Topics

- Episode I: Overview of the Stark Law
- Episode II: Recent Regulatory Developments
- Episode III: Enforcement Trends
- Episode IV: Lessons Learned from a Voluntary Self-Disclosure

Episode I
Overview of the Stark Law

A long time ago in a galaxy far, far away....
The Stark Law prohibits:

- A physician
- From making a Medicare referral
- To an entity (e.g., a hospital)
- For designated health services (DHS)
- If the physician has a financial relationship with the entity
- Unless the relationship meets an exception

The Stark Law also prohibits:

- An entity
- From presenting or causing to be presented a bill or claim
- To Medicare for DHS
- Furnished as a result of a prohibited referral

History and Purpose

- 1989: Enacted to limit the influence of financial relationships on physician referrals
  - Initially applied only to physician referrals for clinical laboratory services
- 1993/1994: Expanded to cover 11 other DHS
Types of DHS

<table>
<thead>
<tr>
<th>Designated Health Services</th>
<th>Types of Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical laboratory services</td>
<td>Durable medical equipment</td>
</tr>
<tr>
<td>Physical therapy services</td>
<td>Parenteral and enteral nutrients/supplies/equipment</td>
</tr>
<tr>
<td>Occupational therapy services</td>
<td>Prosthetics and orthotics</td>
</tr>
<tr>
<td>Outpatient speech-language pathology services</td>
<td>Home health services</td>
</tr>
<tr>
<td>Radiology (X-ray, MRI, CT, ultrasound, nuclear medicine, PET)</td>
<td>Outpatient prescription drugs</td>
</tr>
<tr>
<td>Radiation therapy services</td>
<td>Inpatient and outpatient hospital services</td>
</tr>
</tbody>
</table>

Elements Explained

- “Physicians” include:
  - M.D.s
  - D.O.s
  - Dentists and Dental Surgeons
  - Podiatrists
  - Optometrists
  - Chiropractors

- Does not include Nurse Practitioners, Physician Assistants or other types of Mid-Levels

Elements Explained, cont’d.

- A “referral” is:
  - A request by a physician for, or ordering of, or certifying the need for DHS
  - A request for a consultation with another physician and any test or procedure ordered by or performed by the other physician
  - The establishment of a plan of care by a physician that includes the provision of DHS

- A referral does not include any services that are personally performed
**Elements Explained, cont’d.**

- **Financial Relationships:**
  - If a physician has a "financial relationship" with the entity to which it refers DHS, then the arrangement should be structured to meet an exception to the Stark Law.
  - The term "financial relationship" is defined very broadly by the Stark Law:
    - Includes ownership / investment and compensation relationships.
    - A "compensation relationship" exists whenever a benefit or something of value is provided.
    - Includes both direct and indirect relationships.

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**Exceptions**

- Stark is a "strict liability" statute – if elements are met, arrangement must be structured to meet exception:
  - No bad intent necessary.
  - Even "technical" errors may constitute a violation.
  - No general de minimis exception.
- Many different exceptions exist for different types of arrangements. Common elements include:
  - Compensation must be fair market value.
  - Arrangement must be commercially reasonable.
  - Compensation must not vary with the volume or value of referrals.
  - Arrangement must be documented in a written agreement.

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**Exceptions, cont’d.**

<table>
<thead>
<tr>
<th>Types of Exceptions</th>
<th>In-Office Ancillary Services</th>
<th>Publicly Traded Securities</th>
<th>Mutual Funds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic Medical Centers</td>
<td>Rental of Office Space</td>
<td>Rental of Equipment</td>
<td></td>
</tr>
<tr>
<td>Employment</td>
<td>Personal Services</td>
<td>Recruitment / Retention</td>
<td></td>
</tr>
<tr>
<td>Isolated Transactions</td>
<td>Intra-Family Rural Referrals</td>
<td>E-Prescribing and EHR</td>
<td></td>
</tr>
<tr>
<td>Payments Made by Physicians</td>
<td>Non-Monetary Compensation</td>
<td>Medical Staff Incidental</td>
<td></td>
</tr>
<tr>
<td>Indirect Compensation</td>
<td>Compliance Training</td>
<td>Obstetric Malpractice</td>
<td></td>
</tr>
<tr>
<td>Professional Courtesy</td>
<td>Preventive Screening Tests, Immunizations &amp; Vaccines</td>
<td>And more!</td>
<td></td>
</tr>
</tbody>
</table>
Penalties

- Severe penalties
  - Refund of all amounts billed pursuant to a prohibited referral
  - Penalty of $15,000 per claim
  - Penalty of up to $100,000 for engaging in a circumvention scheme
  - Potential exclusion from Federal health care programs
  - May create False Claims Act liability

Penalties, cont’d.

- False claims can include billing for claims tainted by a violation of the Stark Law
- False Claims Act Primer:
  - Prohibits:
    - Knowingly submitting a false claim to the Government in order to obtain payment
    - Knowing retention of inappropriate funds ("reverse false claims")
  - Whistleblower incentive
  - Penalties:
    - $5,500 to $11,000 per false claim and treble damages
    - Exclusion

Episode II: Recent Regulatory Developments
Timeline of Recent Actions

- **2016 Physician Fee Schedule Final Rule:**
  - CMS eased certain requirements and added new exceptions to the Stark Law

- **2017 Physician Fee Schedule Final Rule:**
  - CMS reissued ban on per-click rental charges in office and equipment leases that are based on services referred by the lessor to the lessee

- **June 1, 2017:**
  - CMS implemented updated self-disclosure protocol process

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### 2016 Physician Fee Schedule

- **New Exceptions**
  - Recruitment of Non-Physician Practitioners
    - Protects remuneration provided by hospitals, FQHCs and RHCs to physicians / physician groups to assist with bona fide recruitment of non-physician practitioners
  - Timeshare Arrangements
    - Protects provision of office space, equipment, personnel, supplies and other services by a hospital/physician group to a physician on a limited or as-needed basis

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### 2016 Physician Fee Schedule, cont'd.

- **Clarifications and Modifications**
  - **Writing Requirement**
    - Changes references to “agreement” in many exceptions to “arrangement”
    - No requirement for a formal contract
    - May rely on collection of documents, including contemporaneous documents evidencing course of conduct
  - **Signature Requirement**
    - Eliminates 30-day exception for late signatures that were “not inadvertent” and permits 90-day late signatures for any reason
    - Exception may still only be utilized once every 3 years per physician / physician group
2016 Physician Fee Schedule, cont’d.

- Clarifications and Modifications, cont’d.
  - Holdover Arrangements
    • Eliminates 6-month holdover provision for space and equipment leases and service agreements and permits indefinite holdovers instead
    • Arrangement must continue on same terms and conditions
  - Miscellaneous other changes to terminology, definitions, etc.

2017 Physician Fee Schedule

- Ban on Per-Click Rental Charges
  - In 2009, CMS generally prohibited per-click compensation formulas under space and equipment leases
  - In 2015, the D.C. Circuit Court of Appeals ruled in Council for Urological Interests v. Burwell that the per-click prohibition should be reconsidered by CMS
  - In response, CMS reissued the ban in the 2017 Physician Fee Schedule Final Rule to be effective January 1, 2017
    • CMS re-emphasized that the ban only applies to the extent the rental charges reflect services provided to patients referred by the lessor to the lessee

Updated Self-Disclosure Protocol

- The CMS Voluntary Self-Referral Disclosure Protocol (SRDP) may be used to resolve matters that involve violations of the Stark Law
- Historically, providers who disclosed Stark issues via the SRDP did so by submitting a detailed letter via e-mail to CMS
- Beginning June 1, 2017, providers of services and suppliers must use specific forms provided by CMS
- NOTE: CMS has also issued special instructions for disclosures involving noncompliance with certain requirements for physician-owned hospitals
### Updated SRDP, cont’d.

<table>
<thead>
<tr>
<th>Forms Required by CMS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SRDP Disclosure Form:</strong></td>
</tr>
<tr>
<td>• Provides information about the disclosing party, including whether there is a history of abuse, pervasiveness of noncompliance, and steps to prevent future noncompliance</td>
</tr>
<tr>
<td><strong>Physician Information Form(s):</strong></td>
</tr>
<tr>
<td>• Must be submitted for each physician included in the disclosure</td>
</tr>
<tr>
<td>• Provides details of the noncompliant financial relationship(s) between the physician and the disclosing party</td>
</tr>
<tr>
<td><strong>Financial Analysis Worksheet:</strong></td>
</tr>
<tr>
<td>• Quantifies the overpayment for each physician included in the disclosure who made referrals</td>
</tr>
<tr>
<td>• Must be submitted in Microsoft Excel®-compatible format</td>
</tr>
</tbody>
</table>

### Updated SRDP, cont’d.

<table>
<thead>
<tr>
<th>Impact of 60-day Repayment Rule and 6-Year Lookback Period on Self-Disclosures:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Self-disclosures made prior to March 14, 2016 may rely on 4-year lookback period specified in previous version of SRDP</td>
</tr>
<tr>
<td>• Self-disclosures made on or after March 14, 2016 are subject to the 6-year lookback period</td>
</tr>
</tbody>
</table>

### Episode III: Enforcement Trends

*I have a very bad feeling about this*
Prevention and Enforcement

- Health Care Fraud and Abuse Control Program Annual Report (FY 2016)
  - For every $1.00 spent on health care-related fraud and abuse investigations from 2014-2016, the government recovered $5.00
  - The government won or negotiated over $2.5 billion in health care fraud judgments and settlements. As a result of these efforts and those from preceding years, over $3.3 billion was returned to the government or paid to private persons
  - DOJ opened 975 criminal investigations, 930 civil investigations, and had 1,422 civil matters pending at the end of the fiscal year
  - OIG investigations resulted in 765 criminal actions and 690 civil actions
  - The OIG also excluded 3,635 individuals and entities from participation in Medicare, Medicaid, and other federal health care programs

Notable Case Law

- 2014: Halifax Hospital Medical Center
  - Employed physicians allowed to divide incentive bonus pool based on each physician’s production
  - Court held arrangement violated Stark – did not meet employment exception because bonus pool must be solely made up of personally performed services
  - Before case went to the jury to determine damages, Halifax and DOJ reached a settlement:
    - $85 million dollars for violation of the FCA by submitting Medicare claims that violated Stark
    - Halifax agreed to enter into a Corporate Integrity Agreement

Notable Case Law, cont’d.

- 2014: All Children’s Health System
  - 4 employed neurosurgeons offered volume based bonuses to maintain volume of procedures performed by 6 neurosurgeons from previous year
  - Emergency room physicians, hem/onc physicians and pediatric surgeons paid above 90th percentile, in contradiction to hospital’s compensation plan
  - Side letters guaranteed additional compensation that was not part of main employment agreement (e.g. cost for tail coverage, indemnification for non-compete lawsuit, employment for spouses)
  - Relator claimed that All Children’s developed and approved a Compensation Plan for guaranteed salary between the 25th% and 75th% based on data from 3 nationwide surveys
  - Case settled for $7 million
Notable Case Law, cont’d.

- **2015: Tuomey**
  - Tuomey entered into part-time employment contracts with 19 specialists. Government alleged that compensation exceeded FMV and took into account referrals
  - Notable that Tuomey had obtained FMV opinions approving the arrangements
  - Jury determined that contracts violated the Stark Law and FCA. Trial court entered judgment for more than $237 million in treble damages and penalties. U.S. Court of Appeals for the Fourth Circuit affirmed.
  - In October 2015, Tuomey paid $72.4 million to resolve the judgment. Also entered into a 5-year Corporate Integrity Agreement
  - In September 2016, Tuomey’s former CEO paid $1 million and was excluded from participation in federal health care programs for 4 years to resolve civil/administrative claims related to his involvement
  - Tuomey was recently sold to Palmetto Health

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**Episode IV:**

*Lessons Learned from a Voluntary Self-Disclosure*

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**Stark Self-Disclosure Settlements**

<table>
<thead>
<tr>
<th>Calendar Year</th>
<th>Number of Disclosures Settled</th>
<th>Range of Amounts of Settlements</th>
<th>Aggregate Amount of Settlements</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>1</td>
<td>$700 - $5,573,000</td>
<td>$1,765,000</td>
</tr>
<tr>
<td>2012</td>
<td>14</td>
<td>$1,000 - $584,700</td>
<td>$7,734,200</td>
</tr>
<tr>
<td>2013</td>
<td>24</td>
<td>$760 - $51,762</td>
<td>$1,456,348</td>
</tr>
<tr>
<td>2014</td>
<td>91</td>
<td>$5,000 - $5,969,393</td>
<td>$4,179,168</td>
</tr>
<tr>
<td>2015</td>
<td>69</td>
<td>$5,500 - $6,183,405</td>
<td>$3,706,458</td>
</tr>
<tr>
<td>2016</td>
<td>102</td>
<td>$500 - $5,573,743</td>
<td>$5,112,508</td>
</tr>
<tr>
<td>Totals</td>
<td>333</td>
<td>$500 - $5,573,743</td>
<td>$23,209,222</td>
</tr>
</tbody>
</table>

- As of December 31, 2016, an additional 92 disclosures to the SRDP were withdrawn, closed without settlement or settled by CMS’ law enforcement partners
Recommendations / Insights

- Be patient
- Maintain robust documentation
- Consider withdrawing disclosed arrangements due to regulatory updates, CMS interpretations, etc. since date of disclosure
- Take advantage of opportunities to advocate
- Reasonable and fair approach by CMS
  - May encourage flexible interpretations of certain Stark Law requirements
  - Settlement offers appear to be reasonable, although non-negotiable

Questions?

Thank You

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