Introduction to the Anti-Kickback Statute and Stark Law

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Federal Anti-Kickback Statute

- Prohibits the offering, paying soliciting or receiving of any remuneration in return for
  - Referral of patients; or
  - Inducing purchases, leases, or orders

- Remuneration includes kickbacks, bribes and rebates, cash or in kind, direct or indirect

- Statute is broad and applies to anyone

- Penalties – Civil and Criminal
Penalties

- Criminal and Civil Penalties
- $25,000 per offense
- Imprisonment up to 5 years
- Civil Money Penalties
  (exclusion and $50,0000)
Health Reform

- **Kickback = False Claim**
  - Previously, prosecutors and whistleblowers were required to bootstrap a claims that a kickback was connected to the submission of a false claim, such as through a certification of compliance.
  - Now, the Anti-Kickback Statute specifically provides that a violation constitutes a false or fraudulent claim under the False Claims Act.

- **Intent Requirement**
  - A person need not have “actual knowledge of” or “specific intent to commit a violation”
Statutory Exceptions

- Discount Exception
- Employee Exception
- Group Purchasing Organization
- Waivers of Certain Co-Payments
- Risk Sharing Arrangements
- Safe Harbors
- Waivers of Part D Cost Sharing
- FQHC’s
- Electronic Prescribing (See 42 USC § 1395-104(e))
Timeline of Safe Harbor Issuances

- July ‘91 – First 11 SHs Finalized
- Sept. ‘93 – 7 SHs Proposed
- Jan. ‘96 - Managed Care SHs Finalized and “Clarifications” to First 11 SHs
- Nov. ‘99 – Interim Final Risk Sharing SHs
- Dec. ‘01 – Ambulance Restocking SH
- Sept. ‘02 – Medicare SELECT Proposed
- Aug. ‘06 – E Prescribing Final
- Oct. ‘08 – FQHC Final
What are Safe Harbors?

- Safe harbors provide immunity, but adherence is not required.

- Failure to comply with a safe harbor can mean one of three things:
  - arrangement does not fall within ambit of the statute
  - arrangement is obviously abusive, constitutes a clear statutory violation, and is very likely to be prosecuted; or
  - arrangement involves risk because it may violate the statute in a less serious manner…
General Investment Interest SHs

- **Large Investment Interests**
  - Large publicly traded company registered with SEC
  - At least $50 million in undepreciated assets

- **Small Investment Interests**
  - 60/40 Investor Rule
  - 60/40 Revenue Rule

- **Investments in Entities in MUAs**
  - No Revenue rule, but 50/50 Investor Rule
  - 75% of business derived from services furnished to persons in MUA
Personal Service, Equipment and Office Space Leases

- Written agreement for a term of at least one year
- Aggregate payment amount as well as the premises, equipment, or services covered must be specified
- If not full-time services, agreement must specify schedule of intervals
- Compensation must be based on FMV and not vary based upon referrals or business
Discounts

- **Statutory exception** “discount or other reduction in price obtained by a provider … if the reduction … is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity…”

- **Safe Harbor** categorizes protection based upon the type of party involved in the transaction (buyers, sellers and offerors) and then further divides based upon the type of purchasing entity (MC/MA risk contractors, cost reporting entities, and all others (e.g., Part B. suppliers))
Other Guidance

- Case Law
- Advisory Opinions
- Special Fraud Alerts and Special Advisory Bulletins
Stark Law

“… If a physician (or an immediately 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 or designated health services for which payment otherwise may be made” under Medicare and to some extent Medicaid.
Brief Overview of the Stark Law

- Stark I – Passed ’89, eff. ’92 (clinical laboratory services only)
- Stark II – Passed ’93, eff. ’95 (remaining 10 DHS)
- Regulations
  - 3/92 – Proposed Stark I
  - 8/95 – Final Stark I
  - 1/98 – Proposed Stark II
  - 1/01 – Phase I Stark II Final Regulations
  - 3/04 – Phase II Stark II Final Regulations
  - 9/07 - Phase III Stark II Final Regulations
  - Additional modification in Medicare Physician Fee Schedules and Hospital PPS Rules
Important Definitions

- "Financial Relationship" defined to include both compensation arrangements and investment and ownership interests

- "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.”
“Designated Health Services”

- clinical laboratory services;
- physical therapy services;
- occupational therapy services;
- radiology, including magnetic resonance imaging, computerized axial tomography scans and ultrasound services;
- home health services and supplies;
- durable medical equipment and supplies;
- radiation therapy services and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services
Penalties

- Civil sanctions
- Exclusion from federal programs
- Recoupment of payments
- Bootstrap of False Claims Act violation
Exceptions

- General exceptions from the scope of the Stark prohibition
- Exceptions relating only to ownership or investment interests
- Exceptions relating only to compensation arrangements
In-Office Exception

- Applies to DHS furnished in a physician’s office except for DME (excluding infusion pumps, crutches, canes, walkers, folding wheelchairs, blood glucose monitors) and parenteral/enteral

- Referring physician or another physician in the same “group practice” must personally furnish the services or “directly supervise” another person performing the tests
  
  Note: for purposes of supervision, the physician can be either an owner or an employee of the practice (which are “members of the practice”) or can be an independent contractor physician
Health Reform

- Amendment to In-Office Ancillary Services Exception (Section 6003)
  - Referring physician must inform patient in writing that the patient may obtain the service from a person other than the referring physician or the physician’s group practice.
  - Referring physician must provide list of suppliers who furnish such services in the area where the patient resides
  - Applies to: MRI, CT, PET and any other DHS the Secretary determines appropriate
  - Applies to services furnished on or after January 2, 2010
Exception for Physician Ownership in a Hospital (and a Rural Hospital)

- Attempts over last several years to limit the scope of this exception (specifically related to Specialty Hospitals)
- Health Reform generally eliminated this exception, unless the following requirements can be met:
  - The physician-owned hospital must have physician ownership or investment and have an effective Medicare provider agreement as of December 31, 2010
  - The aggregate percentage of the total value of ownership in the hospital, or an entity whose assets include the hospital, held by physician owners and investors cannot increase post-enactment
  - Subject to a very limited exception process, hospitals cannot expand the number of operating rooms, procedure rooms, or licensed beds in place as of date of enactment
  - Hospitals must meet other specified requirements regarding conflicts of interest, bona fide investments and patient safety issues
What Constituted A DHS “Entity”

- Pre-10/01/2009 definition of DHS “entity” included only the person or entity that billed Medicare for the DHS
- Under 2009 IPPS final rule, effective 10/1/09, new definition of entity includes both the person or entity that bills for the services and any person or entity that performs the service (DHS)
Under Arrangements Option

- Referring Physicians
- Joint Venture LLC
- Hospital
- Third Party Payors

Ownership

Billings for procedures

Turn-key “under arrangements” agreement
“Under Arrangements” Analysis

- JV is a Stark “entity”, so when the doctors order services furnished by the hospital which are subcontracted to JV, the physicians are “referring” to an entity they own.

- In the 2010 Physician Fee Schedule regulation, CMS sought comments on whether the definition of “entity” should be changed.
  - CMS announced on June 25, 2010, that the comments it received did not convince the agency that it needs to provide any additional guidance or to engage in rulemaking to further define the term "entity."
Provision of Certain Services

- CMS Guidance Regarding Definition of “Entity”
  - No regulatory definition of “performs the service”
    - Example: a service is “performed” if the entity provides medical service and could bill for the service but contracts with a provider and that provider bills for service instead
  - An entity does not “perform” DHS if it only:
    - Leases or sells space/equipment
    - Furnishes supplies
    - Provides management or billing services; or
    - Provides personnel
Compensation Methodologies

- Percentage-based and per-click compensation arrangements prohibited effective October 1, 2009.
- Applies to:
  - Space lease exception
  - Equipment lease exception
  - Fair market value exception
  - Indirect compensation exception
Disclosure Protocol for Stark

- On September 23, 2010 CMS released the Voluntary Self-Referral Disclosure Protocol (SRDP) to facilitate the resolution of matters that are actual or potential violations of the Stark Law.

- Section 6409 of the Affordable Care Act required the Secretary of HHS to establish a Medicare self-referral disclosure protocol that provides a process for providers of services and suppliers to self-disclose actual or potential violations of the Stark Law.
Defining Fair Market Value
“Fair market value” – value in arm’s-length transactions, consistent with the general market value

- “General market value” – price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party.

- Generally, fair market value is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement.

- The price or compensation may not have been determined in any manner that takes into account the volume or value of anticipate or actual referrals.
Stark: Phase II and Phase III

- Phase II created a “safe harbor” methodology to determine FMV, which was eliminated by Phase III

- However …
  - CMS reserves the right to second guess the methodology
  - Reference to multiple, objective, independently, published salary surveys remains a prudent practice for evaluating fair
  - CMS may seek to differentiate between FMV for administrative work and FMV for clinical work
Stark: Rental of Office Space and Equipment

- Value of rental property for general commercial purposes
- Cannot take into account its intended use or its proximity to referral sources
- FMV calculations may include development, maintenance, or improving the property
Anti-Kickback Safe Harbors

- **Space Rental**
  - The value of the rental property for general commercial purposes, but does not vary on the volume or value of any Medicare-covered or state healthcare program covered referrals or business otherwise generated between the parties.
  - Real estate developers or other entities not involved in the delivery of health care services, may enter into arrangements that encourage referrals.
  - OIG recommends an independent fair market valuation using appropriate health care valuation standards.

- **Equipment Rental**
  - The value of the equipment when obtained from a manufacturer or professional distributor, but does not vary on the volume or value of any Medicare-covered or state healthcare program covered referrals or business otherwise generated between the parties.

- **Personal Services and Management Contracts**
  - Based on the value of an arms-length transaction, but does not vary on the volume or value of any Medicare-covered or state healthcare program covered referral or business otherwise generated between the parties.
Managing Fair Market Value

- Basis for Methodology
- Adequate of documentation
  - Memos to File
  - Commercial Sources
  - Independent Valuation
- Availability and Accessibility of documentation
- Contemporaneousness of documentation
Creating Fair Market Value Documentation

- **To Privilege or Not to Privilege**
  - Do you really want a privileged memo to be your only defense?
  - Scope of waiver-broad
- **Create contemporaneous non-privileged documentation or justification**
- **Business memos to file**
- **Fair Market Value – Outside Appraisals, Internal Evidence Files**
- **Detailed Whereas Clauses in agreements**
Thank you

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