GENERAL COUNSEL NOTE

2008

As part of employee orientation to Vanderbilt University, every employee is cautioned about receiving something of value in exchange for a good or service, also known as a kickback. In the health care context, the phrase "kickback" refers generally to what has come to be known as the Anti-kickback Statute (U.S.C. § 1320a-7b). First enacted in 1972, the Anti-kickback Statute is intended to ensure that Medicare and Medicaid beneficiaries received objective medical advice and that health care providers refer patients based on the patients' best medical interests (and not because the provider will benefit from the referral).

INTRODUCTION

Generally, the law prohibits anyone from knowingly and willfully offering, paying, soliciting, or receiving anything of value (generally referred to a "remuneration") to influence the referral of items or services reimbursable by a Federal Health Care Program.1 A violation of the Anti-kickback Statute results in criminal liability to all parties involved (those paying the impermissible "kickback" and those receiving the impermissible kickback) and constitutes a felony, which, upon conviction, is punishable by a maximum fine of $25,000, imprisonment up to five (5) years, or both. Furthermore, a conviction under the Anti-kickback statute also results in automatic exclusion from Federal Health Care Programs.2 One is said to have violated the Anti-kickback statute if even only one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals.3 What this indicates is that even if the parties have legitimate business reasons for the remuneration, if one of the purposes behind the remuneration is for referrals, the transaction will be found to have violated the Anti-kickback statute. A good example of this would be the following:

> Physician A, a primary care physician in private practice, is seeking to lease space for a new office location. Hospital X owns a medical office building on its Hospital campus, which it rents to physicians and others and is currently only about ¾ occupied. Physician A refers frequently to Hospital X for various medical specialties offered by Hospital X. Hospital X typically rents space in its building at the rate of $20 per square foot. Because the building is only ¾ full and Hospital X feels some urgency to rent the vacant space and in an effort to ensure that Physician A continues to refer to Hospital X, Hospital X offers space in the building to Physician X for only $15 per square foot. This transaction would (assuming it does not meet any of the safe harbors set forth below) violate the Anti-kickback Statute. While Hospital X

1 Federal Health Care Program is defined under the statute as: "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government...; or any State health care program...." This therefore includes all claims submitted to CMS under the Medicare program and all claims submitted under the TennCare program.

2 In addition to the criminal penalties associated with the Anti-kickback statute, the Office of Inspector General ("OIG"), which is the governmental body responsible for enforcement of the Anti-kickback statute, has the authority to impose civil monetary penalties under U.S.C. § 1128A(a)(7).

3 *United States v. Kats,* 871 F.2d 105 (9th Cir. 1989); *United States v. Gerber*, 760 F.2d 68 (3d Cir.), *cert. denied* 474 U.S. 988 (1985).

has a legitimate business reason (building is not entirely full and Hospital X needs to rent out the remaining space) for giving Physician A a discount on the rental rate, at least one of the reasons is for the purpose of ensuring that Physician A sees the goodwill of the Hospital and continues to refer to the Hospital for specialty care.

In order to provide guidance to the healthcare industry about when transactions may violate the Anti-kickback statute, the Office of Inspector General (the government agency responsible for enforcement of the statute) issues advisory opinions based on certain requests from the general public. While these advisory opinions are specific to the facts and circumstances of the specific requestor, outside parties are able to read and review the advisory opinions to get a better sense of how their own arrangements might be analyzed and interpreted based on similar facts and circumstances.

SAFE HARBORS

In order to accommodate certain remuneration relationships, the Anti-kickback statute identifies exceptions to the blanket prohibition against remuneration and the Department of Health and Human Services ("HHS") has promulgated certain regulations setting forth a number of "safe harbors."4 If one complies with all of the criteria set forth in a particular safe harbor, one shall be deemed to have complied with the Anti-kickback law and is thus not subject to prosecution under the statute. Compliance with a safe harbor is not required, however, and the fact that an arrangement does not meet the criteria of any of the safe harbors does not necessarily indicate that the arrangement is *per se* illegal. Rather, each arrangement is dependent on the facts and circumstances of such arrangement.

There are currently twenty-five safe harbors that have been promulgated. The safe harbors include the following types of transactions or arrangements involving remuneration from one party to another:

1. Investment interests
2. Space rental;
3. Equipment rental;
4. Personal services and management contracts;
5. Warranties;
6. Discounts;
7. Referral services;
8. Employees;
9. Group purchasing organizations;
10. Waiver of beneficiary and coinsurance amounts;
11. Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans;
12. Price reductions offered to health plans;
13. Investments in ambulatory surgical centers ("ASCs") (including surgeon-owned ASCs, single-specialty ASCs, multi-specialty ASCs, and hospital/physician-owned ASCs);

4 The regulations are found at 42 C.F.R. § 1001.952.

14. Joint ventures in underserved areas;
15. Practitioner recruitment in underserved areas;
16. Sales of physician practices to hospitals in underserved areas;
17. Subsidies for obstetrical malpractice insurance in underserved areas;
18. Investments in group practices;
19. Specialty referral arrangements between providers;
20. Cooperative hospital services organizations;
21. Price reductions to eligible managed care organizations;
22. Price reductions offered by contractors with substantial financial risk to managed care organization;
23. Ambulance replenishing;
24. Electronic prescribing and electronic medical records arrangements;
25. Federally qualified health care center arrangements.

Each of these categories contains certain criteria and if such criteria are complied with, the parties are deemed to be in compliance with the safe harbor. Using the same parties above, but slightly different facts, an example would be as follows:

> Physician A leases space from Hospital X. In order to fit under the safe harbor for space leases, the parties must meet the following criteria: (a) the lease agreement must be set out in writing and signed by the parties; (b) lease covers all of the space leased between the parties for the term of the lease and specifies the space covered by the lease; (c) if the lease is intended to provide the tenant with access to the space for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease must specify exactly the schedule of such intervals, their precise length, and the exact rent for such intervals; (d) the term of the lease must be for not less than one year; (e) the total rental charge must be set in advance, consistent with fair market value in arms-length transactions, and 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 under federal health care programs; and (f) the total space rented does not exceed the space necessary to accomplish the business purposes. The parties currently have a written agreement in place for rental of the office space at a rate that they believe to be fair market value based on the opinion of an independent party. The rental of space is full time and is sufficient space for a one-physician practice. The term of the lease is 6 months. All of the criteria of the safe harbor of the arrangement appear to have been met, except the term of the lease is not for the period of one year. Therefore, the arrangement does not meet the safe harbor exception and whether the parties are in compliance with the Anti-kickback statute is entirely dependent on the facts and circumstances of the arrangement. If even one reason that the term is only 6 months, for example, is because Hospital X, in an effort to induce referrals from Physician A, is willing to amend the rent every 6 months so as to ensure that Physician A's rent is not becoming a financial burden, then failure to comply with the safe harbor in this instance would be a violation of the Anti-kickback statute. If on the other hand, the sole reason for the term of 6 months is because

Physician A is moving out of state permanently in 6 months and only needs a short term lease, then the Office of Inspector General might choose not to impose any sanctions under the Anti-kickback statute, depending on its analysis of the facts and circumstances of the transaction.

SOME COMMON ARRANGEMENTS THAT COULD IMPLICATE THE ANTI-KICKBACK STATUTE

Below are some common place arrangements in the healthcare industry that implicate under the Anti-kickback statute. It is important to recognize what types of arrangements might implicate the Anti-kickback statute so that one can determine when to seek the advice of an attorney.5

1. Medical device company offers free supplies to a hospital so long as hospital agrees to purchase a certain quantity of medical equipment (unrelated to supplies or use of the supplies) manufactured by the medical device company. If even one intent of the medical device company in giving the hospital give free supplies is to attempt to induce the hospital to purchase medical equipment from the device company, then the arrangement is a violation of the Anti-kickback statute, as the free supplies are a form of in kind remuneration from the device company to the hospital. There is no applicable safe harbor provision that protects the provision of free goods or services to a hospital. While failure to meet the criteria of a safe harbor does not necessarily constitute a violation under the Anti-kickback statute, the parties would have to demonstrate a reason or reasons other than the purchase of additional equipment (used to bill for services under federal healthcare programs) to give the hospital fee equipment.

2. Physician leases an MRI from local hospital and has been leasing such equipment for five-years. The parties have no written lease in place, but a mutual understanding that the term is for five-years and the rental rate is $500 per half day. The rent, which was first put in place when the physician first started leasing the equipment five-years ago, is about $50 per half day less than what other physicians and business are paying for similar equipment. There is a safe harbor available for equipment leases, but the parties are not currently in compliance with all of the criteria of the safe harbor. The arrangement is not *per se* illegal under the Anti-kickback statute by virtue of the fact that the parties are not in compliance with the safe harbor, but if one reason for the lower rate being paid by physician to the hospital is for purposes of inducing the physician to refer to the hospital, then the arrangement will be considered a violation of the Anti-kickback statute. It would be the recommendation of our office that the arrangement be amended in order to comply with the Anti-kickback safe harbor (and other laws, such as the Stark law, as may be applicable) by taking such actions as putting the lease in writing and ensuring that the rental rate being paid fair market value.

3. Nursing home contracts with Physician to provide medical director services at the nursing home. The parties enter into a written agreement in which the nursing home agrees to pay the Physician an annual rate of $150 an hour to provide administrative services. The rate is fair market value for physician's services. The agreement pays Physician such amount based on an

5 Please note that the following examples may also implicate other applicable laws, such as the Stark law, but that the analysis for purposes of this memorandum is limited to a legal analysis under the Anti-kickback law. It is always advisable to contact our office regarding arrangements that involved remuneration to or from a physician, other healthcare providers, or companies in the healthcare industry (such as a medical device company), as such arrangement may implicate one or more laws governing the healthcare industry.

estimate that Physician will provide approximately fifteen hours per month. Physician only actually works 3 hours per month, but makes no changes to correct the payment discrepancies and continues to be paid as if she was providing fifteen hours per month of services. The agreement does not comply with the safe harbor because the compensation, while set in advance, is not fair market value because Physician is getting paid in excess of the services that the Physician is actually providing. The arrangement might further fail to meet the criteria if the fifteen hours contracted for in the agreement are not commercially reasonable for what is necessary (that is, the nursing home really only needs someone three hours per month). If one purpose of the failure to meet the criteria of the safe harbor is to induce the Physician to refer patients to the nursing home, then the arrangement violates the Anti-kickback statute. The burden is on the parties to prove that an arrangement that is not in compliance with a safe harbor is not a violation of the Anti-kickback statute. Therefore, if the parties do have a reason or reasons for the discrepancy in compensation being paid relative to the hours worked other than referrals (and the desire for referrals is not one of the reasons), then the parties would need to be able to demonstrate sufficient documentation to prove the purpose of the parties.

4. Drug Company is negotiating with hospital to provide to hospital certain pharmaceuticals for hospital's use for its own patients. As part of the negotiations, drug company tells hospital that it is willing to provide a deep discount on the drugs if the hospital buys a certain volume of drugs. There is a safe harbor under the Anti-kickback statute that permits discounts for a buyer and could permit this arrangement so long as the parties comply with the criteria in the safe harbor, which includes reporting the discount on the hospital's cost reports in the year that it is earned and providing certain information to the government upon request. Absent compliance with the safe harbor, the discount is likely to be suspect under the Anti-kickback statute, as the reason for offering the discount is likely to induce hospital to purchase more pharmaceuticals from the drug company.

These are just a few examples of kinds of arrangements or transactions that require analysis under the Anti-kickback statute (and perhaps under other applicable laws), but there are many other arrangements or transactions that may also implicate the Anti-kickback statute and analysis under its regulations (and the safe harbors). As stated above, ultimately whether a certain arrangement or transaction is in compliance with the Anti-kickback statute is dependant on an analysis of the facts and circumstances of the transactions (keeping in mind the criteria for the safe harbors and guidance in the advisory opinions) to determine the true purposes of the parties. Please feel free to contact the Office of General Counsel at any time should you have any questions about any arrangement or transactions or any general questions about the Anti-kickback statute and the safe harbors.