

Health Care Compliance Association
Kansas City Regional Conference

Stark Wars: The Government Strikes Back

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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 1 ***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



"First we're going to run some tests to help pay off the machine."

Types of DHS

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

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

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

Exceptions, cont'd.

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

Penalties

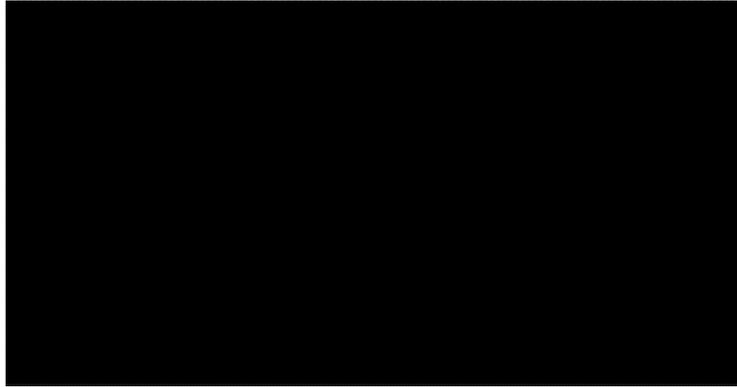
- Severe penalties

- 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

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

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.

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

Updated SRDP, cont'd.

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

Episode III: ***Enforcement Trends***



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

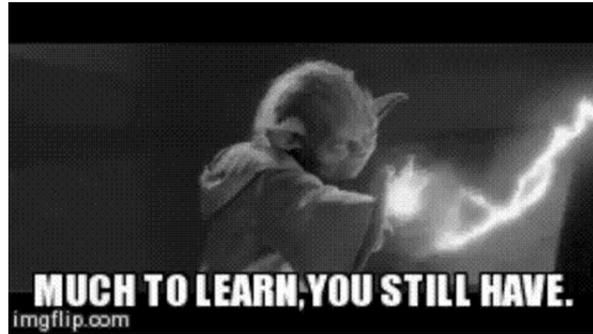
- 4 employed neurosurgeons offered volume based bonuses to maintain volume of procedures performed by 6 neurosurgeons from previous year
- Emergency room physicians, hem/onc physicians and pediatric surgeons paid above 90th percentile, in contradiction to hospital's compensation plan
- Side letters guaranteed 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

**Episode IV:
Lessons Learned from a
Voluntary Self-Disclosure**



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Stark Self-Disclosure Settlements

Calendar Year	Number of Disclosures Settled	Range of Amounts of Settlements	Aggregate Amount of Settlements
2011	3	\$60 - \$579,000	\$709,060
2012	14	\$1,600 - \$584,700	\$1,236,200
2013	24	\$760 - \$317,620	\$2,468,348
2014	41	\$3,322 - \$463,473	\$5,175,168
2015	49	\$5,081 - \$815,405	\$6,706,458
2016	102	\$80-\$1,195,763	\$6,913,988
Totals	233	\$60 - \$1,195,763	\$23,209,222

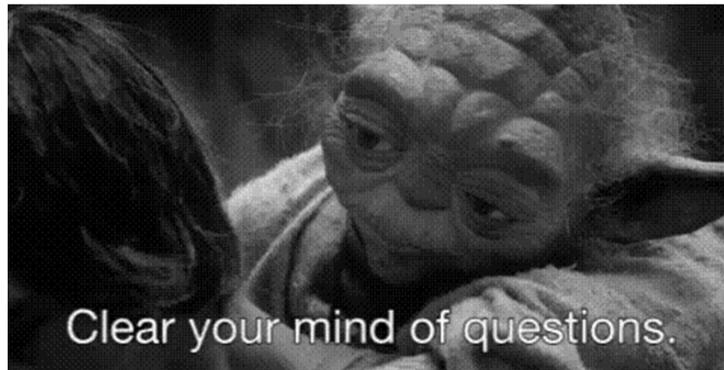
- As of December 31, 2016, an additional 92 disclosures to the SRDP were withdrawn, closed without settlement or settled by CMS' law enforcement partners

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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?





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Thank You

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