Here is a great article from physicianspractice.com regarding the federal Anti-Kickback Statute and Self-Referral Statutes. Every physician should be aware of these rules and how to remain compliant with them, because, as the article points out: "what is generally accepted in many other industries may be illegal in the healthcare industry!" As we move into the era of "Obamacare" this is an area to which the government will give increasing attention. Be careful.

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The government often focuses on potential kickbacks and self-referral arrangements in healthcare fraud investigations. As one federal publication recently stated, "in some industries, it is acceptable to reward those who refer business to you. However, in the federal healthcare programs, paying for referrals is a crime."

These are typically easier cases for the government to prove than cases that turn largely on expert testimony regarding complex medical procedures. The government's concern is that kickbacks and self-referral arrangements can lead to overutilization, increased costs, corruption of medical decision making, patient steering, and unfair competition.

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Kickback and Self-Referral Statutes Physicians May Be Violating

By Sarah Q. Wirsky

The government often focuses on potential kickbacks and self-referral arrangements in healthcare fraud investigations. As one federal publication recently stated, "in some industries, it is acceptable to reward those who refer business to you. However, in the federal healthcare programs, paying for referrals is a crime."

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Federal kickback rules differ for health care

return for referring, directly or indirectly, an individual or for recommending or arranging the purchase, lease, or ordering of an item or service that may be wholly or partially paid for by any federal healthcare program. "Federal healthcare program" not only includes Medicare, but also, Medicaid, Tricare, Veterans Administration, and other federally funded programs. While the AKS prohibits remuneration for referrals wholly or partially paid for by government funds, many state versions of the AKS cover non-government pay.

Notably, "knowing and willful conduct" has been very broadly interpreted to mean that a person need not have actual knowledge or specific intent to violate this law. "Remuneration" has been interpreted to include anything of value (tangible or intangible), such as a reduction or discount, direct payment of cash or loans, and free items or services, including transportation. There are also cases stating that if at least part of the payments were intended to induce referrals, the AKS is violated. Moreover, the government does not need to prove patient harm or financial loss to the program. Finally, there can be a violation of the AKS even if the service was rendered, and the service was medically necessary. A violation of this statute can be the basis for civil or criminal penalties, and collateral consequences such as exclusion and licensure issues.

There are statutory exceptions and voluntary safe harbors to the AKS. Some of the more commonly implicated ones involve discounts, certain employer/employee relationships, space and equipment rental, and practice sales. There are certain rules that must be strictly followed in order to fall within these exceptions and/or safe harbors, however.

Physician Self-Referral Statute ("Stark Law")
The Stark Law limits physician referrals for "designated health services" ("DHS") when a physician or immediate family member has a financial relationship with the entity, unless an exception applies. A financial relationship is defined as either a compensation arrangement (which includes any remuneration) or an ownership or investment interest. A referral includes any direct request for a DHS or a request for a consultation with another doctor who then orders a DHS.

This is a strict liability statute. The individual need not be aware that he or she is referring to an entity with which the provider has a prohibited interest in order to break the law. Penalties include fines and exclusion from Medicare and Medicaid. Unlike the AKS, Stark only applies to Medicare and Medicaid and not all federal healthcare programs.

DHS include 1.) clinical laboratory services; 2.)
physical therapy, occupational therapy, and outpatient speech-language pathology services; 3.) radiology and certain other imaging services; 4.) radiation therapy services and supplies; 5.) durable medical equipment and supplies; 6.) parenteral and enteral nutrients, equipment, and supplies; 7.) prosthetics, orthotics, and prosthetic devices and supplies; 8.) home health services; 9.) outpatient prescription drugs; and 10.) inpatient and outpatient hospital services. There are statutory and regulatory exceptions to the Stark Law as well.

Potentially Problematic Conduct
These statutes have a very broad application. If you or your practice is involved in the following conduct, you may need to conduct further investigation in order to ensure you are in compliance with the statutes discussed in this article: 1.) waivers of co-pays or deductibles; 2.) joint ventures with Medicare/Medicaid pay; 3.) arrangements with doctors, such as medical directors, and incentives for recruitment and retention; 4.) lab discounts; 5.) office rental; 6.) gifts to patients, and particularly Medicare/Medicaid beneficiaries; and 7.) paying employees based upon production.

Proactive Measures
In light of the government focus on these provisions, there are a few steps a provider can take to help minimize his/her exposure. A provider should have a written policy regarding gifts. This should include prohibiting and/or limiting both the giving and receiving of gifts to any patient or referral sources.

In healthcare fraud investigations, the government usually examines a provider's marketing practices, and will examine advertising and mailed materials. Providers need to ensure that their marketing professionals know what is appropriate in the healthcare field. For example, gift cards are a commonly promoted marketing tool used by healthcare consultants that likely violate federal and state law.

The HHS' Office of Inspector General ("OIG") also has a voluntary self-disclosure program to resolve Stark and AKS issues. A careful analysis must be performed when and how to do a disclosure. If the government does not feel the disclosure meets the criteria and is not truthful or complete, it does not offer any protection, and it may actually help the government make a case.

Because what is generally accepted in many other industries may be illegal in the healthcare industry, it is important to make sure you are in compliance with these rules. Be careful!
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