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Stark Law and Anti-Kickback Statute Compliance in Hospital-Physician Transactions

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Speakers

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Agenda

01 Stark Law

02 The Anti-Kickback Statute

03 Pre-Closing Considerations

04 Post-Closing Considerations

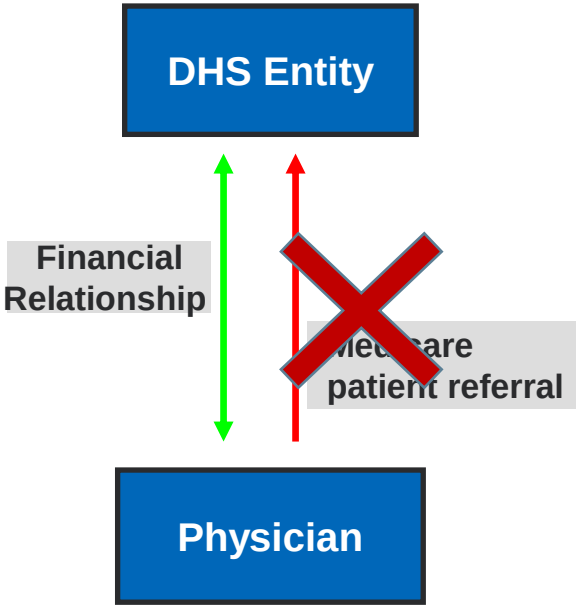
05 Questions

Stark Law Compliance in Hospital-Physician Transactions

Stark Prohibitions

Two Basic Prohibitions

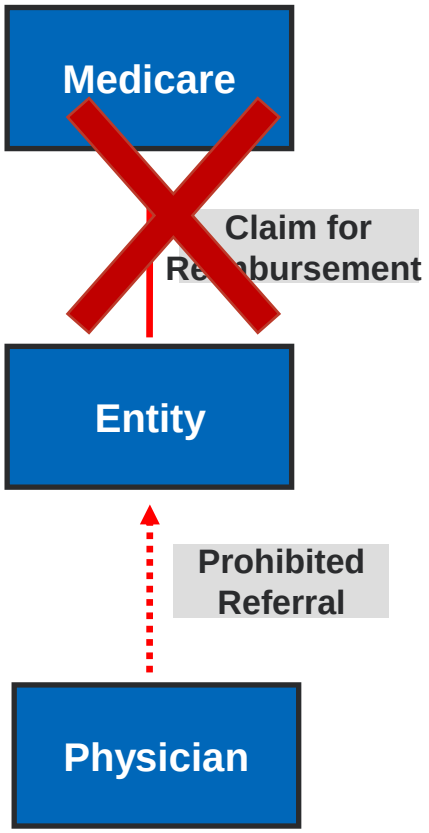
- First
  - if a physician (or "immediate family member") has a ***direct* or *indirect* "financial relationship"** with an entity, the physician may not refer Medicare patients to the entity for the furnishing of "designated health services" (DHS)
  - … unless an exception applies



Stark Prohibitions

Two Basic Prohibitions

- Second
  - an entity may not bill Medicare (or any other individual or entity) for services furnished pursuant to a prohibited referral



Penalties for Violations

- Payment denial/recoupment
- Civil monetary penalties up to $15,000 per prohibited service/billing ($25,820 for 2020)
- Circumvention schemes face civil monetary penalties of up to $100,000 per incident ($172,137 for 2020)
- Exclusion from Medicare/Medicaid participation
- Liability under the False Claims Act (“FCA”)

Overview of Key Exceptions

Ownership Exceptions	Compensation Exceptions	Service-Based Exceptions
• Publicly traded securities • Mutual funds • Rural providers • Whole-hospital exception	• Indirect compensation arrangements • Rental office space/equipment • Employment • Personal service arrangements • Physician recruitment • Isolated transactions • Physician FMV payments	• Physician services • In-Office Ancillary Services • Services furnished to prepaid plan enrollees • Implants by an ASC • Preventive screening tests, immunizations and vaccines • Intra-family rural referrals

. . . And more

Key Elements/Concepts in Stark Exceptions for Common Hospital-Physician Transactions

Fair Market Value

Many compensation exceptions have FMV requirements

- Bona fide employee arrangements
- Personal service arrangements
- Fair market value compensation
- Space and equipment leases
- Indirect compensation
- Payments by a physician

Fair Market Value

- Section 1877(h)(3) of the Act defines FMV as "the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee."

Fair Market Value

Regulatory definition of FMV expands upon the statutory definition:

- "Fair market value means the value in arm's-length transactions, consistent with the general market value."
  - "General market value" is the 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, on the date of acquisition of the asset or at the time of the service agreement.

Fair Market Value

Regulatory definition of FMV (cont'd)

- "Usually, the fair market price 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, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals."

Fair Market Value

Regulatory definition of FMV (cont'd)

- With respect to rentals and leases described in §411.357(a), (b), and (l) (as to equipment leases only), "fair market value" means the value of rental property for general commercial purposes *(not taking into account its intended use).* In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.

Fair Market Value

Guidance from the preamble to the final Phase I rule provides:

- "To establish the fair market value (and general market value) of a transaction that involves compensation paid for assets or services, we intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions who are not in a position to refer to one another." Phase I, 66 FR 856, 944 (Jan. 4, 2001).

FMV Factors in Service Agreements

- For service agreements, FMV may be influenced by the following factors:
  - Education and training that are reasonably required to perform the services
  - The prevailing rate for comparable types of professionals performing comparable services
  - The nature and complexity of the services provided
  - If the services are needed and provided in a specific geographic market, the unique aspects of that market such as cost of living, shortage of individuals entities that are qualified to provide the services, etc.

Fair Market Value – Other Considerations

- Q: If an exception requires FMV and an arrangement between the DHS entity and a physician provides for *less* than FMV for the physician, is the exception not met?
- A: Maybe. Whereas paying less than FMV to a referral source is not a problem under the AKS, several of the Stark exceptions (statute and regulations) use the phrase "consistent with fair market value"
  - no guidance in legislative history or preambles
  - Note that the PSA exception (statute and regulations) uses "does not exceed fair market value"

Fair Market Value – Other Considerations

- Third-Party FMV report?

Commercially Reasonable

- Several exceptions have CR requirement
  - Space and Equipment Lease exceptions
  - Employee
  - Personal Services Agreement
  - FMV Compensation
  - Indirect Compensation
  - Isolated Transactions

Commercially Reasonable

- Several compensation exceptions to the Stark Law also require the compensation or remuneration to be *commercially reasonable*, even if no referrals were made between the parties.
  - CMS has interpreted "commercially reasonable" to mean that the arrangement appears to be a prudent business agreement from the perspective of the parties involved, absent any potential referrals for DHS.

Commercially Reasonable - Examples

- What does it mean for an arrangement to be commercially reasonable in the absence of referrals?
  - Hospital renting space from physician at FMV rate per square foot, but renting much more square footage than it needs
  - Hospital rents lithotripter from physician although it has enough volume to justify purchasing one
  - HHA has multiple medical directorships with referring physicians at FMV
  - Lab has multiple physician managers who refer to the Lab, at a FMV, flat fee per month

Term of 1 year

- Several exceptions require a term of 1 year:
  - Rental of office space
  - Equipment rental
  - Personal service arrangements

Term of 1 year

- In the 2016 Physician Fee Schedule Final Rule, CMS stated:
  - "An arrangement that lasts as a matter of fact for at least 1 year satisfies this [1-year term] requirement. Parties must have contemporaneous writings establishing that the arrangement lasted for at least 1 year, or be able to demonstrate that the arrangement was terminated during the first year and that the parties did not enter into a new arrangement for the same space, equipment, or services during the first year, as required by § 411.357(a)(2), (b)(3), and (d)(1)(iv), as applicable."
  - "A formal contract or other document with an explicit ''term'' provision is generally not necessary to satisfy this element of the exception."

80 Fed. Reg. 70886, 71317 (Nov. 16, 2015)

Term of 1 year – Amendment of compensation?

- According to CMS in the 2009 IPPS Final rule, for leases and PSAs to be amended during the term of the agreement (applies to all exceptions that include a 1-year term requirement):
  - (1) All of the requirements of an applicable exception are satisfied;
  - (2) amended rental charges or other compensation (or formula for same) is determined before the amendment is implemented and the formula is sufficiently detailed so that it can be verified objectively;
  - (3) the formula for the amended rental charges does not take into account V or V of referrals or other business generated; and
  - (4) the amended rental charges or compensation (or the formula for same) remain in place for at least 1 year from the date of the amendment.

  73 Fed. Reg. 48434, 48697 (Aug. 19, 2008)

Term of 1 year – Amendment of compensation?

- At the beginning of the COVID-19 public health emergency, CMS issued blanket waivers in which it further clarified:
  - "CMS has historically interpreted and continues to interpret preamble guidance in the [FY 2009 IPPS final rule] to allow a second or subsequent amendment of the remuneration terms of a compensation arrangement, even within the first year after an initial amendment of the remuneration terms of the arrangement, provided that, each time the remuneration terms are amended, all requirements of an applicable exception are satisfied, the amended remuneration is determined before the amendment is implemented, the formula for the amended remuneration does not take into account the volume or value referrals or other business generated by the referring physician, and the overall arrangement remains in place for at least 1 year following the amendment."

Indirect Compensation Exception

Indirect Compensation Arrangement is…

- An unbroken chain of (more than 1) financial relationships (compensation or ownership or both) going from the referring physician to the DHS entity

- the referring physician receives aggregate compensation from the person or entity in the chain with which the physician has a direct financial relationship that *varies with*, ***or*** *takes into account*, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS
- The DHS entity (e.g. Hospital) has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives compensation that meets the Aggregate Comp Test

Indirect Compensation Exception

- If there is an “indirect compensation arrangement” the only compensation exception that is potentially available is the exception for indirect compensation arrangements.
- The exception has familiar requirements, *which pertain to the compensation paid to the physician by the entity with which the physician has a direct compensation arrangement:*
  - fair market value;
  - prohibition on V or V of referrals;
  - signed written agreement (unless physician is an employee);
  - commercially reasonable
  - does not violate AKS or any law governing billing or claims submission.

Comparing the Stark Law and AKS

Stark Law	Anti-kickback Statute
Regulated by CMS	Regulated by OIG
Prohibits referrals where a financial relationship exists	Prohibits payments intended to induce referrals/other business
Civil penalties only	Criminal and civil penalties
Strict liability	"Intent"
Applies only to physicians	Applies to anyone who offers/gives, requests/accepts remuneration in exchange for a referral/other business
Mandatory exceptions	"Voluntary" safe harbors

Stark Law Changes

- Blanket Waivers of Section 1877(g) of the Social Security Act on account of COVID-19
- Proposed Rule: Modernizing and Clarifying the Physician Self-Referral Regulations

II. The Anti-Kickback Statute

A. Hospital-Physician Ambulatory Surgical Centers

1. Often ASCs initially structured as physician-owned
2. They stripped volume from hospital outpatient surgery
3. But many of these ASCs have found it increasingly difficult to negotiate favorable rates from payors. Hospitals, meanwhile, still enjoy some leverage. A properly structured joint venture can enjoy better pricing in the insurance market, as well as access to capital and other advantages.
4. Usually hospital ownership is 51% and the hospital controls the ASC for antitrust purposes to negotiate with payors as an affiliate of the hospital.

II. The Anti-Kickback Statute

B. The Hospital-Physician ASC Safe Harbor

1. The HHS OIG promulgated a safe harbor specifically for hospital-physician ASC joint ventures.
2. This safe harbor protects ASC joint ventures between hospitals and physicians so long as certain requirements are satisfied, as follows:
    a. The terms on which an investment interest is offered must not be related to previous or expected referrals.
    b. The hospital must not loan funds or guarantee a loan for a physician investor.
    c. The return on investment must be directly proportional to the amount invested by the physician investor.
    d. The ASC and physicians must treat Federal health care program beneficiaries in a non-discriminatory manner.
    e. The ASC may not use hospital space unless the space is leased under a lease that complies with the safe harbor for leases of space. The ASC may not use hospital equipment unless the equipment is used under a lease that complies with the safe harbor for leases of equipment.
    f. Ancillary services for Federal health care program beneficiaries performed at the ASC must be directly related to procedures performed at the ASC, and may not be separately billed.
    g. The hospital may not include in its cost report or in any claim for payment from a Federal health care program any costs associated with the ASC.
    h. The hospital may not be in a position to make or influence referrals to any physician or the ASC.

II. The Anti-Kickback Statute

3. Limitations of the ASC Safe Harbor
   a. Employees
   b. Medical directors and other contractors

C. Clinical Ventures – Gainsharing Arrangements

1. Gainsharing arrangements are a good example of hospital-physician transactions with fraud and abuse implications. They offer benefits to Federal health care programs in the form of cost savings, but involve payments from hospitals to physicians, implicating the anti-kickback statute.
2. The basic gainsharing arrangement
3. The OIG position in general
   a. The “Gainsharing CMP” prohibits a hospital from making payments to a physician to reduce medically necessary care. 42 U.S.C. § 1320a-7a(b)(1).
   b. The AKS prohibits payments by the hospital to physician to induce referrals. 42 U.S.C. § 1320a-7b(b).

II. The Anti-Kickback Statute

4. Nevertheless, the OIG has approved gainsharing arrangements, with necessary features:
   a. Protection against reduction of medically necessary services:
      1. Neurosurgery Spinal Fusion Program Advisory Opinion – Oversight Committee to review utilization of equipment and patient resource utilization. OIG Advisory Opinion No. 17-09 (December 29, 2017)
      2. The Committee also reviews neurosurgeons' patient selection for consistency with historical patterns.
      3. Patients are given written notice of the gainsharing arrangement.
   b. Protection against inappropriate payments.
      1. Base year costs are determined.
      2. Performance year costs are determined.
      3. Performance year cost is compared to base year cost. If volume payable by Federal health care programs increases, no savings are shared. The amount is also adjusted for any inappropriate reductions in the use of items. Savings from utilization recommendations are added to determine total performance year savings. Fifty percent of this amount (after deduction of a fixed management fee) is distributed. Distributions are made to the physician on a per capita basis.

II. The Anti-Kickback Statute

4. Each year then becomes a new base year so that payments for savings are not duplicated.

c. OIG reasoned that protections against underutilization were sufficient to reduce risk that physician would reduce or limit medically necessary services.

d. The OIG found sufficient safeguards under the AKS
   1. Per capital payments to neurosurgeons
   2. Potential savings capped based on base year procedures
   3. Historically consistent selection of patients
   4. Annual rebasing
   5. Evidence-based cost savings
   6. Selection of equipment and supplies unchanged
   7. Participation limited to one group that practices at the hospital

e. This shows that clinical joint ventures between hospitals and physicians are possible under the AKS, but they must be carefully structured to withstand scrutiny.

II. The Anti-Kickback Statute

D. The Proposed Rules

1. Proposed safe harbors for value-based arrangements
   a. Key concepts:

      "Value-based" – should address one or more of the following:

      1. Care coordination
      2. Improved outcomes
      3. Cost control/reduction
      4. Efficiencies

   b. Infrastructure

      1. Accountable body – performs oversight, reporting, utilization review.
      2. Governing document – outlines structure, value-based purpose, and means of achieving the purposes

   c. Risk-bearing payor agreement

      1. Tiers: minimal, substantial, full
      2. Can accomplish through stand alone entity or individual participant

II. The Anti-Kickback Statute

d. Evidence based outcomes measures (EBOM) – require drive to measurable improvements in quality, outcomes, or efficiencies.

e. Value-based purpose (VBP)

1. Coordinating and managing care – required for all safe harbors
2. Improving quality of care
3. Reducing costs or growth in expenditures
4. Transitioning from payment based on volume to payment based on cost control

f. Value-based enterprise (VBE)

1. Network of two or more participants that have agreed to collaborate
2. Excludes Pharma, DMEPOS, and Labs

2. Key Terms

a. Target patient population (TPP).

1. Selected based on legitimate and verifiable criteria – no cherry-picking, lemon dropping
2. Further the VBPs
3. May limit to chronic conditions

II. The Anti-Kickback Statute

b. Value-Based Activity (VB Act).

1. Reasonably designed to achieve VBP of the VBE
2. Providing items or service; taking or not taking action

c. Value-Based Arrangement (VB Arr)

1. Agreement between VBE and VBE participants, or between VBE participants
2. Provide at least one VB Act to TPP

3. Proposed Safe Harbors for Value-Based Arrangements.

a. §1001.952(ee) – Care coordination agreements.

1. 12 elements with subparts and definitions
2. In-kind remuneration only – recipient must pay 15% of offeror's cost of the in kind item or service

b. §1001.952(ff) – Substantial downside financial risk

1. VBE assumes risk through a payor for items or services to TPP (e.g., 40% of shared losses, partial capitation at 60% discount off FFS).
2. Recipient meaningfully shares downside risk
   - 8% of VBE risk under payment
   - Capitation

II. The Anti-Kickback Statute

c. §1001.952(gg) – Full downside financial risk

1. VBE assumes full risk
2. Capitation for all Medicare Part A and B Services
3. Allows for global risk adjustment, risk corridors, reinsurance and stop loss
4. Protection of downstream payments to physicians and other contractors

4. Other Significant Safe Harbor Proposals

a. Personal services agreements

1. Revises set in advance to apply to method, not amount, of compensation
2. Removes requirements for part time arrangements

b. EHR

1. Eliminates sunset provision
2. Aligns with 21st Century Cures Act

c. Local Transportation

1. Increased to 75 miles

d. Cybersecurity

1. Dovetails with EMR
2. Provides protection for in-kind donations for software necessary for cybersecurity

II. The Anti-Kickback Statute

E. Summary on AKS

1. Reflects a recognition by OIG of hospital physician collaboration and the benefits of hospital physician collaboration
2. Reflects new developments in the structure of the marketplace for health care delivery
3. But on cautionary note, the government imposes many requirements on these models, and the penalties for noncompliance can be severe.

III. The False Claims Act

A. In general, the FCA prohibits false claims for benefits against the United States, and allows whistleblowers (relators) to pursue claims on behalf of the United States.

B. Treble damages exposure, coupled with rewards for whistleblowers, makes FCA exposure critical to minimize.

C. Materiality

1. The Supreme Court has ruled that FCA liability only attaches if the alleged falsity is material to the government's decision to pay the claim. *Universal Health Services ex rel. United States v. Escobar*, 136 S. Ct. 1989 (2016). Not merely a condition of payment, but a rigorous and demanding standard.
2. Applied differently in different circuits, but does require a real connection to payment of the claim.
   a. *United States ex rel. Prarther v. Brookdale Senior Living Communities*, 838 F.3d 750 (6th Cir. 2016), *reh. den.* 2017. Doctor certifications of plans of care months after services material.
   b. *Godecke v. Kinetic Concepts, Inc.,* 937 F. 3d 1201 (9th Cir. 2019). Doctor orders after product supplied material.
   c. *United States v. Walgreen Co.*, 417 F. Supp. 1068 (N.D. Ill. 2019). Waiver of deductible not material.
   d. *United States ex rel. Lisitza v. Par Pharmaceutical Companies, Inc.*, 276 F. Supp. 779 (2017). Alleged prescription switching scheme did not support conspiracy claim under FCA.

False Claims Act – Recent Developments

U.S. ex rel. Bookwalter v. UPMC, 946 F.3d 162 (3rd Cir. 2019)

- Relator (a physician) contended that a compensation arrangement existed in which
  - (1) employed physicians were paid by their group practice a certain salary once their minimum RVU level was achieved and
  - (2) then earned a bonus at a rate of $45 per wRVU generated above the minimum level, violated Stark.

False Claims Act – Recent Developments

U.S. ex rel. Bookwalter v. UPMC, 946 F.3d 162 (3rd Cir. 2019)

- Physicians were employed by group practices, and not by the hospital, so the Court analyzed whether an "indirect compensation arrangement" existed.
  - Unbroken chain: 

  - Aggregate comp test was met: Court treated payments over FMV as indication that volume or value of referrals was *taken into account.*
    - ". . . the complaint plausibly alleges that the surgeons' compensation takes into account the volume or value of their referrals. Under the Stark Act and its regulations, compensation *takes into account* referrals if there is a causal relationship between the two. And here, the surgeons' suspiciously high compensation suggests causation."

False Claims Act – Recent Developments

U.S. ex rel. Bookwalter v. UPMC, 946 F.3d 162 (3rd Cir. 2019)

- Because the Court concluded an indirect compensation arrangement existed, the Court next analyzed whether the indirect compensation exception was met.
  - Court concluded that the Relator plausibly pled that the physicians were paid over FMV, a core element to meet the indirect compensation exception.
    - The Court accepted uncritically the Relator's allegation that "[c]ompensation exceeding the 90th percentile is widely viewed in the industry as a 'red flag' …."

III. The False Claims Act

D. Brand Memo – Prevents DOJ from allowing subregulatory guidance to impose new legal obligations by prohibiting DOJ from using its enforcement authority to effectively convert agency guidance documents into binding rules.

E. Granston Memo – Curbing meritless qui tams. Encourages declining to intervene where legal theory is meritless, whether before or after a factual investigation. The government should also decline to intervene and move to dismiss a qui tam that duplicates a government investigation or other qui tam.

Best Practices - Deal planning

- Boxes and arrows
- Incorporate fraud and abuse analysis in the structuring phase
- Use of independent FMV review where appropriate (e.g., technically demanding; need for independence)
- Strong expertise internally to critically review outside appraisals and oversee ordinary course reviews
- Strong internal legal and compliance resources
- Board engagement

V. Post-Closing Considerations

A. Evaluate documentation
B. Evaluate and improve internal audit and compliance systems
C. Revise/replace physician arrangements as necessary
D. Consider self-disclosure

Questions

Thank you

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