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The Anti-Kickback Statute: A continuing compliance challenge

- » The Anti-Kickback Statute (AKS) applies to all federal healthcare programs.
- » Anything of value may constitute “remuneration” under the AKS.
- » It is a violation to “knowingly and willfully” pay for referrals.
- » Safe harbors are voluntary, not mandatory.
- » Penalties for violation include fines, imprisonment, and exclusion.

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In recent months, the spotlight in the healthcare industry has largely been focused on the Congressional debate regarding healthcare reform, including implementation of federal and state Health Insurance Exchanges and Shared Savings Programs.



Castaldo

Despite these ongoing activities directed toward healthcare reform, attention should not be distracted from ensuring compliance with the federal Anti-Kickback Statute (AKS). The AKS, enacted in 1972 and amended on several subsequent occasions, is a not a new development.

However, it needs to be considered in conjunction with the ever-changing regulatory and enforcement environment.

The Patient Protection and Affordable Care Act (PPACA) authorized hundreds of millions of additional dollars to detecting and preventing fraud, waste, and abuse in federal healthcare programs. In 2013, the Department of Justice (DOJ) Medicare Fraud

Strike Force indicted 89 individuals for their alleged participation in healthcare fraud-related crimes involving over \$220 million, including violations of the AKS.¹ Such enforcement actions serve as reminders that healthcare providers and suppliers face continued exposure under the AKS and other healthcare fraud laws.

In May 2013, *Compliance Today* published “STARK 101: Essential questions for every Stark analysis,” a useful reminder of key issues in evaluating Stark liability. This article will similarly provide an overview of the Anti-Kickback Statute and offer suggestions for compliance officers and others to use in evaluating whether potential violations of the AKS may exist in their organizations.

Does the Anti-Kickback Statute apply?

The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral of items or services that may be paid for, directly or indirectly, by a federal healthcare program.² The following key questions may assist in determining whether an arrangement may implicate the AKS.

Is there a referral of healthcare items or services?

The AKS prohibits offering, paying, soliciting, or receiving remuneration to compensate for past referrals or to induce future referrals. It applies not only to remuneration in return for inducing referrals, but also to the offer or payment of anything of value in return for the purchasing, leasing, and ordering of items and services, and for arranging referrals. As such, any referral of healthcare services or items of business may potentially implicate the AKS and, therefore, should be examined further.

Are the items or services paid for under a federal healthcare program?

The AKS is implicated only where items or services are paid for by a federal healthcare program. For example, it is applicable to Medicare, Medicaid, Veteran's healthcare, and TRICARE®. It does not regulate private third-party payers, such as commercial insurance companies.

The AKS does not provide a comprehensive list of all federal healthcare programs, but rather defines them to be "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program...); or any state healthcare program."³

Is there "remuneration"?

Central to the AKS is the concept of "remuneration." Under the AKS, remuneration is broadly interpreted and constitutes the transfer of anything of value or the flow of benefits, directly or indirectly, overtly or covertly, in cash or in kind, that may influence referrals. Therefore, in considering whether an arrangement violates the remuneration prohibition, consider the following question: Is there an exchange of anything of an

economic value? Any economic benefit may constitute "remuneration" under the AKS. For example, remuneration may include kickbacks, bribes, rebates, rent or lease payments above or below fair market value, waivers of payment due, and anything else of value.

It is important to consider the potential economic benefit, regardless of whether you are the payer or payee: Liability under the AKS applies to both parties to an illegal arrangement.

Is one purpose of an arrangement to induce referrals of healthcare items or services?

A payment is illegal under the AKS where any one purpose of the payment is to induce or influence the flow of referrals. The majority of courts follow the "one purpose" test articulated in the landmark case *United States v. Greber*,⁴ in which the Court of Appeals for the Third Circuit established that payment is illegal "if one purpose of the payment was to induce future referrals."

In addition, the AKS requires that it be established that the parties "knowingly and willfully" engaged in the prohibited conduct. PPACA makes clear that the "knowingly and willfully" standard does not require actual knowledge of, or specific intent to violate the statute.⁵

Is there a statutory exception or regulatory safe harbor that applies?

If the AKS is potentially applicable to an arrangement, the final question to be asked is whether the arrangement is protected by a statutory exception or regulatory safe harbor. Although a practice might technically violate the AKS, it may be specifically protected.

The AKS includes several "statutory exceptions" that are deemed not to be illegal. These include arrangements with employees, discounts, and group purchasing arrangements.⁶ In addition, the United States Department of

Health and Human Services, Office of Inspector General has established a number of regulatory safe harbors which immunize specific types of conduct from prosecution under the AKS.

An arrangement is protected under a safe harbor only if *all* requirements of the safe harbor are satisfied. Some commonly used safe harbors address: investment interests, leasing of space or equipment, personal services and management contracts, sale of practice, employees, discounts, referral services, group purchasing organizations (GPOs), waiver of beneficiary coinsurance and deductible amounts, price reductions offered to health plans, practitioner recruitment, investments in group practices, ambulatory surgical centers, referral agreements for specialty services, and price reductions offered to eligible managed care organizations.⁷

Compliance with a safe harbor is voluntary, not mandatory, and failure to fit within a regulatory safe harbor does not necessarily mean that the arrangement violates the AKS. However, structuring an arrangement to fully comply with a safe harbor will provide protection against civil or criminal prosecution for the arrangement.

Conclusion

Violations of the AKS can have significant consequences. Penalties for violating the AKS include fines, imprisonment, civil monetary penalties, and exclusion from participation in federal healthcare programs. Moreover, PPACA amended the law to provide that

violations of the AKS are *per se* violations of the False Claims Act, thus increasing the civil exposure under the AKS.⁸

In analyzing an arrangement, consider the following:

- ▶ Does the arrangement involve a referral of healthcare items or services?
- ▶ Are the items or services paid for under a federal healthcare program?
- ▶ Is remuneration paid or received, directly or indirectly, as a result of the arrangement?
- ▶ Is one purpose of the arrangement to influence referrals?

If the answers to the above questions are “yes,” ask whether the arrangement falls within a statutory exception or safe harbor. Although the regulatory safe harbors are voluntary, structuring an arrangement to fall within a safe harbor provides assurance that the arrangement does not violate the AKS.

The scope of the AKS is enormously broad, and providers/suppliers must be vigilant in assessing whether business practices potentially violate the Statute. This roadmap provides basic guidelines to evaluate arrangements under the AKS. ©

1. Department of Justice press release: Medicare Fraud Strike Force Charges 89 Individuals for Approximately \$223 Million in False Billing, May 14, 2013. Available at <http://1.usa.gov/1emRrF9>
2. 42 U.S.C. § 1320a-7b(b).
3. 42 U.S.C. § 1320a-7b(f).
4. 760 F.2d 68 (3rd Cir. 1985), cert denied, 474 U.S. 988 (1985)
5. 42 U.S.C. § 1320a-7b(h); Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 Section 6402(f).
6. 42 U.S.C. § 1320a-7b(b)(3).
7. 42 CFR 1001.952.
8. 42 U.S.C. § 1320a-7b(g).

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