermissibly paying for the referrals. In order to avoid the potential for abuse inherent in part-time business arrangements between parties in actual or potential referral relationships, we have limited safe harbor protection under these three provisions to periodic leases and contracts which set forth the timing, frequency, and length of services or intervals of use.

We recognize that health care providers, for various reasons, may be unable to specify the timing or duration of business arrangements, or the precise compensation involved. For example, compensation under a management contract requiring the furnishing of supplies and the hiring of personnel may need to vary depending on the costs of the supplies and number of personnel. Or, a health care provider may contract with an allied health practitioner group (such as a physical therapy group) to pay a specific amount per hour of care provided, without being able to anticipate the scheduling of services in advance. We believe that part-time leases or service arrangements that do not meet safe harbor standards need to be analyzed on a case-by-case basis under the statute. Many periodic contracts of this sort would fall outside the statute because the compensation involved is not linked to referral opportunities. A contract to serve as medical director of a small clinic on a part-time basis, for example, is not likely to involve activities or compensation tied to the referral of patients or to arrangement for services reimbursable under Medicare or Medicaid programs.

Finally, we are deleting the word "periodicity" from these three provisions because it duplicates the requirements that the rental or equipment lease or personal services agreement specify the schedule of intervals, their precise length, and payments for the intervals.

Comment: Three commenters requested the OIG to protect marketing and advertising activities because such activities either promote competition or do not violate the statute.

Response: The statute on its face prohibits the offering or acceptance of remuneration, inter alia, for the purposes of "arranging for or recommending purchasing, leasing, or ordering any. . . service or item" payable under Medicare or Medicaid. Thus, we believe that many marketing and advertising activities may involve at least technical violations of the statute. We, of course, recognize that many of these advertising and marketing activities do not warrant prosecution in part because (1) they are passive in nature, i.e., the activities do not involve direct contact with program beneficiaries, or (2) the individual or entity involved in these promotions is not involved in the delivery of health care. Such individuals or entities are not in a position of public trust in the same manner as physicians or other health care professionals who recommend or order products and services for their patients. Thus, we agree that many advertising and marketing activities warrant safe harbor protection under the personal services and management contracts safe harbor.

However, we have experienced many instances where promoters and consultants have become involved in marketing activities that encourage health care providers and others to violate the statute, such as to develop impermissible joint venture arrangements or to routinely waive coinsurance and deductible amounts owed under Medicare Part B. It would be inappropriate to allow such activities to receive safe harbor protection.

Thus, we are adding paragraph (d)(6) to this safe harbor provision to make clear that the service that is contracted for is not protected if it involves the counselling or promotion of a business arrangement or other activity which itself constitutes a violation of any State or Federal law. However, the safe harbor (revised as indicated) protects contracts where the individual paid under the contract counsels or

promotes business arrangements or other activities that are either specifically exempted under one of the provisions of this regulation or otherwise do not violate the statute.

Comment: Four commenters sought specific protection for commission sales arrangements between health care providers and independent contractors.

Response: We see no reason, nor has any commenter claimed to have provided one, for treating commission sales agreements differently under these regulations from other types of contracts for personal services performed by independent contractors. Therefore, commission sales agreements must meet the conditions of the safe harbor provisions governing personal services and management contracts.

3. Sale of Practice--§ 1001.952(e)

Comment: While many commenters supported the one-year limitation on the completion of a sale of a practice, others believed that it is too short. One commenter asserted that such a limitation would effectively ban option agreements on sales of physicians' practices.

Response: We decline to protect option agreements or sales which extend beyond one year because, as we stated in the preamble to the proposed rule, we believe that this is an area of significant abuse. Often, sales and option agreements are designed solely to ensure referrals, and payments for the sale or option agreement are actually payments for referrals. The one-year limit serves to protect sales where the sale occurs because the physician is no longer going to be practicing and not because the purchaser seeks an ongoing stream of referrals. To the extent that one can enter into an option agreement, exercise that option and complete the purchase of the practice within one year from the date the option agreement is entered into, this aspect of the transaction will fall within this safe harbor provision.

Many commenters appeared confused about whether the provision requires payments from the sale to be completed within one year. This provision does not preclude a purchaser from making payments to a practitioner beyond the one- year period as long as the other conditions of this provision have been met.

Comment: Many commenters strongly supported the one-year grace period from the date of a purchase agreement to complete the purchase, and during which time referrals would be permissible. One commenter believed this period should be shortened to six months, but others stated that it should be longer than one year.

Response: We were presented with no persuasive reason to extend or shorten this one-year period and we therefore decline to revise this limitation period.

Comment: Several hospitals requested protection for their purchases of the practices of retiring physicians.

Response: When a hospital purchases a physician's practice and thereafter there are no referrals from that physician to the hospital, the statute would not appear to be implicated. Accordingly, in ordinary circumstances, a hospital is not in violation of the statute if it purchases the practice of a retiring physician who no longer makes referrals to that hospital.

However, many hospitals engage in this practice as part of a physician recruitment effort. Such activities do implicate the statute, but we are considering a new safe harbor provision, that we anticipate publishing as a separate regulation, to protect many such recruitment activities.

Comment: Several hospitals requested that their practice of buying physicians' practices for fair market

value and then retaining the physicians on staff be afforded the protection of a safe harbor. They asserted that the financial pressures of maintaining private practices have drawn physicians to hospitals in order to get management assistance and capital.

Response: As we stated in the preamble of the proposed rule, hospitals often purchase physicians' practices in order to ensure the hospital of a steady stream of referrals. We continue to believe that such practices lead to increased program costs and potential conflicts between the patient's best interests and the physician's business relationship to the hospital. Accordingly, we decline to protect a practice that often leads to the very abuses that the statute is designed to prevent.

Comment: Several commenters requested safe harbor protection for the sale of an individual's practice to a group practice or the sale of part of a practice to another physician or group practice when the physician chooses to change the scope of his or her practice.

Response: We recognize that some buy-out arrangements are not abusive, and we would not want to prosecute such arrangements. However, we are also aware of abusive purchase arrangements, such as between ophthalmologists and optometrists, where one practitioner or group practice seeks to buy another practitioner's practice as a condition for continuing to make referrals. In essence, the sale becomes another mechanism for the buyer to profit from the stream of referrals made to the seller who previously practiced independently without dividing profits with the new "partner." No commenter proposed standards for a safe harbor provision that would cover only arrangements that are not abusive, and we are skeptical that such standards can be formulated. Accordingly, we have not protected this very diverse category of sales of practices. Rather, we are considering a limited new safe harbor provision for the purchase of group practices that we anticipate publishing as a separate regulation.

Comment: Two commenters asked the OIG to clarify the relationship between the safe harbor provision for the sale of a practice and the employee exception.

Response: Where a practitioner purchases another practitioner's practice, makes payments to that other practitioner which continue for some period of time, and retains that other practitioner on his or her staff as an employee, we believe that such payments are not protected under this provision or the employee exception. They do not qualify under this provision because the practitioner who sold the practice remains in a position to make referrals. The payments are not protected by the employee exception because that provision only protects payments "for employment in the provision of covered items or services * * * ." These payments, however, relate to the purchase of a practice and not to services provided pursuant to employment for the provision of items or services. Of course, the employing practitioner who has bought out the other practitioner is making other payments for such employment services, and if a bona fide employment relationship as defined in 26 U.S.C. 3121(d)(2) exists, then these payments are protected under the employee safe harbor provision. As noted in the General comments section in section III.A. above, where parties are attempting to comply with two safe harbor provisions, we would expect separate justifications for compliance with each provision.

4. Referral Services--§ 1001.952(f)

Comment: Many commenters urged the OIG to extend this safe harbor provision beyond only physicians to include payments by chiropractors, dentists, podiatrists, psychologists, nursing homes and other health care providers to entities that refer members of the public to them.

Response: We agree and have revised this provision to protect payments by practitioners and other health care providers who utilize referral services.

Comment: Many commenters requested that the OIG define the term "qualified" with respect to the requirement that a referral service not exclude any "qualified" health care provider from participation in the service.

Response: Whether a particular health care provider is "qualified" as a participant in a referral service will vary depending on how the service is organized. For instance, to be qualified as a participant in a referral service run by a hospital, it may be necessary that the participant be an employee of that hospital. On the other hand, a referral service run by a professional organization may require only that the participant be a dues-paying member of that organization to qualify for participation. The determination as to whether a particular health care provider is "qualified" to participate in the service may be made by the referral service according to its own criteria. To be protected under this safe harbor, the referral service must apply the eligibility criteria equally to all participants in the referral service.

In addition, the referral service must disclose to all persons seeking a referral the criteria it uses to determine who is qualified as a participant. The information that must be disclosed includes the manner in which it selects the pool of participants. In other words, if a pregnant woman calls a hospital's referral service, the referral service must disclose how it selects obstetricians to be qualified to receive referrals and whether the obstetrician has paid a fee to participate. The referral service must also disclose how the particular obstetrician is selected for the referral, for example, on a rotation basis. In addition, the referral service must disclose the relationship between the participant and the referral service, for example, that the obstetrician is on the active medical staff. Finally, the referral service must disclose what criteria it uses to exclude an individual or entity from continuing as a participant, for example, if a malpractice allegation is raised against the obstetrician or if he or she refuses to treat a certain level of uncompensated care cases.

The referral service must maintain a written record certifying that such disclosures have been made to each person seeking a referral. Such a record must be signed by either the person seeking the referral or by the individual making the disclosure on behalf of the referral service. This requirement will not be met if the referral service merely maintains a blank copy of the disclosure form or instructions to staff on how to make the disclosure.

Comment: One commenter suggested that a referral service should be permitted to require the practitioners or providers to charge clients that are referred by the service the same fees as they charge other clients.

Response: We agree and have revised paragraph (f)(3) to permit referral services to bar participants from engaging in discriminatory pricing practices.

Comment: A few commenters were uncertain about what fees could be charged for the referral service. They questioned whether the referral fee must be paid prior to the referral and whether a set amount could be charged for each referral.

Response: This provision protects fee payments that are related only to the cost of operating the referral service. This provision explicitly does not protect fees that in any manner are based on the volume or value of Medicare or Medicaid referrals or business otherwise generated by the participant for the referral service. While a referral fee need not be paid in full before any referrals are made, paragraph (f)(2) specifies that referral fees may not be based on the volume of referrals to the practitioner or provider.

Comment: One commenter asked whether the disclosure requirements of this provision could be satisfied by sending a letter to the referred person after the referral is made.

Response: Although the method of disclosure is not prescribed, to meet the requirements of this provision any disclosure must constitute effective disclosure. Effective disclosure requires that the relevant information is communicated in time for the information to be used by the beneficiary before an important decision is made. Accordingly, it is unlikely that disclosure after the referral has been made would constitute effective disclosure if the beneficiary had already seen the health care provider, or in some cases, if the appointment had already been made.

Comment: Several commenters questioned whether the statute and, therefore, this safe harbor provision, applies to referral services where health care providers are not charged for the services or where the services are provided pursuant to association dues.

Response: The statute applies to such referral services. The statute is implicated not only where direct payments are made in return for referrals, but also where indirect forms of remuneration are given for referrals. For example, hospitals often operate free referral services for members of their medical staffs as one of the benefits that comes with being on that hospital's staff. In return for the benefits of staff privileges (including the free referral service), physicians have a variety of obligations, such as sitting on various hospital committees. Depending on the circumstances, the services physicians furnish a hospital to assist in its operations may constitute a form of remuneration to the hospital for providing the referral service, and would be covered by the statute. As the United States Court of Appeals for the First Circuit found: "Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient." *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, *supra*, 874 F.2d at 29. Therefore, staff physicians and hospitals seeking safe harbor protection must comply with this provision when they are engaged in a referral service that does not charge a specific fee.

5. Warranties--§ 1001.952(g)

Comment: Two commenters objected to the requirement that as a condition for protection the warranty include payments to compensate for any costs associated with the replacement of the product that is the subject of the warranty. These commenters pointed out that virtually no warranties now in existence pay for such expenses and that this requirement will necessitate the revision of warranty policies, which in turn must be paid for by price increases to cover this additional liability expense.

Response: We agree with the concern over the potential that this standard will increase costs, and are deleting it. We are revising this provision based on the Federal Trade Commission interpretation of 15 U.S.C. 2301(6), which does not require the manufacturer to make full payment to compensate for all costs associated with its defective product.

Comment: One pacemaker manufacturer noted that a particular warranty complied with the discount exception, implying that it need not comply with this warranty provision.

Response: We do not believe that warranty arrangements fit within the "discount" safe harbor provision, and are revising that provision accordingly. However, we agree that some of the policies underlying the discount exception should apply to warranties. Consequently, with respect to any reductions of equipment prices offered as part of a warranty agreement, we are requiring the same disclosure requirements as contained in the discount provision.

Comment: Two commenters urged the OIG to expand this safe harbor provision to protect "competitive replacement agreements." Under such an agreement, for example, a company offers various inducements to encourage hospitals (or other entities such as ASCs) and physicians to replace a defective pacemaker with one made by the company offering the inducements. These commenters argued that these

arrangements should be protected because they make it easier to purchase the latest available technology. In addition, the comments pointed out that there is little potential for abuse because Peer Review organizations review virtually every pacemaker implant decision, and because competitive replacement programs put the beneficiary only in the same financial position he or she would be in if he or she purchased a replacement pacemaker from the original manufacturer pursuant to that manufacturer's warranty.

Response: We generally agree with these comments, but we remain concerned that many of these programs either provide additional incentives beyond the original warranty or impose additional costs on the Medicare and Medicaid programs. For example, while some competitive replacement programs replace the item, such as a pacemaker, only on the same terms as those in the warranty of the original manufacturer, others replace the item under other conditions as well; while some provide the replacement item free of charge, others provide a discount on the replacement item capped at a specified dollar amount; and while some make no payments for medical expenses, others assist patients (either directly or by paying the health care provider) with their unreimbursed medical expenses up to a specified dollar amount. Depending on the original manufacturer's warranty, some of these programs do much more than merely put the beneficiary in the same position he or she would be in if he or she bought a replacement item from the original manufacturer under the terms of that warranty.

We believe that safe harbor protection is proper where a replacement program honors the original manufacturer's warranty, which qualifies by itself under this provision, and the agreement provides remuneration on the same terms as the original manufacturer's warranty without providing additional incentives or shifting additional costs to the Medicare and Medicaid programs. Under such programs, any incentive to replace a product under warranty stems from the original warranty, and not from the competitive replacement agreement.

We remain concerned about potential abuse in one additional area. Some competitive replacement agreements pay the health care provider or practitioner directly for the beneficiary's medical expenses. We believe that such direct payments are potentially abusive because the health care provider or practitioner knows that the warranty insures against beneficiaries' bad debts. Thus, we are adding paragraph (g)(4) so that safe harbor protection is not provided when payments are made to any health care provider (such as a hospital or ASC) for expenses such as medical, surgical or hospital expenses incurred by the beneficiary. Payments made to the health care provider or practitioner for the item itself, or price reductions on that item, are protected.

Comment: One commenter suggested that the OIG should provide safe harbor protection for payments made by manufacturers or suppliers to settle claims or to satisfy judgments arising out of product liability claims regardless of whether such payments were included in the warranty at the time of the original sale of the item.

Response: Where such payments are not part of a warranty made at the time of the original sale of an item, they do not appear to be intended to induce the purchase of that item, and hence are not covered by the statute. Where such payments are included in a warranty given at the time of sale, they would only be protected if they were made as part of a warranty that complied with this provision.

Comment: One commenter suggested that the OIG should not provide safe harbor protection for middlemen suppliers that expand the protection afforded by the manufacturer's warranty.

Response: We believe that warranties generally benefit consumers as well as the Medicare and Medicaid program, even though they may constitute a technical violation of the statute. As long as a supplier acting as a middleman wholesaler complies with this safe harbor provision, we fail to see the harm when it

provides greater benefits than those provided by the manufacturer. Such expanded warranties are commonly provided by middlemen in industries other than health care, for example, by automobile dealers, and we believe such expanded warranties should be encouraged.

6. Discounts--§ 1001.952(h)

Comment: A few commenters expressed concern about the meaning of the word "discount." For example, four commenters asked us to clarify whether a discount includes a general price reduction offered across the board to all buyers. One commenter argued that a marketing strategy similar to a warranty, but not falling within that safe harbor provision was, in fact, a discount.

Response: We believe that this first statutory exception is intended to cover discounts and other price reductions offered by a seller through an arms length transaction to induce a buyer to order or purchase goods (including items) or services for which the discount applies or other goods or services payable under Medicare or Medicaid. A discount typically is the difference in the price at which a good or service is normally sold compared to the price at which it is actually sold when the inducement is given.

The statutory discount exception applies only to discounts obtained by health care providers who submit claims to the Medicare and Medicaid programs. We believe that this exception was not intended to cover the offering of discounts by health care providers who submit claims, for example, to beneficiaries as part of a routine waiver program for coinsurance and deductible amounts. We have changed the definition of the term "discount" to clarify the limited scope of this exception. A discussion of the limited safe harbor protection we are providing for routine waivers is found in section III.B.4. In addition, as discussed in section III.B.3., price reductions negotiated by HMOs, preferred provider organizations and other health care plans to protect such discounted fee arrangements are expected to be addressed at a later date in a separate interim final rule.

We believe discounts are distinct from across-the-board price reductions offered to all buyers where the inducement that is made is so diffuse that it does not appear intended to encourage a particular buyer to purchase or order a particular good or service payable under Medicare or Medicaid.

In addition, we believe that Congress did not intend for this discount exception to apply to price reductions offered to one payor but not to Medicare or Medicaid. For example, we are aware of cases where laboratories offer a discount to physicians who then bill the patient, but do not offer the same discount to the Medicare program. In some of these cases, the discount offered to the physician is explicitly conditioned on the physician's referral of all of his or her laboratory business. Such a "discount" does not benefit Medicare, and is therefore inconsistent with the statutory intent for discounts to be reported to the programs with costs and charges reduced appropriately to reflect the discounts.

Another problem exists when an entity, which is both a provider or supplier of items or services and a joint venture partner with referring physicians, makes discounts to the joint venture as a way to share its profits with the physician partners. Very often this entity furnishes items or services to the joint venture, and also acts as the joint venture's general partner or provides management services to the joint venture. For example, in some cases a reference laboratory performs testing for another laboratory at a discount price in accordance with a management contract. In other cases, the services the reference laboratory provides are paid on the basis of a percentage of revenues that the joint venture receives from Medicare. These arrangements are not arms length transactions where the joint venture entity shops around for the best price on a good or service. Rather, it has entered into a collusive arrangement with a particular provider or supplier of items or services that seeks to share its profits with referring physician partners. To clarify that we do not intend to protect these types of transactions which are sometimes made to appear as "discounts," we are clarifying the definition of "discounts" in paragraph (h)(3) of this section to

permit only transactions made on an arms length basis.

Since many of these illegal transactions are made as part of personal services or management contracts, we are clarifying the definition of "discounts" to preclude discounts made as part of such transactions. We are making this revision for the additional reason that Congress did not intend to exempt such arrangements merely because those services were provided at a "discount." Since we believe that contracts for personal or management services do not fit within the ambit of the statutory discount exception, such arrangements must be analyzed under the respective safe harbor provision for those contracts. Of course, to the extent that the failure to report the actual price of the management contract implicates the civil monetary penalties law (section 1128A of the Act) liability may be imposed under that statute.

With respect to warranties, as we discussed in the warranty section immediately above, warranties are not discounts. Therefore to provide clearer guidance, we have modified the definition of the term "discount" in paragraph (h)(3) to exclude warranties and other examples of arrangements that do not constitute "discounts."

Comment: Many commenters urged the OIG to expand this safe harbor provision to include a variety of other discounting practices where the benefit received relates to something other than the specific good or service purchased or provided. Examples of the suggested permissible arrangements include bundled goods closely related to the purchased goods, such as free "surgical packs" (including such items as sutures, Healon, viscoelastics, and disposable gloves provided with purchases of intraocular lenses (IOLs), or credits toward free computers or other items that are useful in a physician's practice.

Response: We believe that such an interpretation goes well beyond the legislative intent of this statutory exception, and vitiates its purpose. We believe that Congress did not intend to include within this provision the practice of a seller giving away, or reducing the price of, one good in connection with the purchase of a different good. Such arrangements, for the most part, do not represent price reductions where the value of the goods received can be measured and fully reported to the Medicare and Medicaid programs.

Although there are many instances where these practices are cost effective arrangements that benefit the health care provider, there is enormous potential for abuse. One of the most common features of a serious kickback violation exists when a seller offers a valuable good, for example a car or a trip, to a person in return for that person's participation in activity prohibited under the statute, for example, referral of business payable by the Medicare and Medicaid programs. Thus, these commenters, while pointing to some potentially beneficial arrangements, are asking us to permit a broad class of arrangements that would include acts which have resulted in criminal convictions and at least one pending criminal prosecution. *See e.g., United States v. Bay State Ambulance and Hospital Rental Service, Inc., supra.*

Even where the particular item that is being given away may result in a more effective means of delivering the supplies to the health care provider, these types of "discounts" cause problems because they often shift costs among reimbursement systems or distort the true costs of all the items. As a result, it may be difficult for the Medicare and Medicaid programs to determine the proper reimbursement levels.

For example, in developing accurate pricing data to assist HCFA in setting the amount of reimbursement for IOLs, we found that bundled pricing arrangements similar to those suggested by our commenters were common, and made it difficult to determine the true acquisition cost of IOLs. (See Medicare certified Ambulatory Surgical Centers, Cataract Surgery Costs and Related Issues, at 9- 12, March 1988, OAI-09-88-00490.) In addition, HCFA determined that its IOL pricing data obtained from the ASCs "revealed significant inconsistencies in reporting net IOL costs." 53 FR 31476. The necessity of

accurately reporting the true acquisition costs of IOLs undistorted by bundling arrangements is underscored by HCFA's stated policy in its final rule promulgating a \$200 add-on rate: "to continue to collect data on IOL acquisition costs and purchasing arrangements to ensure that the IOL rate appropriately reflects lens acquisition costs." 55 FR 436.

Finally, this practice of bundling IOLs with other goods is of sufficient seriousness that it is the subject of at least one pending criminal prosecution.

For these reasons, we decline to broaden the scope of this provision to include discounts on bundled goods and have clarified the definition of the term "discount" to specifically exclude such arrangements. Of course, where discounts are offered on goods that are unbundled and the discount otherwise complies with the rules of this provision, safe harbor protection is granted.

For purchasing practices involving the free provision of another type of item, we will examine the surrounding circumstances to determine the desirability of prosecuting that arrangement. Examples of potential factors which we may consider include: (1) The amount of the benefit that was reported and passed along to the programs, (2) whether the good is separately reimbursable, and (3) the intent behind the arrangement.

A related issue is the practice of giving away free computers. In some cases the computer can only be used as part of a particular service that is being provided, for example, printing out the results of laboratory tests. In this situation, it appears that the computer has no independent value apart from the service that is being provided and that the purpose of the free computer is not to induce an act prohibited by the statute. Rather, the computer is part of a package of services provided at a price that can be accurately reported to the programs. In contrast, sometimes the computer that is given away is a regular personal computer, which the physician is free to use for a variety of purposes in addition to receiving test results. In that situation the computer has a definite value to the physician, and, depending on the circumstances, may well constitute an illegal inducement.

Comment: A large number of commenters urged the OIG to broaden this safe harbor provision to include other reductions in price, such as "rebates" and "credits." These commenters argued that such programs are equivalent to price reductions and are capable of being properly reported.

Response: We generally agree with the thrust of these comments and have revised the definition of discount in paragraph (h)(3) to protect rebate checks, redeemable coupons and credits, subject to the following conditions. First, because of our continued concern about the potential for improper use of redeemable coupons, we are limiting the ability of recipients of such discounts to negotiate these instruments to third parties. As revised, this provision requires these instruments to be redeemed only by the seller. Second, the rebate check, redeemable coupon, or credit can only be applied to the same good or service that was purchased or provided. Thus, a redeemable coupon or credit obtained on the purchase of one good cannot be used toward the purchase of a different good. Third, like other discounts covered under this provision, these forms of discounts must be fully and accurately reported. Finally, except as noted below, such discounts must be given at the time the good or service was purchased or provided.

The reporting of credits presents an unusual situation because the monetary value of the credit only applies to future purchases of goods or services. Thus, to comply with this provision, the buyer must report the credits on the applicable cost report or claim form covering the goods or services for which the credit is being used.

Comment: A large number of commenters urged the OIG to expand this safe harbor provision to include other types of discount mechanisms where the value of the discount is not calculated until after some

period of time has passed. Examples of such a discount mechanism include end-of-year discounts and prompt pay discounts. These commenters believed that these discounting mechanisms encourage legitimate, beneficial business practices that do not harm the program. In addition, many commenters pointed out that such discounting practices have long been encouraged through HCFA's prudent buyer guidelines. (Provider Reimbursement Manual, part I section 2103, HCFA Pub. No. 15-1)

Response: We recognize that there are many legitimate discount programs where the value of the discount is only reported after the good is purchased or the service is provided. Unfortunately, due to the nature of some reimbursement systems, it is sometimes not possible to determine retrospectively how much such discounts reduce the price of the goods or services previously purchased or provided. For example, it would be virtually impossible to take the numerous claims for cataract surgery submitted by a physician in a given year and determine the true acquisition cost of an IOL provided to that physician when the discount is only calculated at year end. Thus, paragraph (h)(1)(iii) of this section, which governs discounts on items and services paid on the basis of charges or acquisition costs, does not permit end-of-year discounts. On the other hand, where the Department or a State agency requires a health care provider to maintain cost reports (including HMOs, CMPs and health care prepayment plans (HCPPs) pursuant to agreements under sections 1876(h) or 1833 of the Act), we believe that end of year calculations of discounts on purchases of the same good or service can be fully and accurately reported, as well as those discounts obtained at the time of the purchase.

Therefore, we are revising this provision in paragraph (h)(1)(i) of this section (which applies only to cost report providers) to protect such end- of-year discounts when all of the following conditions are met. One, end-of- year discounts can only be calculated based on purchases of the same good or service in a single fiscal year. Of course, the discount may be obtained at the time of purchase as well. Two, the entity must claim the benefit of the discount from the seller in the fiscal year in which the discount is earned or the following year. In many cases, a seller will be able to calculate the amount of the discount and give the buyer the benefit of the discount (for example, in a credit or reduced price on future purchases of that same good) in the same fiscal year in which the credit was earned. However, in many other cases, the seller may take several weeks after the end of a fiscal year to give the buyer the necessary information. Under either circumstance, this prong of the safe harbor is satisfied. Three, the buyer must fully and accurately report the discount in the cost report for the fiscal year in which the benefit of the discount is received. And four, if the Secretary or a State Medicaid agency requests information, the buyer must provide the appropriate invoices from the seller. (See discussion below of seller's separate reporting requirements.)

We believe that this revision complies with the most important statutory requirement of the discount exception--full reporting--and accommodates many of these end-of-year discounting programs. In addition, we believe that this revision is consistent with HCFA's prudent buyer rules, which are not applicable to charge-based health care providers.

With respect to prompt pay discounts, we have made no change to include such discount arrangements. No change is necessary because, by definition, they are designed to induce prompt payment, and thus do not appear to violate the statute. Of course, we will continue to scrutinize closely "prompt pay" discounts to make sure that they are not payments made for an illegal purpose cloaked under a legitimate label.

Comment: Three commenters requested the OIG to provide various kinds of special treatment for HMOs and PPOs. For example, one commenter urged the OIG to broaden this provision as it applies to HMOs to permit cash grants and training assistance. Another commenter urged the OIG to change the definition of discount to permit discounts offered to HMOs and PPOs by contract health care providers.

Response: We recognize that HMOs and CMPs paid in accordance with a risk contract with HCFA or a

State health care program deserve special attention, and paragraph (h)(1)(ii) follows the proposed rule recognizing their special status. These HMOs and CMPs need not report discounts they receive except as may otherwise be required under their risk contract.

In addition, we have expanded this provision in significant ways that should be of assistance to all health care providers, including HMOs. However, we do not believe that it would be appropriate to provide special safe harbor protection for purchasing arrangements that go beyond the intended purpose of this statutory exception. As with all arrangements that drift from a safe harbor out to sea, we will examine them on a case-by-case basis to determine whether the statute has been violated in such a way as to warrant prosecution.

With respect to discounts offered to HMOs, CMPs and PPOs by contract health care providers, as discussed in section III.B.3. above, we are expecting to promulgate a new interim final safe harbor provision to protect arrangements between these parties for the furnishing of covered items and services to beneficiaries where certain standards are met.

Comment: Many commenters objected on a variety of grounds to the requirement that charge-based health care providers reduce their charges by the full amount of the discount. These commenters pointed out that historically the Medicare program has not sought to regulate the discrete components that make up a particular charge. In addition, many suggested that the OIG will destroy the incentive of obtaining discounts if it requires health care providers to pass along the full amount of the discount to the programs. Another rationale for suggesting a change in this safe harbor provision is that the OIG should treat cost and charge-based health care providers in the same manner, and because this safe harbor provision does not require a reduction in reported costs for cost-based health care providers, no parallel requirement should be placed on charge-based health care providers.

Response: We agree with the thrust of these comments, and are revising paragraph (h)(1)(iii) of this safe harbor provision to delete the requirement that charge-based health care providers reduce their charges by the full amount of the discount. Such a provision would be largely unenforceable. As many commenters pointed out, the Department has never monitored the various input costs that make up a health care provider's charge. Therefore, we are not in a position to know a health care provider's base from which he or she was reducing the charge. Thus, for example, if a physician receives a discount as defined in this provision valued at \$4 per service, the physician could argue that he or she is not required to reduce the charge by that amount because other costs included in that charge had increased to offset the \$4 discount. We are generally not in a position to prove otherwise.

Although we continue to believe that individuals and entities have an obligation to pass along to the Medicare and Medicaid programs the value of discounts they receive, we believe that the actual savings that would result from requiring such charge reductions would be offset by the cost of enforcement. In many areas of reimbursement, for example, physician or laboratory services and purchases of IOLs, Congress has steadily moved away from charge-based reimbursement or has imposed limitations on charges. We believe that those statutory reforms are better suited to address the problem of excessive charging practices. Nonetheless, even though we are deleting this requirement for the purposes of this safe harbor provision, we strongly encourage charge-based health care providers to pass along discounts to the programs.

With respect to the different treatment of health care providers based on the type of reimbursement system, we believe that reasonable safe harbor rules for discounts must be closely tailored to the various reimbursement principles and cost reporting mechanisms. Just as we believe it is appropriate to treat HMOs reimbursed on a capitated basis differently from other health care providers, we now believe that it is appropriate to treat charge-based health care providers differently from cost-based health care

providers for the purposes of requiring the discount to be passed along to the program. Such an approach is far preferable than a blind adherence to uniform treatment of health care providers. We believe that such a position is a reasonable reading of the statutory requirement that "the reduction in price [be] * * * appropriately reflected in the costs claimed or charges made by the provider or entity * * *." (Section 1128B(b)(3)(A) of the Act.)

We emphasize, however, that paragraph (h)(1)(iii) still requires charge-based health care providers to comply with the respective rules regarding full and accurate reporting of discounts as defined in this provision. This reporting requirement is limited to items or services that are separately claimed as a line item for payment with the Department or a State agency. As discussed below, under paragraph (h)(1)(iii) of this section, we will not require health care providers to report discounts they receive on goods purchased for which a line item charge is not separately made, but rather is included within their professional charge.

In addition, we note that some commenters were confused about the requirements we are placing on health care providers reimbursed on the basis of costs. The regulation need not specify that a health care provider must separately reduce its cost by the amount of the discount because the cost reporting requirements accomplish the statutory purpose of having the amount of the discount "appropriately reflected in the costs claimed." Whether a provider submits cost reports (and complies with paragraph (h)(1)(i) of this section) or submits a seller's invoice to demonstrate its acquisition costs (and complies with paragraph (h)(1)(iii) of this section), the amount of the discount is passed along to the Medicare and Medicaid programs. As a result, this revised discount provision treats items and services reimbursed on the basis of charges differently from those reimbursed on the basis of costs, because costs will be reduced by the amounts of discounts whereas charges will not be affected.

Finally, although we have attempted to tailor this discount provision to make sense within the context of the varying reimbursement rules, as we have explained in section III.A. above, compliance with this safe harbor provision in no way affects Medicare or Medicaid reimbursement rules.

Comment: Five commenters discussed the requirement in the proposed rule that the discount appear on the seller's invoice or statement and the consequent liability of the seller for failing to make such disclosure. They questioned the apparent inconsistency with the preamble to the proposed rule that no requirements need be placed on sellers in order for their discounts to qualify under this exemption.

Response: We agree with the comments that we should clarify the requirement for a seller to report the value of the discount on the invoice or statement provided to a purchaser, and we are modifying this provision in paragraph (h)(2) accordingly. As discussed above, such standards are necessary to assist the Department and State agencies in verifying that the buyer has fully and accurately reported the value of the discount.

This paragraph describes the requirements we are placing on sellers. With respect to those who sell goods or services to risk contract HMOs and CMPs at a discount, paragraph (h)(2)(i) makes clear that the seller is under no obligation to report the discount to the HMO or CMP for purposes of this safe harbor. Paragraph (h)(2)(ii) sets out the seller's requirements with respect to its sales to all other health care providers. It must either fully and accurately report the discount on the invoice or statement. In addition, it must inform the buyer of its obligations under paragraph (h)(1). With respect to permissible end-of-year discounts, this paragraph, as revised, requires the seller's invoice or statement to show clearly the existence of a discount program, and the seller must inform the buyer of its obligations under paragraph (h)(1). The seller is also required to provide the buyer with a separate document, such as a reconciliation statement, showing the calculation of the discount and identifying the specific goods or services purchased to which the discount is attributed.

It was our original intent not to hold sellers liable for the reporting omissions of health care providers, and we believe such a policy remains appropriate. However, we agree with the commenters that some rules should apply to sellers. We believe that the limited conditions we are placing on sellers seeking safe harbor protection will not place an undue burden on them, but are sufficient to prevent them from avoiding liability when they engage in unlawful schemes disguised as discounts.

Comment: Many commenters questioned what information must be reported to the program and the methods to be used in reporting such information. Among the questions that were asked is whether the list price, discount, and final actual price all need to be reported on the invoice, claim, or statement. In addition, many commenters suggested that it was unrealistic to require practitioners to report all discounts on goods they purchase, such as office supplies and surgical gloves, for which they do not charge separately, but rather include within their professional service charge.

Response: The fundamental test for complying with the reporting requirement is whether the actual purchase price net of any discount is fully and accurately reported by the seller on the invoice or statement (or, where applicable for end-of-year discounts, on a reconciliation statement) and by the purchaser on the claim or request for payment submitted to Medicare and Medicaid. We do not necessarily require all the information in the calculation of the discount to be noted specifically on the invoice, statement, claim or request for payment; rather, a notation may be made that the actual purchase price is "net discount." Such reporting is acceptable for the purpose of satisfying this provision.

We agree that no purpose would be accomplished if we were to require practitioners to report the discounts they receive on office supplies where there is no requirement to separately report the item on which the discount is received. Thus, we are clarifying the requirements for reporting discounts under paragraph (h)(1)(iii) of this section to make clear that where a practitioner obtains a discount, defined in this provision, for a good that is included as part of his or her professional service charge, such discounts need not be reported. Where a practitioner, however, purchases an item or service at a discount and such item or service is separately claimed as a line item on the applicable claim form, the discounted price must be fully and accurately reported. For example, where a surgeon performs cataract surgery in his or her office and implants an intraocular lens (IOL), the surgeon must report any discount received on the price of the IOL.

Finally, it is noted that where the discount in question does not qualify as a discount under this provision, no safe harbor protection applies. For example, as we stated above, we are not expanding this safe harbor provision to protect the offering of a free good different from the one that is being purchased. Thus, consistent with that position, we are not willing to protect the offering of free computers even when named as "office supplies" to induce the purchase of other items that are reimbursable separately.

7. Employees--§ 1001.952(i)

Comment: Many commenters urged the OIG to extend this exception to apply to independent contractors paid on a commission basis. Two commenters asserted that the legislative history of the statute makes clear that Congress intended to include independent contractors in the employee exception. In support of this contention, they quoted remarks made by Representative Rostenkowski when the House was considering the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977. (123 Cong. Rec. 30,280 (1977))

Response: We continue to reject this approach because of the existence of widespread abusive practices by salespersons who are independent contractors and, therefore, who are not under appropriate supervision and control. Although two commenters asserted that they could achieve appropriate supervision and control of independent contractors by including restrictive terms in the contract, we

cannot expand this provision to cover such relationships unless we can predict with reasonable certainty that they will not be abusive. We are confident that the employer-employee relationship is unlikely to be abusive, in part because the employer is generally fully liable for the actions of its employees and is therefore more motivated to supervise and control them.

Furthermore, we believe that Representative Rostenkowski's remarks do not reflect congressional intent in this case. His comments related to the House version of the employee exception that was rejected by the Conference Committee. Instead, Congress passed the Senate version, which expressly limited the exception to bona fide employment relationships (See H.Conf.Rep. No. 673, 95th Cong., 1st Sess. 41 (1977)). Consequently, we find no support for the position that Congress intended to cover independent contractors under this exception.

Comment: Two commenters questioned the wisdom of the employee exception, stating that health care providers should not be able to refer patients to other health care providers within their own offices because abuse could be worse than when individuals or entities make referrals to outside sources.

Response: The exception for bona fide employment relationships is clear on the face of the statute, and we are not free to ignore that statutory mandate.

Comment: One commenter asserted that we do not have the statutory authority to limit the definition of "employee" to the meaning it has under 26 U.S.C. 3121(d)(2).

Response: As we have discussed, Congress expressly limited the scope of the employee exception to "bona fide employment relationship[s]" between an employer and an employee. The Secretary clearly has the power, and indeed the duty, to establish the criteria for a bona fide employment relationship. The Internal Revenue Service's (IRS) definition of employee is a longstanding one that has been developed by both agency and court rulings. Furthermore, this definition is sufficiently narrow that it excludes certain types of relationships that we believe tend to be associated with violations of the statute. We are clarifying this safe harbor provision to make clear that the meaning of the term "employee" is defined not only by 26 U.S.C. 3121(d)(2) itself, but also by the IRS's interpretation of that provision as codified in its regulations and other interpretive sources.

Comment: One commenter inquired whether a part-time employee paid on a commission-only basis falls within the employee exception.

Response: As long as a bona fide employer-employee relationship exists between the part-time employee and the employer, such a relationship falls within the scope of this provision.

Comment: Some commenters asserted that many legitimate employment relationships that are common in the health care industry are not protected from prosecution under this exception. One commenter suggested that the employee exception include independent contractors where beneficiaries are being induced to participate in cost-containment programs because such programs are beneficial to Medicare and State health care programs, and therefore should be protected.

Response: We recognize that this provision does not cover some types of personal service arrangements, but our position is necessary to protect the program from abuse to a reasonable degree. However, many of these other arrangements could be protected under the personal services and management contracts safe harbor provision.

Comment: One commenter stated that hospitals are often compelled by State "corporate practice of medicine" requirements to employ physicians and other health care personnel as independent contractors,

and that these employment relationships should be afforded safe harbor protection.

Response: We understand that there may be circumstances where, because of State laws, health care providers may not be able to enter into arrangements with health care personnel that comply with the IRS definition of employee. In such cases, however, health care providers may obtain protection for payments from these arrangements by drafting their personal contracts to satisfy the safe harbor provision for personal services and management contracts.

8. Group Purchasing Organizations--§ 1001.952(j)

Comment: One commenter urged the OIG to further define what constitutes a group purchasing organization (GPO) for purposes of this provision. This commenter specifically questioned whether a nursing home chain that requested percentage payments from laboratories as "GPO fees" in return for the referral of laboratory services from member nursing homes fit this definition.

Response: As stated in the preamble to the proposed rule, this exception applies to payments made by a vendor of goods or services to a person authorized to act on behalf of a group of individuals or entities who are furnishing Medicare or Medicaid services. Our definition of the term "GPO" makes clear that a nursing home chain requesting fees for referrals would not qualify for this safe harbor because a chain of nursing homes that are wholly owned subsidiaries of a single corporate entity for all practical purposes constitutes a single entity and not a "group" of entities. As we discuss in section III.D. below, because of the special relationship wholly-owned subsidiaries have with their parent corporation, we are considering separate protection for payments between these entities. However, following this reasoning, we do not believe it appropriate for a nursing home chain to qualify as a GPO and request "GPO fees" for referrals. If a nursing home directly requested such a fee it would appear to represent an illegal inducement. We see no reason how such a solicitation sanitizes the illegality when it is made indirectly by a wholly-owned subsidiary of the nursing home, instead of directly by the nursing home itself.

In addition, we believe that Congress did not intend this exception to apply where it is the vendor and not the health care provider who is furnishing services and directly billing the Medicare or Medicaid program. For example, in addition to services furnished by the nursing home, other health care providers furnish many part B services to nursing home patients, such as laboratory services and durable medical equipment (DME). We believe that a GPO, acting on behalf of a group of nursing homes, is not serving as a GPO when it receives a "GPO fee" from a laboratory or DME supplier that is supplying goods or services to nursing home patients and billing Medicare or Medicaid directly.

Comment: Several commenters objected to the requirement that a purchasing agent, i.e., a GPO, have a written agreement with each individual or entity in the group that specifies the amount the agent will be paid by each vendor. This requirement, they asserted, would be burdensome and expensive.

Response: We agree with the general thrust of these comments and have modified paragraph (j)(1)(ii). The statutory exception requires that written contracts specify the amount the GPO will be paid by the vendor. We believe that this statutory mandate is satisfied if the GPO discloses to a health care provider the fees it will receive from only those vendors that provide goods or services to that provider. This obviates the need for the GPO to divulge fees from vendors that do not provide goods or services to that particular individual or entity.

Comment: To promote administrative convenience, efficiency, and cost- containment purposes, several commenters requested that the GPO should be permitted to specify the range of fees to be paid by the potential vendors instead of the actual amount. One commenter asserted that because of the varying contracts between GPOs and their vendors, it was impossible to determine and disclose in advance the

amount the GPO would receive from its vendors.

Response: We agree that it is not necessary, in all circumstances, to specify the exact fees the GPO will receive from its vendors as a result of a particular member's purchases. The legislative history to this exception, however, shows Congress's concern for excessive GPO fees, particularly those exceeding 3 percent. (See, H.Conf. Rep. 1012, 99th Cong., 2d Sess. 310-11 (1986)) For this reason, we are revising this provision (see paragraph (j)(1)(i)) so that a GPO needs to specify the administrative fee it is paid from vendors only if any fee will be above 3 percent.

In the event that the fee cannot be ascertained at the time of the contract or the fee is not fixed at 3 percent or less, the contract must state the maximum amount that could be paid to the GPO by the vendor. This mechanism will permit some flexibility in payments made to the GPO, yet retain the focus on excessive fees about which Congress was concerned.

Comment: Several commenters questioned the interrelationship of this provision to the discount safe harbor.

Response: Several commenters appeared confused about the relationship between these two provisions. This is an example of an arrangement where two safe harbor provisions could apply, i.e., one applicable to discounts, and one applicable to GPOs. However, the GPO provision applies only to payments made by a vendor of goods or services to a person authorized to act as a GPO. Payments, such as discounts, made by vendors of goods or services to health care providers must qualify under the discount exception.

D. Comments on Proposals for New Safe Harbor Provisions

In sections III.B.3. and III.C.1. we discussed proposals and our responses regarding new safe harbor provisions for negotiated price reductions and investment interests. In this section we discuss the remaining proposals and our responses regarding potential new safe harbors.

Note: Any discussion below indicating that we are considering a new safe harbor provision should in no way be construed as legalizing the business arrangement at this time.

Comment: A large number of commenters urged the OIG to adopt a safe harbor provision to protect certain physician recruitment activities. They commented that subsidy payments to physicians for recruitment purposes provide important benefits to many communities that have difficulty in obtaining and retaining physicians. Some urged that we also protect hospital recruitment activities even though a physician does not need to move his or her residence to join the medical staff of the new hospital. Others urged a variety of other provisions, for example, that we not require the physician to disclose to his or her patients the relationship between the physician and the hospital, and that we not specify how long the payments may continue.

Response: We agree with the need to protect some recruitment activities for physicians and other practitioners, and we are considering a new safe harbor provision for practitioner recruitment that we anticipate publishing as a separate regulation.

Comment: Three commenters requested the OIG to adopt a safe harbor provision that will protect all payments that subsidize malpractice premiums. These commenters stressed that such payments have an overwhelming public benefit with limited potential for abuse. One of these commenters argued that obstetrician-gynecologists are facing significant difficulty in paying for malpractice insurance, and suggested that many communities are facing a cut-off of obstetrical services as a result.

Response: We understand the need to assist certain physicians in making malpractice insurance more affordable, and we are considering a new safe harbor provision which we anticipate publishing as a separate regulation, that would protect certain arrangements that subsidize the costs of a practitioner's malpractice insurance premiums where there is no likelihood of abuse.

Comment: Several commenters asked the OIG to provide a new safe harbor provision to protect different types of cross-referral arrangements where no money is exchanged between the parties, for example, traditional referral patterns between a primary care practitioner and specialist, between a hospital and nursing home, and among practitioners within a group practice.

Response: We agree that a large majority of these relationships benefit patients by assuring either proper continuity of care or convenient access to a specialist in whom the primary care physician has confidence. Thus, we are considering a new safe harbor provision, that we anticipate publishing as a separate regulation, that would protect many such arrangements where there is no likelihood of abuse.

Comment: Two commenters suggested that the regulation protect payments related to cooperative hospital service organizations qualified under section 501(e) of the Internal Revenue Code of 1986. Under this statute and implementing Internal Revenue Service regulation, these organizations are formed by one or more hospitals (known as "patron-hospitals") to provide specifically enumerated services, such as purchasing, billing, and clinical services solely for the benefit of its patron-hospitals. In addition, these entities are required to distribute "all net earnings to patrons on the basis of services performed." (26 U.S.C. 501(e)(2)) The commenters believed that although such a distribution requirement runs afoul of the anti-kickback statute, the services they perform are beneficial to rural communities in particular, and there has been no indication of abuse by these organizations.

Response: We agree and are considering a new safe harbor provision, that we anticipate publishing as a separate regulation, that would protect payments between cooperative hospital service organizations and patron-hospitals.

Comment: Many commenters requested the OIG to clarify that payments between corporations which have common ownership are not subject to the statute. Commenters cited as examples intracorporate discounts and payments between two wholly-owned subsidiaries. Some commenters argued that referral arrangements between two related corporations do not constitute "referrals" within the meaning of the statute, and suggested that the OIG define the word "referral" to exclude such activity.

Response: We agree that much of the activity described in these comments is either not covered by the statute or deserves safe harbor protection. We believe that the statute is not implicated when payments are transferred within a single entity, for example, from one division to another. Thus, no explicit safe harbor protection is needed for such payments.

Because the statute is implicated when payments are made from one entity to another even though the payments are made between entities with common ownership, we believe that safe harbor protection may be appropriate. However, we remain concerned about wholly-owned shell entities that are established for a fraudulent purpose, for example, to help hide the identity of the owners or to shield assets. Nonetheless, we are considering a new safe harbor provision, that we anticipate publishing as a separate regulation, that would protect payments between wholly owned subsidiaries and other payments between entities where exclusive ownership control is present and the practice is not otherwise abusive.

We do not, however, believe that the situations commenters described require us to define the word "referral." The commenters do not appear concerned with any unusual conduct that warrants special attention. Rather the commenters have focused on the source and recipient of the payment in question.

Thus, our consideration in any proposed rule will be focused on the relationship of the parties making and receiving payments.

IV. Additional Information

A. Regulatory Impact Statement

Executive Order 12291 requires us to prepare and publish a final regulatory impact analysis for any regulation that meets one of the Executive Order criteria for a "major rule," that is, that which would be likely to result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individuals, industries, Federal, State, or local government agencies or geographic regions; or, (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (5 U.S.C. 601-612), unless the Secretary certifies that a final regulation would not have a significant economic impact on a substantial number of small entities.

In the proposed rule published on January 23, 1989, we indicated that this provision was designed to specify the various business and payment practices that would not be considered a kickback for purposes of criminal or civil remedies, and served to clarify departmental policy as to the legality of various commercial arrangements. We stated that the great majority of health care providers and practitioners do not engage in illegal remuneration schemes, and that the aggregate economic impact of this provision should, in effect, be minimal, affecting only those who have chosen to engage in prohibited payment schemes in violation of the statutory intent. As indicated in the proposed regulation's impact statement, the rulemaking is a result of a statutory requirement and not a Department initiative.

The two comments we received on the cost impact indicated that the safe harbors for discounts and personnel services contracts would cast a cloud over a substantial number of legitimate business practices and existing contractual arrangements. Both commenters believed that a comprehensive regulatory flexibility analysis should be performed and a statement added disclosing the possible financial impact of this rulemaking.

Consistent with the intent of the statute, this regulation has been designed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy. However, the regulation imposes no requirements on anyone. 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. Thus, it is impossible to predict how many individuals and entities will be affected by this regulation. For these reasons, we have determined that a regulatory impact analysis is not required. Further we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a number of small business entities, and we have, therefore, not prepared a regulatory flexibility analysis.

B. Department of Justice Review

In accordance with the provisions of Public Law 100-93, this regulation has been developed in consultation with the Department of Justice.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Health facilities, Health professions, Medicare.

TITLE 42--PUBLIC HEALTH

CHAPTER V--OFFICE OF INSPECTOR GENERAL--HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR part 1001 is amended as set forth below:

1. The heading for part 1001 is revised to read as follows:

PART 1001--PROGRAM INTEGRITY--MEDICARE AND STATE HEALTH CARE PROGRAMS

2. The authority citation for part 1001 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(j), 1395u(k), 1395y(e), and 1395hh, and section 14 of Public Law 100-93, unless otherwise noted.

3. Section 1001.1 is revised to read as follows:

§ 1001.1 Scope and purpose.

(a) This part sets forth provisions for the detection of fraud and abuse in the Medicare and certain State health care programs. It implements statutory sections, specifically identified in each subpart, aimed at protecting the integrity of the Medicare and certain State health care programs.

(b) This part also sets forth provisions addressing the OIG's authority to exclude any individual and entity that it determines has committed an act described in section 1128B of the Social Security Act, subject to the exceptions set forth in this part.

4. A new Subpart E is added to read as follows:

Subpart E--Permissive Exclusions

Sec.

1001.951 Fraud, kickbacks and other prohibited activities.

1001.952 Exceptions.

Sec.

1001.953 OIG report on compliance with investment interest safe harbor.

Subpart E--Permissive Exclusions

§ 1001.951 Fraud, kickbacks and other prohibited activities.

The OIG may exclude any individual or entity that it determines has committed an act described in section 1128B of the Social Security Act, subject to the exceptions set forth in § 1001.952.

§ 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 two 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 items and services, all of the following five applicable standards must be met--

(i) With respect to an investment interest that is an equity security, the equity security must be registered with the Securities and Exchange Commission under 15 U.S.C. 78l(b) or (g).

(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 equally available to the public through trading on a registered national securities exchange, such as the New York Stock Exchange or the American Stock Exchange, or on the National Association of Securities Dealers Automated Quotation System.

(iii) 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.

(iv) 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.

(v) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment of that investor.

(2) If the entity possesses investment interests that are held by either active or passive investors, all of the following eight applicable standards must be met--

(i) No more than 40 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.

(ii) 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.

(iii) 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.

(iv) 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.

(v) 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.

(vi) No more than 40 percent of the gross revenue of the entity in the previous fiscal year or previous 12 month period may come from referrals, items or services furnished, or business otherwise generated from investors.

(vii) 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.

(viii) 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.

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 of a partnership, 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.

(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 five standards are met-

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease specifies the premises covered by the lease.

(3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

For purposes of paragraph (b) of this section, the term fair market value means the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in

whole or in part under Medicare or a State health care program.

(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 five standards are met--

- (1) The lease agreement is set out in writing and signed by the parties.
- (2) The lease specifies the equipment covered by the lease.
- (3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.
- (4) The term of the lease is for not less than one year.
- (5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

For purposes of paragraph (c) of this section, the term fair market value means the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a State health care program.

(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 six standards are met--

- (1) The agency agreement is set out in writing and signed by the parties.
- (2) The agency agreement specifies the services to be provided by the agent.
- (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
- (4) The term of the agreement is for not less than one year.
- (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.
- (6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

(e) Sale of practice. 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--

(1) 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.

(2) 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.

(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--

(1) The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.

(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 the participants for the referral service for which payment may be made in whole or in part under Medicare or a State health care program.

(3) The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.

(4) The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service--

(i) The manner in which it selects the group of participants in the referral service to which it could make a referral;

(ii) Whether the participant has paid a fee to the referral service;

(iii) The manner in which it selects a particular participant from this group for that person;

(iv) The nature of the relationship between the referral service and the group of participants to whom it could make the referral; and

(v) The nature of any restrictions that would exclude such an individual or entity from continuing as a participant.

(g) Warranties. As used in section 1128B of the Act, "remuneration" does not include any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item, as long as the buyer complies with all of

the following standards in paragraphs (g)(1) and (g)(2) of this section and the manufacturer or supplier complies with all of the following standards in paragraphs (g)(3) and (g)(4) of this section--

- (1) The buyer must fully and accurately report any price reduction of the item (including a free item), which was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.
- (2) The buyer must provide, upon request by the Secretary or a State agency, information provided by the manufacturer or supplier as specified in paragraph (g)(3) of this section.
- (3) The manufacturer or supplier must comply with either of the following two standards--
 - (i) The manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (a)(1) and (a)(2) of this section.
 - (ii) Where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.
- (4) The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

For purposes of paragraph (g) of this section, the term warranty means either an agreement made in accordance with the provisions of 15 U.S.C. 2301(6), or a manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item (which is covered by an agreement made in accordance with this statutory provision), on terms equal to the agreement that it replaces.

(h) Discounts. As used in section 1128B of the Act, "remuneration" does not include a discount, as defined in paragraph (h)(3) of this section, on a good or service received by a buyer, which submits a claim or request for payment for the good or service for which payment may be made in whole or in part under Medicare or a State health care program, from a seller as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section and the seller complies with the applicable standards of paragraph (h)(2) of this section:

- (1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable standards within each category--
 - (i) If the buyer is an entity which reports its costs on a cost report required by the Department or a State agency, 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.

(ii) If the buyer is an entity which is a health maintenance organization or competitive medical plan 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.

(iii) If the buyer is not an entity described in paragraphs (h)(1)(i) or (h)(1)(ii) of this section, it must comply with all of the following three standards--

(A) the discount must be made at the time of the original sale of the good or service;

(B) where an item or service is separately claimed for payment with the Department or a State agency, the buyer must fully and accurately report the discount on that item or service; and

(C) 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)(A) of this section.

(2) With respect to either of the following two categories of buyers, the seller must comply with all of the applicable standards within each category--

(i) If the buyer is an entity described in paragraph (h)(1)(ii) of this section, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is any other individual or entity, the seller must comply with either of the following two standards--

(A) where a discount is required to be reported to the Department or a State agency under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice or statement submitted to the buyer, and inform the buyer of its obligations to report such discount; 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 or statement submitted to the buyer, inform the buyer of its obligations under paragraph (h)(1) of this section and, 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.

(3) For purposes of this paragraph, the term discount means a reduction in the amount a seller charges a buyer (who buys either directly or through a wholesaler or a group purchasing organization) for a good or service based on an arms length transaction. The term discount may include a rebate check, credit or coupon directly redeemable from the seller only to the extent that such reductions in price are attributable to the original good or service that was purchased or furnished. The term discount does not include--

(i) Cash payment;

(ii) Furnishing one good or service without charge or at a reduced charge in exchange for any agreement to buy a different good or service;

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

(iv) A reduction in price offered to a beneficiary (such as 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 this paragraph.

(i) Employees. As used in section 1128B of the Act, "remuneration" does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a State health care program. For purposes of paragraph (i) of this section, the term employee has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2):

(j) Group purchasing organizations. As used in section 1128B of the Act, "remuneration" does not include any payment by a vendor of goods or services to a group purchasing organization (GPO), as part of an agreement to furnish such goods or services to an individual or entity as long as both of the following two standards are met--

(1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following--

(i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.

(ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).

(2) Where the entity which receives the good or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity.

For purposes of paragraph (j) of this section, the term group purchasing organization (GPO) means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare or a State health care program, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

(k) Waiver of beneficiary coinsurance and deductible amounts. As used in section 1128B of the Act, "remuneration" does not include any reduction or waiver of a Medicare or a State health care program beneficiary's obligation to pay coinsurance or deductible amounts as long as all of the standards are met within either of the following two categories of health care providers:

(1) If the coinsurance or deductible amounts are owed to a hospital for inpatient hospital services for which Medicare pays under the prospective payment system, the hospital must comply with all of the

following three standards--

(i) The hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under Medicare or otherwise shift the burden of the reduction or waiver onto Medicare, a State health care program, other payers, or individuals.

(ii) The hospital must offer to reduce or waive the coinsurance or deductible amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for Medicare reimbursement is filed.

(iii) The hospital's offer to reduce or waive the coinsurance or deductible amounts must not be made as part of a price reduction agreement between a hospital and a third-party payor.

(2) If the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under title V of the Act, the health care center or facility may reduce or waive the coinsurance or deductible amounts for items or services for which payment may be made in whole or in part under part B of Medicare or a State health care program.

§ 1001.953 OIG report on compliance with investment interest safe harbor.

Within 180 days of the effective date of this subpart, the OIG will report to the Secretary on the compliance with §§ 1001.952(a)(2)(i) and 1001.952(a)(2)(vi).

Dated: July 19, 1991.

R.P. Kusserow,

Inspector General, Department of Health and Human Services.

Approved: July 22, 1991.

Louis W. Sullivan,

Secretary.

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