

Seeking Shelter from the Storm: The New Safe Harbor Regulations Under the Anti-Kickback Statute

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The Anti-Kickback statute prohibits individuals and businesses from soliciting, receiving, offering or paying anything of value to induce the referral of patients, or the recommendation, purchase or leasing of any item or service reimbursable under Medicare, Medicaid or other federal governmental health care programs. The statute has been broadly interpreted by the judiciary to implicate any transaction in which a party is motivated by, or obtains payment for the inducement of referrals. Violation of the statute is a felony and is punishable by imprisonment for up to five years, fines of up to \$25,000.00, and exclusion from federal health care programs.

In 1987, Congress amended the Anti-Kickback statute to require the issuance of "safe harbor" regulations to identify business transactions which, although potentially resulting in technical violation of the statute, would not be subjected to prosecution. To date, the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("DHHS") has finalized twenty-three safe harbors under the Anti-Kickback statute and practitioners have expended considerable time and resources in efforts to structure transactions to comply with available safe harbors. This article focuses on the ten safe harbors issued on November 19, 1999.

The new safe harbors issued by the OIG include several safe harbors based on proposed regulations issued in 1993. These include safe harbors for investments in underserved areas, investments in ambulatory surgery centers, investments in group practices, practitioner recruitment, obstetrical malpractice insurance subsidies, referral agreements for specialty services and cooperative hospital service organizations. The November 19, 1999 regulations include an additional safe harbor for the sale of physician practices, and two additional safe harbors for certain shared risk arrangements. The regulations also include clarifications to the current safe harbors for space rentals, equipment rentals, personal services and management agreements, referral services, discounts and large and small entity investment interests.

CLARIFICATIONS TO EXISTING SAFE

HARBORS

Space and Equipment Rentals / Personal Service and Management Agreements

Aggregate Compensation / Fixed Use Schedules

Several of the clarifications to current safe harbors and a number of the OIG preamble comments regarding the existing safe harbors are especially significant. With regard to the safe harbor for personal service and management agreements, the OIG reiterated that part-time or "as needed" service arrangements in which the compensation formula is fixed based on an hourly rate will not satisfy the personal service and management safe harbor which requires that the aggregate compensation be fixed. Similarly, the OIG acknowledged practical difficulties in specifying detailed use schedules for part-time space or equipment rental arrangements. The OIG declined to eliminate these requirements from the safe harbors but reiterated that compliance with a safe harbor is not mandatory.

Commercially Reasonable Business Purpose

The regulations amend the former requirements of the space and equipment rental and personal service and management agreement safe harbor by replacing the "legitimate business purpose" standard with a requirement that such transactions be based upon a "commercially reasonable business purpose"¹. The OIG comments that the change is designed to clarify that an arrangement will only be protected if the services, equipment or space are needed to further the business purposes of the lessee and are used in furtherance of these purposes. The OIG indicates that the amended language is intended to prevent parties from leasing unnecessary space or equipment or from requesting unnecessary services in efforts to induce referrals.

Minimum Term Requirements / Termination Provisions

In addition, the new regulations adopt the

previously proposed requirement that an equipment or space lease or service agreement cover all equipment, space or services. The OIG states again that this requirement is calculated to prevent providers from entering into multiple overlapping agreements for the same space, equipment or services in order to circumvent the requirement for a minimum one (1) year term.

Although the regulations clearly indicate the OIG's concerns regarding short term agreements, the OIG again comments that agreements may include provisions allowing termination "for cause". The preamble comments state, however, that a contract including a "for cause" termination provision will only satisfy a safe harbor if it specified the conditions giving rise to termination for cause and prohibits renegotiation of the agreement *or further financial arrangements between the parties* for the duration of the one year term. The OIG refuses, however, to offer assurances for agreements allowing termination "without cause" and states that such an arrangement could allow parties to disguise payments for referrals by terminating an agreement without cause after payment, but prior to the performance of services. The OIG indicates that a one year prohibition on renegotiation would be ineffective to prevent such abuses.

Discounts

The new regulations regarding the safe harbor for discounts include separate requirements for buyers, sellers and offerors and provide protection to certain rebates². The safe harbors also distinguish among different types of buyers such that standards for health maintenance organizations are different from those for entities that bill based on cost reports or through submission of claims for charges. Most significantly, charge based buyers may now accept both up-front discounts and rebates under the safe harbor provided the buyer maintains appropriate documentation of the discount and agrees to furnish such information upon request of the Secretary of HHS. The terms for any such rebates must be fixed at the time of sale and disclosed to the buyer. The OIG had previously proposed that charge based providers be required to disclose discounts on claims submitted to federal health care programs, but this requirement has been eliminated from the final regulations as the most common claim submission forms do not include fields for disclosure of discounts.

The regulations require sellers and offerors to provide cost-report and charge based buyers with notice that is "reasonably calculated" to alert buyers to their reporting obligations. The preamble comments clarify that a seller or offeror may be protected under the safe harbor regardless of whether the buyer fulfills its reporting obligations, so long as the seller or offeror satisfies any applicable standards for disclosure and notice to the buyer.

Large Entity Investment Interests

The new regulations also make minor changes to the safe harbor for large entity investments interests³. The regulations clarify that only assets from health care lines of business are considered for purposes of the fifty million dollar (\$50,000,000) minimum asset threshold. The regulations further specify that interested investors (i.e. investors in a position to make or influence referrals to the entity) must obtain investment interests in large entities "on terms (including any direct or indirect restrictions on transferability) and at a price equally available to the public." The OIG notes that the prior requirement that interested investors obtain interests "in the same way" as the public was too restrictive. The preamble comments clarify, however, that the OIG remains concerned about restrictions on the transfer of stock intended to "lock" interested investors into specific investments, increasing the incentive for continued referrals⁴. The preamble comments also indicate the OIG's continuing concern that interested investors not be permitted to acquire interests at "insider" prices or on terms more favorable than those available to other investors.

The regulations also adopt the previously proposed requirement prohibiting an entity and its investors from providing loans or loan guarantees to interested investors for the purchase of ownership interests.

Small Entity Investment Interests

The safe harbor for small entity investment interests remains of limited utility as it remains difficult to satisfy each requirement. The new regulations incorporate previously proposed clarifications which allow equivalent classes of equity investments to be combined in order to determine whether an arrangement satisfies the requirement that no more than forty percent of the value of each class of investment be held by interested investors⁵. The regulations also permit equivalent classes of debt investments to be combined for the purposes of satisfying this forty percent standard. The preamble comments clarify that interest need not be identical in all respects in order to be aggregated for the purposes of satisfying the sixty-fourty investor test.

In order to satisfy the small entity investment safe harbor, no more than forty percent (40%) of the entity's gross revenue related to the furnishing of health care items and services may come from referrals generated by investors. The OIG clarifies that, like physicians, hospitals, nursing homes, skilled nursing facility, and other institutions may be in a position to influence referrals and may be considered interested investors for the purposes of the percentage tests for revenues and investors.

The new regulations also incorporate the previously proposed prohibition against an entity or investors (or others acting on their behalf) loaning or providing loan guarantees for an interested investor to obtain an ownership interest in the entity. The preamble

comments clarify that the prohibition does not prevent banks or other unrelated third parties that are not equity investors in the entity from loaning funds to an investor.

Other Safe Harbors

The OIG finalized the 1994 proposed clarification to the safe harbor for referral services without modification. The regulations now specifically require that payments to a referral service not be based on the volume or value of referrals or other business generated between the parties⁶.

The OIG had previously proposed a new provision clarifying that the substance of an arrangement would determine whether safe harbor protection would be merited, regardless of the form of the transaction. The so-called "sham transaction" proposal was widely criticized as being too vague, and the OIG has withdrawn this proposed amendment. The comments clarify, however, that the OIG will evaluate both the form and substance of a transaction in determining compliance with a safe harbor.

THE NEW SAFE HARBORS

Several of the new safe harbors are limited to arrangements in Medically Underserved Areas ("MUAs") and Health Professional Shortage Areas ("HPSAs"). The OIG had previously proposed a safe harbor for investments in rural areas. This safe harbor has been revised in final form to instead protect investment in MUAs, which may include both rural areas and urban areas⁷. Unlike the small entity investment safe harbor, the safe harbor for undeserved areas does not include any limitation upon the percentage of gross revenues which may be generated from interested investors. The safe harbor for investments in undeserved areas does, however, require that no more than fifty percent of investment interests be held by interested investors. Furthermore, the safe harbor now requires that at least seventy-five percent of the entities revenues be derived from residents of a MUA or individuals within a Medically Underserved Population ("MUP"). The proposed rules had established a requirement that eighty-five percent of revenues be generated from residents of a rural area. The original proposed safe harbor would have permitted all interests to be owned by interested investors.

The new regulations rely upon the regulations set forth at 42 C.F.R. Part 51c to define the terms "Medically Underserved Area" and "Medically Underserved Population". The agency responsible for promulgation of these regulations has issued two notices of proposed rule-making to revise these regulations, but proposed revisions have not been released. Due in part to these potential revisions, the safe harbor includes a grace period of up to three years for entities initially located in an undeserved

area which may eventually lose their designation as a medically undeserved area⁸.

Ambulatory Surgical Centers

Perhaps the most significant changes to the previously proposed safe harbors in the context of ambulatory surgical centers ("ASCs"). The safe harbor proposed in 1993 offered protection only to ASCs owned by surgeons. The new safe harbor offers protection not only to surgeon-owned ASCs but also to single specialty ASCs, multi-specialty ASCs, and hospital/physician ASCs⁹. In order to satisfy a safe harbor, each type of ASC is required to meet the following common criteria:

1. The ASC must be certified pursuant to 42 C.F.R. Section 416;
2. The ASC must maintain operating and recovery room space exclusively for the ASC;
3. Patients referred to the ASC by an investor must be informed of the investor's interest;
4. The terms offered for investment interests may not be related to the volume or value of previous or expected referrals for other business generated between the investor and the ASC (subject to the specific requirements listed below);
5. Investment returns must be proportional to an interested investor's capital investment and may not be based upon the volume or value of referrals;
6. Neither the ASC nor other investors may offer loans or loan guarantees to enable another to invest in the ASC;
7. All ancillary services for federal health care program beneficiaries must be directly related to the primary procedures performed at the ASC and may not be separately billed;
8. The ASC and its investors must treat federal health care program beneficiaries in a non-discriminatory manner.

Surgeon Owned ASCs

In addition to the general criteria listed above, surgeon owned ASCs must be owned exclusively by:

1. General surgeons or surgeons engaged in the same surgical specialty who are in a position to refer patients to the ASC;
2. Surgical group practices; or
3. Unrelated investors who are not employed by the ASC or its investors, are not in a position to provide items or services to the ASC the ASC or its investors.

The regulations require that at least one-third (1/3) of each surgeon-investor's medical practice income for all sources be derived from the surgeon's performance of certain defined ASC procedures. This requirement does not specify where these procedures must be performed and would appear to permit a surgeon to invest in multiple ASCs and perform procedures at each.

Single Specialty ASCs

The safe harbor for single specialty ASCs is similar to that for surgeon owned ASCs but permits investment by physicians who may not qualify as surgeons. Under this safe harbor all investors must either be physicians engaged in the same medical practice specialty who are in a position to refer patients to the ASC and perform procedures on such patients, group practices composed exclusively of such physicians, or investors not in a position to influence referrals. As with the safe harbor for surgeon owned ASCs, at least one-third of each physician investor's medical practice income must be derived from the physician's performance of identified ASC procedures.

Multi-Specialty ASCs

In order to satisfy the safe harbor for multi-specialty ASCs, all investors must either be physicians who are in a position to refer patients directly to the ASC and perform procedures on such referred patients, group practices composed exclusively of such physicians, or non-referring parties. Under this safe harbor not all physicians need practice in the same specialty. However, under this safe harbor at least one-third (1/3) of the procedures performed by each physician investor must be performed at the ASC in which the physician maintains an ownership interest.

Hospital/Physician ASCs

In addition to the common requirements set forth above, the safe harbor for hospital/physician ASCs require investment by at least one hospital. All other investors must either be physicians or group practices satisfying the requirements for a surgeon owned ASC, single specialty ASC, or multi-specialty ASC, or non-referral source investors. Moreover, the ASC may not use hospital space, services, or equipment unless such arrangements are structured to comply with applicable safe harbors. The hospital may not include on its cost reports, or any claims of payment from the federal health care programs, any costs associated with the ASC, and the hospital may not be in a position to make or influence referrals directly or indirectly to any investor in the ASC.

In determining whether an investor is a potential source for referrals, the OIG has indicated that it will accept a written stipulation by the individual that he or she will not make referrals to, furnish items or services to or otherwise generate business for the entity or any interested investors for the life of the investment. With respect to hospital ownership for ASCs, the OIG explained that safe harbor protection was extended to hospitals to avoid placing these organizations "at a competitive disadvantage" by forcing them to compete with ASCs owned by physicians who control referrals. The OIG clarified that in no event may the operating rooms or recovery areas for an ASC be shared with the hospital for treatment of the hospital's inpatients or outpatients.

Investment Interest in Group Practices

The OIG has contended that the Anti-Kickback statute potentially implicates payments from a group practice to physician-investors in the practice. The new safe harbor for investments in group practices offers protection for returns on investments in the group practice but does not protect returns on investments in separate subdivision of the practice¹⁰. In order to meet the safe harbor requirements, equity interests in the practice must be held by licensed health care professionals who provide professional services through the practice or group.

In the case of a group practice, the group practice must satisfy the definition set forth in the federal physician self-referral statute ("Stark II") at 42 U.S.C. Section 1395nn(h)(4). The group practice must constitute a unified business with central decision making, pooling of expenses and revenues, and a compensation/profit distribution system that is not based on satellite offices operating as separate profit centers. Moreover, revenues from ancillary services must be derived from "in office ancillary services" as described in Stark II and applicable regulations¹¹. The final safe harbor eliminates the prior requirements that investors be involved in the day-to-day management of the practice. Further, in a change from the original proposed safe harbor, the final safe harbor permits the group practice and members of the group practice to provide loans to enable other investors to purchase interests in the group. The final safe harbor also eliminates the proposed requirement prohibiting a group practice from offering an interest to an investor based on terms related to the previous or expected volume of value of referrals, items of services furnished or other business between the parties. Such terms may be limited, however, by Stark II¹².

Physician Recruitment

The new regulations amend and finalize the proposed safe harbor for physician recruitment. The final physician

recruitment safe harbor protects remuneration to induce a practitioner who has been practicing within his or her current specialty for less than one year to locate, or to induce any other practitioner to relocate, his or her primary place of practice into a HPSA for his or her "specialty area"¹³. In order to satisfy the safe harbor, the following criteria must be met:

1. The parties must enter into a written agreement specifying the benefits to be provided, the terms for such benefits, and the obligations of each party;
2. A practitioner leaving an established practice must generate at least seventy-five percent of the revenues of the new practice from new patients;
3. Recruitment benefits may be provided for no more than three years and the terms of the agreement may not be renegotiated during that period in any substantial aspect;
4. The practitioner may not be required to refer patients to, or be in a position to make or influence referrals or otherwise generate business as a condition to receipt of the benefits;
5. The practitioner may be required to maintain medical staff privileges with the entity, but may not be restricted from establishing staff privileges at or generating business for any other entity;
6. The value of the benefits may not vary based upon the volume or value of referrals;
7. The practitioner must agree to treat federal health care program beneficiaries in a non-discriminatory manner;
8. At least seventy-five percent of the revenues of the new practice must be generated from residents of a HPSA or MUA or who are part of a medically underserved population;
9. The recruitment payments may not directly or indirectly benefit any person other than the recruited practitioner receiving the recruitment payment.

The final safe harbor is drafted to permit recruitment incentives to practitioners relocating to an underserved area which may include urban areas otherwise excluded under the proposed safe harbor for rural areas. The final safe harbor requires that the practitioner relocate to a HPSA for his or her "specialty area." HPSA designations generally apply only to primary care physicians, dental care, and mental health care professionals. Primary care specialties include general practice, family medicine, pediatrics, general internal medicine, and obstetrics and gynecology¹⁴. The final safe harbor eliminates the previously proposed requirement that a practitioner be relocating at least one hundred miles.

The preamble comments clarify that a recruiting entity may require a practitioner to maintain staff privileges and may impose conditions relating to the quality of care, such

as requiring a physician to perform a minimum number of procedures prior to performing the procedure at the entity. The preamble indicates, however, that the recruiting entity may not condition benefits upon aggregate admissions. The OIG comments that income guarantees will not be considered to be based upon the volume or value of referrals if the maximum amount of the income guarantee and the formula for determining payment are set in advance. The OIG declined to permit, however, joint recruitment arrangements between hospitals and group practices. The OIG indicates that such joint recruitment arrangements, while not appropriate for safe harbor protection, will not necessarily violate the Anti-Kickback statute but must be evaluated on a case by case basis.

Obstetrical Malpractice Insurance Subsidies

The final safe harbor for obstetrical malpractice insurance subsidies permits payments by hospitals and other entities to malpractice insurance providers (including reciprocals and other self-funded entities) in order to defray some or all of the costs of malpractice insurance premiums for a practitioner providing obstetrical services in a primary care HPSA. This safe harbor is based upon the safe harbor proposed for such subsidies in 1993.

Cooperative Hospital Service Organizations

The final safe harbors include regulations protecting certain cooperative hospital service organizations organized by tax exempt hospitals to provide purchasing, billing and clinical services¹⁵. The requirements of the final safe harbor are substantially similar to those of the prior proposed safe harbor.

Referral Agreements for Specialty Services

The new regulations include a safe harbor permitting referral agreements whereby one individual or entity agrees to refer a patient to another entity for specialty services in return for an agreement to refer the patient back at a certain time or under certain circumstances¹⁶. Such arrangements typically involve a referral by a primary care physician to a specialist with an agreement for the specialist to refer the patient back to the primary care physician upon recovery. In order to satisfy this safe harbor, the time or circumstances for referring the patient to the originating individual or entity must be clinically appropriate, and parties may not receive payment from each other nor split a global fee from any federal health care program. In addition, the services for which the referral is made must not be within the expertise of the referring party and must be within the special expertise of the party receiving the referral. The parties are not permitted to exchange anything of value other than the

remuneration received from third party payors unless both parties belong to the same group practice.

Sale of Practice in a HPSA

The 1993 proposed safe harbors included a proposed safe harbor for payments between practitioners for the purchase of a practice. This proposed safe harbor has been finalized and an amendment has been included to provide protection for payment by a hospital or other entities to purchase a physician's practice. In order for a payment by a hospital or other entity to satisfy this safe harbor, the following criteria must be satisfied:

1. The practice must be located in a HPSA for the practitioner's specialty area;
2. The period from the date of the first agreement pertaining to the sale to the completion of the resale may not be more than three years;
3. The practitioner selling the practice may not be in a position to make or influence referrals after completion of the sale;
4. From the time of the purchase of the practice, the purchasing entity must diligently pursue "commercially reasonable" recruitment activities for the recruitment of a new practitioner which satisfy the practitioner recruitment safe harbor, and are reasonably expected to result in recruitment within one year.

The sale of a practice between practitioners will satisfy the safe harbor so long as the period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than one year, and the selling practitioner will not be in a position to make referrals or otherwise generate business for the purchasing practitioner after one year from the date of the first agreement pertaining to the sale.

Shared Risk Arrangements

The OIG also issued two new safe harbors for shared risks arrangements, including a safe harbor for price reductions to "Eligible Managed Care Organizations" including health maintenance organizations and competitive medical plans. The OIG has justified the safe harbor for "Eligible Managed Care Organizations" based on the reduced risk of fraud and abuse due to the capitated payment structure for such organizations. An additional safe harbor was issued for price reductions offered to "Qualified Managed Care Plans" in which fraud and abuse risks are minimized because the provider is placed at substantial financial risks for the cost or utilization of health care services.

Conclusion

The recent safe harbors include a number of provisions from the safe harbors proposed in 1993. Although the utility of several of these new safe harbors will be limited, they, along with regulatory comments, nonetheless provide substantial guidance to practitioners regarding the "current wisdom" within the OIG on many common health care transactions. This guidance, along with guidance from advisory opinions and other sources, should prove useful to health care organizations attempting to comply with, and reduce risks under, the Anti-Kickback statute.

¹42 C.F.R. Section 1001.952(b)-(d).

²42 C.F.R. Section 1001.952(h).

³42 C.F.R. Section 1001.952(a)(1).

⁴64 Fed. Reg. 63522.

⁵42 C.F.R. Section 1001.952(a)(2).

⁶42 C.F.R. Section 1001.952(f).

⁷42 C.F.R. Section 1001.952(a)(3).

⁸42 C.F.R. Section 1001.952(a)(3)(ii).

⁹42 C.F.R. Section 1001.952(r).

¹⁰42 C.F.R. Section 1001.952(p).

¹¹The safe harbor regulations do not clearly indicate whether practitioners are to rely upon the final Stark I regulations as currently in effect, or the proposed Stark II regulations. HCFA has indicated that the Stark II proposed regulations reflect current interpretation of the Stark II law, but the regulations remain in proposed form and may be amended when finalized. It is anticipated that the Stark II regulations will be finalized in June, 2000.

¹²Stark II proposed regulations permit compensation to physician investors based on the volume or value of referrals in certain circumstances such as profit sharing arrangements and productivity bonuses satisfying certain criteria.

¹³42 C.F.R. Section 1001.952(n).

¹⁴42 C.F.R. Section 5.4.

¹⁵42 C.F.R. Section 1001.952(q).

¹⁶42 C.F.R. Section 1001.952(s).

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