

## **Medical Office Leases: Navigating Stark Law, Anti-Kickback Statute, Operational Restrictions, and More**

Drafting to Address Reciprocal Easements, Ground Leases, HIPAA, ADA, and Environmental Issues Unique to Medical Office Use

TUESDAY, OCTOBER 20, 2020

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# Medical Office Leases:

Navigating Stark Law, Anti-Kickback Statute,  
Operational Restrictions, and More

October 20, 2020

# Disclaimer

- These materials and associated remarks are intended to facilitate a general discussion of issues that may arise in the context of medical office leasing transactions. They are not intended to be comprehensive or to serve as a substitute for legal or other advice, and they should not be relied upon as such. Attorneys, accountants and other professionals need to draw their own conclusions relative to the facts and circumstances of any particular situation and take into account all applicable laws when formulating advice.

# Key Topics

- Physician Self-Referral (“Stark”) Law Issues
- Anti-Kickback Statute Considerations
- Case Studies on False Claims Act Risks
- Unique Reimbursement Rules Impacting Use of Space
- HIPAA Considerations
- Unique Issues in MOB Leases on Hospital Campuses

# Stark Physician Self-Referral Law

- Applies to **Designated Health Services (DHS)**:  
clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound 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; and **inpatient and outpatient hospital services**. Check the list of DHS at:  
[https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List\\_of\\_Codes](https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes)
- A **Physician** may not refer for DHS if there is a non-exempt financial relationship
- **DHS Provider** may not submit claim for DHS if referred by physician with non-exempt financial relationship
  - Is there a **Referral of DHS?**
  - Made by a **Physician?**
  - Does the physician or a family member have a **Financial relationship?**
  - Does an **Exception** apply?



# Stark Physician Self-Referral Law

## Penalties:

- \$1,500 CMP per claim/prohibited referral
- Denial/refund of payment
- \$100,000 civil monetary penalty for “circumvention scheme.”
- ACA establishes that Stark violation = FCA violation
  - FCA penalties include \$11,665, to \$23,331 per claim; treble damages; exclusion (“death penalty”)

# Stark Physician Self-Referral Law

## SPACE LEASE EXCEPTION

- Lease set out in **writing**, is **signed** by the parties, and specifies the **premises** it covers.
- Duration of the lease arrangement is **at least 1 year**. If terminated < 1 year, may not enter into a new lease arrangement for the same space during the first year of the original lease arrangement.
- Space does not exceed that which is **reasonable and necessary** for the legitimate business purposes of the lease arrangement
- 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 common areas if prorated.

# Stark Physician Self-Referral Law

- Rent **set in advance** and are consistent with **fair market value**
- Not determined in a manner that takes into account the **volume or value** of any referrals or other business generated between the parties.
  - No percentage leases
  - No per unit of service leases
- Commercially reasonable even if no referrals
- Holdover arrangements permitted if same terms

# Stark Physician Self-Referral Law

## **Time-Share Arrangements:**

- Set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services
- Between Physician Organization (PO) and **Hospital** or **PO** of which the physician is not an owner, employee, or contractor.
- Used predominantly for the provision of evaluation and management services to patients on the same schedule.
- Equipment provided is in the same building.
- NOT USED TO FURNISH DHS (except incidentally)
- No advanced imaging (CT/MRI/PET) or lab except CLIA-waived tests
- Not conditioned on referrals
- FMV; Commercially reasonable; no AKS violation
- Percentage or per unit of service fees not permitted (unless time based).
- Not a possessory leasehold

# Anti-Kickback Statute (AKS)

- The AKS is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving **any item or service** payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients).
- Remuneration = **anything of value** -- free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies.
- AKS covers the **payers** of kickbacks-those who offer or pay remuneration- as well as the **recipients** of kickbacks-those who solicit or receive remuneration. Each party's B is a key element of their liability under the AKS.
- Criminal penalties and administrative sanctions for violating the AKS include fines, jail terms, and exclusion from participation in the Federal health care programs.
- CMPL authorizes penalties of up to \$50,000 per kickback plus three times the amount of the remuneration.

# Anti-Kickback Statute (AKS)

- **Safe harbors** protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution.
- To be protected, an arrangement must fit squarely in the safe harbor and satisfy all of its requirements.
- Failure to meet a safe harbor does not result in presumption of illegality.
  - Optional, not mandatory
  - Contrast with Stark exceptions – strict liability

# Anti-Kickback Statute (AKS)

## Space Lease Safe Harbor

- Lease set out in **writing** and **signed** by the parties.
- Must cover **all of the premises** leased between the parties for the term of the lease and specifies the premises covered by the lease.
- If periodic lease, specifies exactly the **schedule** of such intervals, their precise length, and the exact rent for such intervals.
- Term not less than **one year**.
- Aggregate rent **set in advance, FMV**, not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated.
- Does not exceed that which is reasonably necessary to accomplish the **commercially reasonable** business purpose

# Anti-Kickback Statute (AKS)

## OIG SPECIAL FRAUD ALERT: RENTAL OF SPACE IN PHYSICIAN OFFICES BY PERSONS OR ENTITIES TO WHICH PHYSICIANS REFER

- Proration of exclusive office space:

<b>Physician Office Rent Per Day</b>	<b>% of Physician Office Space Rented by Supplier</b>	<b>% of Each Day Rented by Supplier</b>	<b>No. of Days Rented by Supplier Per Year</b>		
$\frac{\text{annual rent of primary lease}}{\text{no. of work days per year}}$	$\times$ $\frac{\text{sq. ft. exclusively occupied by supplier}}{\text{total office sq. ft.}}$	$\times$ $\frac{4 \text{ hours}}{8 \text{ hours}}$	$\times$ 52 days (i.e., 1 day per week)	$=$	Supplier's annual rent for exclusive space



# Anti-Kickback Statute (AKS)

## OIG SPECIAL FRAUD ALERT

- Interior office common space (waiting rooms, etc.)
  - May be appropriate for the suppliers to pay a prorated portion of the charge for such space. The charge for the common space must be apportioned among all physicians and subtenants
- Building Common Space
  - may be appropriate to pay a prorated portion of such charge. As with interior office common space, the cost of the building common space must be apportioned among all physicians and subtenants based on the amount of non-common space they occupy and the duration of such occupation

# Case Studies on False Claims Act Risk

- Violations of Stark Law or AKS can be the basis for liability under the False Claims Act (FCA)
  - FCA allows qui tam whistleblowers to bring cases on behalf of government seeking treble (3x) damages, per claim penalties and attorneys fees
  - Since 2008, at least 19 FCA settlements (totaling \$486M) have involved claims related to improper space lease arrangements with referring physicians
- Bingham case studies
  - Three separate FCA cases brought against hospitals by qui tam relator who formerly served as commercial real estate appraiser
  - One case alleged hospital paid rent to physician group in excess of FMV, while other two alleged remuneration to physician tenants through complex real estate transactions involving MOB's on hospital campuses

# Case Studies on False Claims Act Risk

- US ex rel. Bingham v. HCA (E.D. Tenn)
  - Relator alleged, among other claims, that Parkridge Medical Center agreed to lease office space from physician group at rental rate in excess of FMV so that physician group could meet mortgage obligations
  - HCA settled case for \$16.5M in 2012
- US and State of Florida ex rel. Bingham V. HCA (S.D. Fla)
  - Relator alleged that HCA subsidized third-party developer MOB's on hospital campuses in Missouri and Florida in return for developers' agreement to share portion of MOB's cash flow with physician tenants
  - Alleged subsidization include undervalued ground lease, undervalued parking easement, free parking for physician tenants and HCA paying rent for MOB space it did not use

# Case Studies on False Claims Act Risk

- US and State of Florida ex rel. Bingham V. BayCare Health (M.D. Fla)
  - Relator alleged that Baycare provided remuneration in the form of parking services and tax benefits to referring physician tenants of MOB
  - Benefits of property tax exemption and parking services were provided under ground lease from BayCare to third-party developer of MOB
- Key takeaways from case studies
  - Important to consider both direct and indirect financial arrangements that may be created with physician tenants or physician owners of MOB on hospital campus
  - Important to structure all financial relationship at FMV with commercially reasonable terms and conditions to avoid potential FCA risks

# Unique reimbursement rules impacting space arrangements

- Provider-based billing rules
- IDTF rules
- DMEPOS Supplier Rules and "Consignment Closets"
- Medical Assistance Regulations
- Private Insurer Issues

# Provider-based billing rules

- Must be operated under the provider's (i.e. hospital's) license.
- Clinical services must be integrated with provider.
- Financial operation must be integrated with provider.
- Site must be held out to the public and other payers as part of the main provider.
  - Public awareness requirement can impact signage, access, shared space
- Additional requirements apply if off-campus:
  - Must be 100% owned by provider; same governing body; bylaws; administration; supervision; generally be within 35 miles of campus
- Certain on-campus joint ventures may be provider-based.

# Provider-based billing rules

- **Campus** means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located **within 250 yards of the main buildings**, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

# IDTF rules

- An **Independent Diagnostic Testing Facility (IDTF)** is independent from both an attending and consulting physician's office and from a Hospital. See 42 CFR 410.33.
- It may be a fixed location or a mobile entity.
- It requires enrollment under Medicare Part B.
- It requires one or more supervising physicians. Each physician may supervise no more than 3 IDTFs concurrently (including mobile units).
- It requires an IDTF Technician.
- Diagnostic procedures performed at an IDTF are reimbursed pursuant to the physician fee schedule.



# IDTF rules

- Under CMS regulations, with the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from
  - sharing a practice location with another Medicare-enrolled individual or organization;
  - leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or
  - sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.
- A **mobile IDTF** such as a mobile x-ray, ultrasound, EMG or similar provider can share space with another provider, but a **fixed IDTF** such as an imaging center cannot lease space to other providers.

# IDTF Rules

- Physical site requirements for IDTFs:
  - Must be on a physical site → no PO boxes, hotels, or motels.
  - Must have sufficient space to provide the services listed on the enrollment application. Also, hand washing, patient privacy accommodations, storage for business and medical records.
  - Must make diagnostic equipment available at the physical site.
  - Must have a primary business phone located at the site of the business.
  - Must have liability insurance of at least \$300,000 per location.
- CMS makes site checks! Must be open during posted hours, and CMS needs access.

# DMEPOS Supplier Rules and "Consignment Closets"

- A supplier must:
  - Except for State-licensed orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice, maintain a practice location that is at least 200 square feet
  - Be in a location that is accessible to the public, Medicare beneficiaries, CMS, NSC, and its agents. (The location must not be in a gated community or other area where access is restricted.)
  - Maintain a permanent visible sign in plain view and posts hours of operation. If the supplier's place of business is located within a building complex, the sign must be visible at the main entrance of the building or the hours can be posted at the entrance of the supplier
  - Exceptions for “satellite” locations, i.e. in physician offices

# DMEPOS Supplier Rules and "Consignment Closets"

## "Consignment Closets" ["Stock-and-Bill Arrangements"]

- DMEPOS supplier stores inventory at physician office, with or without paying rent.
- Patient must be offered choice to obtain DMEPOS elsewhere.
- DMEPOS supplier bills Medicare for the products dispensed.
- Rent must be no more than FMV for the amount of space used.
- May pay physicians' staff for fitting, administrative services, no more than FMV.
- Not considered a DMEPOS location subject to 220 sq. ft. requirement, etc.
- *NOTE:* 2009 CMS Transmittal prohibiting common consignment closet arrangements has been rescinded.

# Medical Assistance Regulations

- Vary widely by state
- For example, in Pennsylvania, a relatively obscure Pennsylvania Medical Assistance regulation states:

A participating provider may not lease or rent space, shelves or equipment within a provider's office to another provider or allow the placement of paid or unpaid staff of another provider in a provider's office. This does not preclude a provider from owning or investing in a building in which space is leased for adequate and fair consideration to other providers nor does it prohibit an ophthalmologist or optometrist from providing space to an optician in his office. 55 Pa. Code 101.51(c)(3).

# Private Insurer Issues

- Need to review the policies of the private insurers and managed care companies with which they participate.
  - One example: Highmark Health has adopted provider privileging requirements for diagnostic imaging service, including bone densitometry, ultrasound, CT and MRI, echocardiography, fluoroscopy, mammography, nuclear cardiology, plain films positron emission tomography (PET), urological imaging and women's health.
  - Highmark will only reimburse providers for diagnostic imaging services if the services are provided on **imaging equipment owned by the provider and used by that provider on a full-time basis or leased by the provider on a full-time basis.** Full-time basis is defined as: "the provider has possession of the equipment on the provider's property and the equipment is under the provider's direct control, and the provider has exclusive use of the equipment, such that the provider, and only the provider, uses the equipment."
  - This policy has been interpreted to mean that a single piece of imaging equipment may only be used by one practice but a mobile unit may be moved and used at multiple sites of a single practice entity.

# HIPAA Considerations

- Covered entities must comply with HIPAA, as well as “business associates.”
- A “business associate” acts on behalf of a covered entity in a manner that gives the business associate access to protected health information (PHI).
- Does not include “workforce.” Workforce is employees, volunteers, trainees, and other individuals whose conduct is under the direct control of the covered entity.

# HIPAA Considerations

- A landlord = a business associate when the landlord performs services on behalf of the covered entity tenant that give it access to PHI.
- Examples:
  - Providing office staff.
  - Billing services.
  - Management services.
  - IT services.
- What is not included:
  - Common carriers
  - Janitorial staff



# HIPAA Considerations: Physical Security

- HIPAA requires covered entities that maintain electronic PHI (ePHI) to establish certain administrative, technical, and physical safeguards to protect the security and integrity of ePHI.
- Physical security pertains to the physical site where ePHI is located.
- Examples:
  - Door locks. Simple key? Biometrics? Pass code? Keycards?
  - Computer workstation security. In view of a window? Easily visible from common areas/walkways?
  - Climate control for computer server rooms.
  - Workstation/computer access policies.
- Tenants may make requests to comply with HIPAA.

# HIPAA Considerations

- What can go wrong?
  - Different levels of exposure for landlord, depending on whether it is a business associate.
  - Business associates have contractual liability, and are directly liable under HIPAA itself. If not a business associate, risk is reduced.
- Consider Lahey Hospital example.
  - 2015 HIPAA breach. Unencrypted laptop was stolen from a teaching hospital exposing 599 patients' ePHI. Laptop was in an unlocked treatment room off of a hallway in the radiology department. \$850,000 settlement.
- Covered entities may make specific requests to ensure HIPAA security. E.g., installation of keypad locks and/or physical authentication like security cards or RFID devices. Possibly two-factor authentication.

# Unique issues in MOBs on hospital campuses

- Ground Lease Structure
  - Hospital motivations
  - Developer motivations
- Use restrictions
  - Typically limited to medical office use
  - Obnoxious use restrictions
  - Precluded services to prevent competition with hospital
  - Compliance with hospital and regulatory requirements
- Sublease restrictions
  - Landlord right of first refusal to lease space
  - Qualified subtenants

# Unique issues in MOBs on hospital campuses

- Operational matters
  - Design and construction approvals and process
  - Approvals over subsequent alterations
  - Naming rights
  - Reserved rooftop space
  - Qualified Property Manager
  - Reciprocal Easement Agreements/Campus Security Agreements

# Unique issues in MOBs on hospital campuses

- Limits on Transfer
  - Apply to lease assignments or change in control of tenant
  - Acceptable Transferee/Qualified Transferee/Disqualified Person concepts
  - Landlord right of first offer
  - Landlord right of first refusal
  - Landlord purchase options
- Leasehold mortgage requirements
  - Landlord approval rights as to lender
  - Tri-Party Agreement
  - Mortgagee cure rights
  - New Lease upon rejection of lease in bankruptcy

# Thank You

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