Auditing Physician Arrangements

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Webinar Agenda

- Introductory Concepts
- Applicable Regulatory Standards
  - Stark Law Overview
  - Requirements of the Exceptions
  - The 2016 Changes
- Conducting Stark Compliance Audits
- Process Considerations
- Question and Answer
Introductory Concepts
Introductory Concepts

• The Enforcement Climate
  • More integration and financial relationships with physicians
  • Rigid and technical (e.g., Stark Law) regulatory framework
  • Aggressive government enforcement
  • Disproportionate Penalties = Enterprise Risk

• Considerations for Managing Risk
  • Compensation arrangements with referring physicians must be defensible under the applicable health care regulations
  • Must focus on demonstrating the Three (3) Tenets of Defensibility: Fair market value (“FMV”), commercial reasonableness (“CR”) and not taking into account (“TIA”) referrals
  • Documentation and governance processes (e.g., business planning, valuation, etc.) should support defensibility
Focus on 3 Tenets of Defensibility

• **The Toumey Case**
  
  – FMV
  – CR
  – TIA
  
  a. entered into compensation arrangements with physicians in violation of the Stark Statute, specifically by paying the physicians (who referred designated health services) under contracts that exceeded fair market value, were not commercially reasonable and which took into account the volume or value of the referrals or other business generated between the physician and Toumey;

• **The Halifax Case**
  
  – FMV
  – CR
  – TIA
  
  a. entered into compensation arrangements with physicians in violation of the Stark Statute, specifically by paying the physicians (who referred designated health services) under contracts that exceeded fair market value, were not commercially reasonable, and/or took into account the volume or value of the referrals or other business generated between the physician and Halifax; and
## Recent Cases and Settlements

### 2014
- New York Heart Center: $1.33 million
- Infirmary Health System: $24.5 million
- All Children’s Health System: $7 million
- Halifax Hospital: $85 million
- King’s Daughters Medical Center: $40.9 million
- Memorial Health: $9.8 million

### 2015
- Tuomey Healthcare System: $72.4 million
- Adventist Health System: $115 million
- North Broward Hospital District: $69.5 million
- Columbus Regional Health: $35 million
- Dr. Andrew Pippas: $425 thousand
- Westchester Medical Center: $18.8 million
- Citizens Medical Center: $21.8 million

### 2016
- Lexington Medical Center: $17 million
- Tenet Healthcare Corp.: $513 million
Potential Shifts in Enforcement

- Increases in enforcement (through qui tam suits)
- Expansion into actions against physicians and medical groups
- Allegations that compensation is not FMV, not CR, and that compensation takes into account referrals
- Technical issues with team-based and bonus methodologies
- Testing of the internal compensation methodologies and underlying “group practice” requirements
- June 9, 2015 OIG Fraud Alert – Warned physicians that they too can face significant liability if they enter into inappropriate financial relationships.
- September 9, 2015 DOJ Memo – Warned that the DOJ will place more focus on making individuals accountable for corporate wrongdoing.
Overview of the Regulatory Standards
Regulatory Standards

• False Claims Act (1863)
• Anti-Kickback Statute (1972)
• **Federal Stark Law (1989)**
• Other Relevant Laws
  — Tax-Exemption Laws
    • Private Benefit and Private Inurement
    • Intermediate Sanctions
  — Civil Monetary Penalties Law
  — State Equivalents
The Stark Law Framework

• If **Physician + Financial Relationship + Entity:**
  — The Physician **may not make a Referral** to that Entity for the furnishing of Designated Health Services (**“DHS”**) for which payment may be made under Medicare; and
  — The entity **may not bill Medicare**, an individual or another payor for the DHS performed pursuant to the prohibited Referral...

  ... *unless the arrangement fits squarely within a Stark exception*

• **Threshold Compliance Statute**
  — Strict liability – no intent required. Civil (non-criminal statute)
  — Triggered by “technical” violations, inadvertence and error
  — Your regulatory “Litmus Test”
  — 11 Categories of DHS (e.g., clinical lab services, radiology and certain other imaging services, radiation therapy and supplies, outpatient prescription drugs, inpatient and outpatient hospital services, etc.)
The Stark Exceptions

• Commonly Used Stark Exceptions:
  – Rental of Office Space or Equipment
  – Physician Recruitment
  – Personal Service and FMV Exceptions
  – Isolated Transactions
  – Bona Fide Employment
  – New in 2016 - Assistance to Compensation an NPP
  – New in 2016 - Time Share Arrangements

• Common Elements of the Stark Exceptions:
  – Signed, written agreement that specifies the services or property
  – Arrangement must be CR, and compensation must be consistent with FMV
  – Compensation must be set in advance and not TIA the volume or value of referrals generated between the parties
Stark Rental Exceptions*

• The arrangement must be set out in writing and signed by the parties
• Duration of the lease arrangement must be at least 1 year
• Rental charges must be set in advance and be FMV
• Rental charges must not be determined in a manner that TIA the volume or value of any referrals or other business generated
• Space or equipment rented must be reasonable and necessary (CR)
• No per click or percentage-based formulas allowed
• Exclusive use required
• Special rules for allocating common area expenses
• If the lease arrangement expires after a term of at least 1 year, new writing clarification and/or indefinite holdover rules may apply

* Actually two exceptions. Not all requirements listed.
Personal Services Exception*

- The arrangement must be set out in writing and signed by the parties
- Duration of the arrangement must be at least 1 year
- Compensation must be set in advance and FMV
- Compensation must not be determined in a manner that TIA the volume or value of any referrals, or other business generated between the parties
- Aggregate services contracted for may not exceed those that are reasonable and necessary for legitimate business purposes (CR)
- Very similar to Stark’s fair market value exception
- If the arrangement expires after a term of at least 1 year, new writing clarification and/or indefinite holdover rules may apply

*Not all requirements listed.
Bona Fide Employment Exception*

- FMV remuneration required
- Must not be determined in a manner that TIA the volume or value of any DHS referrals by the referring physician.
- Agreement must be CR “even if no referrals were made to the employer”
- No “in writing” requirement unless requiring or directing referrals
- Recent enforcement actions in what is normally considered the “safer” exception

*Not all requirements listed.
Other Common Exceptions

Non-Monetary Compensation Exception*

- Covers non-monetary compensation transferred from a DHS entity to a referring physician. Is limited to $398 per year (increases each year by the applicable CPI).
- Remuneration must be "non-monetary."

Medical Staff Incidental Benefits Exception*

- Covers incidental benefits transferred from a hospital to a referring physician member of the medical staff. Is limited to $33 per occurrence (increases each year by the applicable CPI).
- Examples: Parking, meals, internet access in physicians' lounge, etc.

*Not all requirements listed.
Stark Group Practices

• **Receive favored treatment with respect to physician compensation:**
  – Stark group practices can compensate physicians for services “incident to” their personally performed services
  – Indirect bonuses and profit shares may include DHS revenues, if the distribution methodology meets certain conditions
  – This additional compensation latitude for group practices is statutory

• **Group Practice status is required for certain exceptions:**
  – In-Office Ancillary Services Exception
  – Physician Services Exception
Group Practice Requirements*

- **Single Legal Entity Test.** Must be a “single legal entity” operated primarily for the purpose of being a group practice (e.g., a hospital cannot be a group practice, etc.)

- **Physicians.** Two (2) physicians must be owners or employees of the group practice (i.e., not independent contractors)

- **Unified Business Test.** A body representative of the group practice must maintain “effective control” over its assets and liabilities

- **Distributions of Income and Expenses.** Methods of distribution must be determined by the group practice prospectively before the receipt of payment for services

- **Range of Care.** Each physician must furnish substantially his or her full range of patient care services through the group practice

- **“Substantially All” Test.** At least 75% of the aggregate total patient care services of the group practice members must be furnished and billed through the group

- **Physician-Patient Encounters.** Members of the group (i.e., not independent contractors), in the aggregate, must personally conduct no less than 75% of the physician-patient encounters of the group practice

- **Volume/Value Compensation Test.** Shares of overall profits and productivity bonuses cannot be determined in a manner that directly relates to the volume or value of a physician’s referrals of DHS

*Not all detailed requirements are listed.*
2016 Stark Law Changes
New Stark Rules

• New Exceptions
  – Assistance to Compensate an NPP – 411.357(x)
  – Time-Share Arrangements – 411.357(y)

• Reducing Burdens on Health Care Organizations
  – Writing requirement
  – Term Requirement
  – Holdover Requirement

• Clarifications/Corrections
  – Remuneration
  – Stand-in The Shoes
  – Temporary Noncompliance
  – Takes into Account
Assistance to Compensate an NPP*

- The arrangement is set out in writing and signed by the hospital, the physician and the NPP.
- The arrangement is not conditioned on the physician or NPP’s referrals to the hospital.
- The remuneration from the hospital:
  - does not exceed 50% of NPP’s actual compensation paid by the physician to the NPP; and
  - is not determined in a manner that takes into account volume or value of referrals.
- Compensation paid to the NPP by the physician does not exceed FMV.
- NPP has not within the past year worked in the “geographic area.”
- NPP has compensation arrangement with the physician and substantially all services provided are primary care or mental health.
- Physician does not unreasonably restrict NPP from providing patient primary care services in the “geographic service area”.

*Not all requirements listed.
Time-Share Arrangements*

- The arrangement is set out in writing, signed and specifies the premises, equipment, personnel, items, supplies and services covered.
- The arrangement is between a physician and a hospital or physician organization.
- Items covered by the arrangement are used primarily for E&M services and on the “same schedule.”
- Any equipment used must be located in same building and only used for DHS incidental to the E&M Services. (some equipment excluded)
- Not conditioned upon the referral of patients by the physician.
- Compensation is set in advance, FMV, and does not take into account the volume or value of referrals.
- The arrangement is Commercially Reasonable.

*Not all requirements listed.
CMS - Reducing Stark Burdens

•  **Writing Requirement**
  – Clarifies that the arrangement need not be reduced to a single “formal” written contract.
  – Moving away from the terms “agreement” and “contract” to the term “arrangement.”

•  **Term Requirement**
  – Exceptions requiring “1 year” term may be satisfied by the arrangement lasting 1 year, even if there is no 1 year provision.

•  **Holdover Requirement**
  – Indefinite holdovers are permitted if certain requirements are met:
    • Same terms and conditions
    • Continues to meet all of the requirements of the exception, including FMV
Conducting Stark Compliance Audits
Planning The Audit

- Scope of audit depends on
  - Size and complexity of the company
  - Prior experience with the process under audit
  - Recent changes in the company or the company’s operations
  - Previously recognized deficiencies
  - Other circumstances that occur during the audit

- Laws auditing for: Stark Law, Anti-Kickback Statute, Private Benefit
Auditing Process

• Compile a list of currently executed contract with physicians.
• Interview individuals commonly involved in physician relationships.
• Reconcile interviews to currently executed physician contracts.
• Reconcile physician payments to physician contracts.
• Review time sheets or other attestation forms for completeness and accuracy.
• Verify that fair market value and commercial reasonableness is documented for each agreement.
• Verify that other terms of agreement and necessary steps are performed in executing agreements.
Common Physician Arrangements

- Employment
- Call Coverage
- Medical Directorships
- Subsidy/Stipend Arrangements
- Equipment Lease/Other Services Agreements (e.g., lithotripsy, perfusion, and dialysis)
- Income Guarantees
- Real Estate Leases
Increasingly Common Arrangements

• Clinical co-management agreements and other quality based compensation arrangements
• Gainsharing and demand matching agreements
• Management and billing agreements
• Risk-sharing agreements
Interview Planning

• Employees generally involved in physician relationships:
  – Hospital and physician practice executive staff;
  – Department administrative staff; and
  – Development and recruiting staff.

• Understand the following processes:
  – Strategy;
  – Documentation;
  – Approval; and
  – Selection.
Reconciliation of Contracts

Most common issues include:

• Use of space, office equipment, and other items by physicians for professional or personal use.
  – U.S. ex rel. Kosenske v. Carlisle HMA

• Payment for services not provided.
  – U.S. v. Campbell
Verify Fair Market Value

• Fair market value means the value in arm’s-length transactions, consistent with the general market value.

• General market value means “. . . 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 agreement.” Stark II, Phase III Final Rule (42 CFR Section 411.351).
## Using Benchmark Surveys

<table>
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<tr>
<th>Specialty: General Cardiology</th>
<th>Compensation per wRVU</th>
<th>Reported Compensation</th>
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Commercial Reasonableness

• An arrangement will be considered ‘commercially reasonable’... if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential designated health services (“DHS”) referrals (69 Fed. Reg. 16093, March 26, 2004).

• Factors to consider:
  – Who is providing the services?
  – Why are the services required?
  – When are the services performed?
  – How are the services provided?

• Hebrew Homes Health Network Settlement
Other Terms and Necessary Steps

• Compensation Structure
  – U.S. ex rel. Elin Baklid-Kunz v. Halifax Hospital

• Length of fair market value opinion versus length of contract

• Compensation set in advance

• Agreements executed

• Expired agreements
Effective Compliance Program

• Implementing written policies and procedures
• Conducting effective training and education
• Developing effective lines of communication
• Conducting internal monitoring and auditing
• Enforcing standards through well-publicized disciplinary guidelines
• Responding promptly to detected problems and undertaking corrective action
Process Considerations
Contracting Oversight and Governance

- Board
- Compensation Committee
- Management
Contracting/Comp Processes

Step #1
Authorized Preliminary Negotiations

Step #2
Contract Checklist Sent to Legal

Step #3
Financial Analysis and Necessary Approvals

Step #4
Compile FMV/CR Documentation

Step #5
Final Regulatory Analysis by Legal

Step #7
Finalize Written Agreement

Step #7
Obtain Final Contract Approvals

Step #8
Execution by Authorized Signatory
### Process Review – Phased Assessment

<table>
<thead>
<tr>
<th>Phase I: Contracting and Compensation Process Review</th>
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<tbody>
<tr>
<td>Review current policies and procedures</td>
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<tr>
<td>Interview key stakeholders</td>
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<tr>
<th>Phase II: Contracting and Compensation Process Development</th>
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<tbody>
<tr>
<td>Revise and/or develop specific policies and procedures</td>
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<table>
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<tr>
<th>Phase III: Compliance and Process Education</th>
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<tbody>
<tr>
<td>Physician Contracting Staff Members</td>
</tr>
<tr>
<td>Management</td>
</tr>
<tr>
<td>Governing Board</td>
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Practical Takeaways

• Compensation arrangements with referring physicians must be defensible

• Focus on Stark’s updated technical requirements and the 3 Tenets of Defensibility

• Consider how to operationalize new Stark exceptions, requirements, interpretations/clarifications

• Documentation and governance should support defensibility: