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What is the Anti-Kickback Statute?

Article By:

Tycko & Zavareei Whistleblower Practice Group

The Anti-Kickback Statute is a powerful anti-fraud law designed to remove the profit motive from medical referrals and decision-making. The Anti-Kickback Statute, like the Stark Law, applies to all medical services that are funded by Medicare, Medicaid, and other federal healthcare programs.

As much as possible, medical decisions and recommendations should be based only on the needs of the individual patient and what will be best suited to their care. Unfortunately, at times health care providers and industries are motivated instead by the urge to make money off patients who come to them for help. The intent of the Anti-Kickback Statute is to move providers as far away from a forprofit mindset as possible, by de-incentivizing and even criminalizing recommendations based purely on financial gain.

What Does the Anti-Kickback Statute Prohibit?

The Anti-Kickback Statute makes it illegal for healthcare providers to offer or accept gifts, bribes, payments, or other financial incentives in exchange for referrals, prescriptions, or other medical services when those services will be paid for partly or wholly by Medicare, Medicaid, or other government-funded health programs. The exchange of benefits as incentive is prohibited by the Anti-Kickback Statute, as is the offer to exchange said benefits—even if the bribe or payment is never carried out.

It is important to understand that the government does not have to illustrate financial loss or even patient harm in order to find a health care provider in violation of the Anti-Kickback Statute. Even if the recommended service was medically necessary for a patient's care, accepting the kickback in the first place puts a health care provider in violation of this criminal law.

Anti-Kickback Statute Remuneration Definition

The Anti-Kickback Statute offers a very broad understanding of what constitutes a kickback. The Anti-Kickback Statute defines "remuneration" as anything of value in order to induce recommendations and medical referrals. Examples of possible remuneration prohibited under the Anti-Kickback Statute include, but are not limited to:

Direct payments, such as cash

- Speaker fees, excessive compensation for directorships, or other roundabout payments related to services rendered in exchange for referrals
- Stock options or shares
- Free or reduced rent
- Free or reduced advertising space
- Expensive hotel stays or meals
- · Gifts of goods or services

A Comparison of the Anti-Kickback Statute and Stark Law

While both the Anti-Kickback Statute and Stark Law are in place to prevent financial incentive from informing medical referrals, they carry vastly different penalties. The Anti-Kickback Statute is a criminal law that also involves civil penalties. The Stark Law is a civil statute that can carry even higher financial fines, but not the threat of imprisonment.

The Stark Law prohibits medical personnel such as doctors, dentists, and chiropractors from making referrals or accepting referrals from anyone with whom they or a family member have a financial relationship. The Stark Law applies only to Medicare and Medicaid patients. It also does not cover referrals made by mid-level providers, such as physician's assistants.

What Is a Referral Under the Anti-Kickback Statute?

Under Anti-Kickback Statute policy and procedure, referrals, just like remuneration, may take a variety of forms. Some processes defined as referrals under the Anti-Kickback Statute include:

- Recommendations: Recommending that a patient take a certain brand of drug may be in violation of the Anti-Kickback Statute if that physician has accepted payments or remuneration from the manufacturer. In this case, the recommendation of the treatment is motivated by the financial relationship between the physician and pharmaceutical company, and not purely from the patient's best interests. Even if the drug will help the patient in question, the physician could still be found guilty of violating the Anti-Kickback Statute due to their acceptance of payments from the manufacturer in question.
- Authorizations: Even a more passive act such as authorizing that a patient receive care in a certain manner may be in violation of the Anti-Kickback Statute. For instance, if a physician authorizes that a patient receive home health care from a company that has offered him payments in exchange for referrals, the physician would be in violation of the Anti-Kickback Statute. It does not matter that the physician did not recommend the patient seek out home health care in the first place. Authorizing the care when the physician has a financial relationship with the provider is in violation of the statute.
- Certifications: Likewise, certifications when there is financial incentive involved may be in violation of the Anti-Kickback Statute. The United States 7th Circuit Court of Appeals decided in the case of <u>United States v. Patel</u>, 778 F.3d 607, 615 (7th Cir. 2015) that "Upon considering

the Statute's main purposes... we are convinced that Congress intended the Statute to extend to the certification and recertification of patients for government-reimbursed care."

Who Does the Anti-Kickback Statute Apply to?

The federal Anti-Kickback Statute prohibits offering financial payments and incentives to the following groups of people:

- Doctors: Doctors who accept payments in exchange for Medicare or Medicaid patients may be in violation of the Medicare Anti-Kickback Statute.
- Marketing/Advertising/Sales Staff: Attempting to market "off-label" uses for pharmaceuticals
 or proposing incentive schemes to increase referrals is illegal in the medical field.
- Patients: It is illegal to offer any type of financial incentive for the purchase of medical goods or services paid for by government-funded insurance.
- Management: Office administrators or procurement staff for medical offices can violate the Anti-Kickback Statute if they accept discounts on rent or advertising or similar discounts and gifts from interested parties.

What Are the Penalties for Violating the Anti-Kickback Statute?

Violating the Anti-Kickback Statute can carry criminal charges, such as the possibility of up to five years in jail as well as civil penalties of up to \$25,000 per claim. Under the Civil Monetary Penalties Law (CMPL), possible additional penalties of \$10,000 to \$50,000 per violation may be assessed. Additionally, health care providers who are convicted of violating the Anti-Kickback Statute may be excluded from Medicare and Medicaid program coverage in the future. Finally, violating the Anti-Kickback Statute may open up a provider to False Claims Act liability, which is a federal civil statute involving up to treble penalties per false claim made to the government.

What is an Example of the Anti-Kickback Statute?

Anti-Kickback Statute violations have been involved in several recent notable cases prosecuted under both the criminal statute and False Claims Act liability.

- 1. Biogen Inc.: In September 2022, <u>Biogen Inc.</u> of Cambridge, MA settled allegations for \$900 million that they caused the submission of false claims to Medicare and Medicaid by offering kickbacks to incentivize prescriptions of Biogen-manufactured drugs. Some samples of kickbacks offered by the company included speaker honoraria, speaker training fees, consulting fees, and meals for physicians. The whistleblower in the case, a former Biogen employee, pursued the matter for seven years before the case was finally settled. He will receive 29.6% of the overall settlement.
- 2. Little River Healthcare: In June 2022, 15 additional Texas physicians were found to have violated the Stark Law and Anti-Kickback Statute by ordering tests from certain facilities who offered kickbacks in exchange for referrals. This brings the total number prosecuted up to 33. Each of the doctors is alleged to have received payments from nine management service

organizations disguised as investment returns. In exchange, they recommended patient testing be done at a conglomerate of testing services, the ringleader of which was said to be Rockdale Hospital dba Little River Healthcare (Little River).

3. athenahealth, Inc. (Athena): Athena, a developer of electronic health records (EHR) services, paid \$18.25 million to settle kickbacks claims and False Claims Act liability in 2021. The case involved lavish remunerations such as "Bucket List" trips to the Kentucky Derby and the Masters Tournament, luxury meals, hotel stays, and alcohol. The company also paid up to \$3,000 per physician in exchange for sign-ups into its "Lead Generation" program, as well as paying for client conversion from discontinued EHR market competitors. United States Attorney Andrew E. Lelling said, "Across the country, physicians rely on electronic health records software to provide vital patient data. Kickbacks corrupt the market for health care services and risk jeopardizing patient safety. We will aggressively pursue organizations that fail to play by the rules; EHR companies are no exception."

Anti-Kickback Statute Safe Harbors

The Anti-Kickback Statute prohibits many financial exchanges in healthcare, with the exception of federal Anti-Kickback Statute safe harbors. Safe harbors are analyzed by the Office of the Inspector General, and may be updated to fit the situation. Examples of previously authorized <u>safe harbors</u> that are not considered in violation of the Anti-Kickback Statute include:

- Discounts: Government health care programs can take advantage of discounts and rebates as long as they are reported in advance.
- Space rental: Oftentimes physicians may share rented office space, or hospitals may lease
 office space to laboratories, pharmacies, or physicians. As long as rental agreements are
 signed for at least a year and are at fair market value, these kinds of collaborations are
 permitted under the Anti-Kickback Statute.
- Legitimate employment: Safe harbors are in place to protect payments made by healthcare companies to their bona fide employees in exchange for services. Contractors and vendors may also be included in the bona fide employee exemption, assuming that their contracts are set at fair market value and do not include consideration for value or volume of referrals.
- Copay waivers: Healthcare providers may offer copay waivers in the interest of caring for
 patients in need. Doing so does not violate the Anti-Kickback Statute as long as the decision
 is unadvertised and made in good faith, not as a method to attract more Medicare or Medicaidfunded patients.
- Investment interests: Certain investment opportunities may be considered safe harbors by the OIG if they meet publicly available disclosure standards.

Speak to a Healthcare Fraud Whistleblower Attorney

Whether you are a physician, marketing professional, patient, or anyone who works in healthcare, the Anti-Kickback Statute has the capacity to shape your decision-making. If you have information about how this criminal statute has been ignored or violated, you may be able to become a whistleblower.

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Acting as a whistleblower may open the door to receiving financial awards and protections.

The Anti-Kickback Statute is a complicated and comprehensive area of law involving criminal as well as civil penalties. When in doubt, speak with a qualified attorney to understand how to report wrongdoing and protect yourself today.

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