An Introduction to the Federal Anti-kickback Statute and Stark Law

By Charles B. Oppenheim, JD and Jenni Rosenberg

Editor's note: Charles B. Oppenheim is a partner specializing in health law in the Los Angeles office of Foley & Lardner LLP. Mr. Oppenheim is a nationally recognized expert on Stark Law issues, and wrote the 2008 American Health Lawyers Association monograph on Stark Law. He may be reached at 310/975-7790.
Jenni Rosenberg was a summer associate at Foley & Lardner LLP and is a student at Harvard Law School.

The federal Anti-kickback Statute and so-called Stark physician self-referral laws are statutes developed to protect federal programs from health care fraud and abuse. In recent years, the federal government has substantially increased its enforcement efforts in the health care fraud arena, and a number of high profile cases have been brought against health care companies and individuals. Because these laws apply broadly to financial relationships with virtually every health care business or organization, it is important for health care administrators, providers, physicians and, of course, all health care compliance professionals to have a basic knowledge of these laws.

Although both statutes aim to prohibit the improper referral of services covered by federal health care programs, they have differing approaches and penalties. The federal Anti-kickback Statute is a criminal statute, and violations can result in fines and even imprisonment. The Stark Law is a civil statute that potentially requires providers to reimburse the government for payments received for services provided pursuant to prohibited referrals. Though separate, the laws may be applied to the same financial relationships, so providers and other health care organizations that fail to comply with the associated regulations may be subject to prosecution or suit under both the federal Anti-kickback Statute and Stark. Also, it is important to note that compliance with anti-kickback regulations does not guarantee compliance with Stark regulations, and vice versa.

This article will aim to provide health care organizations with a basic introduction to compliance with the federal Anti-kickback and Stark laws. However, an individualized analysis of any actual financial arrangement is required to determine compliance under the law.

Federal Anti-kickback Statute

The Anti-kickback Statute prohibits any person from knowingly and willfully paying, offering, soliciting or receiving any "remuneration" (i.e., payment), directly or indirectly, in cash or in kind, to induce the referral of business covered (in whole or in part) by a federal health care program, including Medicare and Medicaid. Prohibited action also includes knowingly and willingly soliciting or receiving remuneration in an attempt to induce purchasing, leasing, ordering, or arranging for or recommending any good, facility, service, or item paid for (in whole or in part) through federal health care programs.[1] Both the person or entity making the payment and the person or entity receiving the payment can be convicted under the statute, as long as the government can show that the conduct was done knowingly and willfully. The Anti-kickback Statute has been broadly interpreted by federal courts to prohibit any remuneration, if one purpose is to induce the referral of federal program business.[2]

The Office of the Inspector General of the Department of Health and Human Services (OIG), which is the agency responsible for the anti-kickback regulations, stresses that certain remuneration practices that are common in other industries are prohibited under the statute. These include free goods, services, and gifts to reward past referrals or induce future referrals of federal health care program business.[3] Even common business courtesies and activities not normally considered "remuneration" can be problematic, such as giving birthday presents or taking a referral source to dinner or a sporting event, if they are lavish or frequent or otherwise provided with wrongful intent to induce or reward referrals.

In fact, the government views the provision of goods and services for free or at below-market rates to current or potential customers as suspect under the Anti-kickback Statute.[4] In a special fraud alert published several years ago, OIG advised that a payment or gift may violate the Anti-kickback Statute if it is made to a person in a position to generate business for the paying party, related to the volume or value of business generated, and of more than nominal value.[5]

OIG further advises that hospitals and other health care entities that have financial relationships with physicians or other referral sources evaluate rigorously whether their particular financial arrangements have the potential to interfere with or skew clinical decisions, increase costs to federal programs, or increase the risk of inappropriate or excessive utilization.[6]

Safe harbors under the Anti-kickback Statute

The federal government has created 23 "safe harbors" under the Anti-kickback Statute that protect certain common, non-abusive financial arrangements in the health care field. If an arrangement satisfies all the requirements of the applicable safe harbor(s), then the arrangement is protected from both criminal prosecution and civil penalties under the Anti-kickback Statute. Compliance with safe harbors is voluntary. Therefore, failure to satisfy the applicable safe harbor(s) does not mean that an arrangement is necessarily illegal, but rather that it may be subject to scrutiny and prosecution under the Anti-kickback Statute.[7]

Some of the more significant safe harbors protect payments to employees, payments to certain independent contractors, and certain types of discount arrangements. It is important to understand that to obtain the protection of a safe harbor, the arrangement must precisely meet the requirements of that safe harbor. There is no immunity for "substantial" compliance if an arrangement comes close, but does not meet all of the requirements of a safe harbor.

Stark Law

Stark is the name commonly used for the federal physician self-referral law, which prohibits physicians from referring Medicare patients to entities for certain designated health services (DHS) if the physician (or an immediate family member of the physician) has a financial relationship with the entity, unless an exception applies.[8] Unlike the Anti-kickback Statute, Stark violations result in liability for health care providers regardless of intent, and violators may be subject to penalty even if they are unaware of the violation. Additionally, compliance with an exception under Stark is mandatory, and any referrals by physicians who have financial arrangements that fall outside of any exception are considered violations of the statute.[9]

Stark regulations were implemented in three phases, with the final phase issued in 2007. The DHS affected by Stark include: clinical laboratory; physical therapy; occupational therapy; radiology (including MRI, CT and ultrasound); radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices; home health services and supplies; outpatient prescription drugs; and inpatient and outpatient hospital services.

Which financial relationships are affected?

Stark defines the term "financial relationship" broadly. Financial arrangements affected by Stark can be practically any direct or indirect ownership, investment, or partnership interest, or direct or indirect compensation arrangement between a referring physician or his/her immediate family member and a hospital. The arrangement at issue need not relate to the prohibited DHS in order to violate Stark. Also, physician partners and shareholders are considered to "stand in the shoes" of their physician organization (such as a medical group) for the purposes of evaluating the financial relationship for Stark compliance.[10]

Penalties for violations

The basic penalty for Stark violations is that the health care provider is not entitled to submit claims (and potentially must refund payments previously received) for services provided pursuant to prohibited referrals.[11] Jurisdiction over this penalty, as well as primary jurisdiction over Stark generally, rests with the Centers for Medicare and Medicaid Services (CMS).

In addition to this basic non-payment/repayment penalty, Stark provides that for "knowing" violations, anyone who submits or causes the submission of claims for Medicare services provided pursuant to prohibited referrals may be subject to civil money penalties of up to $15,000 per service billed.[12]

Exceptions under Stark

As stated previously, referral of DHS through financial arrangements or relationships can escape civil penalty liability only by complying with all elements of the exceptions outlined in the Stark regulations. Generally, the exceptions fall into one of three categories, and each exception outlines specific criteria that must be met in order to qualify for protection.

First, CMS provides general exceptions relating to both ownership/investment and compensation arrangements. These include, among others, exceptions for certain in-office ancillary services provided by physician practices, certain services provided to HMO enrollees, and certain services provided at academic medical centers.[13]

Second, exceptions are provided for ownership or investment relationships relating to rural providers, hospitals located in Puerto Rico, publicly-traded securities and mutual funds, and whole-hospital ownership interests.

Lastly, CMS outlines exceptions relating solely to compensation arrangements. These exceptions include, among others, rental of office space and equipment, bona fide employment relationships, physician recruitment, personal service arrangements, fair market value compensation, risk-sharing arrangements, and compliance training.[14]

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Key points to remember

Compliance with a Stark exception does not necessarily shield an entity from penalties under the Anti-kickback Statute, and vice versa. Further, compliance with Stark exceptions is mandatory to avoid civil liability, but failure to comply completely with an anti-kickback safe harbor does not necessarily give rise to criminal liability.

Substantial changes to the Stark regulations have been implemented in the last couple years, so providers should reevaluate their financial arrangements in order to ensure current compliance.

Organizations concerned about whether their particular financial arrangements comply with either statute may request an advisory opinion from the OIG (for anti-kickback inquiries) or CMS (for Stark inquiries). However, this process can be very time consuming and unpredictable, so health care entities may wish to consult with qualified legal counsel for more information and advice about their arrangements, including the potential benefits and drawbacks of seeking an advisory opinion. ■

1 42 U.S.C. § 1320a-7b(b) (2000).
2 See, e.g., U.S. v. Greber, 760 F.2d 68 (3rd Cir. 1985), cert. denied, 474 U.S. 988 (1985); accord U.S. v. Kats, 871 F.2d 105 (9th Cir. 1989).
3 OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4863 (Jan. 31, 2005).
4 OIG Advisory Opinion 98-13 (Sept. 23, 1998).
5 Special Fraud Alert: Prescription Drug Marketing Schemes (August 1994).
6 OIG Supplemental Compliance Program Guidance for Hospitals, 4864.
7 OIG Supplemental Compliance Program Guidance for Hospitals, 4864.
8 42 U.S.C. § 1395nn.
9 OIG Supplemental Compliance Program Guidance for Hospitals, 4863.
10 42 C.F.R. § 411.354(c)(1)(ii).
11 42 U.S.C. § 1395nn(g).
12 Ibid.
13 42 C.F.R. § 355.
14 42 C.F.R. § 357.