DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 1001

Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions

Monday, January 23, 1989 (54 FR 3088)

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

ACTION: Proposed rule.

SUMMARY: These proposed regulations are designed to implement section 14 of Pub. L. 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, would not be considered kickbacks for purposes of criminal prosecution or civil remedies.

DATE: To assure consideration, public comments must be mailed and delivered to the address provided below by March 24, 1989.

ADDRESSES: Address comments in writing to: Office of Inspector General, Department of Health and Human Services, Attention: LRR-17-P, Room 5246, 330 Independence Avenue, SW., Washington, DC 20201.

If you prefer, you may deliver your comments to Room 5551, 330 Independence Avenue, SW., Washington, DC. In commenting, please refer to file code LRR-17-P.

Comments will be available for public inspection beginning approximately two weeks after publication in Room 5551, 330 Independence Avenue, SW., Washington, DC on Monday through Friday of each week from 9:00 a.m. to 5:00 p.m., (202) 472-5270.

FOR FURTHER INFORMATION CONTACT:

Harvey Yampolsky, Office of the General Counsel, (202) 472-5335


For paperwork reduction and information collection requirements: Allison Herron, Office of Management and Budget, (202) 395-7316.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1128B(b) of the Social Security Act, previously codified at sections 1877 and 1909, 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 by Medicare or State health care programs.

The leading case regarding this statute illustrates its broad scope. In United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988, 106 S.Ct. 396 (1985), the Third Circuit Court of Appeals was asked to examine the nature of payments between a medical diagnostic company, providing holter monitor services, and physicians. The company billed Medicare for the monitoring service it performed, and forwarded 40 percent of those payments (up to $65 per patient) to the referring physician.

The defendant in this case alleged that these payments were merely "interpretation fees" paid to the referring physicians for their initial consultation and for explaining the test results to the patients. Id. at 70. The court, however, declined to examine whether there might have been a legitimate purpose behind those payments, concluding: "if one purpose of the payment is to induce future referrals, the medicare statute has been violated." Id. at 69.

Since the statute on its face is so broad, and the court has recognized its full breadth, 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.

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 a person or entity from participation in the Medicare and State health care programs if it is determined that the party is engaged in a prohibited remuneration scheme. 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 Pub.L. 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). This section reflects the generally accepted view that the language proscribing remuneration that induces referrals is so broadly written as to encompass many harmless or efficient arrangements as well.

In accordance with the stipulation of Pub.L. 100-93, these proposed regulations have been developed in consultation with the Department of Justice.

Notice of Intent

The legislative history of section 14 of Pub.L. 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 21, 1987)
soliciting comments from interested parties prior to developing proposed regulations. As a result of that notice, the OIG received a total of 137 timely 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.

II. Provisions of the Proposed Rule

We are proposing to amend 42 CFR Part 1001 by adding a new § 1001.952 to set forth those specific payment practices that would not be treated as a criminal offense under section 1128B of the Act and would not serve as the basis for an exclusion from the Medicare and State health care programs. Before we discuss the various payment practices that we are proposing to exempt, we will clarify the effect of not having a particular business arrangement exempted, and we invite public comments on the issues of continuing guidance, notice to beneficiaries, and preferred provider organizations.

Business Arrangements Not Exempt

We are aware that it is the unique position physicians occupy in the medical marketplace that has led to the examination of their relationship with varying business arrangements. It is the physician who controls access to a large array of medical items and services in order for third party reimbursement to be available. This is a highly competitive market that is constantly expanding with new drugs, medical devices and tests. While this competitive marketplace is important, it is necessary for the fiscal integrity of the Medicare and Medicaid programs to assure that physicians exercise sound, objective medical judgment when controlling admittance to this market. We have attempted in these proposed regulations to permit physicians to freely engage in business practices and arrangements that encourage competition, innovation and economy. However, we have added criteria to each "safe harbor" in order to reduce the potential for abuse.

In order for a business arrangement to comply with one of the exemptions set forth below, each provision of that exemption must be met. If, however, the business arrangement involves several payments, for example, rental of both space and equipment, then each payment will be analyzed to determine if all the provisions of each applicable exemption have been fulfilled. Thus, fully complying with one exemption may not grant that individual or entity complete immunity under the statute.

Several commenters responding to our notice of intent have asked that we clarify what it means if a particular business arrangement does not fully comply with each element of a particular exemption. In many instances, the failure to comply fully with one of the exemptions will be of no consequence because the arrangement does not fall within the proscriptions of the statute at all. However, where individuals and entities have entered into arrangements that are covered by the statute, 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.

Continuing Guidance

Congress intended that the regulations set forth on "safe harbors" be an evolving rule that would be periodically updated to reflect changing business practices and technologies. In the House Committee Report accompanying Pub.L. 100-93, the Committee stated that it "believes that a mechanism for periodic public input is necessary to ensure that the regulations remain relevant in light of changes in health care delivery and payment and to ensure that published interpretations of the law are not impeding legitimate and beneficial activities. Accordingly, the Committee expects that the Secretary will formally reevaluate the anti-kickback regulations on a periodic basis and, in doing so, will solicit public comments at the outset of the review process."
We, therefore, invite public comments on how we can best achieve the twin goals of keeping the industry aware of our views of particular business practices, and assuring that our regulations remain current with new developments. Comments should address how affected parties can make their questions or views known on a continuing or regular basis, and how the Department can best respond to such concerns.

Notice to Beneficiaries

We considered including in several of the proposed "safe harbors" a requirement that a person notify each Medicare beneficiary or Medicaid State health care program of the financial relationship that exists and any person to whom he or she refers the beneficiary for items or services. This requirement may serve to provide an additional safeguard against the abuse for which there is always some potential when such financial relationships exist. Furthermore, it reiterates the ethical responsibility of physicians as reflected in the Current Opinions of the Council on Ethical and Judicial Affairs of the American Medical Association, and it is a duty imposed by some State statutes as well.

However, such notice requirements may be unduly burdensome compared with the potential benefits to health care consumers. We therefore have not included the requirement in the ownership and financial relationship safe harbors at this time. However, we invite public comments on this issue.

Preferred Provider Organizations

We are aware that there are an increasing variety of arrangements among providers grouped under the generic headings "preferred provider organizations" (PPOs) or "managed care." Unlike HMOs, PPOs and managed care arrangements do not have a single unique identifying structure or concept. In addition, unlike HMOs, there is no single entity that is recognized as the "provider." For these reasons, there is no safe harbor specifically delineated for these arrangements. Rather, we believe that the safe harbors we have designated would cover many relationships in preferred provider and managed care networks. Furthermore, the anti-kickback statute would not apply to participants in PPOs where the discounts and financial relationships are obviously not designed to improperly induce referrals. However, we invite comments from the public regarding additional safe harbors that would provide further assurance to PPOs.

Relationship to Other Laws

The safe harbors being proposed in these regulations are only for purposes of the Federal Medicare and Medicaid anti-kickback statute. They would not provide immunity from civil or criminal prosecution or other sanctions under any other Federal or State laws. For example, a particular arrangement permissible under a safe harbor may violate a law administered by the Federal Trade Commission or the Securities and Exchange Commission (SEC), or may run afoul of a State law that is applied by the State in a stricter fashion than the Federal law.

Proposed Safe Harbors

Set forth below is a description of the various payment practices that we are proposing to exempt and the rationale for their inclusion in this proposed rulemaking.

A. Investment Interests

As written, the anti-kickback provision applicable to the Medicare and State health care programs is so
broad that it could be interpreted literally, for example, to prohibit a physician from receiving dividend payments from a large publicly traded pharmaceutical company if he or she prescribed one of the company's products for a Medicaid patient, knowing that ordering that product would increase his or her dividend payment.

We do not believe that Congress intended to bar all forms of investment or ownership by referral sources in health providers. This conclusion is based on the fact that there are other provisions of Medicare law that pertain specifically to physician-owned home health agencies. Obviously, these provisions would make little sense if the kickback provision prohibited, per se, referrals by physicians to entities in which they had any investment interest.

To reflect this view that Congress did not intend to absolutely bar any investment by physicians in other health care entities, we have included a "safe harbor" for investment interests in large public corporations. We have done this to assure that the companies are sufficiently large enough so that the return on investment is, at most, tangentially related to any referrals of items or services made by a shareholder, for example, the prescribing of a drug by an investing physician. This "safe harbor" describes a minimum number of shareholders and a minimum amount of assets the company must have in order to qualify under this exemption. We have adopted the same bright line employed by the SEC. The SEC applies these same standards to determine which companies are required to register with it, regardless of whether they are traded on a national securities exchange (15 U.S.C. 78l(g) and 17 CFR 240.12g-1). We believe this bright line will be useful to health care providers as it sets forth a standard for permissible investments under this "safe harbor" that can be easily determined.

On the other hand, many commenters have described to us situations where health care entities sell limited partnership interests at nominal cost solely to investors who are in a position to make referrals to the entity, and where the profit distribution in the first year, and each year thereafter, is substantially in excess of the original investment. Competitors of these entities complain of losing a significant share of the market to an entity that establishes a limited partnership with physicians in the service area. We have been urged not to include a "safe harbor" for such practices.

Therefore, under the proposed rule, referrals by physicians to entities in which they have any kind of investment interest (other than in large corporations available to the general public), such as limited partnerships, would be subject to prosecution under the same circumstances as they have been until now under section 1128B of the Social Security Act.

However, we are considering crafting an additional exemption to the anti-kickback statute for certain limited partnerships and managing partnership interests that operate according to standards we would prescribe to assure minimum risk of abuse. Accordingly, we are interested in receiving comments suggesting what those standards should be. This "safe harbor" might include: (1) Investment in an entity such as a limited partnership where a bona fide opportunity to invest is made on an equal basis to people in a position to make referrals as well as others, where there are no requirements to make referrals, where there has been disclosure to a referred patient, and where payments are not related to referrals; and (2) managing partnership interests where there is a disclosure to a referred patient, and where payments are not related to referrals.

B. Space Rental

The anti-kickback statute is so broadly written that it could be interpreted to cover rental payments where one party is in a position to make referrals to the other party, even if there is no explicit or implicit understanding regarding referrals. While many rental arrangements are legitimate, we have been informed of many situations where rental payments were simply a device used to mask the real nature of
the payments, that is, to induce referrals.

Some examples of these kinds of arrangements are where: (1) A health care entity rents space at a rate above market value from a physician by the hour— with the space being used solely to provide care or services to patients referred by the physician—and the hours per week, and thus the payments, varying in direct relationship to the number of referrals; (2) a physician rents space to a health care entity at a rate above what the market would ordinarily bear, but the entity agrees to the high rent because of an understanding that the physician will refer his or her patients to that entity; or (3) a physician rents space to a health care entity on a month-to-month lease, with the rent varying each month based on the number of referrals from the physician in the preceding month. These arrangements obviously fall within the scope of the anti-kickback law, and provide the potential to abuse the Medicare and State health care programs.

Typically, the abusive arrangements involve rental payments either substantially in excess or below the fair market value of the rental space. The Ninth Circuit Court of Appeals, in United States v. Lipkis, 770 F.2d 1447 (9th Cir. 1985), emphasized the importance of determining fair market value when assessing the legitimacy of payments between parties who are in a position to make referrals. In Lipkis, a medical management company providing services to a physician group entered into an arrangement with a laboratory where the laboratory returned 20 percent of its revenues obtained from the physician group's referrals back to the management company. The defendant alleged that these payments were fair compensation for "specimen collection and handling services." Id. at 1449. The court rejected this defense, concluding: "The fair market value of these services was substantially less than the [amount paid], and there is no question that [the laboratory] was paying for referrals as well as the described services." Ibid. Accordingly, one fundamental principle is whether the payment is based on fair market value, regardless of whether the payment is for space rental, equipment rental, personal services, or management contracts.

We have, therefore, crafted an exemption to the anti-kickback law in these proposed regulations for rental arrangements that would require certain standards and safeguards in order to limit the opportunity for abusive relationships that are intended to induce referrals. Proposed § 1001.952(b), Rent, specifically would establish "safe harbors" in cases of rental agreements where: (1) In instances when access is for periodic intervals, those intervals are set in advance in the lease, rather than allowed to vary week-to-week on the basis of the number of referred patients to be served at the premises; (2) the lease is for at least one year so it cannot be readjusted every month based on the number of referrals; and (3) the charges reflect fair market value.

C. Equipment Rental

Diagnostic and other items of medical equipment are sometimes rented rather than purchased. Obviously, there is no per se violation of the anti-kickback statute solely because the owner of the equipment refers a patient to the entity who is paying the individual rent for the equipment. However, we have had situations brought to our attention where payment for the use of the equipment, just like rent for space, is simply a vehicle to provide reimbursement for referrals.

For example, we have had described to us arrangements where a provider rents equipment from a hospital and reimburses the hospital on an hourly basis each time he or she uses the equipment. Under this type of arrangement, the hospital knows it will be paid a fee by the provider each time it refers a patient to the provider for services requiring the use of the equipment. In another case, an ophthalmologist may rent diagnostic equipment to an optometrist at a rate significantly below the usual market rate. In this instance, there is an understanding between the parties that the rate will be adjusted periodically depending on the referral rate of patients from the optometrist to the ophthalmologist. The
reduction in the rental charge, which becomes larger as the number of referrals increase, could obviously be construed as the offer of remuneration in order to induce referrals.

We have, therefore, provided in § 1001.952(c), a "safe harbor" for equipment rentals similar to those applied to real estate rental discussed above, along with the appropriate conditions and safeguards to limit the potential for abuse.

D. Personal Services/Management Contracts

Medical practitioners and providers often have agreements to perform services for each other on a mutually beneficial basis. Sometimes these agreements call for the party requiring the service to pay a fixed amount or hourly rate to the party performing the service. In other instances, both parties may be allegedly contributing some service or benefit to a so-called "joint venture," and taking compensation in the form of a share of the profits generated by the venture. In still other situations, a party may perform a service acting in the capacity of agent for a company. For example, the agent may perform management services for the company, or handle certain billing and collection services.

None of these arrangements is per se illegal solely because referrals between the parties, or to the joint venture, occur. However, if the nature of the agreement is such that payments are intended to induce referrals, or there is an implicit or explicit arrangement where the amount of the payment varies with the volume of referral, the anti-kickback law would apply.

Examples of abusive arrangements that would fall into this category are where: (1) An orthopedist is under contract with a physical therapist to provide billing services for patients he or she refers for the service, thereby receiving compensation in an amount that varies directly with the volume of the referrals; (2) a hospital-employed respiratory therapist is paid by a supplier for servicing home oxygen equipment, but only in cases where the therapist is the source of the patient referral; and (3) a hospital stores and delivers medical equipment to discharged patients on behalf of a supplier and is compensated through a disproportionate share of the net profits of the supplier, although the hospital's only other "service" to the joint venture is the referral of the discharged patients. The variations on these examples are virtually limitless.

We have established in § 1001.952(d) a "safe harbor" for joint ventures and other arrangements involving payments for personal services or management contracts, but only if certain standards are met and safeguards are present to limit the opportunity to provide financial incentives in exchange for referrals. This exemption includes the determination of whether services are paid at fair market value, and is predicated on the same type of standards and qualifications as set forth in the exemption for space and equipment rental.

E. Sale of Practice

It has been brought to our attention that another approach sometimes employed by hospitals to assure a referral of business is to buy, or appear to buy, a physician's practice. Unlike the traditional sale of a practice by a retiring physician to another physician, in these cases the physician continues to practice on the staff of the hospital. Thus, the hospital is able to assure that it will be the provider of both physician services and any hospital services required by any of the physician's patients. The physician's patients, in most cases, may be totally unaware that the physician has "sold" his or her practice to the hospital. Further, such sales often involve much higher rates of compensation that would be the case if a retiring physician sold a comparable practice to another physician. The additional compensation in these instances reflects the value of the referrals.
Another approach in the sale of a practice is for the hospital to pay a practicing physician a monthly fee to keep alive its so-called "option" to purchase his or her practice. We have been advised that in these situations neither party intends for the hospital to ever exercise its option, but that the payments are for referrals and will continue only so long as the physician meets his or her monthly quota of referrals.

We are also aware of practices between practitioners such as optometrists and ophthalmologists whereby the ophthalmologist "buys" the optometrist's practice, but the optometrist keeps practicing, only now substantially salaried by the ophthalmologist. The only purpose of this sale was to lock up referrals.

The "safe harbor" we are proposing in 1001.952(f) would exist 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.

F. Referral Services

Professional societies and other consumer-oriented groups often operate referral services, with a fee sometimes paid to cover the costs of such a service. Because such a service fee could be construed as a payment in order to obtain a referral, we have concluded that it is appropriate to establish a specific "safe harbor" for this type of practice. The proposed regulations at § 1001.952(g), Referral services, provides standards and safeguards to assure that the "safe harbor" is not abused by persons who would attempt to operate exclusive or selective referral services for which they would impose high participation fees.

G. Warranties

We believe that it is in the public interest to have companies offer warranties as an inducement to the consumer to purchase a product. Section 1001.952(h) reflects this belief and provides a "safe harbor" for such purposes. We are aware, however, that some companies, such as some pacemaker manufacturers, offer so-called "warranties" on other manufacturers' products. The reason this occurs is that the Medicare program will reimburse the full costs of a replacement product. As a result, if a patient has no out-of-pocket expenses, he or she can easily be persuaded to make use of another manufacturer's product, and the manufacturer can, in turn, look to the Medicare program for reimbursement. These so-called warranties do not meet the Federal Trade Commission definition of warranty, and these regulations would not provide a "safe harbor" for such warranties.

H. Waiver of Deductibles for Inpatient Hospital Care

With the advent of the prospective payment system in 1984 for reimbursing 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. Because the Federal anti-kickback statute does not distinguish between categories of individuals who are prohibited from receiving something of value as an inducement to arrange for care from a particular provider, as a technical matter, the statute prohibits hospitals from engaging in this kind of practice.

This discrepancy between the technical prohibition on waivers of deductibles and the practices of some hospitals resulted in many comments. Commenters requested policies ranging from complete prohibition to permitting widespread use of waivers.

At this time, we have not included a "safe harbor" for waiving deductibles for inpatient hospital care in

https://oig.hhs.gov/fraud/docs/safeharborregulations/012389.htm
this proposed rule. However, we solicit comments on defining a waiver of deductible "safe harbor" that would be limited to inpatient hospital care, include only the deductible amount, 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 deductible would not be passed on to any Federal program as a bad debt or in any other way. With respect to other situations where deductibles or copayments are routinely waived (such as Part B deductibles and copayments), we believe the anti-kickback statute is clearly violated.

I. Discounts, Employees and Group Purchasing Organizations

The "safe harbors" relating to discounts, employees and group purchasing organizations are specifically required under section 1128B of the Act. The proposed regulations, at § 1001.952(i), (j), and (k), respectively, set forth guidance on the scope of these exemptions.

1. Discounts. The proposed discount exemption we are proposing is intended to meet the legislative intent of encouraging price competition that benefits the Medicare and Medicaid programs.

The exemption applies to individuals and entities, including providers, who solicit or receive price reductions, and to individuals and entities who offer or pay them. However, while the exemption places certain requirements on individuals or entities who solicit or receive the discount, we are not proposing any requirements on the individuals or entities offering or paying it in order for them to qualify for the exemption. In addition, the exemption also applies regardless whether the discount is offered for bulk purchases, prompt payment or other purposes, and whether the buyer buys directly from the seller or through a group purchasing organization.

This proposed discount exemption closely follows the statutory language, limiting its application to reductions in the amount a seller charges in a specific transaction for a good or service to a buyer. We are specifically requiring that the discount be itemized and appear clearly on the invoice or statement. This discount may take the form of a direct and explicit reduction in price, or of an indirect reduction that results from the offer of an extra quantity of the item purchased "at no extra charge." This exemption specifically does not apply to remuneration in the form of other things of value, such as rebates of cash, other free goods or services, redeemable coupons, or credit towards the future purchases of other goods or services. It also does not apply to any reductions in price offered to beneficiaries, such as routine reductions or waiver of coinsurance and deductible amounts owed by program beneficiaries, unless permitted under these regulations for inpatient hospital care.

We have proposed to limit the scope of this exemption because we have become aware of numerous practices whereby practitioners and providers have been offered a variety of things of value, which are not legitimate "discounts," in return for referrals of Medicare or State health care program business. Such forms of remuneration include, among other things, trips, computers or computer terminals, coupons, cash rebates, or in kind offers, such as the inclusion of one free item when one hundred are purchased. We believe that these practices should not qualify for the discount exemption because many of them are subject to abuse and because their benefits cannot be realized by the Medicare and Medicaid programs.

In addition, we believe that it would not be feasible to enforce the requirements of the exemption if remuneration other than price discounts were permitted here. Such an enforcement effort would require the Department to know the precise amount and value of these other goods or services and then be able to apportion that value to each claim or request for payment. It would be very easy for providers seeking to evade enforcement to conceal or undervalue some part of these goods or services. However, we are interested in receiving comments on the prevalence of such arrangements and mechanisms that could be used to recognize other cash or inkind discounts where the benefits can be realized by the Medicare and

Medicaid programs.

For the purposes of qualifying for this discount exemption, we have divided providers, practitioners, and suppliers into three categories, depending on how they are reimbursed under the programs: (1) Payments based on reasonable cost, acquisition cost, and prospectively determined payment amounts, such PPS payments to hospitals, the composite rate paid to providers of maintenance renal dialysis services, or payments made exclusively on a fee schedule; (2) payments based in whole or in part on charges; and (3) payments based on a capitated risk sharing basis under section 1876 of the Act or on a similar basis.

With respect to the first category, cost-based or PPS paid providers, the exemption merely requires the individual or entity to report the discount. Of course, we expect that the full amount of the discount to be reported. For the most part, this would be accomplished through the cost report.

For example, the reasonable cost rules at 42 CFR 413.98 specify how to report discounts. In other cases, such as with payments based on acquisition costs, the discount could alternatively be reported on the claim or request for payment.

With respect to the second category, those paid in whole or in part on the basis of charges, the exemption applies only if the discount is reported, and the actual charge is reduced by the full amount of the discount.

This second discount exemption applies to all individuals or entities that are reimbursed based on the lesser of actual charges or fee schedule amounts. We are aware of many situations, particularly in the case of laboratory-to-laboratory discounts offered by one clinical diagnostic laboratory to another, where fee schedule amounts are being paid by Medicare but if the discount were properly reported and fully reflected, the actual charge would be reduced to below the fee schedule amount.

With respect to the third category, we are proposing not to impose any requirements or risk sharing health maintenance organizations or competitive medical plans paid on a capitated basis under section 1876 of the Act or on a similar basis. Since we do not perceive any circumstance where the Medicare or State health care programs will benefit from any price reductions obtained by these entities, we see no purpose in imposing any requirements on them to comply with this exemption.

2. Employees.

This statutory exemption permits an employer to pay an employee in whatever manner he or she chooses for having that employee assist in the solicitation of Medicare or State health care program business. The proposed exemption follows the statute in that it applies only to bona fide employee-employer relationships. We have decided to adopt the definition of employee from the Internal Revenue Service set forth in 26 U.S.C. 3121(d)(2).

In response to the October 21, 1987 request for comments, many commenters suggested that we broaden the exemption to apply to independent contractors paid on a commission basis. We have declined to adopt this approach because we are aware of many examples of abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision. We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual's acts.

3. Group purchasing organizations.
This exemption applies to payments made by a vendor of goods or services to a person authorized to act as a group purchasing organization (GPO) for a number of individuals or entities who are furnishing Medicare or State health care program services. The exemption closely follows the statute, and requires a written agreement between the GPO and the individual or entity that specifies the amount the GPO will be paid. Where the entity is a provider, the exemption requires the GPO to disclose in writing to the provider at least annually the amounts received from each vendor with respect to purchases made on behalf of that provider. Providers must make such disclosures available to the Department upon request, but we are not proposing at this time to require that these disclosures be submitted on a routine basis. In addition, we are not proposing more specific requirements as to the content of the disclosure. At this time, we have concluded that the purposes of this statutory exemption are fulfilled with these limited disclosure requirements. Of course, providers and GPOs remain free to supplement these requirements as they see fit.

III. Regulatory Impact Statement

A. Introduction

Executive Order 12291 requires us to prepare and publish an initial regulatory impact analysis for any proposed regulation that meets one of the Executive Order criteria for a "major rule," that is, that 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 through 6712), unless the Secretary certifies that a proposed regulation would not have a significant economic impact on a substantial number of small entities.

B. Impact on Providers and Practitioners

The provision providing new authority to the OIG to exclude a person or entity from Medicare and State health care programs if engaged in a prohibited remuneration scheme would ensure that the Department could seek action against those practicing in such prohibited schemes short of criminal prosecution. This provision, is a result of the statute and not this proposed rule. In addition, this proposed rule attempts to specify various business and payment practices that would not be considered a kickback for purposes of criminal or civil remedies. The regulations serve to clarify departmental policy as to the legality of various commercial arrangements. We believe that the great majority of 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 interpret the kickback statute broadly and who have engaged in prohibited payment schemes in violation of the statutory intent.

C. Conclusion

For these reasons, we have determined that a regulatory impact analysis is not required. Further we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a number of small business entities. Therefore, we have not prepared a regulatory flexibility analysis.

IV. Paperwork Reduction Act

Section 1001.952 of this proposed rule contains information collection requirements. As required by the
Paperwork Reduction Act of 1980 (44 U.S.C. 3504), we have submitted a copy of this proposed rule to the Executive Office of Management and Budget (EOMB) for its review of these requirements. Other organizations and individuals desiring to submit comments on the information collection requirements should follow the instructions in the ADDRESS section of this preamble.

V. Response to Comments

Because of the large number of comments we normally receive on proposed regulations, we cannot acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments received timely and respond to the major issues in the preamble to that rule.

List of Subjects in 42 CFR Part 1001

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

42 CFR Chapter V, Part 1001 would be amended as set forth below:

PART 1001--PROGRAM INTEGRITY: MEDICARE

1. The authority citation for Part 1001 would be revised to read as follows:

Authority: Secs. 1102, 1128, 1128B, 1842(j), 1842(k), 1862(d), 1862(e), 1866(b)(2) (D), (E), and (F), and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(j), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2) (D), (E), and (F), and 1395hh), unless otherwise noted.

2. A new Subpart E is added to Part 1001 to read as follows:

Subpart E--Permissive Exclusions

Sec. 1001.951 Fraud, kickbacks and other prohibited activities.

1001.952 Exceptions.

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, such as a dividend, capital gains distribution, or interest income, from an investment obtained for fair market value in the investment securities (including shares in a corporation, bonds, debentures, notes, or other debt instruments) of a corporation that, at the end of the corporation's fiscal year preceding the purchase of the securities, had--
(1) Total assets exceeding $5,000,000, and

(2) A class of equity security held of record by at least 500 persons.

(b) Space rental. As used in section 1128B of the Act, "remuneration" does not including payments made by a lessee to a lessor for the use of premises, as long as--

(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, their periodicity, and the exact rent for such intervals;

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

(5) The rental charge 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 of business between the parties reimbursed under Medicare or Medicaid.

For purposes of this section, the term "fair market value" means the value of the rental property for general commercial purposes (not taking account of its intended use), but shall not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the property as a result of its proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

(c) Equipment rental. As used in section 1128B of the Act, "remuneration" does not include payments made by a lessee of equipment to the owner ("lessee") of the equipment for the use of the equipment, as long as--

(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, their periodicity, and the exact rent for such intervals;

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

(5) The rental charge 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 of business between the parties reimbursed under Medicare or Medicaid.

For purposes 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 the prospective lessee or lessor would attribute to the equipment as a result of its proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.
(d) Personal services and management contracts. As used in section 1128B of the Act, "remuneration" does not include payments made by a principal to an agent as compensation for the services of the agent, as long as--

(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, their periodicity, and the exact charge for such intervals;

(4) The term of the agreement is for not less than one year; and

(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 than takes into account the volume or value of any referrals of business between the parties that is reimbursed under Medicare or any State health care program.

For purposes of this section, an agent of a principal is any person, other than a bona fide employee, 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 payments made to a practitioner by another practitioner where one practitioner is selling his or her practice to another practitioner, as long as--

(1) The period from the date of any agreement pertaining to the sale to the completion of the sale is not more than one year; and

(2) The practitioner who is selling his or her practice will not be in a professional position to make referrals to the purchasing practitioner after one year from the date of the agreement.

(f) Referral services. As used in section 1128B of the Act, "remuneration" does not include payments by a physician to an entity which offers to the public that it will refer a person to a physician for medical services, as long as--

(1) The entity does not exclude any qualified physician from participation in the referral service;

(2) Any fee for participation in the referral service is charged equally to all physicians and is reasonably related to the cost of operating the referral service;

(3) The entity imposes no requirements on the manner in which the physician provides services to a referred person, except that the entity may require that these services be furnished free of charge or at reduced charge to the patient; and

(4) The entity makes a disclosure to each person referred as to--

(i) The manner in which it selects a physician for the person,

(ii) The nature of the relationship between the entity and the physicians to whom it makes referrals, and

(iii) The nature of any restrictions that would exclude a physician from the pool of physicians to whom referrals are made.

(g) Warranties. As used in section 1128B of the Act, "remuneration" does not include payments by a manufacturer or supplier of an item to the purchaser of the item as compensation for any loss sustained by the purchaser due to the failure of the item to operate as intended, as long as the payment--

(1) Is made in accordance with a written affirmation made in connection with the original sale of the item by the supplier to the purchaser, with such affirmation relating to the nature of the material or workmanship and affirming or promising that such material or workmanship is defect-free or will meet a specified level of performance over a specified period of time; and,

(2) Is reasonably related to the economic loss that would otherwise be sustained by the purchaser, including, but not limited to--

(i) either a refund of the purchase price or the repair or replacement of the defective item, and

(ii) reimbursement of any costs associated with replacing the product.

(h) Discounts. (1) As used in section 1128B of the Act, a discount is a reduction in the amount a seller charges for a good or service to a buyer (who buys either directly or through a contract with a group purchasing organization) that appears on the invoice or statement. Discounts do not include rebates of cash, other kinds of free goods or services, redeemable coupons, credit towards the future purchase of any goods or services, routine reductions or waivers of any coinsurance or deductible amount owed by program beneficiaries for other than inpatient hospital services, or other remuneration in cash or in kind.

(2) A reduction in a seller's charge is considered a discount as long as an individual or entity that solicits or receives such discount--

(i) On an item or service for which payment is made on the basis of a reasonable cost, acquisition cost, or prospectively determined payment amounts (such as prospective payments system payments to hospitals, or the composite rate paid to providers of maintenance renal dialysis services), fully and accurately reports the discount in the applicable cost reporting mechanism or claim for payment filed with the Department, a State agency or one of their agents;

(ii) On an item or service for which payment is made in whole or in part on the basis of charges--

(A) Fully and accurately reports the discount in the applicable claim for payment filed with the Department, a State agency, or one of their agents, and

(B) Reduces the charge to the program or the beneficiary by the full amount of the discount; or

(iii) Is a health maintenance organization or competitive medical plan paid for by Medicare as a risk contractor under the Tax Equity and Fiscal Responsibility Act of 1982, as authorized under section 1876 of the Act, or by a Medicaid State agency on a similar basis.

(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 provision of covered items or services. For purposes 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 payments by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed by Medicare or Medicaid, as long as--

(1) The purchasing agent has a written agreement with each individual or entity in the group that specifies the amount the agent 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 purchasing agent); and

(2) In the case of an entity that is a provider of services, the agent discloses 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.


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Otis R. Bowen,

Secretary.

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