J. Stark Primer

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Stark Primer

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Disclaimer

- The views expressed today are those of the speakers in their personal capacity and not the official position of the Centers for Medicare & Medicaid Services or any other governmental agency.
Topics

- I. Introduction
- II. Stark Law Elements
- III. Exceptions
- IV. Penalties
- V. Comparison to the Anti-Kickback Law
- VI. Disclosure
PART I: INTRODUCTION

Stark Law: Regulatory Geometry

- Mechanical thinking
  - “If...then...” similar to geometric theorems
- Strict liability
- No intent
Well maybe it is rather easy…

Find \( x \):

\[
\begin{align*}
\text{There it is} & \quad x \\
5 & \quad 3
\end{align*}
\]

Overview of Stark Law

42 U.S.C. § 1395nn

*If a physician* (or an immediate family member of such physician) has a *financial relationship* with an *entity* . . . , *then* the physician may not make a referral to the entity for the furnishing of *designated health services* for which payment otherwise may be made under *Medicare*.

*(NOTE: The DHS entity is also prohibited from submitting claims.)*
Key Points

- Applies only to physicians and immediate family members of physicians
- Applies only when a financial relationship exists between a physician (or immediate family member of the physician) and an entity furnishing designated health services (DHS)
- Compliance with an exception is mandatory if the physician makes referrals for DHS to the entity with whom he (or his immediate family member) has a financial relationship
- Prohibition is limited to referrals for DHS
- Intent of the parties is irrelevant (“strict liability”)
- Civil penalties only

State Law Considerations

- Must also consider “mini-Stark” state self-referral laws
  - At least 34 states have enacted laws regulating physician self-referral
  - Three main categories: (1) Laws nearly identical to federal Stark that apply to all state programs; (2) Laws prohibiting all self-referrals; and (3) Laws imposing disclosure requirements of financial interests
- Every state is different and has nuances requiring state-specific research (e.g., what entities are covered, what activities are covered, and which payors are covered)
PART II: STARK LAW ELEMENTS

Six Key Elements

In order to implicate the Stark Law’s referral and billing prohibitions, there must be...

- A PHYSICIAN who
- Makes a REFERRAL
- For DHS
- Payable by MEDICARE
- To an ENTITY
- With which the physician (or an immediate family member) has a FINANCIAL RELATIONSHIP
Physician

- Doctor of Medicine or Osteopathy
- DDS/DMD
- Podiatrist
- Doctor of Optometry
- Chiropractor

Hypothetical #1

- A services arrangement between a hospital and a podiatrist is not subject to the Federal Stark law because podiatrists are not subject to the Federal Stark law prohibitions, and in any case, the podiatrist only refers Medicare patients to the hospital for x-rays on very rare occasion. As such, the risk is low.

- True or False?
Referral

- "Referral" defined more broadly than merely recommending a vendor of designated health services to a patient; instead, it is defined as "the request by a physician for the item or service" or the "establishment of a plan of care by a physician which includes the provision of the designated health service."
  - Includes requesting, ordering, or certifying the need for DHS
- Includes a request for a consult and any tests or procedures ordered or performed pursuant to the consult
- Does not include services personally performed by the referring physician
- Does include "incident to" services referred/ordered by the referring physician but performed by others
- Referral is imputed to the physician if he "directs" or "controls" the person making the referral
  - Preamble includes NPs and PAs in this category, but could be anyone

Special rules for pathologists, radiologists, and radiation oncologists – *not a referral* by the pathologist/radiologist/radiation oncologist if:
- The pathologist’s, radiologist’s, or radiation oncologist’s request for DHS is made pursuant to a request for a consultation
  - Initiated by another physician
  - Documented on the patient’s chart
  - Followed with a written report
- Test or service is performed by or under the supervision of the consulting physician
  - Supervision requirement met if the test or service is supervised by a pathologist, radiologist, or radiation oncologist in the same group practice as the consulting physician
  - Supervision by any other physician or type of physician would be a referral by the pathologist/radiologist/radiation oncologist
Designated Health Services

**Designated Health Services (DHS)**

- Clinical Laboratory Services
- Physical Therapy Services, Occupational Therapy Services, and Speech Pathology Services
- Radiology Services, including MRI, CT Scan, PET, Ultrasounds, Includes Nuclear Medicine
- Radiation Therapy Services and Supplies
- Durable Medical Equipment and Supplies
- Parenteral and Enteral Nutrients, Equipment and Supplies
- Prosthetics, Orthotics, Prosthetic Devices, and Supplies
- Home Health Services
- Outpatient Prescription Drugs
- Inpatient and Outpatient Hospital Services

What are *not* DHS?

- Most physician services
- Services paid under SNF PPS
- Services paid under the ASC payment system
- Services paid under the ESRD composite rate
- Services that are specifically carved out from the definitions of certain types of DHS
  - Pass-through items or supplies during ASC procedure
  - Radiological procedures to confirm placement of an implant during a non-radiological procedure
  - CT scans for purposes of radiation therapy guidance
- Lithotripsy
DHS – Inpatient and Outpatient Hospital Services

- Inpatient and Outpatient Hospital Services
  - Services that are not on the list of DHS “become” DHS when furnished as an inpatient or outpatient hospital service
  - ONE EXCEPTION: Lithotripsy is not considered “inpatient or outpatient” hospital service
    - Caution: contractual arrangements between hospitals and physicians regarding lithotripsy constitute a financial relationship
      - Must qualify for an exception if the physician refers patients to hospital for other (non-lithotripsy) DHS
      - If compensation is per-procedure, must be a complete package of services, rather than an equipment lease, in order to qualify for an exception
      - See CMS FAQ 9780

Hypothetical #2

- Physician ownership in an ambulatory surgery center to which he/she refers Medicare/Medicaid patients is not permitted under the Stark Law because this would create an unexcepted financial relationship between the Physician and the ASC?
- True or False?
Medicare

- Generally speaking, the Stark Law's prohibitions relate to Medicare fee-for-service (FFS) referrals
- Medicare Advantage plans are treated more like commercial managed care plans
- There is a broad exception for services to enrollees of specified prepaid health plans
- The Stark Law's application to Medicaid is through section 1903(s) of the Social Security Act, which functions differently than its application to Medicare FFS

Application to Medicaid

- Section 1903(s) of the Social Security Act
- No payment shall be made to a State for expenditures for medical assistance under the State plan consisting of a designated health service furnished to an individual on the basis of a referral that would result in the denial of payment for the service under Medicare (if Medicare provided for coverage of the service to the same extent and under the same terms and conditions as under the State plan)
- Subsections (f) and (g)(5) of section 1877 shall apply to a provider of such a designated health service for which payment may be made under Medicaid in the same manner as such subsections apply to a provider of such a service for which payment may be made under Medicare.
  - Section 1877(f) relates to reporting requirements
  - Section 1877(g)(5) relates to sanctions for failure to report information required under section 1877(f)
Application to Medicaid

- Facially, Stark regulations only apply to Medicare
- Medicaid is financed by both state and federal governments
- FFP (federal financial participation) – amount federal government issues to states
- DOJ believes Stark applies to Medicaid claims in regards to the FCA (see, for example, Halifax)
- CMS proposed but has not finalized regulations regarding Stark and Medicaid; however, the statute is self-implementing

Entity

- Essentially, an “entity” is the person or organization that “furnishes” DHS.
  - Does not include the referring physician but does include his or her medical practice
- A Person or entity is considered to be “furnishing” DHS if it—
  - Is the person or entity that has performed the services that are billed as DHS; or
  - Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned
  - This has been the rule since October 1, 2009.
- Does not include a physician practice when it bills Medicare for the technical component (TC) or professional component (PC) of a diagnostic test in accordance with the anti-markup payment limitation rules in § 414.50
Financial Relationship

- “Financial Relationship”
  - Exists when the physician (or an immediate family member) has a direct or indirect ownership or investment interest in or a direct or indirect compensation arrangement with any entity that furnishes DHS

Financial Relationship

- “Ownership or Investment Interest”
  - Includes equity, debt, and other means
  - Does not include
    - Interest in a retirement plan
    - Stock options earned as compensation until exercised
    - Unsecured loans
    - “Under arrangements” contracts
    - Security interest held by a physician in equipment sold by the physician to a hospital (when financed through a loan to the hospital)
Financial Relationship

- **Direct** ownership/investment interest exists between the referring physician (or a member of his or her immediate family) and the DHS entity if there are no intervening persons or entities between them.

Financial Relationship

- **Indirect** ownership/investment interest
  - Between the physician and the entity furnishing DHS, there exists an unbroken chain of any number (≥1) of persons or entities having ownership or investment interests.
  - DHS entity has actual knowledge (or reckless disregard or deliberate ignorance) of the physician's ownership or investment interest.

- The DHS entity need not know precise composition of chain.
- Common ownership does not create indirect ownership.

≠ indirect ownership interest for B in C or vice versa.
Financial Relationship

- **“Compensation Arrangement”**
  - Any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician’s immediate family) and an entity.
  - Includes contracts between hospitals and entities providing DHS “under arrangements” to the hospital
  - Does not include the portion of any business arrangement that consists solely of remuneration described in section 1877(h)(1)(C) of the Act

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Financial Relationship

- **Direct Compensation Arrangements**
  - Any arrangement involving remuneration between a DHS entity and a referring physician (or immediate family member)
  - No person or entity interposed between them

- **“Deemed” Direct Compensation Arrangements – “Stand in the Shoes” Provisions**
  - Physician is deemed to have a direct compensation with a DHS entity if he or she has an ownership interest in his or her “physician organization”
    - Does not apply to titular ownership
  - The physician is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the “physician organization”
Financial Relationship

- **Indirect Compensation Arrangements**
  - Between the referring physician and the DHS entity, there is an “unbroken chain” of any number of entities (≥1) that have financial relationships (either ownership/investment interests or compensation arrangements)
  - Aggregate compensation to the physician from the closest link in the chain varies with or takes into account the volume or value of referrals to or other business generated by the physician for the entity providing DHS
  - Entity providing DHS has actual knowledge or acts in reckless disregard or deliberate ignorance of the existence of such relationship

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Financial Relationship

- **Indirect Compensation Arrangements – “Stand in the Shoes” Provisions**
  - For purposes of determining whether an indirect compensation arrangement exists, a physician is deemed to stand in the shoes of his or her “physician organization” if he or she has an ownership interest in the “physician organization”
    - Does not apply to titular ownership
  - The physician is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the “physician organization”
Where are you right about now?

PART III: EXCEPTIONS
Exceptions to the Stark Law

- **Generally, there are three types of exceptions:**
  - Ownership/investment interests (§411.356)
  - Compensation arrangements (§411.357)
  - “Services” (applicable to both ownership/investment interests and compensation arrangements)(§411.355)

- **Other “exceptions” (§411.353)**
  - “Knowledge” exception for payments made to an entity that did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the prohibited referral for DHS
  - Temporary noncompliance

Ownership Exceptions

- **Publicly-traded securities**
  - Held in corporations with equity exceeding $75,000,000

- **Mutual funds**
  - Total assets exceeding $75,000,000

- **Rural Providers**
  - Substantially all (≥ 75 percent) of DHS furnished is furnished to residents of a rural area
  - DHS must be furnished in a rural area
  - Rural hospitals must meet the requirements imposed by the Affordable Care Act and implementing regulations by September 23, 2011

- **Hospital located in Puerto Rico**
Ownership Exceptions

- "Whole Hospital" exception
  - Referring physician must be “authorized to perform services at the hospital”
  - Ownership or investment interest may not be merely in a distinct part or department of the hospital
  - Must meet the requirements imposed by the Affordable Care Act and implementing regulations by September 23, 2011
    - Requirements found in §411.362
      - Provider agreement in place by December 31, 2010
      - Prohibition on facility expansion
      - Disclosure of conflicts of interest
      - Bona fide investment
      - Patient safety
      - Cannot convert from ASC

Compensation Arrangement Exceptions

- Statutory
  - Rental of Office Space
  - Rental of Equipment
  - Bona Fide Employment Relationships
  - Personal Service Arrangements
  - Certain Physician Incentive Plans
  - Physician Recruitment
  - Certain Arrangements with Hospitals (remuneration unrelated to DHS)
  - Group Practice Arrangements with a Hospital
  - Payments by a Physician
  - Electronic Prescribing Items and Services (section 1860D-3(e) of the MMA)
Compensation Arrangements Exceptions

- Established using the Secretary’s authority under section 1877(b)(4) of the Act
  - Charitable Donations by a Physician
  - Nonmonetary Compensation
  - Fair Market Value Compensation
  - Medical Staff Incidental Benefits
  - Risk-sharing Arrangements
  - Compliance Training
  - Indirect Compensation Arrangements
  - Referral Services
  - Obstetrical Malpractice Insurance Subsidies
  - Professional Courtesy
  - Retention Payments in Underserved Areas
  - Community-wide Health Information Systems
  - Electronic Health Records Items and Services

Rental of Office Space

- The rental or lease agreement is set out in writing, is signed by the parties, and specifies the premises it covers.
- The term of the agreement is at least 1 year.
  - To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.
- The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee’s pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.
- A holdover month-to-month rental for up to 6 months immediately following the expiration of an agreement of at least 1 year that met the conditions of paragraphs (a)(1) through (a)(6) of this section satisfies the requirements of paragraph (a) of this section, provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.
Rental of Office Space

- The rental charges over the term of the agreement are set in advance and are consistent with fair market value.
- The rental charges over the term of the agreement are not determined—
  - In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or
  - Using a formula based on—
    - A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or
    - Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.
- The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

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Rental of Office Space

- **Term**
  - Must be at least one year
  - Exception states that the term of the “agreement” must be at least one year
    - Other exceptions require that the term of the “arrangement” be at least one year
    - Statutory language (“lease”) treats office space and equipment rentals different from other types of compensation arrangements
- **Termination prior to end of first year of term**
  - Permissible, but may not contract within the first year of the original term for the same space
- **Shared space**
  - Must be block leased because of the “exclusive use” requirement
Rental of Office Space

- Holdovers
  - Permissible up to six months following a compliant arrangement
    - Must continue on same terms and for same space
    - Escalator clauses permissible, but must be in the original agreement (i.e., “set in advance”)
- Other available exceptions
  - Per CMS guidance, no other exceptions are applicable to the rental of office space
  - Not eligible for the exceptions for fair market value compensation or payments by a physician (Phase III)
  - Office space is not an “item” or “service”

Rental of Office Space

- Rental Charges
  - Who is lessor? Who is lessee? Why does it matter?

Percentage-based: IMPERMISSIBLE  Per-click: IMPERMISSIBLE
Rental of Office Space

- Rental Charges
  - Who is lessor? Who is lessee? Why does it matter?

  | Percentage-based: IMPERMISSIBLE | Per-click: PERMISSIBLE |

Rental of Equipment

- The rental or lease agreement is set out in writing, is signed by the parties, and specifies the equipment it covers.

- The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee and is not shared with or used by the lessor or any person or entity related to the lessor.

- The agreement provides for a term of rental or lease of at least 1 year.
  - To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.

- A holdover month-to-month rental for up to 6 months immediately following the expiration of an agreement of at least 1 year that met the conditions of paragraphs (b)(1) through (b)(5) of this section satisfies the requirements of paragraph (b) of this section, provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.
Rental of Equipment

- The rental charges over the term of the agreement are set in advance, are consistent with fair market value, and are not determined—
  - In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or
  - Using a formula based on—
    - A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated by the use of the equipment; or
    - Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.
- The agreement would be commercially reasonable even if no referrals were made between the parties.

Rental of Equipment

- **Per-click compensation:** Physician Organization is Lessor

  Physician makes referrals for services to patients that will be provided on the leased equipment

  Stands in the Shoes

  Physician Organization Lessor

  Per-click Lease Arrangement

  IMPERMISSIBLE

  Lessee
Rental of Equipment

- Per-click compensation: Physician-owned LLC is Lessor
  
  Physician makes referrals for services to patients that will be provided on the leased equipment

  Does NOT stand in the shoes of the LLC

  Physician-owned LLC
  Lessor

  Hospital does not make referrals for services to patients that will be provided on the leased equipment

  Stands in the shoes

  Physician Organization
  Lessee

  PERMISSIBLE

Rental of Equipment

- Per-click compensation: Physician Organization is Lessee
  
  Physician makes referrals for services to patients that will be provided on the leased equipment

  Does NOT stand in the shoes of the LLC

  Physician-owned LLC
  Lessor

  Hospital does not make referrals for services to patients that will be provided on the leased equipment

  Stands in the shoes

  Physician Organization
  Lessee

  PERMISSIBLE
Rental of Equipment

- Percentage-based compensation

Physician-owned LLC OR Physician Organization is Lessor

Percentage-based Lease Arrangement IMPELLIBLE

Lessee

Rental of Equipment

- Percentage-based compensation

Physician-owned LLC OR Physician Organization is Lessee

Percentage-based Lease Arrangement IMPELLIBLE

Lessor
Rental of Equipment

- Lithotripsy
  - Although not DHS due to CMS’s acquiescence with a court ruling in *American Lithotripsy*, the rental of lithotripsy equipment creates a compensation arrangement that must satisfy an exception in order for the physician-owner of the lithotripsy equipment to refer other DHS to the entity.

Bona Fide Employment

- The employment is for identifiable services.
- The amount of the remuneration under the employment is:
  - Consistent with the fair market value of the services; and
  - Is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.
- The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.
- Payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician) is permissible.
Bona Fide Employment

- No requirement for written agreement
  - If you have a written agreement, leave flexibility in case services/duties change
- Employment is determined by using IRS factors, per CMS guidance
  - Whether physician receives a W-2 is not dispositive
  - Facts and circumstances control whether a physician is an employee for Stark Law purposes
- Total compensation must be FMV
  - Including all bonus compensation

Personal Service Arrangements

- Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.
- The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.
  - This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts.
  - A physician or family member can “furnish” services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through locum tenens physicians (as defined at §411.351, except that the regular physician need not be a member of a group practice).
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).
Personal Service Arrangements

- The term of each arrangement is for at least 1 year.
  - To meet this requirement, if an arrangement is terminated during the term with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement.

- The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.

- The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at §411.351 of this subpart), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

- A holdover personal service arrangement for up to 6 months following the expiration of an agreement of at least 1 year that met the conditions of paragraph (d) of this section satisfies the requirements of paragraph (d) of this section, provided that the holdover personal service arrangement is on the same terms and conditions as the immediately preceding agreement.

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Personal Service Arrangements

- Amending arrangements
  - Prior to October 1, 2008, CMS position was that terms affecting the rental charges could not be amended
    - Announced in Phase III rule
    - Arguably, this position applies to the period from September 5, 2007 through October 1, 2008

  - Rules on amendments apply to arrangements that satisfy any exception for compensation arrangements that includes a one-year term requirement for satisfying the exception
    - Amendments to arrangements that satisfy the exception for fair market value compensation are not permitted
Personal Service Arrangements

- Arrangements may be amended at any time and as many times as the parties choose, provided that, at the time of the amendment:
  - All of the requirements of the exception are satisfied
  - The amended compensation terms, or the formula for the compensation, is determined before the amendment is implemented
  - The formula for the amended compensation does not take into account the volume or value of referrals or other business generated by the referring physician
  - The amended compensation, or the formula for the amended compensation, remains in place for at least one year from the date of the amendment

Physician Recruitment

- Payments made to induce physician to relocate to “geographic area served by hospital” and join the hospital’s medical staff
  - GSA defined as lowest number of contiguous zip codes drawing >75% of inpatients
  - Physician must join hospital’s medical staff (that is, no prior privileges, including courtesy)
  - Relocation defined: recruited physician moves his/her practice location from outside hospital’s service area into hospital’s service area if:
    - Moving at least 25 miles, or
    - Deriving >75% of revenues from new patients during preceding 3 years.
- Significant, detailed requirements when recruited physician joins an existing (private) medical practice in the hospital’s GSA
Recruitment: Payments to Group Practices

- Permits payments to be paid to the recruited physician by passing payments through the existing medical practice that he or she joins.

- Except for actual costs incurred by the medical practice in recruiting the physician (which may be retained by the practice), all remuneration must be passed directly to the recruited physician.

- Income Guarantee - guarantee against collections
  - Practice costs allocated to the recruited physician may not exceed actual additional incremental costs for that physician.

Isolated Transactions

Isolated transactions (such as one-time sale of property or practice) do not constitute financial relationships if:

- The amount of remuneration under the transaction is:
  - Consistent with FMV; and
  - Not determined in any manner that takes into account volume/value of referrals.

- Agreement is commercially reasonable even without any referrals made.

- No additional transactions between the parties for 6-months after the isolated transaction.
Payments by a Physician

Certain payments that a physician makes:

- to a laboratory in exchange for clinical laboratory services or
- to an entity as compensation for other items or services that are furnished at a price that is consistent with FMV
- “Hierarchy of Exceptions” – payments are not specifically excepted by another provision in §§ 411.355 through 411.357.

Nonmonetary Compensation

- Compensation from an entity to a physician in the form of items or services (not including cash or cash equivalents) will not constitute a financial relationship if all of the following requirements are satisfied:
  - 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.
  - The compensation may not be solicited by the physician or the physician’s practice (including employees and staff members).
  - 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.
- The annual aggregate nonmonetary compensation limit is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral Web site:
  http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.
Nonmonetary Compensation

- **What is nonmonetary compensation?**
  - Meals
  - Tickets for sporting events, concerts, plays, etc.
  - Transportation to events
  - Flowers or plant sent to congratulate the physician on his or her new office, new home, or birth of a child
  - Rounds of golf
  - Birthday presents
  - Use of entity-owned vacation home

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Nonmonetary Compensation

- Where an entity has inadvertently provided nonmonetary compensation to a physician in excess of the limit, such compensation is deemed to be within the limit if—
  - The value of the excess nonmonetary compensation is no more than 50 percent of the limit; and
  - The physician returns to the entity the excess nonmonetary compensation (or an amount equal to the value of the excess nonmonetary compensation) by the end of the calendar year in which the excess nonmonetary compensation was received or within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier.

- The ability to pay back excess nonmonetary compensation and remain in compliance with the exception may be used by an entity only once every 3 years with respect to the same referring physician.
Nonmonetary Compensation

- In addition to nonmonetary compensation up to the annual limit, an entity that has a formal medical staff may provide one local medical staff appreciation event per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the annual limit.
  - Entities without formal medical staffs (e.g., clinical laboratories) may not provide a local medical staff appreciation event unless another exception applies and is satisfied.
  - CMS does not define “formal medical staff”
  - Group or totality of referring physicians do not generally constitute a “formal medical staff”

Appplies to all entities

- Hospital providing nonmonetary compensation to physicians
  - Regardless of physician’s medical staff privileges (except with respect to provision of local medical staff appreciation event)
- Specialty group practice providing nonmonetary compensation to primary care physicians
  - Example: Orthopedic surgical practice takes primary care physicians to dinner to discuss the expertise of the surgeons
Nonmonetary Compensation

- Applies only to nonmonetary compensation provided to individual physicians (Phase I)
  - A gift to a group practice could be considered a gift to each physician in the group practice and the full value must be accounted for as such
  - No mention in the regulation or preamble of “immediate family member”
- Cash and cash equivalents are not covered by the exception
  - Gift certificates and gift cards are considered “cash equivalents”
  - Exception applies only to “items and services”
- Calculated on a calendar-year basis

Nonmonetary Compensation

- **Limits**
  - For CY 2014, limit is $385 per physician
  - Calculated based on cost of item, not value to the physician
    - Example: Hospital pays $100 for and gives physician a sweater that she thinks is ugly and worthless; Hospital must count $100 toward the annual limit for nonmonetary compensation to the physician
    - Example: Hospital CEO receives free guest passes to his brother’s country club and invites the Chief of Surgery; there is no cost to count toward the annual limit for nonmonetary compensation to the physician
Nonmonetary Compensation

- Repayment of excess nonmonetary compensation
  - Physician may return the item or the dollar value of the excess
  - Must be returned within 180 days of receipt or the end of the calendar year in which it was conferred, whichever is earlier
    - If excess is repaid within the required time frame, referrals are not prohibited and claims submission does not violate the Stark Law
  - Prudent to hold claims for services referred by the physician until repayment is made
  - May only use the repayment “compliance option” once very three years with respect to the same referring physician
  - Excess nonmonetary compensation must have been inadvertent

Hypothetical #3

- The CEO of Everytown Hospital took Dr. Drink, an orthopedic surgeon, and his wife to dinner and things got a bit out of control with the wine list. The dinner tab totaled $475. Dr. Drink has already received $275 in non-monetary compensation this year. What do you do?
- Can the Hospital can rely on the “exception for certain arrangements involving temporary noncompliance” found at 42 C.F.R. 411.353(f)?
Medical Staff Incidental Benefits

- Items and services, but not cash or cash equivalents
- Provided to all members of medical staff within same specialty
- Not based on volume/value of referrals
- Offered only during rounds or performance of duties that benefit the hospital/patients
- Provided and used only on hospital's campus
- Reasonably related to delivery of medical services at hospital
- Consistent with what other hospitals in region offer
- Less than $25 value for each occurrence (indexed)
  - For CY 2014, must be less than $32 per occurrence
- Does not violate Anti-Kickback Statute

Medical Staff Incidental Benefits

- **In**
  - Free parking
  - Meals while on call
  - Free computer/Internet access

- **Out**
  - Medical transcription services
  - Malpractice insurance
  - Holiday parties or office equipment for a group practice (as compared to party with entire Medical Staff)
Fair Market Value Compensation

- An arrangement for compensation for items or services must satisfy the following requirements:
  - The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.
  - The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.
  - The arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.
  - The 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.
  - The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

- The writing specifies the compensation that will be provided under the arrangement.
  - The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.
  - Compensation for the rental of equipment may not be determined using a formula based on—
    - A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated through the use of the equipment; or
    - Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.
Fair Market Value Compensation

- When to use the exception
  - Either entity or physician (or physician group) may provide the items or services
  - Term of less than one year
    - Equipment leases for less than one year fall under this exception
- May not use this exception for the rental of office space per CMS preamble guidance (Phase III)
- Compensation terms must be included in the written agreement to satisfy the requirements of the exception
- May renew any number of times on exactly the same terms
  - May not amend an arrangement that satisfies this exception (because there is no requirement for a one-year term) (FY 2009 IPPS Final Rule)

IT: Community-Wide Information Systems

Items or services of IT that entity provides to a physician that allow access to, and sharing of, EMR and any complementary drug information, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community’s overall health provided that—

- Items provided are principally used for the system and not provided in a manner that takes into account volume/value of referrals
- Available to all community providers who wish to participate
- Does not violate Anti-Kickback Statute
IT: Electronic Prescribing of Items & Services

Non-monetary remuneration necessary and used solely to receive and transmit electronic prescription information, if—

- Items and services are provided by a: Hospital to a physician who is a member of its medical staff; Group practice to a physician who is a member of the group; or PDP sponsor or MA organization to a prescribing physician
- At the time Items/services are provided, they are provided as part of or are used to access a prescription drug program that meets Part D standards

IT: Electronic Prescribing

- Donor does not take action to limit or restrict use or compatibility of the items with other electronic prescribing or EMR systems
- Physician or group practice cannot make the system a condition of doing business with the donor
- Other requirements
IT: Electronic Health Records

Non-monetary remuneration necessary and used predominantly to create, maintain, transmit, or receive electronic health records if—

- Entity/physician provides items or services
- Software is interoperable at the time it is provided to the physician
- Donor does not take action to limit or restrict use, compatibility, or interoperability of items or services with other electronic prescribing or electronic health record systems
- Donor is not a laboratory company (as of March 27, 2014)
- Other requirements

Issues Related to Compensation Arrangements

- Fair market value
- Prohibited compensation formulae
- Special rules on compensation
  - Set in advance
  - Takes into account the volume or value of referrals
  - Restricting referrals
Fair Market Value

- Fair market value is a **key element** to many Stark law exceptions

- Phase III removes the “safe harbor” for FMV of hourly payments to physicians
  - CMS determined the safe harbor was not feasible and might implicate antitrust concerns

Fair Market Value: Uncertainty Since Phase III

- Phase III added **uncertainty** to how organizations determine fair market value
  - CMS reserves the right to second guess the methodology and amount of fair market value
  - “Reference to multiple, objective, independently, published salary surveys remains a prudent practice for evaluating fair market value”
  - Administrative vs. clinical services

72 Fed. Reg. 51015
Per-Click and Percentage Compensation Limitations

**Per-click compensation**
- Compensation may not be determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee
  - Corrected in e-CFR for office space rental, but e-CFR remains incorrect for equipment rental, fair market value compensation, and indirect compensation arrangements
- Where hospital is lessor and does not make referrals to the physician (or physician group) lessee, per-click rental charges remain permissible
- Where physician (or physician group) is lessor, per-click rental charges are prohibited, unless the physician (or any physician group owner) does not makes referrals to the hospital that affect the rental charges paid to the physician (or physician group) lessor
  - Through preamble language, CMS intends to make this applicable to physician-owned lessors, regardless of whether they are physician organizations in which the physician owner “stands in the shoes”

**Percentage-based compensation**
- Limitation on use of percentage-based compensation formulae for rental of office space and equipment
  - All other use is permissible, provided that the requirements of the regulations are satisfied
- Compensation may not be determined using a formula based on a percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services performed or business generated in the office space or through the use of the equipment
- Does not matter whether physician (or physician group) is lessor or lessee
Special Rules on Compensation

- Per-click and fee schedule-based services is deemed not to take into account "volume or value of referrals"

- “Set in advance” includes time based or per-unit of service or a specific formula for calculating compensation and may not be modified for during term if takes into account business generated/referrals.

- “Other business between the parties” does not include fair market value of compensation for services or items that does not vary during term that does not take into account referrals/business generated including private pay business but excluding personally performed services.

Set in Advance

- Flat amount of aggregate compensation
- Amount is based on unit-of-time or unit-of-service (includes per-use and per-service); or
- Specific formula for calculating the compensation
  - Includes “percentage compensation” formulae
  - Formula must be in sufficient detail so that it can be objectively verified
  - May not be modified during the course of the agreement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician
- Must be set in an agreement between the parties before the furnishing of items or services for which the compensation is paid
Special Compensation Conditioned on Referrals

Compensation arrangement must be:
- Set in advance for term of agreement
- Fair market value
- Cannot take into account anticipated referrals or required referrals
- Meets another exception
- In a written agreement
- Signed by the parties
- Does not apply if the patient expresses a preference or is not in the patient’s medical best interest
- Required referrals relates solely to the physician’s services within the scope of contract

“Services” Exceptions

- Physician Services
- In-office Ancillary Services
- Services Furnished by an Organization (or its Contractors or Subcontractors) to Enrollees (prepaid health plans)
- Academic Medical Centers
- Implants Furnished by an ASC
- EPO and Other Dialysis-related Drugs
- Preventive Screening Tests, Immunizations, and Vaccines
- Eyeglasses and Contact Lenses Following Cataract Surgery
- Intra-family Rural Referrals
In-office Ancillary Services Exception

- Available to “group practices” (by definition at 42 C.F.R. 411.352) and physicians in solo practice
- Applies to
  - Some DME Services
- Three main requirements
  - Who
    - Who performed or supervised the service?
    - Referring physician or another physician in the same group practice must personally furnish the services or meet supervision requirements
  - Location
    - Centralized building or same building
  - Billing
    - In whose name and billing number was the service billed?

In-office Ancillary Services Exception – Notice Requirement

- Applies only to MRI, CT and PET services furnished on or after January 1, 2011
- Must provide for each referral – not just initial patient visit
- Must include at least 5 (or as many that exist if less than 5) other suppliers
  - Within a 25-mile radius of the “physician’s office location at the time of the referral”
  - Not tied to the location of the patient’s residence (as stated in PPACA) or necessarily to the location at which the DHS will be furnished
- Group practice/physician may choose which suppliers to include
- Need not include any available providers of services (e.g., hospitals)
- Must include name, address and phone number for each listed supplier
- No notice required if there are no alternative suppliers within a 25-mile radius of the physician’s office location
- Should be tracked by physician
Medicare Supervision Standards

- **Direct Supervision** = Present in the office suite and immediately available to furnish assistance and direction throughout the duration of the procedure, does not mean that the physician is in the office when the procedure is performed.
- **Personal Supervision** = in the room
- **General Supervision** = under the physician’s overall direction and control; physician’s presence is not required during the performance of the procedure.
- 42 C.F.R. § 410.32(b)(3)
- Even if Medicare coverage/billing rules do not require supervision, the IOAS exception requires some level of supervision.

Hypothetical #4

- We R Doctors is an orthopedic practice with its own x-ray and MRI capabilities on-site at its offices. Testing is performed at an offsite location co-owned by another large physician practice. The tests are sometimes supervised by a physician, but not always. Mr. Patient has an MRI ordered, performed and billed to Medicare by We R Doctors. Mr. Patient was never given any information regarding other MRI providers. Issues?
Requirements for Group Practices

- Two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association

- Each physician who is a member of the group must provide substantially the full range of services of their practice as a member of the group

- “Substantially all” of the services of members of group must be provided through the group, billed in the name of the group, and treated as receipts of the group

Requirements for Group Practices

- Overhead expenses and income distributed in accordance with previously determined methods

- No compensation directly or indirectly based on the volume or value of referrals by the physician, except for certain productivity bonuses

- Group members must personally conduct no less than 75% of the physician-patient encounters of the group practice
## Group Practice Examples

<table>
<thead>
<tr>
<th>Potentially Protected Structures</th>
<th>Potentially Unprotected Structures</th>
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</thead>
<tbody>
<tr>
<td>P’ship between 2 or more MDs</td>
<td>“Bifurcated” foundation-model groups</td>
</tr>
<tr>
<td>P’ship of 1 MD and other party, must employ at least 1 more MD</td>
<td>Collection of practices using same MSO or affiliated health system</td>
</tr>
<tr>
<td>Corp/LLC owned by 1 or more MDs or owned by 1 MD who employs at least 1 more MD</td>
<td>Practice owned by functioning practices</td>
</tr>
<tr>
<td>Corp/LLC owned by non-MDs that employ at least 2 MDs</td>
<td>Hospital as a “group”</td>
</tr>
<tr>
<td>Solo practitioner employing at least 1 more MD</td>
<td>Provider-based clinics may not qualify as groups depending upon state laws</td>
</tr>
</tbody>
</table>

## Group Practice Compensation

- General rule is that no compensation may be based directly or indirectly on volume or value of referrals
- Productivity bonuses: services personally performed or “incident to”
- Profit shares: share of “overall profits” of the group
  - Pooling permitted if 5 or more physicians
- No bonus based directly on referrals
- Members vs. independent contractors
“Incident to” Services

- Under the Stark statute, group practices are permitted to pay profit shares and productivity bonuses to their physicians based on services personally performed or services “incident to” these personally performed services provided that the profit share or bonus is not determined in any manner that is directly related to the volume or value of the physician’s referrals.
- Other DHS entities cannot compensate based on profit or productivity.

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“Incident to” Services

- In Phase II, CMS stated, “profit shares or productivity bonuses can be based directly on services that are ‘incident to’ the physician’s personally performed services.”
- However in Phase III, CMS withdraws this statement claiming that the Stark statute only includes bonuses paid for “incident to” services in the context of productivity.
- Phase III makes clear that “incident to” services expressly include supplies, not just services, namely drugs.
- Services covered by Medicare under a separate benefit category (diagnostics) do not qualify as “incident to” services under Medicare coverage and payment rules and therefore also do not qualify under the Stark Law.
Academic Medical Centers (AMCs)

- AMC exception protects services referred within an academic medical center
  - Affiliated medical school
  - Faculty practice plan
  - Hospital
  - Teaching facility (not defined)
  - Institution of higher education (not defined)
  - Departmental professional corporation (not defined)

AMC: Referring Physician Requirements

- *Bona fide* employee of AMC *component-plus-bona fide* faculty appointment at affiliated medical school
- Licensed to practice medicine in the state
- Provides "substantial" academic or clinical teaching services. CMS provides a safe harbor, which is measured by:
  - 20% of Professional Time
  - 8 Hours per week
  - *See Villafane*
AMC: Potentially Not Protected

- Physicians with substantial clinical practices who do not provide substantial academic/clinical teaching functions;
- Non-employed faculty who receive compensation;
- Physicians employed by entity in the system that is not an AMC "component" -- e.g., hospital subsidiary or nursing home;
- Physicians with incentive compensation (?)

Additional Requirements for AMCs

- Compensation is set in advance, does not exceed FMV (in the aggregate); does not take into account volume or value of referral; does not violate Anti-Kickback
- All transfers between components of AMC must support missions of teaching, indigent care, research or community services (patient care)
- There must be a written agreement between components of the AMC
- All research money paid to physicians must be used for bona fide research
Other Exceptions, Rules and Guidance

- Temporary noncompliance (following compliance)
- Grace periods for signature requirements
- Amending an existing arrangement
- Holdover provisions
- Waivers for entities participating in the Medicare Shared Savings Program

Temporary Non-Compliance

- The Stark regulations allow for a period of temporary noncompliance where:
  - The arrangement was formerly in compliance for at least 180 days.
  - The arrangement fell out of compliance for reasons beyond the entity’s control.
  - The entity promptly took steps to remedy the situation, and
  - The period of non-compliance cannot exceed 90 days
- May only be used by an entity once every 3 years with respect to the same referring physician
Temporary Non-Compliance

- Arrangements never in compliance cannot satisfy requirements.
- Documentation that should be maintained for relationships that fall out of compliance:
  - Terms of the arrangement;
  - How the arrangement fell out of compliance;
  - The reason the arrangement fell out of compliance;
  - Steps taken to bring arrangement into compliance;
  - Relevant dates; and
  - Other similar information.
- List of documentation in preamble only, *not in the regulations*.

Grace Periods: Signature Requirements

- 42 C.F.R. §411.353(g)
  - Provided that all other requirements of an exception are satisfied, if the parties failed to obtain a signature at the commencement of the arrangement, the arrangement will be considered compliant from its commencement if the signature is obtained within:
    - 30 days if the failure was knowing
    - 90 days if the failure was inadvertent
  - The “grace period” may be used by an entity only once every 3 years with respect to the same referring physician.
Amending Existing Arrangement: Nonfinancial Terms

- “Parties may amend a lease agreement [or personnel services agreement] multiple times during or after the first year of its term, provided that [the financial terms] are not changed and all other requirements of the exception are satisfied.” 72 Fed. Reg. 51044

- So, terms that do not effect rental charges or compensation under a personal services arrangement may be amended anytime without needed to enter into a new agreement.

Amending Existing Arrangement: Financial Terms

Financial terms of agreements may be modified if:

- (1) The agreement qualifies for an exception;
- (2) the amended rental or compensation terms (or formula) is determined prior to the amendment’s execution and can be verified objectively;
- (3) the formula does not take into account the volume or value of referrals or other business generated by the referring physician; and
- (4) the rental or compensation terms (or formula) remain in place for at least 1 year from the date of the amendment.

FY 2009 IPPS Final Rule, 73 FR 48697
Holdover Provisions

- Applies to rental of office space/equipment and personal services exceptions
- An arrangement will continue to satisfy the requirements of the relevant exception for up to six months immediately following the expiration of an agreement of at least one year that satisfied the requirements of the exception, provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.

Only Means of Curing Defects?

- “[T]he Stark Law is intended to deter inappropriate financial relationships through a strict liability regime..... We believe that the temporary non-compliance provision, along with the holdover provisions …provide adequate relief to parties to arrangements of these types that would otherwise temporarily fall out of compliance with the physician self referral law.” 72 Fed. Reg. 51025, emphasis added.
Fraud and Abuse Waivers: ACOs

- Waiver from the Stark Law and the federal health care program Anti-kickback Statute for:
  - Shared savings paid by CMS to the ACO and then distributed to ACO participants, providers, and suppliers during the year shared savings were earned.
  - Shared savings paid by CMS to the ACO and then distributed outside the ACO for activities necessary for or directly related to the ACO’s participation in and operations under the MSSP.
- Other financial relationships with physicians that implicate the Stark Law must meet a Stark Law exception

Gaps in the Stark Law and its Exceptions

- Note there are no exceptions under the Stark Law for:
  - Joint Ventures
  - Loosely structured networks of physicians
- Stark Law favors certain types of organizations that qualify for broad protection
  - Academic Medical Centers
  - Group practices
Hypothetical #5

- Mytown Hospital has a medical director agreement with Dr. Jones that expired three months ago, but otherwise met the Stark Law personal services exception. The Hospital forgot to send a renewal agreement, but continued to pay under the same terms as the original agreement, and Dr. Jones continued to perform the same services. Issues?

- Protected. While the Agreement fell out of technical compliance because it expired (no writing covering the three month time period) compensation and services continued under the old agreement, holdover applies for up to 6 months.

Hypothetical #6

- Same facts as Hypothetical #5, but at the end of month three, Dr. Jones and Mytown Hospital enter into a new agreement with additional compensation made retroactive to the expiration date of the previous agreement. Protected by holdover?

- No. Because the new compensation was made retroactive, holdover does not apply.
Hypothetical #7

- General Health System has agreed to purchase the failing Down and Out Hospital. In the course of the due diligence, you find that the Hospital has numerous office leases with local physicians for office space in the Hospital’s medical office building. The Hospital uses a standard form for all of its physician leases. The standard lease form provides for the first three month’s rent free, which the physician tenants really love. Furthermore, many of the leases have expired months ago, but the physician tenants were still in the space. Issues?

PART IV: PENALTIES
Penalties

- Automatic overpayment or disallowance
  - Strict Liability
  - DHS entity, not referring physician
- Knowing violation can result in CMP liability of up to $15,000 per violation plus 3 times claims and/or $100,000 per circumvention scheme
- Exclusion from Federal Programs

Clarification of Burden of Proof/Persuasion

- Burden of proof/persuasion is on the entity submitting the claim – not the Government
- This has long been CMS position during investigations – made official in 2008 (73 FR 48738)
- The burden of proof on each issue on appeal is initially on the entity submitting the claim but may shift to CMS “depending on the evidence” – unclear what that means
Sanctions for Noncompliance

- CMS is responsible for imposing claims liability
  - Generally, 4-year time limit (from date of initial determination) to reopen and revise claim allowance and take back money; no time limit where allowance was procured by fraud or similar fault
- OIG is responsible for imposing penalties for knowing violations
  - 6-year time limit (from date of presentment of claim) to impose sanction

Sanctions for Noncompliance

- CMS historically had limited authority to compromise or waive Stark sanctions (or any other claims liability)
  - Under §405.376 claim can be compromised (incl. compromised to 0) only for certain reasons and §405.376 may be amended only with concurrence of DOJ and Treasury
- With Self-referral Disclosure Protocol, CMS authority has expanded significantly
- OIG has broad discretion to decide whether to impose CMP/assessment and the amount of CMP/assessment, and whether to impose exclusion and length of exclusion
  - See section 1128A(a) of the Act; 42 CFR Part 1003
Potential Liability

- Potential for Qui Tam Litigation under the Federal False Claims Act

- Liability under FCA for Stark violation relates to all referrals by the physician to the DHS entity (plus penalties)

V. COMPARISON TO THE ANTI-KICKBACK LAW
### Stark Law vs. Anti-Kickback Statute

<table>
<thead>
<tr>
<th>Stark Law</th>
<th>Anti-Kickback Statute</th>
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</thead>
<tbody>
<tr>
<td>Regulated by CMS</td>
<td>Regulated by the OIG</td>
</tr>
<tr>
<td>Prohibits referrals where a financial relationship exists</td>
<td>Prohibits payments intended to induce referrals</td>
</tr>
<tr>
<td>Civil penalties only</td>
<td>Criminal + Civil penalties</td>
</tr>
<tr>
<td>Strict liability</td>
<td>“Intent” element</td>
</tr>
<tr>
<td>Applies only to physicians (and immediate family members)</td>
<td>Applies to anyone who attempts, accepts, or gives kickbacks</td>
</tr>
<tr>
<td>Mandatory Exceptions</td>
<td>“Voluntary” Safe Harbors</td>
</tr>
</tbody>
</table>

### Form Over Substance

- Anti-Kickback focuses on facts and circumstances, Fair Market Value, and the intent of the parties.
- Stark focuses on meeting specific standards, such as writings, valuation, timing, geographic indicators, rural versus urban, location of buildings, contiguous zip codes, repayment terms, holdover clauses, per click services, level of supervision, how and when bonuses can be paid and for what, direct versus indirect financial relationships, ownership versus compensation, full time versus part time employment, financial relationships with family members, etc.
When is there a Legal Obligation to Disclose?

- Medicare statute
  - Felony for anyone “having knowledge of the occurrence of any event affecting his initial or continued right to any such benefit or payment, or the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment” from concealing or “failing to disclose” such an event with an “intent fraudulently to secure” payment which is excessive or unauthorized.
  - 42 U.S.C. § 1320a-7b(a)(3)
  - 2002 CMS proposed rule purporting to implement the statute “clarified” that providers must return excess payments within 60 days of “identifying or learning of the excess payment”. (67 Fed. Reg. 3,662 (Jan. 25, 2002)). Regulation never finalized.
FERA

- False Claims Act – Changes to the FCA language made as part of Fraud Enforcement and Recovery Act of 2009 (FERA)
  - it is now illegal to “knowingly conceal...or knowingly and improperly avoid...or decrease...an obligation to pay or transmit money or property to the Government...” see 31 U.S.C. § 3729(a)(1)(G)
- Eliminated the old statutory language’s need for a “false statement or record” – mere knowledge is apparently enough

Patient Protection and Affordable Health Care Act

- Section 6402
  - Requires reporting of overpayments within 60 days of identification (or due date of next cost report, if applicable)
  - Reports to be made to:
    - Secretary (OIG, CMS)
    - State, or
    - Carrier, intermediary, or contractor
  - Violations actionable under the FCA
CMS Voluntary Disclosure Protocol

- March 24, 2009 OIG issued Open Letter stating that it would not take pure Stark related voluntary self-disclosure
- CMS protocol mandated by ACA after industry outcry
- Not an advisory opinion on questions of legality – entity has already determined there to be a violation

Broad scope of required disclosure
- Parties, time periods, amounts, facts, and circumstances
- Requires legal analysis of any applicable exceptions
- Complete financial analysis
- Remedial measures and compliance
- Certification within 60 days
Potential Benefits of Disclosure

- Potential to avoid criminal liability
- Potential to minimize civil exposure
- Potential to avoid Corporate Integrity Agreements
- Potential to neutralize *qui tam* suits

To Whom to Disclose – Not an Easy Question

- The Department of Justice?
- Office of Inspector General?
- Centers for Medicare and Medicaid Services?
- Assume any information produced to a federal agency will be shared
Protecting Integrity in Medicare Act of 2010 (PIMA)

- Proposed bill released Aug. 7, 2014
- Would formalize manner in which CMS addresses “technical noncompliance violations” disclosed through the SRDP
- Technical violations defined as noncompliance for one of several reasons: (1) arrangement not set out in writing; (2) arrangement not signed by one more of participating entities; (3) services continued after prior amendment expired; (4) arrangement fails to satisfy other requirements that CMS determines are technical
- Sanctions for technical noncompliance violations would be limited to $5,000 if disclosed within one year of initial noncompliance; $10,000 if disclosed thereafter
- Would also impose time limits: for disclosures prior to PIMA, 180 days from PIMA's enactment; for disclosures within a year of PIMA, 180 days from disclosure; for disclosures thereafter, 90 days from disclosure

Tips and Takeaways

- Remember to consider state “mini-Stark” laws in your analysis.
- Always refer to your Statute and Regulations.
- Draw diagrams to better understand the relationships at hand.
- Be thorough and take the time to go back through the history of the rules, the preamble, etc.
- Separate your Stark law analysis from the Anti-Kickback considerations.