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FUNDAMENTALS OF THE ANTI-KICKBACK LAW

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I. General Rule

Under the federal health care program Anti-Kickback law, it is illegal for any individual or entity "knowingly and willfully" to offer or pay "remuneration" --- directly or indirectly, overtly or covertly, in cash or in kind --- to "induce" a person to:

- "refer" an individual to a person for the furnishing (or arranging for the furnishing) of any item or service "for which payment may be made" under a federal health care program; or
- "purchase" or "order" such an item or service; or
- "arrange for or recommend" purchasing or ordering such an item or service.1

It also is illegal under the Anti-Kickback law to "solicit" or "receive" remuneration for such purposes.[2]

The policy objectives behind the Anti-Kickback law are: (1) preventing the corruption of medical judgment, (2) preventing the overutilization of items or services covered by a federal health program (and the concomitant increase in program costs), and (3) preventing unfair competition.[3]

Where the statute has been violated, the government may proceed criminally or administratively. If the government proceeds criminally, a violation of the statute is a felony punishable by up to five years imprisonment, a fine of up to $25,000, and mandatory exclusion form participation in all federal health care programs. If the government proceeds civilly, it may impose a civil monetary penalty of $50,000 per violation and an assessment of not more than three times the total amount of "remuneration" involved, and it may exclude the offering or receiving party from participation in all federal health care programs.[4]

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1 42 U.S.C. § 1320a-7b(b)(2). In contrast to the Stark law, the Anti-Kickback law covers federally-funded health care programs other than Medicare and Medicaid.

2 Id. § 1320a-7b(b)(1).

3 See, eg., OIG Advisory Opinion 98-3 (April 6, 1998).

4 42 U.S.C. §§ 1320a-7b(b) and 1320a-7a(a)(7).

II. Elements

A. Knowingly and Willfully

Although the Anti-Kickback law has a scienter, or "state of mind," requirement, whereby the government must prove that violations were "knowing and willful." Federal courts are divided concerning precisely what constitutes such conduct. For example:

- The Ninth Circuit has held that conduct is knowing and willful only if the defendant knows of the statute, knows that it "prohibits offering or paying remuneration to induce referrals," and engages "in prohibited conduct with the specific intent to disobey the law."[5]

- The Eighth Circuit has held that the government need only prove that the defendant knew that his conduct was "wrongful."[6]

- The Eleventh Circuit has forged a middle ground, holding that although the government does not have to prove that the defendant knew that his conduct violated the Anti-Kickback law itself, the government does have to prove that the defendant acted with an intent to "disobey or disregard the law."[7]

B. Remuneration

Although the statue does not define "remuneration" -- other than to say that it may be "in cash or in kind" -- the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") has interpreted "remuneration" broadly to "cover the transferring of anything of value in any form or manner whatsoever."[8]

C. Inducement

The term "inducement" also has been interpreted broadly to cover virtually any act that is intended "to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business."[9] The fact that there are legitimate reasons for the remuneration at issue is irrelevant. The government takes the position that as long as "one of the purposes" of the payment is to induce the referral of program-related business, the Anti-Kickback law is implicated.[10]

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5 Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995)

6 United States v. Jain, 93 F.3d 436, 440-41 (8th Cir. 1996), cert. denied, 520 U.S. 1273 (1997).

7 United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998).

8 56 Fed. Reg. 35952, 35958 (1991).

9 Hanlester Network v. Shalala. 51 F.3d at 1398.

10 OIG Advisory Opinion No. 99-14 (December 28, 1999); United States v. Kats, 971 F.2d 105, 108 (9th Cir. 1989).

For example, in United States v. Greber, a company that provided cardiac diagnostic services billed Medicare for these services and thereafter forwarded a portion of this payment to the referring physician for "consultation" and "interpretation" services provided by the physician.[11] The Third Circuit held that, even if true this allegation was irrelevant: "[I]f the payments were intended to induce the physician to use [the company's] services, the statute was violated, even if the payments wee also intended to compensate for professional services."[12] This rule applies even if the market value of the services that were performed was equal to or greater than the amount of the "kickback" at issue.[13]

III. Exceptions and Safe Harbors

Recognizing that the Anti-Kickback law "is so broadly written as to encompass many harmless or efficient arrangements,"[14] Congress and HHS have created a series of statutory "exceptions"[15] and regulatory "safe harbors."[16] An arrangement that fits into one or more of these exceptions or safe harbors is immune from prosecution, even if the arrangement would otherwise violate the statute. Importantly, such protection is afforded only to those arrangements that "precisely meet" all of the often numerous conditions set forth in an exception or safe harbor."[17] "Material" or "substantial" compliance with an exception or safe harbor is insufficient.[18]

A. The Statutory Exceptions

The Anti-Kickback law contains five exceptions enacted by Congress. The OIG has taken the position that it has the legal authority to define and limit these statutory exceptions, but this proposition was rejected by the only court which has addressed the issue so far.[19] The statutory exceptions include:

1. Discounts or other reductions in price;

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11 760 F.2d 68, 69-70 (3d Cir.) cert. denied, 474 U.S. 988 (1985).

12 Id. at 72.

13 United States v. Bay State Ambulance & Hosp. Rental Srv., 874 F.2d 20, 30-31 (1st Cir. 1989). Nor does the fact that a defendant's conduct does not result in direct financial loss to the government alter the analysis. Id. at 32 n.21 ("Although the reason for enacting the statute was to prevent drains on the public fisc, the statute does not require that there be a drain on the public fisc in order for payments to be illegal.")

14 53 Fed. Reg. 51856 (1988).

15 42 U.S.C. § 1320a-7b(b)(3).

16 42 C.F.R. § 1001.952. The statute specifically authorizes HHS to develop such safe harbors. 42 U.S.C. § 1320a-7(b)(3)(E).

17 OIG Advisory Opinion 98-5 (April 24, 1998).

18 Id.

19 United States v. Shaw, 106 F. Supp. 2d 103 (D. Mass, 2000).

2. Payments from an employer to an employee;

3. An amount paid by a vendor of goods or services to a group purchasing agent;

4. Waivers of Part B copayments by Federally qualified health centers; and

5. Certain contractual arrangements where the person supplying items or services is at risk for the cost or utilization of the items or services provided (otherwise known as the "shared-risk" exception).

B. The Safe Harbors

There are 24 regulatory "safe harbors" that create narrowly defined exceptions to the statute's prohibitions for certain arrangements that pose a minimal risk of fraud or abuse. The regulations, at 42 C.F.R. 1001.952, set forth specific payment practices, which, although potentially capable of encouraging referrals of Federal health care program business, are not to be considered kickbacks for purposes of criminal prosecution or administrative sanctions.

The following is a brief summary of the safe harbors:

Investments in large entities. This safe harbor protects returns paid by large publicly traded corporations.

Investments in small entities. This safe harbor protects certain investment interests in "small entities". The key conditions are the so-called "60/40 tests." These tests ensure that the entity is a legitimate business and not merely a vehicle to reward or generate referrals. The safe harbor requires that sixty percent of the value of the investment interests must be held by those who are not in a position to make or influence referrals or furnish items or services to the entity or otherwise generate business for the entity (the "60/40 investors" test). In other words, sixty percent of the investment interest must be held by persons who have no interest other than simply holding the investment. The safe harbor also requires that sixty percent of the revenue of the entity must be derived from business generated by non-investors during the previous fiscal year or previous twelvemonth period (the "60/40 revenue" test).

Investments in small entities in underserved areas. This safe harbor covers investments in entities in rural and urban underserved areas (defined as Medically Underserved Areas (MUAs) under HHS regulations). This safe harbor eliminates the 60/40 revenue test from the small entities safe harbor and changes the 60/40 investors test to a 50/50 test. This safe harbor is designed to make it easier for health care entities to raise investment capital in areas with shortages of services.

Investments in group practices. This safe harbor protects investments by physicians in their own group practices, if the group practice meets the physician self-referral (Stark) law definition of a group practice. The safe harbor also protects

investments in solo practices where the practice is conducted through the solo practitioner's professional corporation or other separate legal entity. The safe harbor does not protect investments by group practices or members of group practices in ancillary services joint ventures.

Investments in ambulatory surgical centers ("ASCs"). This safe harbor protects certain investment interests in four categories of freestanding Medicare-certified ASCs: surgeon-owned ASCs; single-specialty ASCs (e.g., all gastroenterologists); multi-specialty ASCs (e.g., a mix of surgeons and gastroenterologists); and hospital/physician-owned ASCs. In general, to be protected, physician investors must be physicians for whom the ASC is an extension of their office practice pursuant to conditions set forth in the safe harbor. Hospital investors must not be in a position to make or influence referrals. Certain investors who are not existing or potential referral sources are permitted. The ASC safe harbor does not apply to other physician-owned clinical joint ventures, such as cardiac catheterization labs, end-stage renal dialysis facilities or radiation oncology facilities.

Space and equipment rental. These two very similar safe harbors address payments for the use of space or equipment. The basic theory of these safe harbors is that "fair market value" payments are permissible, as long as the total amount of payments is fixed no less than on a yearly basis. In other words, the payments cannot vary with referrals in any way during the minimum one-year term. This last provision denies safe harbor protection for "per use" payments. In addition, "fair market value" for safe harbor purposes cannot include the value that one of the parties attributes to the likelihood of receiving business from the other party.

Personal services and management contracts. This safe harbor covers arrangements for the provision of personal services by non-employees, and is structured in very similar terms to the space and equipment rental safe harbors discussed above. The total amount of compensation must be fixed in advance for a minimum period of one year, and payments are limited to "fair market value."

Employees. Payments made by an employer to an employee under a *bona fide* employment relationship for the provision of covered items or services are protected. The final rule adopts the Internal Revenue Services definition of "employee." Payments (even commission payments) to a part-time employee would be protected, as long as a *bona fide* employer/employee relationship exists.

Discounts. The operative theory of this complex safe harbor is that (1) price competition should be encouraged, and (2) Federal programs should share in the financial benefit of the discount to the extent possible. The safe harbor contains separate specific conditions for sellers, buyers, and "offerors" (most often manufacturers who are not direct sellers to end users). A seller, buyer or offeror can obtain safe harbor protection by fulfilling its own duties, regardless of what the others in the chain do. In general, a discount can include rebate checks, credits, and coupons that are directly redeemable by the seller, but not cash payments. The definition of discounts specifically excludes: cash payments; the provision of free or reduced-charge goods in

exchange for purchasing a different good or service (i.e., "bundled" payment arrangements); deductions applicable to one payer, but not to Medicare or Medicaid; and routine waivers of co-insurance and deductibles. Most so-called "bundled" purchase arrangements are not protected under the safe harbor, but can be protected where Medicare pays for all the bundled items under the same payment mechanism (e.g., an inpatient DRG).

Managed care. There are two safe harbors related to general managed care arrangements. The first safe harbor protects certain arrangements involving increased coverage, reduced cost sharing amounts, or reductions in premium amounts offered by health plans to beneficiaries. The second safe harbor protects certain price reductions offered by providers to health plans.

Managed care "shared risk" arrangements There are two safe harbors which protect certain "shared-risk" arrangements. The first safe harbor protects payments between (1) certain Medicare and Medicaid managed care plans and Medicare+Choice coordinated care plans and (2) their contractors (first tier entities) and subcontractors (downstream entities), if the managed care organization is paid by the government on a capitated or fixed aggregate basis, so that the government's financial exposure is fixed in advance. The second safe harbor is quite narrow. It protects certain "shared-risk" arrangements involving employer group health plans that place a health care provider under "substantial financial risk" for the cost or utilization of items or services provided to Federal beneficiaries who are enrolled in the employer plan (typically retirees). Most providers in these health plans are paid on a fee-for-service basis for such beneficiaries and are not at risk for the items or services provided to them. Thus, there are few, if any, arrangements that fit in this safe harbor.

Practitioner recruitment in underserved areas This safe harbor protects recruitment payments made by entities to attract needed physicians and other health care professionals to rural and urban health professional shortage areas (HPSAs), as designated by the Health Resources and Services Administration. The safe harbor requires that at least 75 percent of the recruited practitioner's revenue be from patients who reside in HSPAs or medically underserved areas or are members of medically underserved populations, such as the homeless or migrant workers. The safe harbor limits the duration of payments to three years. The safe harbor does not prescribe the types of protected payments, such as income guarantees or moving expenses, leaving that determination to negotiation by the parties. The safe harbor does not protect payments made by hospitals to existing group practices to recruit physicians to join the group, nor does it protect payments to retain existing practitioners

Sale of practice. This safe harbor has two parts. The first part protects the sale of a practice by a retiring physician, i.e., one who is leaving the area or leaving practice altogether. The second part protects hospitals in health professional shortage areas (HPSAs), that buy and "hold" the practice of a retiring physician until a new physician can be recruited to replace the retiring one.

Referral services. This safe harbor protects payments that physicians and other providers make to many traditional referral services run by hospitals, medical societies, and consumer groups.

Warranties. This safe harbor protects certain payments made pursuant to warranty obligations.

Group purchasing organizations. This safe harbor protects payments by vendors to group purchasing organizations under certain conditions, focused on full disclosure of fees.

Routine waiver of copayments and deductibles. This safe harbor has two parts: (1) the routine waiver of coinsurance amounts for inpatient hospital services payable under the prospective payment system and (2) the routine waiver of coinsurance amounts by community health centers under the Public Health Services Act to certain qualified beneficiaries.

Subsidies for obstetrical malpractice insurance in underserved areas. This safe harbor protects a hospital or other entity that pays all or part of the malpractice insurance premiums for practitioners engaging in obstetrical practice in HPSAs. To qualify for protection, the arrangement must meet several tests, including that at least 75 percent of the subsidized practitioners' patients must be medically underserved patients.

Cooperative Hospital Services Organizations. This safe harbor protects cooperative hospital service organizations (CHSOs) that qualify under section 501 (e) of the Internal Revenue Code. CHSOs are organizations 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 patron hospitals.

Specialty referral arrangements between providers The safe harbor protects certain arrangements when an individual or entity agrees to refer a patient to another individual or entity for specialty services in return for the party receiving the referral to refer the patient back at a certain time or under certain circumstances. For example, a primary care physician and a specialist to whom the primary care physician has made a referral may agree that, when the referred patient reaches a particular stage of recovery, the primary care physician should resume treatment of the patient.

Ambulance restocking. This safe harbor protects many common methodologies for hospital restocking drugs and supplies for an emergency ambulance that delivers a patient to the hospital's emergency room.

IV. Advisory Opinions

In 1996, Congress authorized the OIG to issue advisory opinions concerning whether an existing or contemplated arrangement violates the Anti-Kickback law.[20] Specifically, parties may seek an opinion concerning whether (1) there is remuneration within the meaning of the law, (2) the arrangement satisfies any of the law's exceptions or safe harbors, or (3) the arrangement warrants the imposition of a sanction.[21] As of the end of 2004, 122 advisory opinions had been issued, the great majority being favorable to the requestor(s).

V. Special Fraud Alerts and Special Advisory Bulletins

A. Special Fraud Alerts

1. Joint Venture Arrangements, Aug. 1989

2. Routine Waiver of Copayments or Deductibles Under Medicare Part B, May 1991

3. Hospital Incentives to Physicians, May 1992

4. Prescription Drug Marketing Schemes, Aug. 1994

5. Arrangements for the Provision of Clinical Lab Services, Oct. 1994

6. Home Health Fraud, June 1995

7. Medical Supplies to Nursing Facilities, Aug. 1995

8. Provision of Services in Nursing Facilities, June 1996

9. Fraud and Abuse in Nursing Home Arrangements with Hospices, Mar. 1998

10. Physician Liability for Certifications in the Provision of Medical Equipment and Supplies in Home Health Services, Jan. 1999

11. Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer, Feb. 2000

12. Telemarketing by Durable Medical Equipment Suppliers, March 2003

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[20] 42 U.S.C. § 1320a-7d(b).

[21] Id. the OIG publishes its advisory opinions on its website at www.hhs.gov/progorg/oig/advopn/index.htm.

B. Special Advisory Bulletins

1. Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce of Limit Services to Beneficiaries, July 1999

2. The Effect of Exclusion From Participation in Federal Health Care Programs, Sept. 1999

3. OIG/HCFA Special Advisory Bulletin on the Patient Anti-Dumping Statute, Nov. 1999

4. Practices of Business Consultants, June 2001

5. Offering Gifts and Other Inducements to Beneficiaries, Aug. 2002

6. Contractual Joint Ventures, April 2003

VI. How to Analyze Transactions Under the Anti-Kickback Law

The principal issues in assessing a transaction under the Anti-Kickback law are as follows:

- Are the parties exchanging "remuneration" (i.e., something of value)?

- If so, does one or more of the parties intend that (or could the government perceive that) one of the purposes of this exchange of remuneration to induce the other party to:

- refer federal health care program patients:

    - ♦ order or purchase items or services covered by a federal health care program; or

    - ♦ recommend or arrange for the ordering or purchasing of items or services covered by a federal health care program.

- If so, is the remuneration at issue protected by a statutory exception or regulatory safe harbor?

- If not, does the exchange of remuneration raise material fraud and abuse concerns (with reference to the policy objectives of the Anti-Kickback law) that could motivate the government to impose sanctions against the parties?

- Could the transaction be restructured, or safeguards put in place, substantially to eliminate the material fraud and abuse concerns? [The relevant safe harbors, advisory opinions, safe harbor preambles and other OIG guidance contain a wealth of information about OIG concerns and how to mitigate them.]

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