



MD Briefly - Stark & Anti-Kickback Laws

So, you are probably asking, “Why should someone in healthcare meetings and events care about Stark or Anti-Kickback Laws?” To put it simply, because we often work with physicians and the entities they conduct business with, so it just makes sense that we are aware of issues that are important to our clients. Also, many of us work in a tradeshow

booth environment or sales capacity and understanding these laws is vital. Many pharmaceutical or medical device company marketing, events and tradeshow employees must go through training to understand the complexities of the Stark and Anti-Kickback laws. Anti-Kickback laws are easier to understand. It is easier to know when someone has willfully paid another for patient referrals or new business opportunities. But when it comes to physician referrals and the Stark Law it can be a bit more complicated. However, when large fines and penalties can be levied, sometimes as much as six figures, you’d be hard pressed to find anyone that would want to break this law. With that said, it can be difficult to ascertain what’s safe and what’s not when it comes to referrals.

While the Stark Law can be somewhat convoluted, the key point for you to understand? It is important to re-evaluate any, and all business arrangements, to prevent potential violation of Stark/Anti-Kickback laws. Remember, it is important to review these arrangements on an individual basis.

Let’s review and define some of the key points of the Stark and Anti-Trust Law, as well as provide some real-world examples of violations. While the information in this article is certainly not legal advice, it will provide you some basic knowledge so that you are aware of potential violations and more importantly, when to ask questions. It is meant to raise your awareness level.

What is the Stark Law?

Stark Law are federal laws that prohibit physician self-referral, specifically by a physician of a Medicare or Medicaid patient to another person/business that provides designated health services (DHS) if the physician or an immediate family member has financial ties with that person or business. (A list of DHS services provided later in this article).

What is the Anti-Kickback Statute (AKS)?

The AKS is a law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients).

What is the False Claim Act?

The False Claim Act says it is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent. If that claim results from a kickback or is made in violation of the

Stark law also may render it false or fraudulent, creating liability under the civil False Claim Act as well as the AKS or Stark law.

What are the penalties for violating the Stark Law and AKS?

Penalties for violating Stark can be severe. They include denial of payment, refund of payment, imposition of a \$15,000 per service civil monetary penalty and imposition of a \$100,000 civil monetary penalty for each arrangement considered to be a circumvention scheme.

Anti-Kickback violations are punishable by up to five years in prison, with the potential for additional criminal fines up to \$25,000, and administrative civil money penalties reaching as much as \$50,000.

What is a kickback in healthcare?

A kickback is when payments are made with the intent of gaining something from a company or a person. Medicare kickbacks are when health care providers intentionally accept payments, products, or services for the purposes of soliciting Medicare or other healthcare program business. This includes not only direct bribes, but also in-kind rewards such as:

- Free vacations
- Gifts
- Free Meals
- Paid contracts / physician compensation
- Financial support of CME programs
- Other indirect forms of remuneration

What is a safe harbor?

The Anti-Kickback Statute contains certain exceptions, known as safe harbors, which allow transactions that would otherwise violate the statute, providing various qualifications are met. This list can change regularly, so be sure to involve legal counsel:

- Space rental
- Equipment rental
- EHR items and services
- Electronic prescribing items and services
- Discounts
- Health centers
- Payments made to bona fide employees
- Personal services and management contracts
- Warranties
- Investment interests
- Referral services
- Practitioner recruitment
- Ambulatory surgical centers

Stark Law Primer

The Stark Law prohibits referrals by physicians, for designated health service, generally for patients with Medicare or Medicaid when the referral is made to an entity that the referring physician, or a member of his or her immediate family, has a financial relationship with that entity.

The Stark law, 42 U.S.C. § 1395nn, in part; the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

The entity may not present or cause to be presented a claim under this subchapter to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A). It is also important to note;

- There is no intent requirement
- There is strict liability

To be protected by a safe harbor, an arrangement must satisfy all of its requirements

False Claims Act may be indicated with false certification of Stark Law compliance

While covering similar areas of jurisdiction, it's also important to note that the Stark Law is different from anti-kickback laws, and is a separate law. The purpose of the anti-kickback statute is to eliminate the potential for conflict of interest, where a physician could end up over-utilizing certain services, even if they are medically necessary; ultimately, driving up healthcare costs.

What Classifies as a Designated Health Service?

While the list of designated health services is a large one, these are the primary things that are contained within its definition:

- Clinical lab services
- Physical therapy services
- Occupational therapy
- Speech and language services
- Radiology services, including MRIs, CTs, and Ultrasounds
- Home health
- Medical devices
- Radiation
- Outpatient prescription drugs
- Parenteral and enteral nutritional services
- Prosthetics
- Orthotics
- In- and out-patient hospital services

What Constitutes a Financial Relationship?

When it comes to defining a financial relationship, it's a bit more difficult. As listed earlier in this article, there are 20 exceptions or "safe harbors" that allow for financial arrangements between manufacturers and purchasers. But what is key to these relationships is that they are clearly documented and incorporate pricing at fair market value for the exchange of any goods and services.

Historically, health fraud enforcers and whistleblowers have focused on the pharmaceutical companies, device manufacturers, hospitals, laboratories and others who have made payments to docs with the intent of getting referrals of Medicare and Medicaid business. But the OIG (Office of Inspector General) has also focused on physicians, issuing a [Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability](#) that urges physicians to consider carefully the arrangements and terms of medical directorships and payments.

For more information visit the CMS website:

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/physicianselfreferral/>

Examples of Stark and Anti-Kickback Law Violations

1. *Part-Time and Consulting Contracts with Referring Physicians*
A jury has found that a healthcare system violated the Stark Law by paying doctors in ways that rewarded them financially for referring patients to the hospital. The jury found that more than 20,000 Medicare claims were tainted by the illegal compensation arrangements.
2. *Incentive Payments to Doctors*
A healthcare system agreed to pay \$9.3 million to resolve allegations that it knowingly provided incentive pay to physicians who referred patients to the hospital system. The settlement resolves claims by the U.S. government that such incentive payments violated the False Claims Act and the Stark Law.
3. *Physician Office Leases*
A company agreed to pay \$16.5 million to settle claims that it violated the False Claims Act and the Stark Statute by entering into favorable leases with physicians who referred patients to the hospital. The whistleblower who brought the case will receive 18.5% of the settlement as a reward, or more than \$3 million.
4. *Free Drugs*
A pharmaceutical company paid \$109 Million to settle allegations it provided free units of a knee injection drug to induce physicians to purchase and prescribe the product.
5. *Use of Medical Device*
A medical device company paid \$646 million in a 2016 global settlement, including \$267.3 million in federal recoveries under the False Claims Act, \$43.5 million in recoveries for state Medicaid programs, and \$335.2 million in criminal penalties. The settlement resolved allegations that kickbacks were paid to doctors and hospitals in exchange for their purchases of their medical and surgical devices.
6. *Physicians*
The largest settlement with a physician was with cardiologist. He paid \$2 million, and released claims to an additional \$5.3 million in suspended Medicare funds, to settle allegations that he and his practice billed Medicare, Medicaid, and TRICARE for medically unnecessary procedures and paid kickbacks to patients by waiving Medicare copayments irrespective of financial hardship.

This brief overview, is yet another example of how laws pertaining to doing business in healthcare are different. What might be a perfectly normal, appropriate and often accepted practice in other industry sectors, may be prohibited by law in healthcare. While this may not directly apply to what healthcare meeting planners do in their everyday duties, knowing what our customers must abide by is an important aspect of excellence.

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