Physician Relationships and Compliance Risks

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Disclaimer

Today’s presentation will cover topics related to the False Claims Act, the so-called Stark Law, and the Anti-Kickback Statute.

Relationships with Potential Referral Sources ("PRS") can be complex. There is no substitute for a qualified Legal or Compliance guidance. Questions or concerns regarding such should be directed to competent Legal Counsel or your Compliance Officer.
Objectives

Today’s presentation will:

• Affirm, for all participants, the importance of a commitment to ethical business practices as well as the expectation placed upon those in positions of management and/or administration to conduct all business according to the highest ethical standards
• Introduce the participants to several pivotal laws governing relationships with physicians
• Demonstrate the commitment of law enforcement to enforce the laws related to fraud and abuse in the health care industry
• Educate the participants on the more common relationship risk areas and the attendant requirements necessary to remain compliant with the law

The Laws:
The False Claims Act
The Physician Self-Referral Law (“Stark”)
The Anti-Kickback Statute

Part I
False Claims Act ("FCA")

- The civil FCA protects the Government from being overcharged or sold shoddy goods or services. It is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent.
  - Filing false claims may result in fines of up to three times the programs' loss plus $11,000 per claim filed. Under the civil FCA, each instance of an item or a service billed to Medicare or Medicaid counts as a claim, so fines can add up quickly.
  - The fact that a claim results from a kickback or is made in violation of the Stark law may also render it false or fraudulent, creating liability under the civil FCA as well as the Anti-Kickback Statute ("AKS") or Stark law.
  - Under the civil FCA, no specific intent to defraud is required. The civil FCA defines "knowing" to include not only actual knowledge but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information.
  - There also is a criminal FCA (18 U.S.C. § 287). Criminal penalties for submitting false claims include imprisonment and criminal fines.
- Contains whistleblower ("qui tam") provisions. Qui tam relators can get a portion of the recovery:
  - If the government proceeds with the case; 15 - 25% depending upon the contributions of the individual to the case.
  - If the government declines; 25 – 30% plus reasonable expenses and attorney’s fee and costs awarded against the defendant

False Claims Act [31 U.S.C. §§ 3729-3733]

Stark Law – Basic Prohibition

- Prohibits “physicians” from referring Medicare patients for certain “designated health services” (“DHS”) to an entity with which the physician or a member of the physician’s “immediate family” has a “financial relationship” – unless an exception applies

- It also prohibits presenting or causing to be presented a bill or claim to anyone for a DHS furnished as a result of a prohibited referral
Three Pillars of Stark

- Physician
- Financial Arrangement
- DHS

Stark Law

• Is a strict liability law, meaning no requirement exists to prove intent. You are either compliant or in violation.

• Prohibits billing for services and/or items while an unallowable compensation arrangement exists. Payments for such items or services received, must be refunded.¹

• If claims are filed “knowingly” in violation of the Stark statute, the government may pursue False Claims Act remedies as well

¹42 CFR § 411.353 Prohibition on certain referrals by physicians and limitations on billing
**Stark Law**

**Key Definitions Under Stark**

<table>
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<tr>
<th>DESIGNATED HEALTH SERVICES</th>
<th>POTENTIAL REFERRAL SOURCE</th>
<th>IMMEDIATE FAMILY MEMBER</th>
<th>FINANCIAL RELATIONSHIP</th>
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<td>i. Clinical laboratory services.</td>
<td>• Includes: a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of pediatric medicine, a doctor of optometry, or a chiropractor.</td>
<td>• Includes: husband or wife; natural or adoptive parent, child, sibling, stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of grandparent or grandchild.</td>
<td>• Includes any ownership interest or compensation relationship between a physician (or his/her immediate family member) and an entity. Note that compensation relationship includes any remuneration, whether direct or indirect.</td>
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<td>ii. Physical therapy, occupational therapy, and speech-language pathology services.</td>
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<td>iii. Radiology and certain other imaging services.</td>
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<td>iv. Radiation therapy services and supplies.</td>
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<td>v. Durable medical equipment and supplies.</td>
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<td>vi. Parenteral and enteral nutrients, equipment, and supplies.</td>
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<td>vii. Prosthetics, orthotics, and prosthetic devices and supplies.</td>
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<td>viii. Home health services.</td>
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<td>ix. Outpatient prescription drugs.</td>
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<td>x. Inpatient and outpatient hospital services.</td>
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**Advanced Approval Governs Relationships**

- **Do not** pay a physician or their immediate family member...

- **Do not** give occupancy or change lease terms to/for a physician or their immediate family member...

- **Do not** accept payments or waive payments to/from a physician or their immediate family member...

- **Without:**
  - A fully reviewed, approved, written, and executed *in advance* agreement
### Exceptions and Safe Harbors

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<th>Exceptions</th>
<th>Safe Harbors</th>
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<td>• Stark provides ‘exceptions’ for certain financial arrangements. Stark’s ‘exceptions’ differ from safe harbors in that the arrangement must exactly fit the exception. Close doesn’t count!</td>
<td>• The Anti-Kickback Statute contains several so-called &quot;safe harbors,&quot; which have been revised and supplemented from time to time since the statute's enactment. The intent of the safe harbor provisions is to provide organizational guidance that, if complied with in full, will ensure compliance. Essentially, the closer the better, but an exact fit within the safe harbor is not necessarily required for AKS compliance.</td>
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### General Exceptions Related to Both Ownership/Investment and Compensation § 411.355

- Physician services
- In-office ancillary services
- Services furnished by an organization to its enrollees
- Academic medical centers
- Implants furnished by an ASC
- EPO and other dialysis related drugs furnished in or by and ESRD facility
- Preventive screening tests, immunizations, and vaccines
- Eyeglasses and contact lenses, following cataract surgery
- Intra-family rural referrals
**Exceptions to Ownership or Investment Interest § 411.356**

- Publicly-traded securities and mutual funds
- Hospitals located in Puerto Rico
- Rural providers
- Ownership interest in a whole hospital
  (this exception was changed as part of the Affordable Care Act)

**Exceptions Related to Compensation § 411.357**

- Rental of office space
- Rental of equipment
- Bona fide employment relationships
- Personal service agreements
- Physician recruitment
- Isolated transactions
- Remuneration unrelated to DHS
- Group practice arrangements with a hospital
- Payments by a physician
- Charitable donations by a physician
- Nonmonetary compensation
- Fair market value (FMV) 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 services
**Anti-Kickback Statute**

**Differs from Stark:**

- No physician involvement is required
- Intent-based; However, “knowingly and willfully” has been defined to include the concept of reckless disregard
- Criminal penalties are possible - Stark is strictly civil
- The “one purpose rule” makes the whole arrangement bad if ‘one purpose’ is to obtain money for the referral of services or to induce further referrals

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1. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989) – This language appears in every Advisory Opinion published by the OIG.

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**Anti-Kickback Statute**

- (b)(1) Whoever knowingly and willfully *solicits* or *receives* any *remuneration* (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
  - (A) in *return for* referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
  - (B) in *return for* purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Federal health care program,

- (2) Whoever knowingly and willfully *offers* or *pays* any *remuneration* (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
  - (A) to *refer* an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
  - (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.
  - (Emphasis added)

42 U.S.C. 1320a-7b
Anti-Kickback Statute

Remuneration

The term “remuneration” has a well-established meaning in the context of various health care fraud and abuse statutes. Generally, it has been interpreted broadly to include “anything of value.”

Anyone who knowingly and willfully receives or pays anything of value to influence the referral of federal health care program business, including Medicare and Medicaid, can be held accountable for...

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<th>A felony</th>
<th>Punishable by a maximum fine of $25,000, or</th>
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<td>Imprisonment up to five years, or both.</td>
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<td>Administrative CMP $50,000</td>
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<td>Conviction will also lead to automatic exclusion from Federal health care programs.</td>
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Why Are Physician Relationships an Area of Concern?

• On the OIG list of “special areas of concern”
• Stark law
• Anti-Kickback Statute
• False Claims Act
• Deficit Reduction Act provisions
• State laws
• Sarbanes-Oxley
**Enforcement Actions**

- **St. Mary’s of Michigan Standish Hospital**, Michigan – 12-18-2014
  After it self-disclosed conduct to OIG, Standish Community Hospital, Inc. d/b/a St. Mary’s of Michigan Standish Hospital (SMMSH), Michigan, agreed to pay $64,854.41 for allegedly violating the Civil Monetary Penalties Law provisions applicable to physician self-referrals and kickbacks. OIG alleged that SMMSH paid remuneration in the form of below-fair market value rates for the use of two hospital employees.

- **Harris Methodist Hospital**, Dallas, Texas 01-02-2008
  284 bed acute-care facility will pay $1.9 million to settle allegations that it violated the False Claims Act by improperly submitting claims for payment for orthopedic-related items and services. These services were paid by Medicare and Texas Medicaid during the period when the physician group received free rent from the hospital.

- **St. Agnes Hospital**, Maryland 12-18-2014
  After it self-disclosed conduct to OIG, St. Agnes Healthcare, Inc. d/b/a St. Agnes Hospital (St. Agnes), Maryland, agreed to pay $1,414,248 for allegedly violating the Civil Monetary Penalties Law provisions applicable to physician self-referrals and kickbacks. OIG alleged that St. Agnes paid remuneration to a cardiology practice in the form of equipment, supplies, staff and space needed to provide certain nuclear diagnostic cardiology testing services. OIG alleged that the cardiology practice paid St. Agnes less than fair market value for these services.

- **Tomball Hospital Authority**, Texas 2007
  Agreed to pay the United States $9,600,000 to resolve apparent Stark and FCA liabilities.
Requirements for Specific High-Risk Relationships

Part III

Real Estate Leases

• Stark has a real estate lease exception – must meet all elements or hospital cannot lease space to or from the referral source
• Areas of Risk:
  ▪ Offering rent below fair market value ("FMV")
  ▪ Permitting a physician or physician group to move into rented space without a written lease that has been fully executed by both parties
  ▪ Failure to act like a landlord in collecting rent
  ▪ Failure to renew leases in a timely manner
  ▪ Entering into part-time leases that are not appropriately structured (don’t charge for vacancy rates or furniture/equipment or staffing bundled into the lease)
**Real Estate Leases**

- Lease agreements may be terminated with or without cause as long as no other lease agreement for that same space is entered into within the first year of the original lease term and any new lease fits an exception.
- Parties may amend lease agreements during the first year provided no change is made to the rental charge.
- Such amendments do not require the agreement to be extended for an additional year.
- If the parties wish to change any material lease term, including the amount paid, the amount of space leased, or type of equipment rented, the existing agreement should be terminated and a new agreement entered into.
- The new agreement may not begin until the first year of the original lease is complete.

**Office Space and Equipment**

- Lease agreement must be in writing.
- Space/equipment leased does not exceed what is reasonable and necessary for legitimate business purposes and is used exclusively by lessee.
- Term is at least one year.
- Rental charges over term are set in advance and do not take into account the volume or value of referrals or other business generated between the parties.
- The lease would be commercially reasonable even if there were no referrals between the parties.
Payments to Physicians

- Stark has exceptions for Professional Service Agreement ("PSA") and FMV – the arrangement must meet all the elements.
- Payment to potential referral sources must meet the following requirements:
  - Be in writing, signed by the parties and specify the services covered; and
  - Specify the length of the agreement (the "term"); and
  - Specify the compensation exchanged (which must be set in advance, consistent with FMV for the services or items provided without taking into account the value or volume of referrals or other business generated by the physician).
- Fair market value payments for necessary services that were actually rendered (appropriate documentation needs to be received and reviewed before payment).
- No *de minimus* exception for cash or cash equivalent payments.

Non-Monetary Compensation

- Pursuant to the Stark regulations, an exception for non-monetary compensation exists.
- The non-monetary compensation exception may be used to protect items or services provided to a physician.
  - Examples of non-monetary compensation include:
    - Meals
    - Gift baskets (i.e., flowers for birthdays, anniversary, or funerals)
    - Other non-cash items
- Resource agreements are a mechanism for those situations where a physician maybe utilized in special and/or recurring roles.
Non-Monetary Compensation Annual Limit and Adjustment

• For calendar year 2015, hospitals and other healthcare entities subject to the federal Stark Law are allowed to provide non-monetary compensation to physicians up to an aggregate amount of **$392.00**

• The 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 as soon as possible after September 30 each year both the increase in the CPI-U for the 12-month period and the new non-monetary compensation limit on the physician self-referral.

• This is not a value or limit set by public or privately held companies or hospitals

Requirements for Compliance with the Non-monetary Compensation Exception (§411.357(k))

• The compensation must not be determined in any manner that takes into account the **volume** or **value** of referrals or other business generated by the referring physician

• The compensation cannot be **solicited** by the physician or the physician practice (including employees and staff members)

• The compensation arrangement must not violate the Anti-Kickback Statue or any Federal or State law or regulation governing billing or claims submission

• The compensation cannot be aggregated for a Group Practice to provide a single gift greater than $392

*Example: providing a gift valued at $1960 for Group Practice of 5 physicians ($385x5)*
**Non-Monetary Compensation – OOPS!!**

- When an entity has inadvertently provided non-monetary compensation to a physician in excess of the $392 limit, such compensation is deemed to be within the $392 limit if:
  - The value of the non-monetary compensation is no more than 50% of the $392 limit (i.e., $588.00); and
  - The physician returns to the entity the excess non-monetary compensation (or an amount equal to the value of the excess non-monetary compensation) by the end of the calendar year in which the excess non-monetary compensation was received or within 180 consecutive calendar days following the date the excess non-monetary compensation was received by the physician, whichever is earlier.

**Non-Monetary Compensation – Return Option**

- This “return” option, regarding excess non-monetary compensation, may be used by an entity only once every three years with respect to the same referring physician.

Actively track and never have to use the return option.
**Non-Monetary Compensation – Annual Appreciation Event**

- In addition to non-monetary compensation up to the $392 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 provided in connection with the medical staff appreciation event are subject to the $392 limit.

**Medical Staff Incidental Benefits (§ 411.357 (m))**

- The Stark regulations set forth an exception to the physician self-referral prohibition for certain medical staff incidental benefits that are less than $33 per day.
- The exception for medical staff incidental benefits applies only to items or services provided by a hospital to members of its medical staff while the physicians are on campus.
Requirements for Compliance for the Incidental Medical Staff Benefits Exception

• Compensation in the form of items or services from a hospital to the members of its medical staff when the item or service is used on the hospital’s campus must meet **all** of the following conditions in order to meet the medical staff incidental benefits Stark exception

Incidental Benefit Must Be...

• Offered to (but not necessarily accepted by) all members of the medical staff practicing in the same specialty, without regard to the volume or value of referrals or other business generated between the parties

• Provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients
Incidental Benefit Must Be:

- Provided by the hospital and used by the medical staff members only on the hospital’s campus
- Reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital
- Of low value (less than $33) with respect to each occurrence of the benefit

Incidental Benefit Must Not Be:

- Determined in any manner that takes into account the volume or value of referrals or other business generated between the parties
- In violation of the Anti-Kickback Statute or any Federal or State law or regulation governing billing or claims submission
Items That Are Always Prohibited

- Cash or cash equivalents **do not** meet the exception for non-monetary compensation or medical staff incidental benefits
- Gift certificates and gift cards are generally considered to be cash equivalents and should not be given to medical staff members at any time

“On Campus” Requirement

The following meet this requirement:

- Compensation in the form of internet access, pagers, or two-way radios used away from the campus **ONLY** to access hospital medical records or information or to access patients or personnel who are on the hospital campus
- Identification of the medical staff on a hospital website or in hospital advertising; however, must include **all** members of the medical staff or same specialty
$33 Limit

• 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 30th

• Applies to each occurrence of the benefit - for example, each meal given to a physician, while he or she is serving patients who are hospitalized, must be of low value

• As with the non-monetary compensation exception, the value is not set by the hospital

Questions
The **Quorum Difference** is the extraordinary combination of consulting guidance and operations experience that enables client healthcare organizations to achieve a sustainable future.

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**THANK YOU**

Intended for internal guidance only, and not as recommendations for specific situations. Readers should consult a qualified attorney for specific legal guidance.