

The Anti-Kickback Statute and Civil Monetary Penalties Law: Back to Basics

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Agenda

- Statutes and Regulations
- Anti-Kickback Basics
 - Intent Test
 - Safe Harbors
- AKS Regulatory Developments
 - Modified Safe Harbors
- Civil Monetary Penalties/Beneficiary Inducement
- Key Takeaways



Anti-Kickback Statute (AKS) - Overview

The Anti-Kickback Statute makes it a criminal offense for any person to:



- AKS is designed to prevent certain payments in connection with the furnishing of services reimbursable under the Medicare and Medicaid programs as well as other governmental health care initiatives
- This means that an arrangement may be covered if the federal program is secondary to private insurance. This is an important nuance in that many Medicare-eligible individuals are covered by an employer's insurance plan, which is almost always primary to Medicare.

Core Elements

Anti-Kickback Statute – Who?

- The AKS is a criminal statute that applies to all individuals and entities
- Not limited to arrangements involving physicians or their immediate family
- This means that the AKS implicates arrangements involving a variety of players in the industry, including:
 - Physicians, mid-levels and other practitioners
 - Hospitals and health care facilities
 - Drug manufacturers and pharmaceutical companies
 - Third party payors
 - Health IT vendors and suppliers

Anti-Kickback Statute - Referrals

The Anti-Kickback Statute makes it a criminal offense for any person to:



- The AKS covers any items or services that may be payable (in whole or in part) by government health care programs
 - Includes Medicare and Medicaid, but also other government health care programs like TriCare
 - Differs from Stark Law in that there is no expressly limited list of covered services and items

Anti-Kickback Statute - Remuneration

The Anti-Kickback Statute makes it a criminal offense for any person to:



- Remuneration under the AKS is very broad and encompasses nearly anything of value.
- Remuneration can take many forms – free services, discounted items, professional courtesies, infrastructure support, excess compensation, etc.

Anti-Kickback Statute - Intent

The Anti-Kickback Statute makes it a criminal offense for any person to:



- Unlike Stark Law, AKS is an intent-based statute
- This means to be convicted of an AKS violation, the person must have the requisite intent under the law
- This means that an arrangement may be covered if the federal program is secondary to private insurance. This is an important nuance in that many Medicare-eligible individuals are covered by an employer's insurance plan, which is almost always primary to Medicare.

Anti-Kickback Statute – Intent (cont.)

- For those new to the health care industry, the AKS may cause frustration because it prohibits conduct that is generally acceptable in other industries - rewarding those who refer or generate business to or for you.
- However, the OIG believes the AKS is necessary because it believes that arrangements where the parties intend to induce or reward referrals or other business can lead to:
 - Overutilization
 - Increased program costs
 - Corruption of medical decision making
 - Patient steering
 - Unfair competition

Intent Test

- **Greber or “One Purpose” Test**
 - If one purpose of the arrangement or deal is to induce referrals, the Anti-Kickback Statute is violated. *U.S. v. Greber*, 760 F.2d 69 (3rd Cir. 1985)
- **The ACA Test**
 - There is no requirement of actual knowledge of or specific intent to commit a violation of the Anti-Kickback Statute

Be careful with communications to avoid risk that illegal intent could be misconstrued!

Anti-Kickback Statute - Penalties

- Violation is a felony, punishable by fines up to \$25,000 and up to 5 years imprisonment. Violation can also result in imposition of civil monetary penalties and/or exclusion from such government health care programs
- Safeguards:
 - It is imperative that any arrangement not be pursued for the purpose to induce referrals
 - It is always possible that a trier of fact, such as a judge or jury, could misconstrue the facts and find differently
 - Intent and structure of an arrangement are vital!
 - Whenever possible, structure arrangements to meet all elements of an enumerated safe harbor



Emphasis on Individual Liability

- DOJ is still focused on individual liability for AKS violations
 - 2015: DOJ announces Yates memo highlighting individual accountability for corporate wrongdoing
 - DOJ offers cooperation credit for corporations that cooperate with DOJ to identify individuals involved in corporate wrongdoing
- AKS settlements and cases demonstrate heightened emphasis on individuals in enforcement
 - Executives bear hefty personal financial penalties
 - Potential jail time, particularly for schemes

Mechanisms of Enforcement

- Criminal Prosecution (organizations and individuals) – particularly for AKS schemes
- FCA suits (government initiated or *qui tam*)
- OIG Provider Self-Disclosure Protocol (SDP)
 - Increasing number of disclosures through SDP
 - Appropriate for reporting AKS violations and dual Stark and AKS violations
 - Suspends 60-day refund obligation
 - Includes settlement publications
 - Guidance recognizes standard 1.5 multiplier, reaffirms six-year lookback period, and focuses on damages based on remuneration approach

Safe Harbors and AKS Special Topics

Compliance/Safe Harbors

- OIG has issued safe harbor regulations to protect certain arrangements
- An arrangement must meet each element of a safe harbor in order to be safe from investigation or prosecution as a criminal offense or as a basis for exclusion from participating in the government health care programs
- However, an arrangement does not necessarily violate the Anti-Kickback Statute if it does not satisfy a safe harbor. Such an arrangement is judged under the language of the Anti-Kickback Statute itself

Safe Harbors

- Investment Interests (large entity, small entity, underserved area)
- Space Rental
- Equipment Rental
- Personal Services and Management Contracts and Outcomes-Based Payments
- Sale of Practice
- Practitioner Recruitment
- Waiver of Coinsurance/ Deductibles
- Price Reductions for Health Plans/Managed Care Organizations
- Referral Services
- Warranties
- CMS-Sponsored Models
- Discounts
- Employees
- Group Purchasing Organizations
- Ambulatory Surgical Centers
- Group Practices
- Obstetrical Malpractice and Insurance Subsidies
- Referral Agreements for Specialty Services
- Ambulance Replenishing
- Health Centers
- Electronic Prescribing/Health Records
- Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency
- ACO Beneficiary Incentive Program
- Value-Based Arrangements
- Telehealth for In-Home Dialysis

Proof of Violation

- Ultimately, the government must prove a violation of the AKS based on the totality of facts and circumstances, including the intent of the parties.
 - For example, if one party emailed another party an offer to compensate them for increased referrals, the government can use that fact to show the existence of prohibited intent in violation of the AKS.
 - Even in the absence of a direct statement of intent, the government can use the existence of other circumstances (increased referrals following a specific payment) to prove a violation.
- Please note that the Government need not prove actual patient harm or financial loss to federal programs to show that someone violated the AKS.
- Compliance with a promulgated safe harbor typically eliminates risk of non-compliance, but beware of contractual joint ventures.

Anti-Kickback Statute – Special Topics

- The OIG has expressed concern with certain carve out arrangements and thinks that payments related to private pay patients can constitute prohibited remuneration in exchange for federal program patient referrals.
- The government has also used other statutes (e.g. the Travel Act) to prosecute arrangements that may not violate the AKS (because federal program patients are not involved) but do violate state laws (e.g. commercial bribery laws). See Forest Park
- Contractual Joint Ventures
 - OIG and DOJ look with scrutiny on certain contractual joint venture arrangements between potential referral sources
 - Particularly relevant for management and support services arrangements
 - Entities should follow guardrails outlined in OIG's Special Advisory Bulletin on contractual JVs when exploring these types of transactions

Regulatory and Case Law Developments



Safe Harbor Modifications

- **Personal Services and Management Contracts Safe Harbor (42 CFR 1001.952[d])**
 - "Methodology" for determining compensation set in advance
 - Eliminates requirement that part-time arrangements must specify the exact schedule, precise length and the exact charge for those intervals
- **"Outcomes-Based Payment" Arrangements within Personal Services and Management Contracts Safe Harbor**
- **Local Transportation Safe Harbor (42 CFR 1001.952[bb])**
 - Extending distance for rural areas from 50 to 75 miles
 - Discharge to residence after inpatient stay/observation – no mileage limit
- **Warranty Safe Harbor (42 CFR 1001.952[g])**
 - Permits bundled items/services warranties – reimburse costs only!
 - Alters reporting requirements to accommodate outcome-based warranties

Safe Harbor Updates

- **Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes and Efficiency (42 CFR 1001.952[hh])**
 - Help patients participate and engage in their care
 - In-kind preventive items or services
 - \$591/year
 - Only available to "Value-Based Enterprises"
- **CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives (42 CFR 1001.952[ii])**
 - An alternative to the fraud and abuse waiver process
 - "Patients over Paperwork" initiative
 - CMS may impose additional requirements for particular models
- **Donations of Cybersecurity Technology (42 CFR 1001.952[jj])**
 - Excludes multifunctional hardware and monetary support
 - Requirements track corollary Stark Exception
- **Value Based Delivery Safe Harbors**

Value-Based Delivery Safe Harbors

- **Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency (42 CFR 1001.952[ee])**
 - Remuneration must be in-kind
 - Recipient pays at least 15% of the offeror's costs
- **Value-Based Arrangements with Substantial Downside Financial Risk (42 CFR 1001.952[ff])**
 - VBE must assume substantial downside financial risk (one methodology = 20% of any loss)
- **Value-Based Arrangements with Full Financial Risk (42 CFR 1001.952[gg])**
 - Full financial risk is determined on a prospective basis

Note that pharmaceutical manufacturers; DMEPOS manufacturers, distributors and suppliers; and laboratories are permitted to participate but **not** afforded Safe Harbor protection.

U.S. v. Anderson: Background

- **The Defendants:** Physicians (Drs. Robert and Ronald LaHue); Hospital Executives (CEO, COO, VP); and Attorneys who represented the Hospital (alleged to be a part of the conspiracy)
- The LaHues were paid \$75,000 each per year to be Co-Directors of Gerontology
 - After entering into this arrangement, the LaHues' referrals to the Hospital increased dramatically
 - Only minimal services were provided under this contract
 - Trial testimony showed that the LaHues only consulted at Baptist approximately two hours per week – giving them an effective compensation of \$1,442 per hour

U.S. v. Anderson: Outcomes

The defendants were found to have violated the Anti-Kickback Statute:

- Dr. Robert LaHue was sentenced to 70 months in prison
- Dr. Donald LaHue was sentenced to 51 months in prison
- The Hospital CEO was sentenced to 51 months in prison

Civil Monetary Penalties Law (CMPL)

Civil Monetary Penalties Law

- Substantial civil money penalties may be imposed if an entity:
 - knowingly presents a false or fraudulent claim for services;
 - knowingly gives false or misleading information reasonably expected to influence the decision to discharge a patient;
 - offers/gives remuneration to any beneficiary likely to influence the receipt of reimbursable items or services;
 - arranges for reimbursable services with an entity which is excluded from participation from a federal health care program;
 - knowingly or willfully solicits or receives remuneration for a referral of a federal health care program beneficiary; or
 - uses a payment intended for a federal health care program beneficiary for another use.
- OIG is authorized to seek different amounts of CMPs based on the type of violation at issue.

Civil Monetary Penalties Law

- 42 U.S.C. 1320a-7a(b) – Payments to Induce Reduction or Limitation of Services
 - Hospital may not knowingly make a payment, directly or indirectly, to a physician as an inducement to *reduce or limit medically necessary services* provided with respect to individuals who—
 - are entitled to benefits under Medicare part A or B or to medical assistance under a State plan, and
 - are under the direct care of the physician.

Civil Monetary Penalties Law

- Prohibition on Beneficiary Inducements
 - Incentives of nominal value are permitted
 - Other exceptions:
 - Properly disclosed differentials in coinsurance/deductibles
 - Items or services that promote the delivery of preventive care
 - Reductions in copayments for certain hospital outpatient services
 - Remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs
 - Transfer of coupons/rebates/retailer rewards that are offered on equal terms available to the general public and are not tied to the provision of other items or services
 - Transfer of items or services that are based on financial need, are not part of an advertisement, and are not tied to the provision of other Medicare or Medicaid items or services
 - Waiver of copayments for the first fill of Part D drugs

Key Takeaways

Impact to Health Care Providers

- CMS and OIG are enforcing Stark and Anti-Kickback laws with continued vigor
- All agreements made with physicians' past, present and future must be scrutinized for compliance with these laws
- Failure to ensure compliance and make appropriate corrections in a prompt manner has severe consequences



Core Differences – Stark vs. AKS

ANTI-KICKBACK (AKS)

APPLIES TO ALL HEALTH CARE
COMPENSATION ARRANGEMENTS

INTENT BASED

SHOULD MEET AN AKS SAFE HARBOR

STARK LAW

ONLY APPLIES TO PHYSICIAN
COMPENSATION ARRANGEMENTS

STRICT LIABILITY

MUST MEET A STARK EXCEPTION

Compliance Strategies

- Understand the risks of a proposed arrangement.
- Implement and follow a compliance program that includes standards and procedures for arrangements with other health care providers and suppliers.
- Attempt to fit arrangements within available safe harbor.
- For arrangements outside of a safe harbor, answer the following questions regarding the proposed arrangement to assess the specific risk that the government would consider an activity as creating an actionable level of fraud and abuse risk: (i) is there any improper intent; and (ii) does the arrangement (a) increase the risk of overutilization, (b) result in increased program costs, (c) negatively impact patient freedom of choice, or (d) create an unfair competitive advantage for the participants? If the answer is “no” to each of the above questions, then the arrangement may not create significant risk of liability.

Questions?

For more information on these topics visit
[hallrender.com](https://www.hallrender.com).



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