

# Practice Management Series, Part 3

Stark Law and Anti-Kickback Statute

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# Agenda

- **What are the Stark Law and AKS?**
- **Stark Law Overview & Key Definitions**
- **Stark Law Analysis & Exceptions**
- **Anti-Kickback Statute Overview**
- **Examples**
- **Updates for Covid-19**
- **Submitted questions**

# Purpose of Stark and AKS

Kickbacks in health care can lead to:

- Overutilization
- Increased program costs
- Corruption of medical decision making
- Patient steering
- Unfair competition

# Stark vs AKS

## STARK LAW

- Stark enacted in 1989 by Congress
- Prohibits referrals by physicians to an entity that the physician has a financial relationship with
- Prohibits billing for improper referrals
- Civil enforcement only (strict liability)
- Medicare and Medicaid only

## AKS

- AKS enacted by Congress in 1972
- Prohibits offering, receiving, or soliciting remuneration in exchange for referrals
- Claims submitted in violation can be pursued under the False Claims Act
- Criminal and Civil Enforcement
- Any federal healthcare program

# Stark Law Overview

- Prohibits referrals for designated health services paid for by Medicare to any entity that has a financial relationship.
- Strict Liability

# Stark Analysis

- Does this arrangement involve a referral of a Medicare or Medicaid patient by a physician or an immediate family member of a physician?
- Is the referral for a “designated health service”?
- Is there a financial relationship of any kind between the referring physician or a family member and the entity to which the referral is being made?

# “Designated Health Service”

- 42 CFR § 411.351
- *Designated health services (DHS)* means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:
  - (1)
    - (i) Clinical laboratory services.
    - (ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services.
    - (iii) Radiology and certain other imaging services.
    - (iv) Radiation therapy services and supplies.
    - (v) Durable medical equipment and supplies.
    - (vi) Parenteral and enteral nutrients, equipment, and supplies.
    - (vii) Prosthetics, orthotics, and prosthetic devices and supplies.
    - (viii) Home health services.
    - (ix) Outpatient prescription drugs.
    - (x) Inpatient and outpatient hospital services.

# “Financial Relationship”

- Compensation - any remuneration (payment or benefit, directly or indirectly) between physician (or immediate family member) and an entity
- Ownership/Investment – including equity, stock, options, partnerships, loans, etc



# “Referral”

- Request (written, oral, electronic, other) by a physician for DHS
- Ordering of DHS
- Certifying the need for any DHS
- DHS ordered by a consulting physician is a referral by the physician who ordered the consult
  - (does not include personally performed services of consulting physician)

# “Entity”

- An entity either furnishes DHS or bills for DHS
  - Person or organization that performs DHS service billed to Medicare, or
  - The person or organization that bills for the DHS service

# Recap

- If a PHYSICIAN (or immediate family member) has a direct or indirect FINACIAL RELATIONSHIP with an ENTITY, unless FINANCIAL RELATIONSHIP meets the requirements of an EXCEPTION
  - The physician may not refer any DHS to the entity
  - The entity may not bill for any DHS service referred by the physician
  - No Medicare payments may be made for the DHS referred by the physician, and;
  - The entity must refund all money collected for DHS referred by the physician

# Liability

- Strict Liability
- Civil penalties only
- Up to \$15,000 per violation
- Up to \$100,000 for schemes
- Exclusion

# Stark Law Exceptions

- In-Office Ancillary Services
- Rental of Office Space/Rental of Equipment
- Personal Service Agreements
- Fair Market Compensation
- Non-Monetary

# In-Office Ancillary Services

- Supervision
- Site of Service
- Billing Method
- Group Practice

# In-Office Ancillary Services

- Group Practice
- 1) The practice must be organized as a single legal entity formed for the purpose of operating as a physician practice;
- (2) The practice must have at least two physicians who are owners or employees of the practice and who provide patient care services;
- (3) Each physician owner or employee must furnish to patients of the practice using the facilities, equipment, and staff of the practice, substantially the full range of patient care services that physician regularly renders to patients, regardless of where the patients are treated;
- (4) At least 75 percent of the total patient care services furnished by physician owners and employees to all patients treated by the physicians must be furnished to patients of the practice;
- (5) Physician owners or employees must personally conduct at least 75 percent of the practice's total physician-patient encounters;
- (6) The practice must be a unified business with centralized decision-making and consolidated billing, accounting and financial reporting;
- (7) Overhead expenses should be distributed according to a method that does not take into account the amount of income a physician generates;
- (8) No physician owners or employees receive compensation based on volume or value of referrals by that physician. However, a physician may receive a share of overall group profits or productivity bonus based on personally performed services

# Anti-Kickback Statute Overview

- Unlawful to
  - Knowingly and willfully
  - Offer, give, solicit, or receive
  - Any remuneration
  - In return for
    - Referring for any item or service reimbursable by Federal health care programs or
    - Purchasing, leasing, ordering or arranging for any good, facility or service reimbursable by Federal health care programs.



# AKS Penalties

- Criminal
  - Fined not more than \$100,000
  - Imprisoned not more than 10 years
- Civil
  - OIG Civil penalties up to \$100,000
  - Up to 3x the amount of improper remuneration
  - Exclusion for federal programs

# “Remuneration”

- For purposes of the AKS remuneration includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly.
  - From OIG Advisory Opinion
  - NO de-minimis exception

# Knowing and Willful

- “Person need not have actual knowledge of this section or specific intent to commit a violation in this section”
- One Purpose Test

# Examples

- US v Carroll – free pumps given with the sale of enteral nutrients and supplies.
- Sanofi – Free knee injections from drug manufacturer
  - \$109 million
  - Prison time
- Biodiagnostics Lab

# AKS Safeharbors

- Legislatively created Safe harbors (CFR § 1001.952)
- Satisfy all elements
- Voluntary

# Joint Ventures

- Risk area
- Must organize under exceptions and safe harbors

# Updates

- Covid-19 Waivers
- Stark waivers vs AKS Policy Statement

# Thank you!

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