Stark Law Contracting Tips and Problem-Solving
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Presented by:
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Presentation Agenda

- Overview of the Stark Law and Differences from the Anti-Kickback Statute
- Breakdown of Stark Law Elements
- Overview of Commonly Used Exceptions:
  - Personal Services Arrangements
  - Fair Market Value Compensation
  - Rental of Office Space
  - Rental of Equipment
- Overall Themes
- Contracting Tips and “Lessons Learned”
“The [Stark Law] started out very simple. There is a federal regulation that says if you take a bribe, commission or fee for referring a patient for additional service that the government pays for, you're liable for a criminal penalty of five years in prison or $50,000 . . . So we passed it into law. The minute we did that, smart lawyers found eight ways around it. So we amended it to close those loopholes, and they came up with more ideas to get around it. Before we were done, there were a bunch of rules about as thick as a phone book, and it was super complicated.”
Basics

- **Stark Law**
  - Statute: 42 U.S.C. § 1395nn
  - Regulation: 42 C.F.R. § 411.353(a)
  - **Prohibition:** If a *physician*, or a member of the physician’s *immediate family*, has a *financial relationship* with an *entity*, then the physician is prohibited from making a *referral* to the entity for the provision of a *designated health service* paid for by Medicare, and the entity is prohibited from billing for such service, unless an *exception* is satisfied
  - Strict liability statute = No intent requirement
  - **Compare:** Federal Anti-Kickback Statute is *intent*-based
Strict Liability

= No Margin for Error!

Basics
Penalties

- Monetary penalties of up to $15,000 per service
- An assessment of up to three times the amount claimed
- Possible exclusion from the Medicare and Medicaid programs
- False claim actions i.e., violations of Stark can create violations of the Federal False Claims Act
- Payment is denied for Medicare DHS claims
- Any amounts collected from individual patients or third-party payers for DHS must be refunded on a timely basis (60 days)
- Penalties can add up quickly – Example – Damages in Tuomey equal $237 million (a sum that exceeds its annual revenue)
- Compare: Stark Law penalties are CIVIL; Anti-Kickback are CRIMINAL and CIVIL
Elements of the Stark Law

1. Physician
2. Physician Referral
3. Entity
4. Designated Health Service ("DHS") billed to Medicare or Medicaid
5. Financial Relationship between Physician (or immediate family member) and the DHS Entity

Each element is an escape hatch – if one element isn’t met, Stark doesn’t apply!
Overview of the Stark Law

A typical Stark Law scenario:

Entity

Hospital

DHS REFERRAL

$ $

Medical Director Services

Dr. X
Overview of the Stark Law

Element 1 - Physician

A Physician includes:

- Medical Doctors
- Doctors of Osteopathy
- Dentists
- Podiatrists
- Chiropractors

*Not:* Nurses, Therapists, Social Workers, Physiologists, etc.

*Compare:* Federal Anti-Kickback Statute applies to all individuals, not just Physicians
Element 2 - Referral

– The definition of “referral” is very broad
– If a physician orders a test or prescribes a medication, there will almost always be a “referral”
Element 3 - Entity

A DHS referral must be made to an *entity*:

Generally, any business association (e.g., LLC, corporation) that:

- Performs services that are billed to Medicare
- Presents a claim to Medicare for DHS

Examples of *Entities*: Hospital, physician groups, DME suppliers
Overview of the Stark Law

Element 4 - Designated Health Services

The Stark Law **only applies** to certain “designated health services” that are billed by an entity to Medicare.

DHS include: Clinical laboratory services*; PT*; OT and outpatient speech language pathology services*; radiology and certain other imaging services*; radiation therapy services and supplies*; DME; parental and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices and supplies; home health services; outpatient prescription drugs; and **inpatient/outpatient hospital services**.

*Only DHS if included on CMS annually-published list of CPT codes

**Compare:** Federal Anti-Kickback Statute applies to all types of health care services that are billed to the government
Element 4 Continued - Designated Health Services

Generally, the following entities do not furnish DHS:

- Skilled Nursing Facilities
- Ambulatory Surgical Centers
- Independent Living Facilities
- Hospices
Element 4 Continued - Medicare*

The Stark Law only applies to services billed to Medicare, but not other payors (e.g., Medicaid, Tricare)

- *But see U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center; U.S. ex rel. Schubert v. All Children’s Health System.

- Compare: Federal Anti-Kickback Statute applies to services billed to all government payors
Overview of the Stark Law

Element 5 - Financial Relationship – Four Types

- **Compensation**
  - Direct
  - Indirect

- **Ownership**
  - Direct
  - Indirect
Overview of the Stark Law

- Stark is all about **EXCEPTIONS**.
- If a Stark Law exception is met, it is permissible for the physician to make a referral of DHS to a DHS entity with which the physician (or the physician’s immediate family member) has a financial relationship.
- Every element of an Exception must be met.
- **Compare**: Federal Anti-Kickback Statute Safe Harbors do not require strict compliance to avoid prosecution.
Overview of the Stark Law

- Wait a second, does this all really matter?

- The Facts:
  - 1992: Hospital and anesthesiology group enter into a mutually exclusive arrangement for Group’s provision of anesthesia services. Hospital
  - 1998: Hospital builds ASC and Group begins to provide pain management services to Hospital’s patients and Group bills for its physicians’ services. Hospital doesn’t amend agreement to contemplate provision of pain management services at new location, including Hospital’s provision of provider-based space to anesthesiologists.
The Kosenske Case

Main issues in Kosenske:

- Does the opportunity to become an exclusive provider of a service constitute remuneration under the Stark Law?
- Does a change in the scope of services need to be documented to comply with the Stark Law Personal Services Arrangement Exception?

Court’s Holding:

- Exclusive provider arrangements constitute a remunerative relationship between a physician group and a hospital under the Stark Law
- Changes in scope and location of services need to be documented to comply with the Stark Law
Overview of the Stark Law

- **Stark exceptions generally relate to:**
  - **Direct and Indirect Compensation relationships**
    - Typically require a signed agreement and payment set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
  - **Direct and Indirect Ownership relationships**
    - Exceptions are very limited (e.g., rural provider exception, hospital in Puerto Rico)
  - **Both (Compensation/Ownership)**
    - Very complicated and detailed
      - Academic Medical Centers
      - In-Office Ancillary Services (used in a Group Practice context)
Overview of the Stark Law

Direct or Indirect Compensation Arrangement?

Entity

Hospital

$>

Medical Director Services

DHS REFERRAL

owner

Dr. X

Physician Org/Group Practice

real challenges. real answers. sm
Overview of the Stark Law

- “Stand In The Shoes” Dr. X = Owner
- Physician (non-owner) employees do not stand in the shoes

• Note: Physicians do not SITS of equipment companies, leasing entities, etc.
Overview of the Stark Law

- Some Common Stark Law Exceptions
  - Space Leases (§ 411.357(a))
  - Equipment Leases (§ 411.357(b))
  - Fair Market Value (§ 411.357(l))
  - Personal Services (§ 411.357(d))
  - Employment (Does not require a written agreement) (§ 411.357(c))
  - Physician Recruitment (very complicated) (§ 411.357(e))
  - Medical Staff Incidental Benefit (§ 411.357(m))
Lease Agreements

Generally, leases for real and personal property must be:

- In writing and signed by the parties prior to the effective date/commencement of the lease term
- Specify the exact premises (floor plan)
- A minimum 1-year term (but can be terminated within first year)
- Rent is FMV and “set in advance”
- Commercially reasonable business purpose
- Space is reasonably necessary for tenant’s legitimate business purpose
- Access on an exclusive basis (with the exception of common areas)
- Timeshare Lease – Describe occupancy schedule
Independent Contractor Agreements

Independent Contractor Agreements must generally be:

- Set forth in a signed, written agreement
- Fair market value and commercially reasonable
- Describe the services being performed
- Not take into account the volume or value of Physician’s referrals of DHS or other business generated
- For a term of 1 year (or not…)

real challenges. real answers.
Employment Agreements

Employment Agreements must be:

- For identifiable services
- Commercially reasonable and set forth fair market value compensation
- Not based upon the volume or value of referrals (this can cause trouble) – this comes up when giving physician credit for ancillary revenue

NO WRITTEN AGREEMENT IS REQUIRED (but backdating is not ideal)
Medical Staff Incidental Benefits

- Compensation in form of items/services (not $) to member of medical staff when used on campus if:
  - Provided to all members of staff in same specialty without regard to referrals/business
  - Provided when making rounds or engaged in services benefiting hospital or patients
  - Provided and used by staff on campus
  - Related to provision of medical services at hospital
  - Less than $25 per occurrence
  - Not tied to referrals
  - Must comply with Anti-Kickback statute
  - E.g., website/advertising identification, internet access, pagers, 2-way radios
Uh Oh!

Common mistakes we see in leases:

- Lease doesn’t specify occupancy schedule and is “on-demand” – example: “Physician rents space every Thursday for $40/day, but is not required to pay for days she doesn’t use
- Rental rate isn’t set in advance: e.g. – Lease states “after year one, the rent charge will be a fair market value rate determined by the parties”
- Lease is for a longer term (e.g., 5 years) but has no rent escalators
- Lease goes into holdover but rental rate isn’t increased for FMV
- Hospital is lessor, and requires physician lessee to maintain active medical staff privileges at the Hospital
- Lease is less than 1 year
- Timeshare lease with blocks of time fewer than 4 hours
Common mistakes we see in services agreements (independent contractor and employment):

- Compensation is not FMV
- Compensation takes into account volume or value of referrals
- Services are paid on a flat-fee basis without a minimum hours requirement – e.g., $5,000/month for medical director services
- Agreement is not for identifiable services (for independent contractors, must be described *in the agreement*).
- Agreement has “quality incentives” or vaguely stated incentive payments that take into account volume or value of referrals
- Services are duplicative or unnecessary
Uh Oh!

- Common mistakes we see in both leases and independent contractor services agreements:
  - Services/Occupancy starts before agreement is fully signed (see 30 and 90 day exceptions)
  - **Agreement expires and does not have automatic renewals**
  - The compensation terms of an agreement are amended within the first year

- 30 day/90 day signature exceptions
  - Can only use once every three years
  - Agreement must be in final form **EXCEPT** for signatures
Overview of the Stark Law

WHAT IF AN EXCEPTION IS NOT MET?

PERIOD OF DISALLOWANCE

– Where the noncompliance is unrelated to compensation, the date that the financial relationship satisfies all the requirements of an applicable exception.

– Where the noncompliance is due to compensation, the date when the compensation is returned (or paid) and the financial relationship satisfies all the requirements of an applicable exception.

– “PERIOD OF DISALLOWANCE” = PENALTY PERIOD

– How many claims related to the prohibited DHS referrals were submitted to Medicare during the “Period of Disallowance”?

– How much did Medicare pay the hospital for those claims?
Provider Self-Disclosure

A “culture” of self-disclosure

- The CMS Self-Referral Disclosure Protocol ("SRDP")
  - Disclosure to CMS
  - Use when disclosing provider believes there is an actual or potential violation of the Stark Law
  - Cannot use SRDP if there is a “colorable” Anti-Kickback Statute violation or the arrangement(s) implicates federal criminal, civil or administrative laws other than Stark

- Repayment to the DHS entity’s Medicare Administrative Contractor

- OIG Voluntary Self-Disclosure Protocol
  - Use when disclosing provider believes there is an actual or potential violation of the Stark Law and there is a “colorable” Anti-Kickback Statute violation or other federal criminal, civil or administrative laws are implicated
  - OIG is solely vested with Civil Monetary Penalty and Exclusion Authority
  - Reimbursements at issue must be at least $50,000
# Provider Self-Disclosure

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<tr>
<th>Advantages of Disclosing through SRDP</th>
<th>Disadvantages of Disclosing through SRDP</th>
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<tbody>
<tr>
<td>CMS will typically offer a negotiated settlement to disclosing parties for significantly less money, but results may vary</td>
<td>CMS has absolute discretion in amount of settlement – Pennock will have no room to negotiate or right to appeal</td>
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<tr>
<td>CMS may release the disclosing party from administrative liabilities and claims under the Stark Law</td>
<td>CMS does not have the authority to release claims related to the False Claims Act, Anti-Kickback Statute, or the Civil Monetary Penalties Law</td>
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<td>Repayment will suspend legal obligation to refund claims received in violation of the Stark Law within 60 days of their discovery – reduces (but does not eliminate) risk of whistleblower claims</td>
<td>CMS might request additional information, and reserves the right to refer any issues to the OIG or DOJ</td>
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<td>CMS has unpredictable response time – could be 3+ years before determining exposure</td>
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Lessons Learned – Best Practices for Contracting with Referring Physicians

Purpose of the Transaction – Keep a File!

- Justifiable Business Case
  - Increased Access
  - Increased Capability
  - Community Benefit

- Payment Arrangements
  - Not reflective of past/future referral streams
  - Independent verification by objective data or 3rd party consultant
Contract Management Requires Diligence

- **Template Contracts – Use With Care**
- Templates often have sample language – one size does not fit all
- Terms and conditions need to be carefully reviewed and revised to specifically reflect the agreed-upon business arrangement
- Signed writings that reflect the actual arrangement must be in place prior to commencement of the arrangement
Financial Terms

- All financial terms must be specifically set forth in written agreement
- Fair Market Value:
  - All payments are evaluated
  - Financial terms must be re-evaluated and adjusted periodically to reflect FMV
  - Compensation opinions for Physician personal services – maximum of 3 years, trending downward to 2 years
  - Leases should have annual escalators for longer term leases
Document the Actual Arrangement

- All items and services provided must be described in the written agreement
- Verify performance of services
  - Be wary of using Template Time Sheets
  - Importance of reviewing the actual services performed
- Timeshare Arrangements/Leases
  - Space, Supplies, Staff, Equipment
  - Storage of Personal Items
Document Changes in Arrangement

- Document the agreement to change the services before the same are implemented
- Scope of service
- Amount of space (increase or decrease)
- Items provided (staff, supplies, storage space)
- Compensation changes (not more than once annually)
Term and Termination

- Day-to-day extension language is important to avoid inadvertent lapse
- Contracts must be in place before services are provided
- Employment arrangements have more flexibility but are not to be used as the “catch-all” fix for undocumented arrangements
Monitor Existing Agreements

- Responsible Executive – clear communication between Contract Management and Responsible Executive
  - Use of Meditract – Reminders for expiring agreements
  - Correct data input
- Ensure compliance with terms of existing agreements
- Begin re-negotiations of expiring contracts early enough to have adequate time to complete renewal before expiration date
- No Backdating
  - If renewal negotiations are not complete, extend the agreement in writing under the same terms and conditions until negotiations are concluded – new terms will begin as of the date the negotiations are finalized and agreed to in writing
I think we may have an issue…

- Run through the elements of Stark to make sure it applies!
- Check if Agreement is in holdover (6 months, if all terms still in effect)
- Determine if late signature meets the 30/90 days signature exception
- Determine whether prior agreement automatically renews
- Check for emails, scraps of paper, text messages, sign-in sheets, etc. (use the UETA)
- Determine the first date of service, occupancy, or payment
- Check if the referring physician referred any DHS during the period of non-compliance
- Make sure agreement is with a physician-owned entity – agreements with entities with no physician ownership might not need a written agreement between the DHS entity and the contracting entity
- Do not backdate!
- Implied renewal – state law argument
Questions?
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