

Compliance Issues for Consulting Fees, Honoraria, Medical Directorships, and Other Types of Remuneration

January 15, 2023

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Doctors need to be very careful about accepting consulting fees, honoraria, and other compensation and awards. Physicians need to know the source of the remuneration and why the fees and other benefits are being offered. Any payments or compensation that are paid in order to entice the doctor to refer patients to the source of the payments (such as a pharmaceutical company), may result in criminal charges that the doctor violated the federal Anti-Kickback Statute (AKS) or other anti-referral laws.

The consequences for violations of the AKS and other anti-referral laws can be quite severe. In addition to being required to return the compensation or awards, the physician may be subject to fines. His/her medical license can be in jeopardy. Criminal charges could be filed which could result in imprisonment.

Our skilled healthcare compliance lawyers review the following questions and concerns with physicians.

- What is the Anti-Kickback Statute?
- What are the statutory provisions of the AKS?
- What types of payments and awards may lead to AKS violations?
- What safe harbors are available for the AKS?
- Do you have any examples of AKS actions against physicians who wrongfully accept medical compensation or benefits?
- What laws other than the federal AKS regulate the acceptance of compensation or benefits?

What is the Anti-Kickback Statute?

The AKS was enacted to ensure that patient care is prioritized over the financial concerns of physicians and the entities the doctors work with – for services and products billed to federal healthcare programs. The law was also enacted to ensure fair competition among healthcare providers and companies.

According to the [US Office of Inspector General](#), there are four things physicians should know about the

- **What transactions are illegal.** The AKS makes it illegal to “*knowingly and willfully offer, pay, solicit or receive anything of value to induce or reward for referrals of Federal health care program business.*” While it may be OK in some businesses to have referral arrangements, referrals for federal healthcare programs such as Medicare and Medicaid are generally illegal unless a “safe harbor” applies. The AKS applies to both the physician who receives the compensation and the entity that

provides the compensation.

Illegal compensation (kickbacks) include the following among other types of compensation:

- - Cash
 - Gifts
 - Vacations
 - “Sham” consulting fees
 - “Sham” medical directorships
 - Bribes
 - Rebates

Sham essentially means that the payments are for services that aren’t offered or for payments that are above the fair market value of those services.

- **The penalties for violating the AKS.** The AKS is a criminal statute. A violation of the AKS is a felony. If convicted, a physician or an entity that offered the compensation can be imprisoned for up to 10 years and ordered to pay up to \$100,000 (or both) for each violation. In addition, the US Department of Justice may file a False Claim Act claim (the FCA is a civil statute) demanding repayment of funds received from the government based on the illegal referral arrangement. In addition, the offender may be penalized up to three times the amount of money the government lost – plus \$11,000 for each improper claim. The doctor may be precluded from submitting any future claims to the federal healthcare programs (for a period of time), such as Medicare and Medicaid, covered by the AKS. A civil complaint may also be brought through the Civil Monetary Penalties Law (CMPL). A physician may also be subject to disciplinary action by the state medical boards which could result in the loss of the physician’s license to practice medicine.
- **The types of programs covered by the AKS.** The AKS generally applies to federal healthcare programs. Another commonly used federal healthcare program, in addition to Medicare and Medicaid, is TRICARE – the medical program for military members and their families. CHAMPVA is another commonly used federal healthcare program.
- **What safe harbors can be used so that the compensation is likely to be considered legal?** The AKS does have safe harbors that do cover many types of referral arrangements. While you do not have to have a safe harbor arrangement, if you do – then the safe harbor can help protect you a physician from AKS legal actions. For example, there are AKS safe harbors for certain employment arrangements and for the leasing of office space or equipment – provided very specific conditions are met. Our skilled healthcare compliance lawyers understand when you may be able to use a safe harbor and the requirements to meet the safe harbor conditions.

Other exceptions may apply which our healthcare lawyers will explain.

What are the statutory provisions of the AKS?

The US Department of Justice (DOJ) states that The Anti-Kickback Act of 1986 is codified in 42 U.S. Code § 1320a–7b.

The prosecution must show the following conditions apply in order to pursue an AKS claim:

- **The prohibited conduct.** The Act prohibits attempted as well as completed “kickbacks.” Kickbacks include *“any money, fees, commission, credit, gift, gratuity, thing of value, or compensation of any kind. The act also provides that the “inclusion of kickback amounts in contract prices is prohibited conduct in itself.”*
- **The purpose of kickback.** The government must show that the *“purpose of the kickback was for improperly obtaining or*

rewarding favorable treatment. It is intended to embrace the full range of government contracting. Prior to 1986, the “kickback” was required to be for the inducement or acknowledgment of a subcontract.”

- **Covered class of “kickback” recipients.** The AKS prohibits “kickbacks” to prime contractors, prime contractor employees, subcontractors, and subcontractor employees. Physicians are generally part of this covered class.
- **The type of contract.** The Act defines kickbacks to include payments under any government contract. Prior to this legislation, the statutes’ applicability was limited to negotiated contracts.

A key part of an AKS prosecution is that the government must show that the defendant/physician *“knowingly and willfully engaged in the prohibited conduct for the imposition of criminal sanctions.”*

OIG ADVISORY OPINION REGARDING POSSIBLE AKS VIOLATIONS. PART ONE.

A pharmaceutical company sought an advisory opinion to determine if payment for travel, lodging, and other costs are an inducement that violates the federal Anti-Kickback Statute.

What types of payments and awards may lead to AKS violations?

Some of the many entities that have been involved with providing kickbacks or illegal compensation in return for the expectation a doctor will refer patients are – hospitals, nursing homes, pharmaceutical companies, medical device manufacturers, dialysis centers, diagnostic centers, and other healthcare companies.

Illegal incentives include:

- Cash payments
- Paying doctors consulting fees or large salaries to serve as medical directors or consultants – where the doctors don’t do any work or very little work of any value or merit.
- Offering the physicians the opportunity to gain a financial interest in an ambulatory surgical center, joint ventures, or other investments – especially if the financial opportunities are based on the value of the referrals.
- Providing office space, support staff, and other benefits at below-market value
- Paying bonuses and salaries based on the volume of referrals
- Buying medical practices for prices above market value
- Paying kickbacks to pharmacies and doctors to get the pharmacies and doctors to use a specific pharmaceutical drug
- Expensive vacations and dinners

The AKS can even apply to marketing and sales representatives and patients.

What safe harbors are available for the AKS?

A physician or other entity requesting payment from Medicare or any other federal healthcare program may be in violation of the AKS: unless there is a safe harbor, when pays for any of the purchase. Covered payments include ordering, or leasing of any service, good, or facility paid by the government – provided the request for payment is based on the improper remuneration.

For example, the space rental safe harbor allows a provider to rent space to a potential referral source. Hospitals frequently lease space to independent physicians, pharmacies, or testing laboratories.

Other safe harbors include:

- Bona fide employment
- Personal services contracts
- Discounts
- Copay and deductible waiver
- Other safe harbors

Generally, the safe harbor arrangements must be in writing, be valid for at least one year, consistent with the fair market value, not tied into the amount of any referrals, and other specific requirements. Our healthcare lawyers will explain whether a safe harbor may be available and the very specific requirements for meeting the requirements.

THE NEW STARK AND AKS LAWS

Physicians and medical practices should review their MSO and referral arrangements to help comply with the new Stark Law and AKS changes.

DO YOU KNOW THE KEY DIFFERENCES BETWEEN THE 4 AMBULATORY SAFE-HARBORS TO THE FEDERAL ANTI-KICKBACK STATUTE (AKS)?

There are four types of ambulatory safe harbors in the federal Anti-Kickback Statute. We explain the key differences between the ambulatory safe harbors to the federal anti-kickback statute (AKS)

Do you have any examples of AKS actions against physicians who wrongfully accept medical compensation or benefits?

A few examples of AKS violations that have also resulted in False Claims Act actions according to the [US DOJ](#) included the following:

- Arriva Medical LLC and its parent, Alere Inc., a mail-order diabetic testing supply company settled a False Claims Act claim based on allegations that Arriva paid *“kickbacks to Medicare beneficiaries by providing them ‘free’ or ‘no cost’ diabetic testing glucometers and by routinely waiving or not making reasonable efforts to collect their copayments for glucometers and diabetic testing supplies.”*
- David McCollum and related laboratories and clinics paid \$140 million and another \$9 million civil consent judgment for paying unlawful kickbacks to providers *“to include their referrals of urine drug tests.”*

Athenahealth Inc., an electronic health records technology vendor paid \$18.25 million to settle allegations *“it invited customers and prospective customers to lavish all-expense-paid sporting, entertainment, and recreational events to generate sales of its EHR product.”*

Other matters relating to kickback violations involved psychiatric hospitals and a substance abuse treatment facility (Oglethorpe Inc.), home health care agencies (BAYADA), hospitals (Akron General Health System, Texas Heart Hospital of the Southwest LLP, and Prime Healthcare Services), pharmaceutical companies (Biogen Inc.), diagnostic testing (Alliance Family of Companies LLC) and medical devices (Merit Medical Systems Inc).

What laws other than the federal AKS regulate the acceptance of compensation or benefits?

California has its own AKS statute. [California, Welfare and Institutions Code; Kickbacks, Bribes or Rebates, Cal. Welf. & Inst. Code § 14107.2](#). Most other states also have some type of AKS statute.

Any type of compensation to induce doctors to make referrals to the health companies that provide the compensation may violate the Anti-Kickback Statute – if the doctor or health company submits bills for payment to a federal healthcare program such as Medicare or Medicaid. Before you accept any payments, vacations, consulting fees, or other forms of remuneration that are based on referring patients, you should speak with an experienced healthcare lawyer. The compensation may lead to

civil and criminal actions that could cost you much more than the amount of the compensation.

Physicians, other health providers, and medical companies should contact Cohen Healthcare Law Group, PC to discuss the laws that govern providing any form of compensation in return for patient referrals. Our experienced healthcare attorneys advise physicians and medical companies about the federal and state Anti-Kickback Statutes.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.