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Fraud, Waste, and Abuse Education for Physician Arrangements

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Your Speaker

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Topics Covered

- The Stark Law
- The Anti-kickback Statute
- The False Claims Act
- Beneficiary Inducement Statute

The Stark Law

The Stark Law

- **The Physician Self-Referral Law, commonly known as the "Stark Law" after its principal architect, Congressman Pete Stark, has been in effect for three decades. Enacted in 1989, to be effective as of January 1, 1992, the Stark Law has been amended by Congress several times.**

- **The Stark Law is a strict liability law**
  - Non-compliance does NOT require intent to violate the law or intent to engage in non-compliant acts
  - Non-compliance is a factual question and highly dependent on the type of arrangement

- **The Stark Law is enforced by CMS and regulates financial relationships between physicians and certain entities to which the physician refers Medicare beneficiaries for "designated health services" (DHS)**
  - The Stark Law has had a significant impact on provider-physician financial relationships

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Key Elements of the Stark Law

The Stark Law prohibits…

A physician

from making a referral

of a Medicare patient

to an entity that furnishes "designated health services"

if the physician has a financial relationship with the entity

unless an exception applies.

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The Operational Impact of the Stark Law

If a DHS entity and a physician have any type of financial relationship (Ownership or compensation), this impacts the physician's referrals to the DHS entity

The Stark Law also…

Prohibits the DHS entity from billing payors for the referral unless an exception applies to the financial relationship

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Three Step Analysis

Is there a referral from a physician for Designated Health Service ("DHS")?

Does the physician (or an immediate family member) have a financial relationship with the entity providing the DHS?

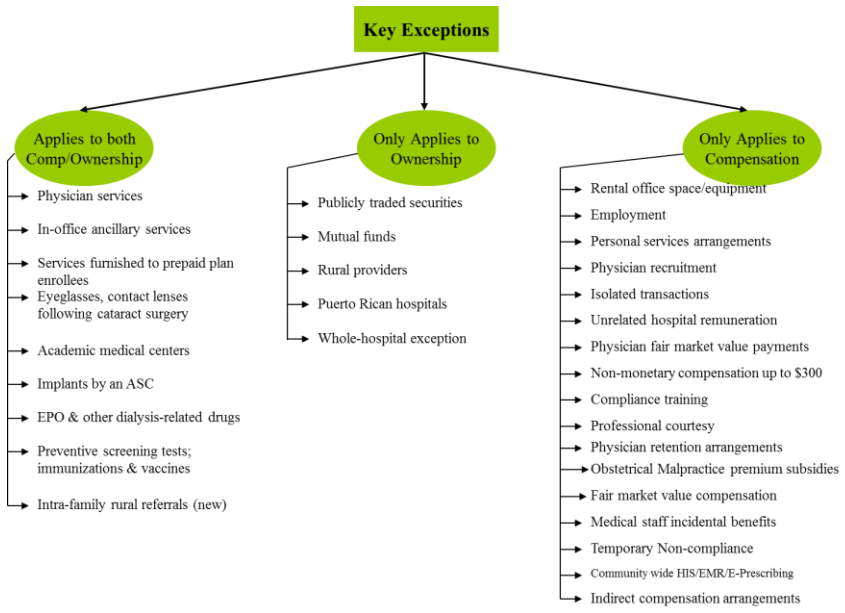
Does the financial relationship satisfy an exception?

The Stark Law—Exceptions & Enforcement

- Exceptions: Over 40 structured exceptions based on the type of financial arrangement
  - An "exception" MUST be completely met in order for the referral to occur AND the DHS entity to bill Medicare for referrals
  - Many exceptions require a written contract and fair market value
  - Employment exception does not require a written contract but does require compensation be fair market value and bonuses be based on personal productivity
  - Fair market value is an objective assessment
  - The statute prohibits billing any payor, but CMS only enforces the Stark Law currently against Medicare claims
  - Many states have "mini" Stark Laws that apply to Medicaid or all payors

- Billing as the result of a "tainted referral" renders the payment an overpayment which must be returned to Medicare or self-disclosed to the federal government. Failure to promptly refund a known overpayment raises additional compliance concerns.

- The Stark Law can be the basis for a False Claims Act complaint and prosecution



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New(er) Exceptions

- On December 2, 2020, CMS published a final rule (largely effective January 19, 2021) which modified existing Stark Law exceptions and added new exceptions.
- The new exceptions aim to advance the transition to a value-based healthcare delivery and payment system that improves the coordination of care among physicians and other healthcare providers, across different healthcare settings, in both the federal and commercial sectors.

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A Note on Exceptions

- All exceptions have detailed criteria.
- All criteria in an exception must be met in order to use an exception.
- If any criterion is not met, then arrangement does not meet the exception. If an arrangement does not satisfy an exception, then there is a Stark Law violation.
- Note that some exceptions have special definitions within the exception

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The Stark Law—Key Terms

- Physician: includes immediate family members (e.g., spouse, children)
  - All immediate family members of a physician must have Stark compliant arrangements with health care providers
- Designated Health Services: a detailed list of items and services that fall under the scope of the Stark Law
  - All inpatient and outpatient hospital services are Designated Health Services
  - Also: radiology, lab, PT/OT, DME, outpatient drugs, home health and other services
  - Physician services are not DHS but physician-physician financial relationships can implicate Stark if the physician or the office provide any Designated Health Services
- Financial Relationship: any ownership or investment interest OR compensation arrangement with the DHS entity receiving the referrals

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Stark – Inducements to Referring Physicians

- Alleged Facts: Flower Mound Hospital is partially owned by physician investors. As older physicians retired, the hospital would repurchase the shares owned by these physicians and then resell those shares to new physicians. The individual physicians that were offered shares and the number of shares offered to each physician was determined on how busy each physician was and how many patients he or she saw at the hospital.
- Allegation: The hospital took referrals into consideration when determining who could invest and at what level, and conditioned ownership decisions on the owners making or influencing referrals to the Hospital
- Verdict: The allegations were settled for a total of $18.2 million. The lawsuit stemmed from a qui tam (whistleblower) action and the relators received 17% of the settlement and the hospital was placed under a Corporate Integrity Agreement

https://www.justice.gov/opa/press-release/file/1452851/download

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The Anti-kickback Statute

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The Anti-kickback Statute

- Enacted in 1971
- Prohibits anyone from purposefully offering, soliciting, or receiving anything of value to induce (or reward) referrals for items or services payable by any Federal health care program (Medicare, Medicaid, Tricare)
- A referral source is broadly construed and does not need to be another health care provider. A referral source could be:
  - Vendors
  - Drug companies
  - Patients (also known as beneficiary inducement)

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The Anti-kickback Statute

- "Remuneration" includes anything of value
- AKS is a criminal law (fines & imprisonment), but also allows for the imposition of civil monetary penalties and exclusion
- The government must prove intent, but numerous situations could have the "appearance" of intent
  - A person need not have actual knowledge or specific intent to violate the AKS
  - 11th Circuit US vs. Shah in 2020 established intent is to accept the money, and the motivation is irrelevant.
- AKS offers statutory exceptions and "safe harbors" to structure an arrangement in order to avoid the appearance of a kickback
- The OIG offers "Advisory Opinions" on arrangements at the request of the parties
- Like the Stark Law, the AKS can be the basis for a False Claims Act complaint

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AKS Safe Harbors

- **Investment Interests**
- **Space Rental**
- **Equipment Rental**
- **Personal Services and Management Contracts**
- **Sale of Practice**
- **Referral Services**
- **Warranties**
- **Discounts**
- **Employees**
- **GPOs**
- **Waiver of Beneficiary Coinsurance and Deductible Amounts**
- **Increased Coverage, Reduced Cost-Sharing Amounts or Reduced Premium Amounts Offered by Health Plans**
- **E-prescribing**
- **EHRs**
- **Price Reductions Offered to Health Plans**
- **Practitioner Recruitment**
- **Obstetrical Malpractice Insurance Subsidies**
- **Investments in Group Practices**
- **Cooperative Hospital Service Organizations**
- **ASCs**
- **Referral Agreements for Specialty Services**
- **Price Reductions Offered to Eligible Managed Care Organizations**
- **Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations**
- **Ambulance replenishing**
- **Health Centers**
- **Value Based Enterprises for Patient Engagement**
- **Patient Transportation Assistance**
- **Telehealth**

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New Safe Harbors

- On December 2, 2020, the OIG published a final rule (effective January 19, 2021) which modified existing AKS safe harbors and added new safe harbors.
- Like the new Stark Law exceptions, the new AKS safe harbors aim to advance the transition to a value-based healthcare delivery and payment system that improves the coordination of care among physicians and other healthcare providers, across different healthcare settings, in both the federal and commercial sectors.
- If you believe that an arrangement may implicate AKS concerns, you should always seek legal advice.

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AKS & Stark Law—A Comparison

Stark Law

- **Civil only**
- **Medicare only**
- **Strict liability**
- **Must be a physician and an entity in the mix**
- **Exceptions**
- **CMS Advisory Opinions**

AKS

- **Criminal/Civil**
- **Any Federal Healthcare Program**
- **Requires proof of improper intent**
- **Applies to any referral source**
- **Safe Harbors**
- **OIG Advisory Opinions**

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The AKS—Dr. Thomas Witten

- Alleged Facts: Whitten received kickbacks of $100k from pharmaceutical company Insys in return for prescribing its painkiller Subsys without any medical indication; Subsys is only approved for use with cancer patients. Whitten also conspired with several pain management clinics to dispense controlled substances under Whitten's DEA registration number.
- Allegations: that a pain specialist (Whitten) conspired to violate the AKS by prescribing powerful painkillers in exchanges for kickbacks and conspiracy to distribute Schedule IV controlled substances.
- Plea: in December 2021, Whitten plead guilty to the charges and was sentenced to 57 months imprisonment and pay restitution totaling $8 million. Whitten was also required to forfeit his medical license and DEA registration.

https://www.justice.gov/usao-wdpa/pr/greensburg-doctor-sentenced-nearly-five-years-prison-accepting-kickbacks-exchange

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The False Claims Act

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The False Claims Act

- The FCA is a very old law dating back to the Civil War (1863) initially designed to deal with fraud such as the sale of unsuitable goods to the government. Think lame horses.
- Has been expanded over the years to apply to the presentation of any claim for payment to the government where the following are satisfied:
  - A claim is presented for payment;
  - The submitted knowingly makes or uses a false record to seek payment; and
  - Payment is received
- As applied to healthcare services, the above hold true plus:
  - The performance of the service would have no possibility to improve the patient's condition; or
  - The performance of the service was so poor that it was analogous to nothing being done.
- The FCA is often used as a "bootstrap" whereby a claim submitted in violation of Stark, AKS, or BIP is considered fruit of the forbidden tree and therefore also a False Claim.
- Has a whistleblower or *qui tam* provision that allows relators to bring forth allegations and share in the pecuniary damages. 2021 whistleblower share was ~$240M
- Civil penalties can include repayment of the monies received, treble damages, and fines up to $23,607 per clam.
- Criminal penalties include imprisonment for up to 5 years, $25,000 fine, and exclusion.
- $5.6B recovered in 2021: 801 cases opened, 598 were whistleblower initiated.

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The FCA—Bellamah Vein & Surgery

- Alleged Facts: surgeon conducted improper ultrasounds, used the findings to justify medically unnecessary procedures, then billed CMS, Tricare, and CHAMPVA.
- Allegation: that vascular surgeon violated the FCA by performing medically unnecessary surgeries at his practice then submitting false claims for payment to Federal health care programs.
- Qui Tam: suit was originally filed by sonographer formerly employed by surgeon; Federal government partially intervened.
- Settlement: in December 2021, surgeon agreed to pay $3.7 million to settle alleged violations of the FCA; as Federal government was an intervenor, qui tam plaintiff took 17% of settlement as her share.

https://www.justice.gov/usao-mt/pr/missoula-vascular-surgeon-settles-alleged-health-care-fraud-claims-37-million

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The FCA—Princeton Pathology

- Alleged Facts: by submitting claims to CMS using CPT code 85390-26, a code requiring written analysis by a pathologist, when patient medical records did not contain any analysis. Practice then billed CMS, resulting in overpayment.
- Allegation: that a pathology practice violated the FCA.
- Qui Tam: suit was originally filed by a pathologist who consulted at the practice; Federal government intervened.
- Settlement: in December 2021, practice agreed to pay $2.4 million to settle alleged violations of the FCA and entered into a 3-year Integrity Agreement; as Federal government was an intervenor, qui tam plaintiff took 19% of settlement as his share.

https://www.justice.gov/usao-nj/pr/pathology-practice-agrees-pay-24-million-resolve-false-claims-act-allegations

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Beneficiary Inducement Statute

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Beneficiary Inducement Statute

- Establishes a prohibition on the provision of any remuneration that the person or entity knows or should know is likely to influence a Medicare or Medicaid beneficiary's selection of a particular provider or supplier.
- Generally speaking – a prohibition on patient bribery.
- Remuneration exceptions:
  - Non-routine and unadvertised waivers or copayments or deductible amounts based upon an individualized assessment of financial need or unsuccessful collection efforts
  - Certain incentives for encouraging preventative care
  - Any practice that fits in an AKS safe-harbor.
- Note: Marketing trinkets or giveaways are subject to this prohibition but are acceptable if each individual item is no more than $15 and no patient receives items in excess of $50 annually.
- Giveaways can never be in the form of cash or cash equivalents (gift-cards).
- Activities that implicate the BIS should fit into a safe harbor at 42 CFR 1001.952

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Beneficiary Inducement—Universal Health Services

- Alleged Facts: UHS, a provider of inpatient psychiatric services, induced beneficiaries to seek treatment at UHS facilities by providing free or discounted transportation services, admitted beneficiaries ineligible for inpatient treatment, and failed to discharge patients when they no longer required care.
- Allegation: Universal Health Services (UHS) paid illegal inducements to Medicare beneficiaries, billed for medically unnecessary procedures, and failed to provide adequate services.
- Settlement: the allegations were settled for a total of $122 million from the defendant. UHS also entered into a Corporate Integrity Agreement, which will remain in effect for five years.

https://www.justice.gov/opa/pr/universal-health-services-inc-and-related-entities-pay-122-million-settle-false-claims-act

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Questions?

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