DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991-AA66

Health Care Programs: Fraud and Abuse; Additional Safe Harbor Provisions Under

the OIG Anti-Kickback Statute

Tuesday, September 21, 1993 (58 FR 49008)

AGENCY: Office of Inspector General, HHS.

ACTION: Proposed rule.

SUMMARY: This proposed regulation is designed to set forth an expanded listing of safe harbor
provisions as authorized under section 14 of the Medicare and Medicaid Patient and Program Protection
Act of 1987. This new listing of proposed safe harbors delineates additional payment and business
practices under Medicare and State health care programs that would be protected from criminal
prosecution or civil sanctions under the anti-kickback provisions of the statute.

DATES: To assure consideration, public comments must be mailed or delivered to the address provided

ADDRESSES: Address comments in writing to: Office of Inspector General, Department of Health and
Human Services, Attention: LRR-27-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-27- P. Comments will be available for
public inspection in room 5551, 330 Independence Avenue, SW., Washington, DC on Monday through
Friday of each week from 9 a.m. to 5 p.m., (202) 619-3270.

FOR FURTHER INFORMATION CONTACT:

Joel Schaefer, Office of Inspector General; (202) 619-3270.
SUPPLEMENTARY INFORMATION:

I. Background

Public Law 100-93

Section 14 of Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987, requires the promulgation of regulations specifying those payment and business practices which, although potentially capable of inducing referrals of business under the Medicare and State health care programs, would not be treated as criminal offenses under section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)) and would not serve as a basis for a program exclusion under section 1128(b) (7) of the Act (42 U.S.C. 1320a- 7(b)(7)).

Congress intended that the regulations setting forth various "safe harbors" would be evolving rules that would be periodically updated to reflect changing business practices and technologies in the health care industry. As evidenced in the House Committee Report accompanying Public Law 100-93, the Committee stated that it believed that periodic public input was 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 re-evaluate the anti- kickback regulations on a periodic basis and, in doing so, will solicit public comments at the outset of the review process.

Initial Proposed Rulemaking

On January 23, 1989, we published a notice of proposed rulemaking setting forth various business and payment practices that we proposed to exempt from the anti-kickback statute, and the rationale for their inclusion in a listing of "safe harbor" provisions (54 FR 3088). The rulemaking proposed the establishment of safe harbors in ten broad areas: investment interests, space rental, equipment rental, personal services/management contracts, sales of practice, referral services, warranties, discounts, employees and group purchasing.

In response to the proposed rulemaking, we received over 750 public comments that included both general and broad-reaching concerns regarding the impact of these regulations. The majority of the comments received specifically addressed the ten proposed safe harbors. A summary of these comments and our analysis and response to those concerns are set out in the preamble to the final regulation that was published in the Federal Register on July 29, 1991 (56 FR 35952). In addition, the public comments contained several suggestions for the consideration and adoption of additional safe harbor provisions under 42 CFR 1001.952. Set forth below are seven proposed new safe harbor provisions. We invite public comment on these new provisions.
We wish to emphasize that nothing in this proposed regulation changes reimbursement rules promulgated by the Health Care Financing Administration (HCFA) or a State health care program. If a provider chooses to engage in a particular 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 rulemaking.

In addition, because this is simply a notice of proposed rulemaking, compliance with either the terms of this proposed rule or standards discussed in this preamble does not provide safe harbor protection at the present time. The only way to protect behavior which implicates the anti-kickback statute is compliance with a safe harbor provision which has been published in final form.

II. Provisions of the Proposed Rule

Set forth below is a description of the additional payment practices that we are proposing to exempt under §1001.952 of our regulations and the rationale for their inclusion in this proposed rulemaking.

A. Additional Investment Interests

We are proposing three additional investment interest safe harbor provisions in §1001.952(a) to protect payments to investors who engage in business with the entity in which they have invested.

1. Investment Interests in Rural Areas

We have been informed that many rural areas have particular problems that make it difficult for them to comply with the two 60-40 rules of the "small entity" investment interest safe harbor provision as currently set forth in §§ 1001.952(a)(2) (i) and (vi). The first 60-40 rule, known as the "60-40 investor rule," requires that no more than 40 percent of the investment interests of the entity be held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. The second 60-40 rule, known as the "60-40 revenue rule," requires that no more than 40 percent of the gross revenue of the entity may come from referrals or business otherwise generated from investors. Rural areas have an especially difficult time complying with these two standards in many cases because physicians may be the only source of capital, and they may have no alternative facility to which they can refer.

Consequently, in a third investment interest safe harbor, § 1001.952(a)(3), we are proposing to eliminate these two 60-40 rules for entities serving rural areas. This safe harbor would apply to entities located in rural areas as defined by the Office of Management and Budget and used by the Bureau of the Census. According to the 1991 Statistical Abstract of the United States, 22.5 percent of the population in 1990 reside in such areas. We are soliciting comments on the appropriateness of this definition of a rural area, and we will consider comments on how the definition could be adapted to further the intent of this proposed safe harbor. We stress, however, that the method used for designating rural areas must ensure that this safe harbor only protects entities that truly serve a rural population. One alternative would be to...
adopt the definition of rural area found in 42 CFR 412.62(f)(1)(ii).

We are not proposing, however, to modify any of the other six standards in the small investment interest safe harbor for rural areas that are set forth in §§ 1001.952(a)(2) (ii)-(v), (vii), and (viii). These six standards provide fundamental assurances against abuse, and we have not been apprised of any particular difficulty that rural entities are experiencing with these other standards. Therefore, we are not requesting public comments regarding the applicability of these six standards to the proposed small investment interest safe harbor for rural areas.

In place of the 60-40 investor rule we are proposing a more flexible standard that will still assure that referring sources, physicians in particular, are not inappropriately selected as investors. We are proposing to require the entity to make a bona fide offer of the investment interest to any individual or entity irrespective of whether such prospective investor is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. In other words, the entity may comply with this first standard by offering the opportunity for investment in a good faith, nondiscriminatory manner to any individuals or entities who are potential sources of capital.

Although we are eliminating the 60-40 revenue rule, we remain concerned that a sham joint venture structure could be established that does not intend to serve the rural area in which it is located. Consequently, we are proposing to incorporate a standard that would require that at least 85 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12 month period must be derived from the service of persons who reside in a rural area. In the case of an entity that has not yet been in business for 12 months, compliance with this standard will be determined by examining the composition of the entity's business over the entire period of its existence.

2. Investment Interests in Ambulatory Surgical Centers

In a fourth investment interest safe harbor, §1001.952(a)(4), we are proposing to protect payments to investors in ambulatory surgical centers (ASCs) who are surgeons who refer patients directly to the ASC and perform surgery themselves on these referred patients.

As stated in the preamble of the original set of safe harbor provisions published on July 29, 1991 (56 FR 35971):

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.

This concept is often referred to as an extension of the physician's office practice. In the above situation, the physician-investor receives two payments: (1) the professional fee for furnishing the service, and (2) the profit distribution from the entity based on the program payment the entity receives that was generated from the referral. We do not consider the statute to be implicated by the first payment.
However, we believe that the second payment is potentially covered by the statute.

As with any investment interest held by a potential referral source, the profit distribution provides some financial incentive to refer patients to the entity. To the extent this payment has the potential to induce physician-investors to overutilize the entity, no safe harbor protection is warranted.

In contrast, where these payments do not constitute a significant inducement to make referrals, they may merit safe harbor protection. Where the professional fee generated by a referral is substantially greater than the facility fee generated by the referral, we believe that the profit distribution payment (which results from the facility fee) does not constitute a significant improper inducement. Only where a great disparity between the facility and professional fees exists will the incremental increase in profit distribution from a referral be so small as to be inconsequential when compared to the corresponding professional fee. Therefore, we will only consider providing safe harbor protection to types of extensions of practice that receive facility fees from referrals that are greatly disparate from the professional fee generated by the referral.

Because we believe that ASCs generally fit this criterion, we have proposed a safe harbor for certain investment interests in ASCs. When a patient is referred to an ASC for surgery, there is a great disparity between the surgeon's professional fee and the ASC's facility fee. Therefore, we propose to protect the payment of profit distributions from the ASC to investors where all investors in the ASC are surgeons in a position to refer to the ASC and perform services.

This proposed safe harbor applies only to ASCs certified under 42 CFR part 416. We are not proposing to protect ASCs located on the premises of a hospital that share their operating or recovery room space with the hospital for treatment of the hospital's inpatients or outpatients.

This proposed fourth investment interest provision contains five standards. The first standard precludes an investor from being afforded better investment terms based on past or expected referrals or amount of services furnished to the entity. The second standard requires that a passive investor not be required to make referrals to the entity in order to continue as an investor. The third standard prohibits the entity or any investor from loaning funds to the investor for use in obtaining an investment interest. Standard four requires that payments not be based on referrals. Finally, the practitioner must agree to treat Medicare and Medicaid patients.

In contrast to the other investment interest safe harbors which seek to limit investment by individuals in a position to refer, this proposed ASC safe harbor only protects entities whose investment interests are held entirely by such individuals. With that distinction in mind, four of the five proposed standards have been adapted from those in the small entity safe harbor at § 1001.952(a)(2). We believe these standards provide fundamental assurances against abuse; however, we are soliciting comments on the extent to which other standards are appropriate to safeguard against potential abuse.

Further, while this proposed safe harbor only applies to ASCs certified under 42 CFR part 416, we are
also soliciting comments on whether this rationale is applicable to entities other than ASCs. Specifically, we are soliciting comments on what degree of disparity should exist between the professional fees and facility fees generated by referrals to a type of entity for that type of entity to receive safe harbor protection.

The rationale underlying this safe harbor does not extend to investment interests held by physicians who are not in a position to refer patients directly to the ASC and perform surgery. Such physicians do not receive a professional fee as a result of services performed by the entity. An example to illustrate the potential perils of protecting profit distributions to such investors would be where a non-surgeon physician investor may refer a patient to a surgeon-investor who may, in turn, refer the patient to the ASC where the surgeon-investor may perform the surgery. In this scenario, the non-surgeon investor would receive a return, through the ASC's profit distribution, for the "indirect referral" of the patient. Because of the potential for improper inducement of referrals illustrated in this example, we do not think investment interests held by non-surgeon investors merit safe harbor protection.

3. Investment Interests in Group Practices Composed Exclusively of Active Investors

We are considering promulgating a fifth investment interest safe harbor to protect payments to investors in entities composed only of active investors in a group practice. Although there may be other types of joint ventures composed exclusively of active investors which should receive safe harbor protection, we do not propose to protect them at this time. Rather, we are presently soliciting comments on how to expand this limited safe harbor provision.

This fifth investment interest safe harbor, §1001.952(a)(5), would protect the investment interests of members of group practices that meet two prerequisites and three standards. The two prerequisites are that all the investors must meet our definition of "active investor," and all the investors must be physician members of a "group practice."

We propose to adopt the definition of group practice contained in section 1877(h)(4) of the Act (as added by section 6204(a) of the Omnibus Budget Reconciliation Act of 1989, Public Law 101-239), which restricts physicians from making referrals for clinical laboratory services to entities with which they have an ownership interest or other compensation arrangement. This definition requires (a) physician members of the group to provide substantially the full range of their services through the shared use of office space, facilities, equipment and personnel; (b) substantially all of the services of the members to be provided through the group, billed through the group, with payments received as receipts of the group; and (c) overhead expenses and income of the group to be distributed in accordance with a predetermined formula. We intend principally to protect investors who are individuals who qualify as "physicians" under this definition. However, because our definition of investor includes entities as well as individuals, our definition of group practice permits physicians to invest as a professional corporation, but only to the extent that the corporation is exclusively owned by the physicians. We are soliciting comments on the appropriateness of using this definition of "group practice" for the purposes of this safe harbor provision. One alternative would be to adopt the definition contained in the regulations.
implementing section 1877(h)(4) of the Act when that regulation is published in final form (see 57 FR 8588, March 11, 1992). Another alternative would be to use the definition currently set forth in 42 CFR 417.100.

The three standards in this safe harbor are derived directly from the second investment interest safe harbor in §1001.952(a)(2). First, we are requiring that the terms of the investment interest not be preferentially given to certain physicians in the group practice based on their expected referrals. Second, the entity or another investor cannot loan or guarantee a loan to the investors to be used to obtain the investment interest. And third, the amount of return must be directly proportional to the capital invested. We are specifically inviting comments on the appropriateness of applying these standards to group practices. In particular, we are soliciting information in the types of compensation arrangements that exist within group practices, and the extent to which they create inappropriate incentives that distort the professional judgment of the members of the group.

We recognize that there may be other non-abusive joint ventures consisting exclusively of active investors. Typically, such entities are partnerships consisting of general partner investors. The general partners are involved in the day-to-day operation of the entity, and undertake personal liability. However, entities structured in this manner can have a variety of different characteristics. For example, as discussed above, the entity can be a physicians group practice where all the physicians are general partners, or the entity can be a joint venture between two other entities, such as a hospital and durable medical equipment (DME) supplier or a DME manufacturer and a DME distributor. In addition, the entity may be a subchapter S corporation instead of a partnership.

In view of the wide variety of types of entities that may warrant protection, and the varying degree of safeguards that may be warranted for different types, we are soliciting comments on whether we should protect other types of joint ventures composed exclusively of active investors, and the extent to which we should adopt the standards we have included in the second investment interest safe harbor (§1001.952 (a)(2)). Among the areas about which we are specifically soliciting comments are the varying degree of safeguards that are needed when the general partners are entities as opposed to individuals, the extent to which such a provision should apply in the context of a subchapter S corporation or other business structure, and the extent to which protection should be afforded to these entities when they have passive investors who are not in a position to make referrals.

B. Practitioner Recruitment

We are proposing a safe harbor provision for certain payments or benefits offered by rural hospitals and entities in their efforts to recruit physicians and other practitioners to join their staffs. It has come to our attention that hospitals located in rural areas have been encountering problems in helping to attract physicians needed by the community. With this proposed safe harbor we hope to address this problem without protecting arrangements designed to channel Medicare and Medicaid business to recruiting hospitals. We have proposed to limit the safe harbor to hospitals and other entities located in "rural areas" as that term is defined in the proposed investment interest safe harbor for entities located in rural
We are soliciting comments on alternative geographic criteria for protecting recruitment of physicians under this safe harbor. One example may be limiting the safe harbor to recruitment of practitioners by hospitals and entities located in areas which are health professional shortage areas for the practitioner's specialty category.

We are proposing to protect recruitment activities aimed at only two types of health care providers: (1) A practitioner who will need to relocate to a new geographic area and start a new practice, or (2) a new practitioner to assist him or her in starting a practice or specialty after completing an internship or residency program. Not covered within this safe harbor are arrangements between hospitals and physicians that are, in reality, payments to obtain the referrals of established practitioners who work at least in part at another hospital in the same area.

For the recruitment activity to be protected, we propose seven standards: (1) the arrangement and its terms must be in writing; (2) if a practitioner is leaving an established practice, the physical location of the new primary place of practice must be not less than 100 miles from the location of the established primary place of practice and at least 85 percent of the revenue of the new practice must be generated from new patients not previously seen by the practitioner at his or her former practice; (3) unless the practitioner's new primary place of practice is designated as a health professional shortage area (HPSA) for the practitioner's HPSA specialty category during the entire duration of the payments or benefits, the duration of the payments or benefits cannot exceed 3 years; (4) the entity providing the benefits cannot condition the agreement on the practitioner's referral of business to the entity; (5) the practitioner cannot be restricted from establishing staff privileges at another entity or referring business to another entity; (6) the entity cannot vary, adjust or renegotiate the amount or value of benefits based on the volume of business the practitioner generates for the entity; and (7) the practitioner must treat medicare and medicaid patients.

Hospitals would not fall within this safe harbor if they use recruitment efforts as a means of offering compensation to physicians as inducements for referrals. Thus, we do not propose to protect subsidy payments beyond the 3-year period. However, after three years, hospitals may still engage in financial relationships with these physicians that qualify under other safe harbor provisions, such as space rental, personal services/management contracts, or the safe harbor proposed below on malpractice insurance.

The one exception to the 3-year limit on payments or benefits would be where the practitioner has been recruited to a HPSA. The designated shortage would have to be in the practitioner's HPSA specialty category. In addition, in order to be exempted from the 3-year limit, the area would have to be designated a HPSA during the duration of the relationship between the entity and the practitioner.

We are also soliciting comments on how to protect payments designed to retain physicians already practicing in an area that has been designated a HPSA for the physician's specialty category.

C. Obstetrical Malpractice Insurance Subsidies

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We are proposing a new safe harbor provision that would permit a hospital or other entity to pay all or part of the malpractice insurance premiums for practitioners engaging in obstetrical practice in primary care health professional shortage areas. For the purposes of this provision, "practitioner" includes a "certified nurse-midwife" as defined in section 1861(gg) of the Act. Seven standards would need to be met. The first five standards are adopted from concepts in the rural investment interest and practitioner recruitment safe harbor provisions proposed above. These standards require that: (1) the agreement must be set forth in writing; (2) at least 85 percent of the practitioner's obstetrical patients treated under the coverage of the malpractice insurance reside in the shortage area or be a part of a designated shortage area population; (3) there is no requirement that the practitioner refer any level of patients to the entity; (4) there is no restriction placed on the practitioner from establishing staff privileges at, referring patients to, or otherwise generating business for other entities; and (5) the amount of the payment may not vary based on referrals made by the practitioner to the entity.

Two additional standards are also being proposed. The sixth standard attempts to assure access to Medicaid patients seeking obstetrical care by requiring the practitioner, as a condition of safe harbor protection, to treat such patients. Finally, the seventh standard requires bona fide insurance policies to assure that this provision is not used as a mechanism to disguise improper inducements to physicians or other practitioners. Such insurance policies are regulated under State law and are exempt from antitrust and Federal Trade Commission enforcement in accordance with 15 U.S.C. 1012.

Under this proposed safe harbor provision, entities would be permitted to limit the coverage of the malpractice insurance to services performed at that entity. Although we are concerned that such restrictive policies have the effect of limiting a practitioner's professional mobility, we recognize that there are important reasons for such restrictions. Often a hospital's malpractice policy is limited to insure against misconduct on its premises. Although a hospital can provide reasonable assurances to its underwriter that it is overseeing the conduct of its medical staff, it has little ability to make any assurances of the conduct of its staff when they are working at other hospitals. Thus, the underwriter could be engaging in a much higher risk, and therefore might legitimately charge a much higher premium, if it were to provide insurance for the hospital's medical staff when it furnishes services off-site. Finally, we believe that any potential for influencing the practitioner's choice of where to practice that may result from this standard is mitigated by other standards within this proposed provision that limit the ability of the entity to use malpractice subsidies to control the stream of referrals from that practitioner.

As we noted above, nothing in this proposed rule should be construed as authorizing Medicare payment to hospitals or other institutional providers for the cost they may incur for such malpractice insurance. Any allowable costs for such insurance is governed strictly by Medicare and Medicaid rules.

We recognize the narrowness of this safe harbor provision, which is limited to malpractice subsidies for obstetrical care in HPSAs. Although the malpractice problem affects many more practitioners than those we are proposing to protect here, we remain concerned that such subsidies may lead to inappropriate incentives and loyalties created by such incentives. However, we are soliciting comments on specific, narrowly drawn circumstances where this safe harbor provision could be expanded to help assure
beneficiary access to services that may be significantly affected by the cost of malpractice insurance premiums. In addition, we are soliciting views regarding the feasibility of expanding this provision to protect malpractice insurance programs that are not regulated under State law, but which are operated directly by providers.

D. Referral Agreements for Specialty Services

We are proposing to protect arrangements under which an individual or entity agrees to refer a patient to another individual or entity for specialty services in return for an agreement on the part of the party receiving the referral to refer that patient back at a certain time or under certain circumstances. For example, a primary care physician and a specialist may agree that, when their patient reaches a particular stage of recovery, the primary care physician should resume treatment of the patient.

The first standard we are proposing clarifies what is meant by specialty services; that is, the service for which the referral is made may not be within the medical expertise of the referring individual or entity, but is within the special expertise of the other party receiving the referral. The second standard we are proposing prohibits any actual payment to be made between the parties for the referral. The third standard requires that the only exchange of value between the parties, with one exception to be discussed below, is the opportunity to obtain monetary remuneration directly from third-party payors or the patient, as compensation for his or her respective professional services. As the United States Court of Appeals for the First Circuit has recognized: "Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments toward a particular recipient." United States v. Bay State Ambulance and Hospital Rental Service, Inc., 874 F.2d 20, 29 (1st Cir. 1989).

Since the opportunity to generate a fee may constitute the requisite remuneration under the statute, generally speaking, we believe that the statute is implicated in many of these agreements. However, we also believe that these relationships benefit patients by assuring proper continuity of care or convenient access to a specialist in whom the primary care physician has confidence.

The one exception where we are proposing to permit remuneration between the parties is where both parties belong to the same group practice. Obviously in such situations revenues are shared between members of the group practice, and thus it appears that the referring physician receives remuneration for the referral. However, such financial benefits are an inherent part of belonging to a group practice, and therefore we are proposing to protect such remuneration.

As discussed in sections II.A.2. and B. above, we are concerned about potentially abusive combinations of physicians that are a "group practice" in name only. Consequently, we are proposing to use the same definition of group practice as we are proposing for the fourth investment interest safe harbor. This definition is the same definition of "group practice" as is contained in section 1877(h)(4) of the Act, as added by section 6204(a) of Public Law 101-239.

E. Cooperative Hospital Service Organizations
We are proposing to provide a new safe harbor provision for most cooperative hospital service organizations (CHSOs) that qualify under section 501(c)(3) of the Internal Revenue Code. Under this statute and the implementing regulation (26 CFR 1.501(e)-1), these organizations are formed by two or more tax exempt hospitals (known as "patron-hospitals") to provide specifically enumerated services, such as purchasing, billing, and clinical services solely for the benefit of 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)).

Where a health care provider engages in an activity which is specifically required by another statutory provision and the provider is afforded no discretion in the manner of compliance, such a requirement is a valid defense to an alleged violation of the anti-kickback statute. However, where the health care provider is engaging in the activity to fulfill a general statutory obligation, but is afforded discretion in the manner of compliance, such a defense is not available because the provider's choice in the method of compliance may be motivated by an intent to generate program-related business. With respect to the payments the CHSO makes to its patron-hospitals, we believe that the level of discretion given to these providers as to what payment formula to use warrants safe harbor protection. However, we specifically invite comments regarding the various types of payment formula (which comply with the Internal Revenue Service (IRS) rules) that are used, but some of which may be more abusive than others.

This proposed provision would protect payments from a patron-hospital to a CHSO to support the CHSO's operational costs and those payments from a CHSO to a patron-hospital that are required under IRS rules. This proposed provision requires as a condition of protection that the CHSO must be wholly owned by its patron-hospitals. Such a condition protects against potentially abusive joint venture arrangements that are formed under the guise of CHSOs.

To the extent a CHSO acts as a group purchasing organization or a patron-hospital obtains discounts as a result of the CHSO's activities, CHSOs and patron-hospitals must comply with the respective safe harbor provisions applicable to group purchasing organizations and discounts to be fully protected.

We are soliciting comments on the extent to which we should expand this provision to protect other similar entities specifically organized and protected under Federal or State laws.

III. Solicitation of Comments for Modifying the Sale of Practice Safe Harbor

In addition to the proposed provisions discussed above, we are soliciting comments on the desirability of modifying the existing sale of practice safe harbor set forth in §1001.952(e) to accommodate transactions involving the rural hospital purchase of practice as part of a practitioner recruitment program.

The sale of practice safe harbor set forth in §1001.952(e) does not protect a hospital purchasing the practice of a retiring physician. We have been informed that many rural hospitals, as part of their efforts to recruit practitioners, buy and "hold" the practice of a retiring physician, often using locum tenens
physicians until a new physician can be recruited to replace the retiring one. We are soliciting comments on the desirability of modifying the existing sale of practice safe harbor to permit such a practice where the recruitment program complies with any safe harbor we establish to protect practitioner recruitment.

IV. Regulatory Impact Statement

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 areas; 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 612), unless the Secretary certifies that a proposed regulation would not have a significant economic impact on a substantial number of small entities.

For the reasons set forth in the final rule published on July 29, 1991 (56 FR 35952), 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.

V. Additional Information

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 of that rule.

List of Subjects in 42 CFR Part 1001

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

TITLE 42--PUBLIC HEALTH

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

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

PART 1001--PROGRAM INTEGRITY--MEDICARE AND STATE HEALTH CARE PROGRAMS
1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(j), 1395u(k), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh, and section 14 of Pub. L. 100-93.

2. Section 1001.952 would be amended by revising paragraph (a) introductory text, paragraph (a)(1) introductory text, paragraphs (a)(1)(v) and (a)(2)(viii); by adding paragraphs (a)(3) through (a)(5); by revising paragraph (a) concluding text; and by adding paragraphs (n) through (q) to read as follows:

§1001.952 Exceptions.

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(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 five 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 standards must be met--

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(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) ***

(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.

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

(i) The entity must offer equal and bona fide opportunities to acquire investment interests to individuals or entities irrespective of whether such prospective investor is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity.
(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) At least 85 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period must be derived from the service of persons who reside in a rural area.

(vii) The entity or any investor 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.

(4) If the entity is a certified ambulatory surgical center (ASC) under part 416 of this title, whose operating and recovery room space is dedicated exclusively to the ASC (and not a part of a hospital), and all of the investors are surgeons who are in a position to refer patients directly to the entity and perform surgery on such referred patients, all of the following five standards must be met--

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

(ii) There is no requirement that a passive investor, if any, make referrals to the entity as a condition for remaining as an investor.

(iii) The entity or any investor must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.
(iv) The amount of payment to an investor in return for the investment 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.

(v) The practitioner must agree to treat patients receiving medical benefits or assistance under title XVIII or XIX of the Act.

(5) If the entity possesses investment interests all of which are held by active investors and all of these investors are physician members of a group practice, all of the following three standards must be met--

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

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

(iii) The amount of payment to the 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. Group practice means a group of two or more physicians that meets the definition of group practice under section 1877 (h)(4) of the Act. 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 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. Rural area means any defined geographic area that is not a metropolitan area as defined by the Office of Management and Budget.

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(n) Practitioner recruitment. As used in section 1128B of the Act, "remuneration" does not include any payment or exchange of anything of value by an entity located in rural areas (as defined in paragraph (a) of this section) in order to induce a practitioner who has been practicing within his or her current
specialty for less than one year to establish staff privileges at the entity, or to induce any other practitioner to relocate his or her primary place of practice to the geographic area served by the entity, as long as all of the following seven standards are met--

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

(2) If a practitioner is leaving an established practice, the physical location of the new primary place of practice must be not less than 100 miles from the location of the established primary place of practice and at least 85 percent of the revenues of the new practices must be generated from new patients not previously seen by the practitioner at his or her former practice.

(3) The benefits are provided by the entity for a period not in excess of 3 years, and the terms of the agreement are not renegotiated during this 3 year period in any substantial aspect, unless the practitioner's new primary place of practice is designated as a health professional shortage area (HPSA) for the practitioner's specialty category during the entire duration of the relationship between the practitioner and the entity.

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

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

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

(7) The practitioner agrees to treat patients receiving medical benefits or assistance under title XVIII or XIX of the Act.

(o) Obstetrical malpractice insurance subsidies. As used in section 1128B of the Act, "remuneration" does not include any payment made by a hospital or other entity to another entity that is providing malpractice insurance regulated by State law, where such payment is used to pay for some or all of the costs of malpractice insurance premiums for a practitioner who engages in obstetrical practice (including a certified nurse-midwife as defined in section 1861(gg) of the Act) in primary care HPSAs, as long as all of the following eight standards are met--

(1) The payment is made in accordance with a written agreement between the entity paying the premiums and the practitioner, which sets out the payments to be made by the entity, and the terms under which the payments are to be provided.
(2) At least 85 percent of the practitioner's obstetrical patients treated under the coverage of the malpractice insurance must either:

(i) Reside in an area designated by the Secretary under part 5 of this title as having a shortage of primary medical care manpower, or

(ii) Be part of a population group designated by the Secretary under part 5 of this title as having a shortage of primary medical care manpower.

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

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

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

(6) The practitioner agrees to treat obstetrical patients who receive medical assistance under title XIX of the Act.

(7) The insurance premium is calculated based on a bona fide assessment of the liability risk covered under the insurance policy.

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

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

(2) The parties receive no payment from each other for the referral.

(3) Unless both parties belong to the same group practice as defined in paragraph (a) of this section, the only exchange of value between the parties is the remuneration the parties receive directly from third-party payors or the patient compensating the parties for the services they each have furnished to the patient.
(q) Cooperative hospital service organizations. As used in section 1128B of the Act, "remuneration" does not include any payment made between a cooperative hospital service organization (CHSO) and its patron-hospital, both of which are described in section 501(e) of the Internal Revenue Code of 1986 and are tax-exempt under section 501(c)(3) of the Internal Revenue Code, where the CHSO is wholly owned by two or more patron-hospitals, as long as all of the standards are met within either of the following two categories of payments--

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

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


Bryan B. Mitchell,
Principal Deputy Inspector General.

Approved: June 28, 1993.

Donna E. Shalala,
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