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Better Safe (Harbor) Than Sorry: Understanding How the Safe Harbors to the Anti-Kickback Statute Apply to Your Healthcare Practice, Organization or Business Arrangement

In this article, we discuss the Anti-kickback safe harbors and key factors to any Anti-kickback analysis – intent and fair market value. The Anti-Kickback Statute is a federal law that prohibits giving or receiving anything of value in exchange for referrals to federal healthcare programs.[1] The law has broad reach, with application to anyone paying or accepting remuneration directly or indirectly for any service or item covered by a federal healthcare program (such as Medicare, Medicaid or TriCare). This clearly includes healthcare providers, pharmaceutical companies, the medical device industry and companies that own healthcare businesses. However, the law applies to anyone violating the statute, and the prohibition applies to both sides of the transaction – the kickback requester/receiver and the offeror/payer. The law carries significant civil and criminal penalties. Violations may be punishable by fines of up to $100,000; 10 years' imprisonment; and exclusion from the Medicare and Medicaid programs. Moreover, an Anti-Kickback Statue violation can be grounds for liability under the False Claims Act, which carries additional penalties and treble damages that apply *per claim* billed to Medicare or Medicaid, so the fines can be massive.[2] However, the law offers "safe harbor" regulations for certain types of arrangements that could potentially implicate the Anti-Kickback Statute but that the government has determined will not be grounds for anti-kickback liability. Below, we discuss these safe harbors and how they apply to your healthcare practice, organization or business arrangement.

Background – The Anti-Kickback Statute

The Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration of any kind in order to induce, or in exchange for, the referral for the furnishing of, or the arrangement of the furnishing of, any item or service reimbursable under a federal healthcare program.[3] Conduct that is common and acceptable in other industries may be prohibited under the Anti-Kickback Statute, and healthcare providers are often surprised by the type of conduct that is impermissible under the law. For instance, financial incentives for referrals, compensation that is above fair market value for physician speaking engagements or medical directorships, and free or very low rent for medical office space could all be deemed violations of the Anti-Kickback Statute. As discussed above, the penalties for violating the statute are severe and include fines, jail time and exclusion from the Medicare and Medicaid programs.

Safe Harbor Compliance

Providers can shield themselves from anti-kickback liability by complying with the Anti-Kickback Statute safe harbor regulations.[4] These regulations detail certain business arrangements and payment practices that, while potentially implicating the Anti-Kickback Statute, shall not be treated as offenses under the law. Currently, the regulations offer more than 35 safe harbors that cover a wide variety of arrangements, including the following:[5]

- Payments for returns on investment interests
- Rental of space or equipment
- Personal services and management contracts and outcomes-based payment arrangements
- Sale of a medical practice

- Discounts and warranties
- Employment arrangements
- Group purchasing organizations
- Waivers of beneficiary copayments, coinsurance and deductible amounts
- Investments in group practices
- Investments in ambulatory surgery centers
- Value-based healthcare arrangements[6]
- Practitioner recruitment arrangements

Common requirements for the safe harbors include that the arrangement is set out in writing, is signed by the parties involved and has a duration of at least one year. Additionally, compensation must generally be consistent with fair market value and not determined in a manner that takes into account the volume or value of referrals or business that is otherwise generated between the parties. Adhering to these requirements is essential for providers or organizations seeking to take advantage of safe harbor protection.

In order to receive safe harbor protection, providers or organizations must fit squarely within all the requirements of the applicable safe harbor. There is no partial protection for an arrangement that meets some but not all of the conditions of a given safe harbor. On the other hand, compliance with the safe harbors is voluntary, and noncompliance with a safe harbor does not necessarily mean that an arrangement is illegal. When an arrangement does not fit entirely within a safe harbor to the Anti-Kickback Statute, that arrangement would be assessed by courts or regulators based on the totality of the circumstances. In assessing arrangements that do not fit within a safe harbor, two important factors the courts and regulators will look at are intent of the parties and fair market value.

The Importance of Intent

The Anti-Kickback Statute is fundamentally an intent-based law, meaning that liability hinges on the mindset of the parties involved in a healthcare arrangement. Specifically, to be found liable for an anti-kickback violation, defendants must "knowingly" and "willfully" engage in prohibited conduct, with an understanding that their actions are unlawful. The U.S. Court of Appeals for the Second Circuit has recently clarified that in order to act "willfully" under the Anti-Kickback Statute, a defendant "must act knowing that its conduct is in some way unlawful."[7] The court further explained that even if the defendant is unaware of the specific anti-kickback violation, their actions must demonstrate a "bad purpose" or intent to violate the law in order to establish a violation. The court explained the potential confusion that may arise as healthcare providers or other organizations seek to comply in good faith with the Anti-Kickback Statute safe harbors but struggle to do so:

> [E]ven a well-counseled defendant who has taken every effort to comply with the [Anti-Kickback Statute] and all other relevant laws could still find herself accidentally in violation of the statute.... **[D]efining "willfully" to require that a defendant act knowing that her conduct is in some way unlawful avoids sweeping in such innocent conduct.**[8]

Therefore, even if a defendant fails to fit within a safe harbor, that defendant must act "willfully" and with knowledge that their conduct was unlawful in order to be found liable for violating the Anti-Kickback Statute. This focus on intent ensures that the law targets deliberate violations while excluding inadvertent or innocent actions from liability. However, the determination of intent can be complex, as it involves evaluating whether the parties acted with the requisite knowledge of wrongdoing at the time of the action.

Fair Market Value

In addition to the intent requirement, to establish a violation of the Anti-Kickback Statute, there must also be remuneration. The term "remuneration" is defined, in part, as "transfers of items or services for free or for other than fair market value."[9] Notably, "fair market value" is not defined for purposes of the Anti-Kickback Statute; however, courts have interpreted the

term in this context to mean the value negotiated between a buyer and a seller in an arm's-length transaction.[10] Therefore, if a transaction or another business arrangement takes place at fair market value, the parties to that transaction may have a defense against claims for violating the Anti-Kickback Statute, even if such transaction or arrangement does not fit squarely within all requirements of an anti-kickback safe harbor.

Conclusion

The Anti-Kickback Statute is a broad and complex federal law that applies to the healthcare, pharmaceutical and medical device industries and to other healthcare-related business entities. Compliance with the safe harbors to the Anti-Kickback Statute provides protection against liability for violating the law. For those arrangements that do not fit within the safe harbors, a good faith attempt to obey the law and the exchange at fair market value may be defenses to an alleged violation of the statute.

Day Pitney's Healthcare attorneys regularly counsel clients on the safe harbor requirements and compliance with the Anti-Kickback Statute, and are available to assist with questions about whether your business or a particular arrangement is compliant with the Anti-Kickback Statute, the safe harbors, or other state or federal healthcare laws.

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[1]42 U.S.C. 1320a-7b(b).
[2]31 U.S.C. 3729-3733. For instance, settlements and judgments under the False Claims Act exceeded $2.68 billion in the fiscal year that ended on September 30, 2023. See https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023.
[3]42 U.S.C. 1320a-7b(b).
[4]42 CFR § 1001.952.
[5]A complete list of the Anti-Kickback Statute safe harbors can be found at 42 CFR § 1001.952.
[6]42 CFR § 1001.952(ee)-(hh).
[7]U.S. ex rel. Hart v. McKesson Corp., 96 F.4th 145 (2d Cir. 2024), cert. denied sub nom. U.S. ex rel. Hart v. McKesson Corp., No. 23-1293, 2024 WL 4426646 (U.S. Oct. 7, 2024).
[8]Id.at 155.
[9]42 USC 1320a-7a(i)(6).
[10]See, e.g., U.S. ex rel. Jamison v. McKesson Corp., 900 F. Supp. 2d 683, 699-700 (N.D. Miss. 2012).

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