DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991-AA74

Medicare and State Health Care Programs: Fraud and Abuse;

Clarification of the OIG Safe Harbor Anti-Kickback Provisions

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would clarify various aspects of safe harbor provisions originally published in the Federal Register on July 29, 1991 as a final rule (56 FR 35952). The safe harbor provisions have been specifically designed to set forth those payment practices and business arrangements that will be protected from criminal prosecution and civil sanctions under the anti-kickback provisions of the statute. This proposed rule would modify the original set of final safe harbor provisions to give greater clarity to the rulemaking's original intent.

DATES: To assure consideration, public comments must be delivered to the address provided below by September 19, 1994. Comments are available for public inspection August 4, 1994.

ADDRESSES: Address comments to: Office of Inspector General, Department of Health and Human Services, Attention: LRR-35-P, room 5246, 330 Independence Ave., 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-35-P. Comments are available for public inspection in

room 5551 330 Independence Avenue, SW., Washington, DC, on Monday through Friday each week from 9 a.m. to 5 p.m., (202) 619-3270.

FOR FURTHER INFORMATION CONTACT:

Sandra Sands, Office of the General Counsel, (202) 619-1306

Joel Schaer, Office of Inspector General, (202) 619-3270

SUPPLEMENTARY INFORMATION:

I. Background

On July 29, 1991, we published in the Federal Register a final rule setting forth various safe harbor provisions to the Medicare and Medicaid anti-kickback statute (56 FR 35952). This regulation was authorized under section 14 of Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987. The final rule specified those payment practices that will not be subject to criminal prosecution under section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a-7b(b)), and that will not provide a basis for exclusion from Medicare or the State health care programs under section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)).

Since publication of the final rule, we have become aware of a limited number of ambiguities that have created uncertainties for health care providers trying to comply with the safe harbor provisions. We have also become aware of certain instances where our intent, either to protect or preclude protection for particular business arrangements, is not fully reflected in the text of the regulation even though it is reflected in the preamble. This proposed rule would serve to modify the text of the July 29, 1991 final rule to conform to the rulemaking's

original intent.

The clarifications contained in this proposed rule do not represent an attempt to reevaluate the wisdom of the original safe-harbor decisions. Instead, the changes set forth in this proposed rule would serve only to protect business practices originally intended to be protected by removing ambiguities in the regulatory language. This clarity should aid the formation of legal business practices without establishing any new significant legal obligations on the parties affected by the regulations.

II. Summary of the Proposed Changes

A. Clarification to the General Comments Section of Preamble

-- Several individuals have commented that the following sentence in the preamble has created confusion:

``Because the statute is broad, the payment practices described in these safe harbor provisions would be prohibited by the statute but for their inclusion here." (56 FR 35958)

This sentence was not meant to imply that, in all instances irrespective of the parties intent, the government could prosecute conduct described in the regulation, but for its inclusion in the regulation. Whether a particular payment practice violates the statute is a question that can only be resolved by an analysis of the elements of the statute as applied to that set of facts. Generally speaking, however, the original final rule did describe payment practices that would be prohibited, where the unlawful intent exists, but for the safe harbor protection that has been granted.

-- In discussing the space and equipment rental and personal services and management contracts, we stated that if a ``sham contract is entered into * * * we will look behind the contract'' to its substance in evaluating whether the arrangement qualifies for safe-harbor protection (56 FR 35972). We received numerous inquiries as to whether we would similarly look behind the form of other arrangements to determine whether the substance of the arrangement fits within a particular safe harbor.

In some cases, such inquiries have led us to clarify particular safe harbors, as is illustrated by the following discussions of the safe harbors for investment interests, space and equipment rental, and personal services and management contracts. However, because of the broad variety of transactions subject to the Medicare and Medicaid anti-kickback statute and the ability of individuals to manipulate the safe harbors in ways not contemplated, we believe that a general rule preventing sham arrangements from receiving safe harbor protection would be appropriate. Thus, we are proposing adding a new Sec. 1001.954 to the regulations. Such an approach has several precedents. The Federal Trade Commission (FTC) with the concurrence of the Department of Justice promulgated Sec. 801.90 of the FTC's rules implementing the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (16 CFR 801.90), which disregards sham transactions entered into for the purpose of avoiding obligations under the Act. In addition, other Federal agencies (such as the Securities Exchange Commission and the Internal Revenue Service) have promulgated regulations and policies that seek to protect

the government from making enforcement decisions based on information that does not accurately reflect the substance of the transaction. (See, for example, 17 CFR 240.12b-20; Estate of Korman versus Comm., TC Memo 1987-120; and Rev. Rul. 81-149, 1981-1 CB 77.) Moreover, the courts have historically disregarded sham arrangements when examining the rights and obligations of the parties in tax cases. (See, for example, Knetsch versus United States, 364 U.S. 361 (1960); and Thompson versus Commissioner of Internal Revenue, 631 F.2d 642 (9th Cir. 1981), cert. denied, 452 U.S. 961 (1981).)

B. Clarifications to Investment Interests Safe Harbor

(Sec. 1001.952(a))

-- Health Care Assets and Revenues

In qualifying for the ``large entity'' or ``small entity'' investment interest safe harbors, the monetary value or amount of certain assets and revenues must be determined. Specifically, the safe harbors include: (1) The $50,000,000 asset threshold in Sec. 1001.952(a)(1); and (2) the gross revenues in the ``60-40 revenue rule'' in Sec. 1001.952(a)(2)(vi). In these cases, only the assets or revenues related to the furnishing of health care items or services will be counted for the purposes of qualifying for these safe harbor requirements. It would be an obvious sham, inconsistent with our original intent, if a joint venture could merge with a non-health care business and have those non-health care assets, and the revenues derived from that non-health care line of business counted for the purposes of qualifying for safe harbor protection. We are thus

proposing to revise these safe harbor provisions to further clarify our original intent that only health care assets and revenues will be counted in determining these values and amounts.

-- Acquisition of Investment Interests

As set forth in Sec. 1001.952(a)(1)(ii), an ``interested'' 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 obtain his or her investment interest through trading on a registered national securities exchange on terms equally available to the public. This does not mean that an interested investor may acquire his or her interest in any way other than the methods available to the general public to acquire investment interests. We believe that the investor must acquire his or her investment interest in the same way as members of the public--directly off of a registered national securities exchange through a broker--and it must be the same type of investment interest that is available to the public. For example, a transaction in which the interested investor receives restricted or ``lettered'' stock from the entity would not be considered a valid acquisition of investment interests under this requirement.

The discussion above does not represent a change in this standard. Rather, it serves only to emphasize that the investment interest ``must be obtained on terms equally available to the public through trading on a registered national securities exchange * * *''

(Sec. 1001.952(a)(1)(ii)) (Emphasis added). Moreover, to obtain an investment interest ``on terms equally available to the public,'' there

cannot be any side agreements that require stock to be purchased or that restrict in any manner the investor's ability to dispose of the stock. Any such agreement would constitute a sham transaction which would disqualify dividend payments to that investor from safe harbor protection.

-- Loans for the Purchase of the Investment Interest

One of the standards in the large and small entity investment interest safe harbors prohibits the entity from loaning an investor funds that are used by the investor to purchase his or her investment interest. (See Secs. 1001.952(a)(1)(iv) and 1001.952(a)(2)(vii).) We are proposing to change this standard to prohibit other investors, individuals or entities as well as the entity from making such loans.

-- Class of Investment Interests

In the 60-40 investor rule in the small entity investment interest safe harbor (Sec. 1001.952(a)(2)(i)), we established two categories of investors: (1) ``untainted'' or ``disinterested'' investors are those who do no business with the entity, but hold the investment interest purely as an investment; and (2) ``tainted'' or ``interested'' investors are those who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. For purposes of determining in which category to place an investor, we require ``each class of investments'' to meet the 60-40 apportionment between the two categories.

We have become aware of the difficulty in applying the 60-40 rule to each class of investors in a joint venture where the general

partners hold a separate class of stock or investment interest from the limited partners. In such a situation, that class of investment interest for the general partners consists of 100 percent ``tainted'' or ``interested'' investors since the general partners are providing services to the entity. Therefore, we believe that the entire joint venture does not qualify for safe harbor protection.

While it is not always true that an active investor holds a different class of investment interest from a passive investor, we have found that it is unnecessarily restrictive to have this 60-40 investor rule only apply to each class of investment interest. Thus, we are proposing to modify this first investment interest standard to allow an alternative to the class-by-class analysis. The new alternative would allow equity investment interests to be combined together or debt investment interests to be combined together (separate from the equity investments) for purposes of apportioning investors into ``untainted'' and ``tainted'' pools and meeting the 60-40 test. Only equivalent classes of equity investment interests could be combined, and only equivalent classes of debt investment interests could be combined. That is, the classes of investment interests combined would have to be similar in all material respects. For example, the classes to be combined would have to have equivalent returns in proportion to amounts invested. In addition, if one class is given preferential treatment (e.g., in the case of disposition), such an interest could not be combined with subservient interests for purposes of compliance with the 60-40 investor rule.

If a limited partnership has a general partner who holds 20 percent of the value of the investment interests, referring physicians hold 20 percent, and all the other investors have no business relationship with the partnerships, then the 60-40 investor rule would be met, as long as all other requirements are satisfied.

The 60-40 investor rule would not be met if any of the other disinterested investors in the above example holds a debt instrument instead of an equity instrument. For example, if a joint venture raises one-third of its capital through a debt instrument held by disinterested investors, with the remaining two thirds of its capital derived from equity instruments held equally by interested (physicians and general partners) and disinterested investors, the safe harbor would not be met. In this example, even though interested investors hold only one-third of all the investment interests, they hold one-half of the equity investment interests, and thus no safe harbor protection would be available.

We note that other standards in this small entity safe harbor preclude protection for abusive schemes to give referring investors preferential treatment in any way by creating different classes of investment. For example, if a joint venture creates two classes of stock, with one of the classes reserved for referring physicians who receive a higher dividend per share than non-referring investors in the other class, such an arrangement would not comply with at least sections 1001.952(a)(2) (ii), (iii) and (viii).

-- Items or Services Furnished by an Investor

As discussed above, when an investor furnishes items or services to the joint venture, such as management services, he or she is a tainted or interested investor for the purposes of complying with the 60-40 investor rule (Sec. 1001.952(a)(2)(vi)). It was not our intent to have any revenues that the joint venture derives from this investor's services to be considered tainted for the purpose of qualifying for the 60-40 revenue rule.

Because of the apparent confusion caused by the language ``items or services furnished" in this safe harbor standard, we are proposing striking it. The focus of the inquiry in this standard is where the business and clients are coming from. In other words, the revenues are tainted, and may not exceed 40 percent of total revenues, if they are derived ``from referrals* * * or business otherwise generated from investors." We note that the language we are proposing to strike--``items or services furnished"--is superfluous because, if the revenue is ``generated" (i.e., induced to come to the joint venture for items or services by an investor), it is tainted. Thus, the language we are proposing to delete appears not to have added anything and merely caused confusion.

The following example demonstrates the confusion and our solution. If a radiologist holds an investment interest in an imaging center and reads all the films at the center, his or her reading of the film does not taint all the revenues from the referrals by non-investors. However, we have received a few questions from people who read the 60-40 revenue rule as making such referrals tainted because the investor

furnished services at the joint venture.

We emphasize that if a radiologist-investor is reading the film and making referrals or otherwise generating business, then the revenues the joint venture derives from that activity would become tainted. For example, revenues would be tainted when a radiologist-investor takes part in a consultation with a non-investor internist, and during that consultation the radiologist recommends a procedure which is performed at the joint venture.

C. Clarifications to Space and Equipment Rental and Personal Services and Management Contracts Safe Harbors (Secs. 1001.952 (b), (c) and (d))

-- In the preamble discussing the safe harbor provisions for space and equipment rental and personal services and management contracts (56 FR 35971-74), we made clear that one of our concerns was that health care providers in a position to make referrals to each other who engaged in these business arrangements could renegotiate their contracts on a regular basis depending on the volume of business generated. It is for this reason that we require the leases or contracts be for a term of not less than one year. (See Secs. 1001.952(b)(4), 1001.952(c)(4), and 1001.952(d)(4).)

It has come to our attention that a small number of health care providers believe they are complying with the literal terms of these safe harbor provisions, but are circumventing our intent not to protect agreements that are renegotiated based on the volume of business generated between the parties. They believe that they are protected if they enter into multiple agreements, each of which is for a period of

one year, but when all the agreements are viewed together renegotiations are taking place more frequently (e.g., every month), with the terms of the additional agreements based in part on the volume of business being generated between the parties under existing agreements. For example, a one year personal services contract between a hospital and a high-volume referring physician is created for the physician to perform certain services. The next month a new one year contract is created for a slightly different service, with the amount of payment influenced by the previous months referrals.

This scenario does not comply with the requirement in each of these safe harbor provisions that the compensation not take ``into account the volume or value of any referrals or business otherwise generated between the parties * * * ." (Secs. 1001.952(b)(5), 1001.952(c)(5), and 1001.952(d)(5)). However, because the principal problem in this situation is that the parties are creating multiple overlapping agreements, we are proposing to revise these three safe harbor provisions to expressly preclude such schemes.

In addition, it appears that some health care providers are attempting to pay for referrals by renting more space than they actually need from referral sources. Although such an arrangement would not fit within a safe harbor because the aggregate rental charge would be determined in a manner that would account for the volume or value of referrals or business otherwise generated between the parties, we are proposing to revise the safe harbor provisions in Secs. 1001.952 (b)(5), (c)(5) and (d)(5) to expressly preclude this practice.

D. Clarifications to Referral Services Safe-Harbor (Sec. 1001.952(f))

-- One of the standards in the referral services safe harbor provision requires that any fee the referral service charges the participant be ``based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by the participants for the referral service * * * ." (Emphasis added) (Sec. 1001.952(f)(2)). This language precludes protection where a referral service, such as one operated by a hospital, lowers its referral service fee to one of its staff physicians who participates in the service because that physician is a high-volume referrer.

This language creates an ambiguity where the referral service tries to adjust its fee based on the volume of referrals it makes to the participant. Thus, we propose clarifying the second prong to preclude safe harbor protection for payments that are based on the volume or value of referrals to or business otherwise generated by either party for the other party.

E. Clarifications To Discount Safe Harbor (Sec. 1001.952(h))

-- Many people requested clarification of the safe harbor for discounts. Because there has been some uncertainty over what obligations individuals or entities have to meet in order to receive protection under this safe harbor, we propose dividing the parties into three groups: buyers, sellers, and offerors of discounts. In describing each party's obligations, we would revise paragraphs (h)(1) and (h)(2), and add a new paragraph (h)(3).

In addition, through a proposed new paragraph (h)(4), we would clarify that, for purposes of this regulation, a ``rebate'' is any discount which is not given at the time of sale. Consequently, a rebate transaction may be covered within the safe harbor if it involves a buyer under Sec. 1001.952 (h)(1)(i) or (h)(1)(ii), but it is not covered if it involves a buyer under Sec. 1001.952(h)(1)(iii) because, under that provision, all discounts must be given at the time of sale. We also wish to clarify what has to happen for sellers to receive safe harbor protection. In the safe harbor regulation itself, we state that discounts will be safe harbored if both the seller ``and'' the buyer comply with the applicable standards as described in the rule. Yet in the preamble we state that sellers should not be held liable for the omissions of buyers. If a seller has done everything that it reasonably could under the circumstances to ensure that the buyer understands its obligations to accurately report the discount, the seller is safe harbored irrespective of the omissions of the buyer. To receive such protection, however, the seller must report the discount to the buyer and inform the buyer of its obligation to report the discount. To emphasize that the seller's obligations require more than superficial compliance with the safe harbor, we propose to add to that the seller must inform the buyer ``in an effective manner'' of its obligations to report the discount. We also propose adding a requirement that the seller ``refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.'' Thus, if the seller, in good faith, meets its obligations under the

safe harbor and the buyer does not meet its obligations due to no fault of the seller, the seller would receive safe harbor protection.

However, when the seller submits a claim or request for payment on behalf of the buyer, the seller must fully and accurately report the discount to Medicare or the State health care program. Likewise, when an offeror of a discount meets its obligations under Sec. 1001.952(h)(3), and the buyer or seller does not meet its obligations due to no fault of the offeror, the offeror would receive safe harbor protection.

In addition, we are proposing to clarify whether any reduction in price offered to a beneficiary could be safe harbored under this regulation. Congress protected ``a discount or other reduction in price obtained by a provider of services or other entity'' (emphasis added) and made no provision for such discounts obtained by a beneficiary. In Sec. 1001.952(h)(3)(iv) of the regulation, we removed from safe harbor protection a ``reduction in price offered to a beneficiary * * * .'' In that section, all we intended to remove from this safe harbor was ``routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary.'' Thus, to the extent that a discount is offered to a beneficiary and all other applicable standards in the safe harbor are met, such a discount would receive safe harbor protection.

Many people have expressed confusion regarding the relationship between the safe harbor for discounts and the statutory exception for discounts. (See section 1128B(b)(3)(A) of the Act.) Specifically, we are asked if there are any practices involving discounts which were

protected by Congress under the statutory exception which do not fit within the safe harbor for discounts. Our intention is that all the discounts or reductions in price that Congress intended to protect under the statutory exception for discounts are protected under the safe harbor for discounts. Moreover, as is illustrated by the discussion above regarding discounts to beneficiaries, we are proposing to expand the safe harbor for discounts to include additional practices that we do not consider abusive.

In the preamble to the final regulation, we stated that when reporting a discount, one only need report the actual purchase price and note that it is a ``net discount'' (56 FR 35981). However, for purposes of submitting a claim or request for payment, what is necessary is that the value of the discount is accurately reflected in the actual purchase price. It is not necessary to distinguish whether this price is the result of a discount, or to state ``net discount.'' Consequently, buyers who were uncertain about how and where to report on a particular form the fact that the price was due to a discount need not be concerned with reporting that fact, as long as the actual purchase price accurately reflects the discount.

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

F. Technical Correction

-- A typographical error at 56 FR 35978 gave a citation to a HCFA rule on payment for intraocular lenses as ``55 FR 436.'' We would

correct this citation to the HCFA rule to read as ``55 FR 4536."

-- We are proposing the deletion of Sec. 1001.953 which calls for the completion of an OIG report on compliance with the investment interest safe harbor at Sec. 1001.952(a)(2)(i) and 1001.952(a)(2)(vi) within a specified period of time after publication of the original safe harbor provisions. While the OIG is continuing its work on evaluating this safe harbor provision, we believe completion of this report to be an internal administrative process that need not be set forth in the regulations.

III. Regulatory Impact Statement

As we indicated in the original safe harbor final rule published on July 29, 1991, consistent with the intent of the statute, the original safe harbor rulemaking and these proposed clarifications are designed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy. In doing so, the regulations impose no requirements on any party. Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement action under the anti-kickback statute. We believe that the economic impact of these provisions would be minimal.

In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (5 U.S.C. 601-612). We have determined, and the Secretary certifies, that this proposed regulation would not have a significant economic impact on a

substantial number of small business entities, and we have, therefore,

not prepared a regulatory flexibility analysis.

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 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 would continue to read as

follow:

Authority: 42 U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(j),

1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and

1395hh, and section 14 of Public Law 100-93.

2. Section 1001.952 would be amended by:

a. republishing the introductory text for this section;

b. republishing the introductory text for paragraph (a)(1), and by

revising paragraphs (a)(1)(iv), (a)(2)(i), (a)(2)(vi) and (a)(2)(vii);

c. revising paragraphs (b)(2) and (b)(5);

d. adding a new paragraph (b)(6);

c. revising paragraphs (c)(2) and (c)(5);

f. adding a new paragraph (c)(6);

g. revising paragraphs (d)(2), (d)(5) and (d)(6);

h. adding a new paragraph (d)(7);

i. revising paragraphs (f)(2); and

j. revising paragraph (h), to read as follows--

Sec. 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. * * *

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

* * * * *

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

* * * * *

(2) * * *

(i) No more than 40 percent of the value of the investment interests of each class of investment interests may be held in the

previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. (For purposes of Sec. 1001.952(a)(2)(i), equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.)

* * * * *

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

(vii) The entity or any investor 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.

* * * * *

(b) Space rental. * * *

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

* * * * *

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

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

* * * * *

(c) Equipment rental.

* * * * *

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

* * * * *

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

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

* * * * *

(d) Personal services and management contracts.

* * * * *

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

* * * * *

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

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

(7) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

* * * * *

(f) Referral services. * * *

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

* * * * *

(h) Discounts. As used in section 1128B of the Act,

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

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

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

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

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

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

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

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

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

(A) the discount must be made at the time of the sale of the good or service (rebates are therefore not allowable);

(B) where an item or service is separately claimed for payment with the Medicare program or a State health care program, the buyer (if submitting the claim) must fully and accurately report the discount on that item or service; and

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

(2) The seller is an individual or entity that furnishes an item or

service for which payment may be made, in whole or in part, under Medicare or a State health care program to the buyer and who permits a discount to be taken off the buyer's purchase price. The seller must comply with all of the applicable standards within the following three categories--

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

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

(A) where a discount is required to be reported to Medicare or a State health care program under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer, inform the buyer in an effective manner of its obligations to report such discount, and refrain from doing anything which would impede the buyer from meeting its obligations under this paragraph; or

(B) where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice, coupon or statement submitted to the buyer, inform the buyer in an effective manner of its obligations to report such discount under paragraph (h)(1) of this section and, when

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

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

(A) where the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed, the seller must fully and accurately report the discount on the claim or request for payment to Medicare or a State health care program and the seller must provide, upon request by the Secretary or a State agency, information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section; or

(B) where the buyer submits a claim, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in an effective manner of its obligations to report such discount; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.

(3) The offeror of a discount is an individual or entity who is not a seller under paragraph (h)(2) of this section, but promotes the purchase of an item or service by a buyer under paragraph (h)(1) of this section at a reduced price for which payment may be made, in whole

or in part, under Medicare or a State health care program. The offeror must comply with all of the applicable standards within the following three categories--

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

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

(A) the offeror must inform the buyer in an effective manner of its obligation to report such a discount; and

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

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

(A) the offeror must inform the individual or entity submitting the claim or request for payment in an effective manner of their obligations to report such a discount; and

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

(4) For purposes of this paragraph (a), a rebate is any discount which is not given at the time of sale.

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

(i) Cash payment;

(ii) Furnishing one good or service without charge or at a reduced charge to include the purchase of a different good or service;

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

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

(v) Warranties;

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

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

* * * * *

Sec. 1001.953 [Removed]

3. Section 1001.953 would be removed.

4. Section 1001.954 would be added to read as follows:

Sec. 1001.954 Sham Transactions or Devices.

Any transaction or other device entered into or employed for the purpose of appearing to fit within a safe harbor when the substance of the transaction or device is not accurately reflected by the form will be disregarded, and whether the arrangement receives the protection of a safe harbor will be determined by the substance of the transaction or device.

Dated: March 14, 1994.

June Gibbs Brown,

Inspector General.

Approved: April 22, 1994.

Donna E. Shalala,

Secretary, Department of Health and Human Services.

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