

The Anti-Kickback Statute and Civil Monetary Penalties Law: Back to Basics 2.0

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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 \$100,000 and up to 10 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 based on the specific facts and circumstances at issue and intent of the parties.

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

Safe Harbors – Investment Interests

- Protects investments made in large publicly traded companies that do not directly influence referrals or generate business based on investor status.
- Investments in smaller entities are subject to specific limitations on ownership percentages held by referring providers.
- Entities that serve medically underserved populations are subject to specific regulations on dollar volume.
- Advisory Opinion 21-18
 - Under the Proposed Arrangement, a contract therapy services company, would enter into a joint venture with a company that directly or indirectly owns long-term care facilities, and the joint venture entity would provide contract therapy services to rehabilitation programs in such facilities.
 - The Proposed Arrangement would implicate the Federal anti-kickback statute because it would involve a joint venture for the furnishing of items and services that are reimbursable by a Federal health care program between a party in a position to refer, arrange for, or recommend those items and services and a party that currently provides those covered items or services.
 - OIG has longstanding and continuing concerns about these types of joint venture arrangements, especially where all or most of the business from the joint venture is derived from one of the joint venture investors.

Safe Harbors – Equipment and Space Rentals

- Space Rental: Payments made by a lessee to a lessor for use of premises are not considered “remuneration” if the lease agreement is written and signed by both parties, specifies the premises covered and schedule of use (if applicable), is not for a term less than 1 year, the aggregate rental charge is set in advance, consistent with fair market value, and does not take into account the volume or value of any referrals or generated business for federal reimbursement, and the aggregate space rented is reasonably necessary to accomplish the business purpose of the rental.
 - Example: A lab rental space agreement in which a provider receives payment in exchange for referral of specimens to the lab would likely violate the AKS and would not fit within its Space Rental exception because it takes into account the volume of referrals in which federal dollars would be paid.
- Equipment Rental: Similar to Space Rental, but for the lease of equipment.
 - Example: An agreement between a medical practice and a vendor in which the medical practice is offered free or discounted equipment in exchange for patient referrals would likely violate the AKS and would not fit within its Equipment Rental exception because it takes into account the volume of referrals in which federal dollars would be paid.

Safe Harbors – Personal Services and Management Contracts and Outcomes-Based Payment Arrangements

- Similar to the requirements for Space and Equipment Rentals, but protects payments made by a principal to an agent as compensation for the agent's services and arrangements for payment that are based on legitimate outcome measures.
- An agent here would not include a bona fide employee of the principal but would include independent contractors or individuals hired to serve as medical directors.
- Example: An arrangement where a hospital compensates a group of PCPs to achieve specific quality metrics related to diabetes management by paying them a bonus per patient for reaching target A1C levels is likely protected as long as the bonus amount is tied to patient health outcomes and not the volume of referrals.

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 Developments



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
 - 2025: \$605/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.

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.



Prohibition on Beneficiary Inducements

- Improper Beneficiary Inducements:
 - Offering free or discounted items or services to patients (e.g., free exams, gifts, etc.)
 - Regularly waiving copayments, deductibles, or coinsurance without assessing financial need.
 - Providing free transportation (beyond limited exceptions) to incentivize patients to use a specific provide
 - Exceeding the nominal value

Prohibition on Beneficiary Inducements

- Examples of improper beneficiary inducement:
 - An imaging center offers \$100 gift cards to Medicare beneficiaries who schedule an MRI or CT scan and \$50 referral bonuses to existing patients who bring in new Medicare patients.
 - XYZ Pharmacy offers free transportation to Medicare and Medicaid beneficiaries but only if they fill their prescriptions at XYZ.
- Example of Compliant Beneficiary Incentive:
 - **OIG Advisory Opinion 09-11: Free Blood Pressure Screenings**
 - Free screenings did **not** improperly induce patients to seek reimbursable services.
 - **Key Factors:**
 - No requirement to use hospital or affiliated providers.
 - No referrals to specific practitioners.
 - No special discounts on follow-up care.
 - Patients advised to see their own healthcare provider if needed.

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
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