Stark and Anti-Kickback Provisions in Health Care Real Estate Transactions:

Key Drafting Considerations

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Agenda

- Regulatory Context and Risk
- Anti-Kickback Statute and Safe Harbors
- Stark Law and Exceptions
- Space Rental and Timeshare Requirements
- Purchase and Sale Agreements
- Fair Market Value and Commercial Reasonableness
- Common Pitfalls
- Practical Drafting Tips

Why It Matters: The Intersectionality

- Leasing of medical office buildings ("MOBs") is prevalent
- Health care leases are distinct from other commercial leases
- An effective lease compliance program:
    - Reduces regulatory enforcement risk
    - Protects Medicare and Medicaid revenue
    - Strengthens negotiating position for transactions
    - Reduces operational waste
    - Improves audit readiness
    - Supports board and executive team

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Regulatory Primer

Anti Kickback Statute

Anti-Kickback Statute: Background

- **42 U.S.C. § 1320a-7b(b)**
  - Designed to prevent certain payments in connection with the furnishing of services reimbursable under the Medicare and Medicaid programs as well as other governmental health care initiatives
  - Prohibits **knowingly and willfully** soliciting, receiving, offering or paying **remuneration**, directly or indirectly, overtly or covertly, in cash or in kind, *in* **exchange for or to induce the referral** of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other government health programs

Anti-Kickback Statute: Intent Test

- *Greber* test
  - If one purpose of the arrangement or deal is to induce referrals, the Anti-Kickback Statute is violated. *U.S. v. Greber*, 760 F.2d 69 (3rd Cir. 1985)
- The ACA test
  - There is no requirement of actual knowledge of or specific intent to commit a violation of the Anti-Kickback Statute

Be careful with communications to avoid risk that illegal intent could be misconstrued!

Anti-Kickback Statute: Safe Harbors

- OIG has issued safe harbor regulations to protect certain arrangements
- An arrangement must meet each element of a safe harbor in order to be safe from investigation or prosecution as a criminal offense or as a basis for exclusion from participating in the government health care programs
- However, an arrangement does not necessarily violate the Anti-Kickback Statute if it does not satisfy a safe harbor. Such an arrangement is judged under the language of the Anti-Kickback law itself

Anti-Kickback Statute: Safe Harbors

- **Investment Interests (large entity, small entity, underserved area)**
- **Space Rental**
- **Equipment Rental**
- **Personal Services and Management Contracts**
- Sale of Practice
- Practitioner Recruitment
- Waiver of Coinsurance/ Deductibles
- Price Reductions for Health Plans/Managed Care Organizations
- Referral Services
- Warranties
- Discounts
- Employees
- Group Purchasing Organizations
- **Ambulatory Surgical Centers**
- Group Practices
- Obstetrical Malpractice and Insurance Subsidies
- Referral Agreements for Specialty Services
- Ambulance Replenishing
- **Health Centers**
- Electronic Prescribing/Health Records

Anti-Kickback Statute: Penalties

- Violation is a felony, punishable by fines up to $25,000 and up to 5 years imprisonment. Violation can also result in imposition of civil monetary penalties and/or exclusion from such government health care programs
- Safeguards:
  - It is **imperative** that any arrangement **not** be pursued for the purpose to induce referrals
  - It is always possible that a trier of fact, such as a judge or jury, could misconstrue the facts and find differently
  - Intent and structure of an arrangement are vital!

Stark Law

Stark Law: Background

- When a **physician** (or physician's immediate family member) has a **financial relationship** with an entity (*unless an exception applies), the federal Stark Law provides that:
  - Physician **may not make referrals** to the entity for "designated health services"; and
  - Entity **may not present a claim or bill** to the government, patient, or any other party for designated health services furnished pursuant to a prohibited referral.

*If Stark is implicated, an exception must be found.

Stark Law: Strict Liability

- No intent required
- Prohibited financial relationships are per se improper (if no exception applies)
- Exceptions depend on the type of relationship
- **Must** meet all elements of an exception

Designated Health Services

- Clinical laboratory services
- Physical therapy, occupational therapy and speech-language pathology services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

Stark Law: Exceptions

- Stark has numerous exceptions based on the type of financial relationship
- Exceptions are in three categories:
  - Both an ownership interest and compensation arrangement
  - Only an ownership interest
  - Only a compensation arrangement
- When reviewing a particular physician practice or other arrangement, it is imperative that the correct type of exception is used

Stark Law: Exceptions

Ownership <u>and</u> Compensation Exceptions

- Physician Services (for Physician Groups)
- In-Office Ancillary Services (for Physician Groups)
- Prepaid Health Plans
- Academic Medical Centers
- Implants furnished by an ASC
- Preventive Screening Tests, Immunizations and Vaccines
- Eyeglasses and Contact Lenses Following Cataract Surgery
- Intra-Family Rural Referrals

Stark Law: Exceptions

Ownership Interest Exceptions

- Publicly Traded Securities
- Mutual Funds
- Specific Providers
  - Rural Providers
  - Ownership in a Whole Hospital (significantly limited by ACA)

Stark Law: Compensation Arrangement Exceptions

- **Rental of Equipment**
- **Rental of Office Space**
- Bona Fide Employment Relationships
- **Timeshare Arrangements**
- Physician Recruitment
- **Isolated Transactions**
- Non-Monetary Compensation (up to $429 annually)
- Fair Market Value Compensation
- Medical Staff Incidental Benefits (up to $37 per occurrence)

Stark Law: Compensation Arrangement Exceptions

- Risk-Sharing Arrangements
- Compliance Training
- Electronic Health Records Items and Services
- Non-Physician Practitioner Recruitment
- Personal services arrangement
- Limited Remuneration to a Physician
- Arrangements that Facilitate Value-Based Health Care Delivery and Payment
- Cybersecurity Technology and Related Services

Stark Law: Penalties

- OIG may impose a civil money penalty of up to $15,000 against any person whom:
  - Has presented or caused to be presented a claim for a payment that such person knows, or should know, may not be made under Medicare or Medicaid; or
  - Against any person whom it determines has not refunded on a timely basis (within 60 days) amounts collected as a result of billing an individual, third party payor, or other entity for a designated health service that was provided in accordance with a prohibited referral under Stark
  - Stark sanctions include exclusion from Medicare and Medicaid and fines of up to $100,000 for circumvention schemes
  - *Qui tam*/false claim actions may also reference Stark violations

Differences Between AKS and Stark

Stark Law

- Strict liability
- Civil Liability
- Applies only to financial relationships with “physicians” or immediate family members
- Exceptions = “must”

Anti-Kickback Statute (“AKS”)

- Intent-based
- Criminal liability
- Broader application – implicates more relationships
- Safe harbors = “should”

Lessons From Enforcement Actions

Lessons from Enforcement: DOJ

Settlement Amount	Alleged Violation
$135 million	Hospital paid **above-fair market value rent** to a physician-owned real estate partnership to induce the physician owners to refer patients to a hospital-owned ambulatory surgical center
$93 million	Hospital **provided free office space** to a local physician group
$84 million	Lease of office space to physicians **for free or at a below market rate**
$72 million	**Free office space, employees, and supplies**; **Sham real estate arrangements for unnecessary space**
$42 million	Hospital paid **above-market rent** to lease space from physicians
$15 million	Office space leased at **below fair market value** rates to physicians
$4 million	Office lease arrangements that did not comply with Stark
$425,000	Hospital only charged a physician **half of the rent** as an inducement for patient referrals

Applying Fraud & Abuse Laws to Health Care Real Estate Transactions

Trends in Health Care Real Estate

- Shift to outpatient care
  - MOBs
  - Ambulatory surgery centers
- Modern facilities
  - Multi-specialty
  - Rising construction costs
  - Specialized build outs and evolving lease structures
- No longer purely an administrative function

Leases and Licenses

- Stark and AKS apply to both leases and licenses
- Regulators focus on the substance of the arrangement, not its label
- Different structures may require different Stark exceptions or compliance analyses
- Shared-use, timeshare, and license arrangements often face increased fair market value and commercial reasonableness scrutiny
- Calling an arrangement a “license” does not eliminate Stark or AKS risk

Anti-Kickback Statute: Space Rental Safe Harbor

- Written, signed lease specifically identifying the leased premises
- Space must be limited to what is reasonably necessary for a commercially reasonable business purpose
- Minimum one-year term
- Rent must be:
  - Set in advance;
  - Fair market value; and
  - Not based on the volume or value of referrals

Failure to meet every element is not a per se violation of the AKS

Stark Law: Rental of Office Space Exception

- Written, signed lease identifying the leased premises
- Minimum one-year term
- Space must be reasonable and necessary for the business purpose and used exclusively by the tenant
- Lease must be commercially reasonable
- Rent must be:
  - Set in advance;
  - Fair market value; and
  - Not based on the volume or value of referrals

Stark Law: Timeshare Exception

- Written, signed agreement
- Specifically identifies the space, equipment, personnel, items, supplies, and services covered
- Between a physician and a hospital or unrelated physician organization
- Primarily for patient evaluation and management services on the same, set schedule
- Equipment must be located where evaluation and management services are provided
- Equipment may not be used to furnish DHS, except those incidental to the patient visit
- Prohibits use of advanced imaging, radiation therapy, and most laboratory equipment
- Arrangement cannot be conditioned on patient referrals

Stark Law: Time Share Exception *(cont.)*

- Compensation must be set in advance and consistent with fair market value
- Compensation cannot be based on the volume or value of referrals
- Prohibited compensation formulas include:
  - Referral-based payments;
  - Percentage-of-revenue arrangements; and
  - Per-service fees tied to referred patients
- Arrangement must be commercially reasonable, even without referrals
- Must comply with the Anti-Kickback Statute and applicable billing laws
- Cannot grant the physician a leasehold or possessory interest in the space

Stark Law: Time Share Exception Example

Fact Pattern:

- Hospital provides physician group scheduled access to space and resources
- No floor plan attached
- Additional storage space included
- Does arrangement satisfy timeshare exception?

Key Considerations:

- Premises and resources must be specifically identified
- Additional space should be clearly described
- Compensation should reflect all space provided
- Arrangement cannot create a possessory interest

Purchase and Sale Agreements

Purchase and Sale Transactions

- Acquisition or disposition of real estate or other assets
- Usually a one-time transaction rather than an ongoing arrangement
- Can involve hospitals, health systems, physicians, or physician organizations
- Stark Law may apply if there is a financial relationship between referral sources

Stark Law: Isolated Transactions Exception

- One-time transaction (e.g., sale or settlement)
- Commercially reasonable
- No follow-on transactions for 6 months
- Fair market value
- Not referral-based

Practical Strategies for Compliance

Common Pitfalls

- Expired contracts
- Late signatures
- Failure to execute amendments
- Lack of written agreement
- Compensation formulas
- Failure to apply rent escalators
- Exclusive use issues
- Timeshare issues

Determining Fair Market Value

- FMV is a key requirement under both Stark and AKS
- Rent must reflect market rates in an arm's-length transaction
- Value cannot be influenced by referral relationships or location convenience
- Any commercially reasonable valuation methodology may be used

Determining Commercial Reasonableness

- Arrangement serves a legitimate business purpose
- Reasonable based on the parties':
  - Size
  - Type
  - Scope
  - Specialty
- Does not need to be profitable to be commercially reasonable

Determining Square Footage

- Supports accurate rent and expense calculations
- Enables consistent market benchmarking and property valuation
- Measurement errors can cause rent discrepancies and potential Stark compliance risks

Review Specific Lease Provisions

- Important lease provisions:
  - Assignment, Change in Control, Subletting
  - ROFO, ROFR and Purchase Option Rights
  - Subordination and Estoppels
  - Renewal and Holdover
  - Surrender Obligations

Practical Drafting Tips

- Written lease agreement
- Fair Market Value rent
- Commercially reasonable terms
- Understand the appraisal or valuation report
- Defined leased premises
- One-year term where required
- Appropriate assignment provisions
- Proper administration throughout the lease term

Issue Spotting

- Providing physicians with items or services for free or less than fair market value
- Relieving physicians of financial obligations they would otherwise incur
- Inflating compensation paid to physicians for items and services
- A lease agreement that includes more space than is needed for the tenant's business

Questions?

For more information on these topics visit hallrender.com.

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