Stark Compliance Audits in Hospital-Physician Arrangements: Mitigating Provider Liability
Implementing Monitoring Processes to Avoid Penalties, Denial of Payment, and CMS Program Exclusion

THURSDAY, APRIL 9, 2015
1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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Stark Compliance Audits in Hospital-Physician Arrangements: Mitigating Provider Liability

Implementing Monitoring Processes to Avoid Penalties, Denial of Payment and CMS Program Exclusion

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Session Agenda

• Introduction
• Overview of the Stark Law
• Reasons to Conduct a Stark Compliance Audit
• Conducting Stark Compliance Audits
• Common Issues and Corrective Actions
• Strategies for Mitigating Risk
• Question and Answer
Stark in a Nutshell

• Stark’s “General Prohibition”

  If a physician has a financial relationship with an entity,
  
  – then the physician may not make a referral to that entity for the furnishing of designated health services (“DHS”) for which payment otherwise 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.
  
  – Disproportionately large penalties.
  
  – Aggressive government enforcement efforts.
The Core Stark Analysis

• All financial relationships with referring physicians must be analyzed and monitored for Stark compliance.

• **Core Stark Analysis:**
  – Is there a referral from a physician for a DHS?
  – Does the physician have a financial relationship with the entity furnishing the DHS (e.g., the hospital)?
  – Does the financial relationship fit in a Stark exception?

• Must meet **all** of the conditions of an exception **at all times**.

• Apply the Stark rules that were in effect at the time.
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
The Stark Exceptions

• **Common Stark Compensation Exceptions:**
  – Rental of Office Space;
  – Rental of Equipment;
  – Bona Fide Employment;
  – Personal Service Arrangements;
  – Physician Recruitment;
  – Isolated Transactions;
  – Non-monetary Compensation; and
  – Fair Market Value Exception.

• **Stark Exceptions: Common Elements**
  – Signed, written agreement that specifies the services or property covered.
  – Compensation must be commercially reasonable and consistent with fair market value.
  – Compensation must be set in advance and not take into account the volume or value of referrals generated between the parties.
Common Exceptions

Rental (Space and Equipment) Exceptions*

- Must be set out in writing.
- One year requirement.
- Rental charges must be set in advance and be fair market value.
- Rental charges must not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- Space or equipment rented must be reasonable and necessary.
- No per click or percentage-based formulas allowed.
- Exclusive use required.
- Special rules for calculation/allocation of common area expenses.

* Actually two separate exceptions. Not all requirements are listed.
Common Exceptions

*Bona Fide Employment Relationships Exception*

- Fair market value remuneration required.
- Must not be determined in a manner that takes into account the volume or value of any referrals by the referring physician.
- Agreement must be commercially reasonable “even if no referrals were made to the employer.”
- No “in writing” requirement unless requiring or directing referrals.
  - Business and operational reasons that such arrangements should be in writing.
- Recent enforcement actions in what is normally considered the “safer” situation of employment.

*Not all requirements listed.*
Common Exceptions

Personal Service Arrangements Exception*

– Must be set out in writing.
– One year requirement.
  • If terminated during year one, cannot enter into the same arrangement during the remainder of such year.
– Compensation must be set in advance and be fair market value.
– Compensation must not be determined in a manner that takes into account the volume or value of any referrals, or other business generated between the parties.
– Cross reference requirement for other arrangements between the parties.
– Similar to the Stark fair market value exception.

*Not all requirements listed.
Common Exceptions

Non-Monetary Compensation Exception*
  – Covers non-monetary compensation transferred from a DHS entity to a referring physician is limited to $385 per year (increased each year by CPI).
  – Be careful that remuneration is "non-monetary." For example, a gift card is a monetary transfer, not a non-monetary transfer.

Medical Staff Incidental Benefits Exception*
  – Medical Staff Incidental Benefits transferred from a DHS entity to a referring physician member of the medical staff is limited to $32 per occurrence (increased each year by CPI).
  – Free parking, meals, internet access in physicians' lounge, etc.

*Not all requirements listed.
Disproportionate Penalties

• **Stark Sanctions**
  – Denial of payment/repayment of reimbursement.
  – CMPs of up to $15,000 per item or service.
  – CMPs of up to $100,000 for each arrangement considered to be a circumvention scheme.
  – Exclusion from Medicare and Medicaid.

• **Potential for False Claims Liability**
  – A Stark violation renders all related claims false or fraudulent overpayments, thus giving rise to an FCA violation.
  – Retention of “identified” overpayments for over 60 days is a false claim unless repaid or self-disclosed.
  – Triple (3x) the amount of damages suffered by the government.
  – Mandatory CMPs of $5,500 to $11,000 for each claim.
Why Conduct a Stark Audit?

• **The Regulatory Climate**
  – Increases in government enforcement.
  – Allegations that compensation is not fair market value, not commercially reasonable, and that compensation takes into account referrals.
  – Scrutiny of “Team-Based” and “Group Practice” arrangements.

• **Recent Enforcement Actions:**
  – Tuomey Healthcare – South Carolina ($237.5 million judgment)
  – Infirmary Health System – Alabama (2014 – $25 million)
  – Halifax Hospital – Florida (2014 – $85 million)
  – New York Heart Center – (2014 – $1.3 million)

• **Astronomical damages: Tuomey Example**
  
  21,730 claims x $5,500 = $119,515,000
  
  $39,313,065 x 3 = $117,939,195
  
  $237,454,195
Why Conduct a Stark Audit?

• **Period of Disallowance**
  – **Begins** – when the financial relationship fails to satisfy all of the requirements of an exception.
  – **Ends** – “no later than” when the financial relationship again fits squarely within a Stark exception.
  – During the disallowance period Stark’s “general prohibition” on referrals and billing applies.
  – Focus on appropriate strategies that shorten potential periods of disallowance.

• **Alternative Methods of Compliance**
  – Other exceptions may be available, such as:
    • Six month “holdover” provisions;
    • Delayed signature rule (30-days intentional, 90-days inadvertent);
    • Temporary noncompliance rule; and
    • Indirect analysis.
  – Apply the rules in effect during the time period at issue.
Stark Compliance Hazards

• Total compensation exceeds fair market value.
• Hospital revenues are “credited” to the physician.
• Crediting physicians for services provided by non-physician providers.
• Excluding pay for on-call services, directorships or other duties in when evaluation total compensation.
• Unsigned or expired contracts.
• Examining downstream data when determining compensation (i.e., examining future referrals).
• Lack of time records supporting administrative services provided.
  – Submission of identical time records.
• Incentive monies paid with no identified-measurable goals.
Self Referral Disclosure Protocol

• For perceived problematic financial relationships with referring physicians under Stark.

• Still a relatively new self-disclosure option –
  – CMS implemented SRDP on September 23, 2010, pursuant to Affordable Care Act directives.

• SRDP suspends the obligation to refund overpayments within 60 days.
  – Submission consistent with SRDP specifications.
  – Importance of Corporate Responsibility Program.
  – Four-year “look back” period.
  – Process lengthy and hundreds of self-disclosing providers currently in the queue to settle with CMS.

• Preliminary returns encouraging – CMS using its authority to settle for less than the statutory overpayment amounts.
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;
  – Development and recruiting staff; and

• 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>
<thead>
<tr>
<th>Specialty: General Cardiology</th>
<th>Compensation per wRVU</th>
<th>Reported Compensation</th>
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<tbody>
<tr>
<td></td>
<td>25th %ile = $46.30</td>
<td>50th %ile = $57.95</td>
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<tr>
<td>wRVUs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25th %ile = 4,710</td>
<td>$218,073</td>
<td>$272,945</td>
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<tr>
<td>50th %ile = 6,634</td>
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<td>75th %ile = 9,078</td>
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<td>526,070</td>
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<tr>
<td>90th %ile = 12,092</td>
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</tr>
</tbody>
</table>
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?
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
Strategies for Mitigating Risk

• **Perfect Storm**
  – More integration and financial relationships with physicians
  – Rigid and technical (e.g., Stark Law) framework
  – Aggressive government enforcement
  – *Payment prohibition + FCA liability = Astronomical Damages*

• **Considerations for Managing Risk:**
  – Compensation models must be [defensible](#) under the Stark Law
  – Documentation and governance must support defensibility
  – Focus on the Three (3) Tenets of Compliance:
    Fair market value, commercial reasonableness (and not taking into account referrals)
Strategies for Mitigating Risk

- **High Level – Organizational Commitment to Stark Compliance**
  - Formalize physician transaction process.
  - Regular auditing and monitoring.
  - Development of policies and procedures for self-disclosure.
  - Stark compliance training.
  - Engagement of health care regulatory counsel.

- **Mid Level – Internal Controls**
  - Legal review of all physician contracts and/or templates.
  - Centralized contract approval process.
  - Implement a contract database.
    - Periodic expiration reports.
    - Confirm signed, dated contract prior to performance of any services.
  - A/P confirmation prior to payment.
Strategies for Mitigating Risk

• **Ground Level – Contracting Techniques**
  – Keep it simple – draft to fit the appropriate Stark exception.
  – Consider evergreen clauses.
  – Do not include provisions you do not intend to enforce.
  – Avoid late fees or other penalties.
  – Avoid reconciliation/payback provisions.

• **Compensation-Focused Compliance**
  – Must also keep focus on the compensation models.
    • The technical compliance of the model is critical.
  – Processes and communications should document “good purposes.”
  – Adopt and follow a compensation plan, parameters, etc.
  – External third-party documentation of fair market value and commercial reasonableness.
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