

## Stark and the Anti-Kickback Statute

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## Regulating Referral Relationship

- Goals:
  - Prevent overutilization
  - Prevent abuse of federal healthcare program funds

### Anti-Kickback Statute & Stark: Highlights

AKS

1. Criminal/Civil
2. Any Federal Healthcare Program
3. Requires proof of improper intent
4. Applies to any referral source
5. Safe Harbors
6. OIG Advisory Opinions

STARK

1. Civil only
2. Currently enforced only against Medicare payments but statute includes Medicaid
3. Strict liability
4. Must be a physician and an entity in the mix
5. Exceptions
6. CMS Advisory Opinions

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### Stark Law Technical citations

- Stark Law:
  - Statute: 42 USC 1395nn
  - Regulations: 42 CFR §411.35o, et seq
  
- Enforcement:
  - Centers for Medicare & Medicaid Services
  - HHS-Office of Inspector General
  - Department of Justice

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## Stark 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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## Another way of saying it

- Stark is an absolute prohibition of a physician referring “designated health services” to a health care provider with which the physician has a financial relationship
  - The provider that receives the referral cannot bill Medicare for the services if there is a Stark financial relationship
- However, if the financial relationship fits into an “exception,” then the referral and the billing is allowed
- This is a strict liability law – there is only one question: does the financial relationship squarely comply with all the criteria of one of the Stark exceptions

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## Sanctions

- Denial. CMS will not pay claims for improperly referred DHS
- Refund. Entity has duty to refund
- Civil Monetary Penalties.
  - \$15,000 for knowingly presenting or causing another to present improper claim
  - \$100,000 for “scheme” to circumvent
- Exclusion potential
- Potential False Claims Act Liability.

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## Key Definitions

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## Period of Disallowance

- Begins when financial relationship fails to satisfy applicable exception
- Ends no later than:
  - Date financial relationship satisfies exception (where not related to compensation); or
  - Date excess compensation is returned by party that received it, or if additional compensation is owed, on the date additional compensation is paid by party owing it, and all other requirements of exception are met

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## Need to Know Definitions

- “Physician”: Means a medical doctor, osteopathic doctor, doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry or a chiropractor
- “Immediate family members” of the physician include:
  - Spouse
  - Natural or Adoptive Parents, Children, Siblings
  - Step-siblings
  - In-laws
  - Grandparents/grandchildren

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## Designated Health Services

- Clinical laboratory services
- Physical therapy services
- Outpatient speech-language pathology services
- Occupational therapy services
- Radiology services, including MRI, CT, and ultrasound services (also includes nuclear medicine services)
- Radiation therapy services and supplies

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## Designated Health Services

- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

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## Key Definitions (*cont'd*)

- “Financial Relationship”
  - May be ownership/investment interest or compensation arrangement
  - May be direct or indirect

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## The Stark Exceptions

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## Understanding Exceptions to the Stark Law

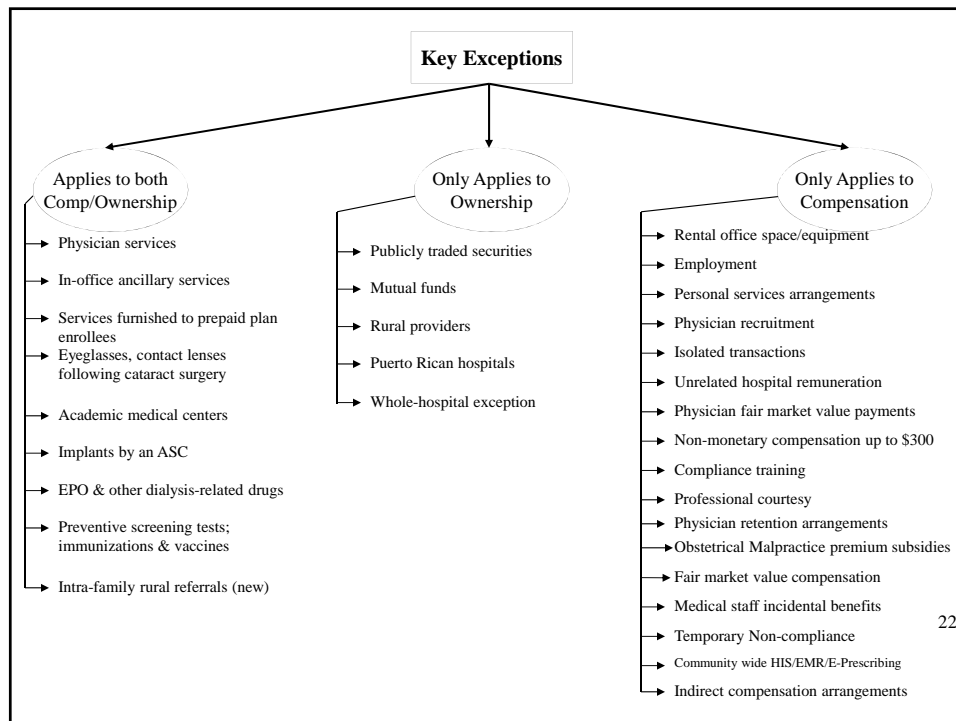
### ■ Three Types of Statutory/Regulatory Exceptions:

1. Exceptions that apply to all financial relationships
2. Exceptions that apply only to ownership/investment interests
3. Exceptions that apply only to compensation interests

### ■ Also, a number of definitional exceptions

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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.
- Note that some exceptions have special definitions within the exception

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## Examples of Exceptions

- Office Space and Equipment Leases
  1. Must be in writing
  2. Space/equipment may not exceed what is reasonable and necessary and must be exclusively used by lessee
  3. Term must be at least one year
  4. Rental charges must be set in advance and consistent with fair market value
  5. Rental charges may not take into account referrals or other business generated between the parties
  6. Must be otherwise commercially reasonable, even if no referrals were made between the lessee and lessor

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## Office Space and Equipment Leases

- May terminate with or without cause at any time, but may not enter into another lease for the same space or equipment during the first year of the original lease term
- Month-to-month holdovers allowed indefinitely if terms are not changed
- “Exclusive use” includes subleases if lessee does not share rented office space/equipment with lessor when rented

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## *Bona Fide* Employment Relationships

- Employment must be for identifiable services
- Remuneration must be consistent with fair market value and, except for certain productivity bonuses, not take into account the volume or value of any referrals by the referring physician
- Agreement would be commercially reasonable, even if no referrals were made to employer

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## *Bona Fide* Employment Relationships

- Protects physicians who are employees under usual common law and Internal Revenue Code definitions
- Productivity bonus not prohibited if based on services performed personally by the physician
- May not receive payment for generating referrals of DHS performed by others

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## Medical Staff Incidental Benefits

42 CFR §411.357(m)(5)

- Applies only to hospitals and entities that have *bona fide* medical staffs
- Items or services, less than \$33 per occurrence of the benefit (for CY 2017)
  - No limit on number of occurrences
  - Reasonably related to the provision of, or designed to facilitate the delivery of, medical services at the hospital
- May not be cash or cash equivalents
- Compensation must be offered to all medical staff members practicing in the same specialty
- Compensation must be offered without regard to the volume or value of referrals or other business generated between the parties

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## Medical Staff Incidental Benefits

- Compensation may be provided *only* while the physician is making rounds or engaged in other services or activities that benefit the hospital or its patients
- Compensation is used by the physician only on the hospital's campus (except two-way pagers and radios)
- Compensation may not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission

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## Non-monetary Compensation

### 42 CFR §411.357(k)

- 1) Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of \$398 (CY 2017) per year, if all of the following conditions are satisfied:
  - (i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.
  - (ii) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).
  - (iii) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission.

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## Non-monetary Compensation

- Important: Non-monetary compensation should be tracked
- Tracking is not a regulatory requirement, but...how else to defend?
- Exceeding the limit and not meeting another exception triggers the disallowance period

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## The Anti-Kickback Statute (AKS)

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## The Anti-Kickback Statute

- **Core of AKS – Prohibits anyone from purposefully offering, soliciting, or receiving anything of value to generate referrals for items or services payable by any Federal health care program.**

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## Elements

- **Remuneration**
- **Offered, paid, solicited, or received**
- **Knowingly and willfully**
- **To induce or in exchange for Federal program referrals**

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Remuneration

- **Anything of value**
- **“In-cash or in-kind”**
- **Paid directly or indirectly**
- **Examples: cash, free goods or services, discounts, below market rent, relief of financial obligations**

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Offered, Paid, Solicited, or Received

- **Different perspectives – payors and payees**
- **“It takes two to tango”**
- **Old focus: payors subject to prosecution**
- **New focus: payors and payees (usually doctors)**

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## To Induce Federal Program Referrals

- Any Federal health care program
- A nexus between payments and referrals
- Covers any act that is intended to influence and cause referrals to a Federal health care program
- One purpose test and culpability can be established without a showing of specific intent to violate the statutory prohibitions

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## Fines and Penalties

- The Government may elect to proceed:

### Criminal:

- Felony, imprisonment up to 5 years and a fine up to \$25,000 or both
- Mandatory exclusion from participating in Federal health care programs
- Brought by the DOJ

### Civil

- A violation of the Anti-Kickback Statute constitutes a false or fraudulent claim under the Civil False Claims Act
- Penalties are same as under False Claims Act (more later)
- Controversial, yet expanding use of the FCA

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Fines and Penalties (cont'd.)

- **Administratively:**

- **Monetary penalty of \$50,000 per violation and assessment of up to three times the remuneration involved**
- **Discretionary exclusion from participating in Federal health care programs**
- **Brought by the OIG**

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Exceptions and Safe Harbors

- **Many harmless business arrangements may be subject to the statute**
- **Approximately 26 “Safe Harbors” have been created by the OIG**
- **Compliance with a Safe Harbor is voluntary**
- **Must meet all conditions to qualify for Safe Harbor protection**
- **But is substantial compliance enough?**

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### Anti-Kickback Statute Safe Harbors

- Investment Interests
- Space Rental
- Equipment Rental
- Personal Services and Management Contracts
- Sale of Practice
- Referral Services
- Warranties
- Discounts
- Employees
- Group Purchasing
- Waiver of Beneficiary Coinsurance and Deductible Amounts
- Increased Coverage, Reduced Cost-Sharing Amounts or Reduced Premium Amounts Offered by Health Plans
- Electronic Health Records
- Federally Qualified Health Centers and Medicare Advantage Organizations.
- Price Reductions Offered to Health Plans
- Practitioner Recruitment
- Obstetrical Malpractice Insurance Subsidies
- Investments in Group Practices
- Cooperative Hospital Service Organizations
- Ambulatory Surgical Centers
- 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.
- Medicare Coverage Gap Discount Program.
- Local Transportation

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### Guidance on the Anti-Kickback Statute

- **Advisory Opinions from the OIG**
  - A party may request advice on the law, concerning (1) remuneration within the meaning of the law, (2) whether they are meeting one of the law's exceptions or safe harbors, or whether their arrangement warrants the imposition of a sanction
  - Recent Advisory Opinions on gainsharing arrangements in hospitals

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Guidance on the Anti-Kickback Statute (cont'd.)

- **Fraud Alerts and Special Advisory Bulletins**
- **Preamble to the Safe Harbor Regulations**
- **Compliance Program Guidance's**
- **[www.oig.hhs.gov](http://www.oig.hhs.gov)**

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Questions?



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