Stark Law: What Have We Learned from Recent Cases and the SRDP?

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Disclaimer

- The views expressed today are those of the speakers in their personal capacity and not the official position of the Centers for Medicare & Medicaid Services or any other governmental agency.

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Overview

- Key cases and settlements, including Halifax Health, Tuomey, and Infirmary.
- What does “takes into account” the volume or value of referrals really mean?
- History and regulatory guidance regarding self-reporting Stark issues, and key learning points from the SRDP both from the perspective of the government and private practice.

Halifax Health

- **Allegations:**
  - Lawsuit brought by the former Director of Physician Services at Halifax Health alleges that contracts with six (6) oncologists violated the Stark law and other relevant Medicare laws.
  - Allegations that Halifax submitted 74,000 false claims to Medicare with potential damages and penalties exceeding $1 Billion.
- **Settlement:**
  - March 2014 – Stark Law Allegations Settled for $85 Million
  - July 2014 – Short Stay (Observation vs. Inpatient Admission) Allegations Settled for $1 Million

Halifax Health

- **Arrangement:**
  - Bonus pool would be equal to 15 percent operating margin for the medical oncology program. The payments to individual doctors would be based on each individual oncologist's personally performed services.
  - Halifax argued that the arrangement met the employment exception under the Stark law since the physicians were employed.
  - Summary Judgment: The bonus was not based solely on personally performed services but also included services provided including revenue from referrals made by the oncologists for DHS.

U.S. ex rel. Drakeford v. Tuomey Healthcare System

- **Allegation:**
  - The government and relator alleged that the part-time employment agreements for roughly 19 physicians in various specialties violated the Stark Law and the Anti-Kickback Statute.
- **Outcome:**
  - Jury originally found that Tuomey violated the Stark Law, but not "willfully and knowingly," and thus had not violated the FCA.
  - District Court set aside jury verdict and granted judgment in favor of Government. Tuomey ordered to pay $44.9 M for the Stark Law violation.

U.S. ex rel. Drakeford v. Tuomey Healthcare System

- **Subsequently. . .**
  - Judge acknowledged he erred when ruling that the deposition of Tuomey's COO was inadmissible, and ordered a new trial specifically on the FCA issue (not Stark Law).
  - July 16, 2010: Tuomey filed an appeal on the determination of the Stark Law violation.
  - September 7, 2010: Tuomey filed a petition for permission to appeal the District Court's order granting a new trial.

U.S. ex rel. Drakeford v. Tuomey Healthcare System

- October 26, 2010: Fourth Circuit Court of appeals denied Tuomey's petition to appeal the District Court's order granting a new a trial.
- January 20, 2012: Oral arguments held in the Fourth Circuit for the Stark Law violation.

- Gov't seeks to recover $300 M for the alleged FCA violations.

U.S. ex rel. Drakeford v. Tuomey Healthcare System

- March 30, 2012: Fourth Circuit vacated judgment in favor of Government and remanded for trial.
  - New trial ordered by District Court on FCA, in effect, vacated jury's findings, thus denying Tuomey Seventh Amendment right to jury trial.
  - Fourth Circuit focused on facility fee/technical component of referrals while performing services under employment arrangement.

U.S. ex rel. Drakeford v. Tuomey Healthcare System

- March 30, 2012: *(cont.)*
  - Court held that jury can be instructed on preamble regulations (Phase I-III)
  - Court rejected Tuomey's assertion that the technical component of a personally performed service is not a "referral."
  - "Taking into account the volume or value of referrals" means anticipated and historical referrals.

U.S. ex rel. Drakeford v. Tuomey Healthcare System

- May, 2013: *(cont.)*
  - Jury found that Tuomey had violated both the Stark Law and the False Claims Act.
  - Tuomey was required to repay $39.3 million plus interest in Medicare payments and up to $337 million in additional penalties.
  - The crux of the case focused on the fair market value and commercial reasonableness of the employment contracts.

U.S. ex rel. Drakeford v. Tuomey Healthcare System

- July, 2014: *(cont.)*
  - Tuomey appealing as representatives of the organization stated that paying the jury verdict amount would effectively bankrupt the organization.
  - Court ordered Tuomey to place $40 million in an account to continue the process of appealing the jury verdict.
  - Hearing is scheduled in September of 2014 to discuss continuing the case.

U.S. ex rel. Drakeford v. Tuomey Healthcare System

- July 2, 2015:
  - 4th Circuit Court of Appeals upholds $237M judgment.
  - Held Toumey "shopped" for legal opinions to obtain favorable opinion.
  - Rejected Excessive Fines Clause of 8th Amendment (3.6 to 1.0 punitive – compensatory damages ratio)

U.S. ex rel. Drakeford v. Tuomey Healthcare System

- Contract Analysis
  - 10 year terms
  - Contracts included requirements of only outpatient procedures
  - Exclusive use requirement – all outpatient surgeries at Tuomey
  - Yearly salary based on previous year's net collections
  - Bonus
    - 80% of net collections of professional fees
    - Additional 7% of productivity bonus for other factors
  - Agreement not to compete – prohibited physicians from performing surgeries elsewhere within 30 miles of the hospital (during and post-two years)
  - Full time benefits: Including health insurance, malpractice premiums (covered physicians for office and inpatient services), cell phones, journals, CME

U.S. ex rel. Drakeford v. Tuomey Healthcare System

- Cejka, a valuation firm evaluated the contracts for purposes of the fair market value requirement at inception.
  - Analysis indicated productivity levels of physician's were between the 50th and 75th percentiles
  - Compensation level exceeded the 90th percentile
  - Evaluation did not include full time benefits
- Government expert analyzed the contracts at trial.
  - Impossible to ever make profit on these contracts
  - Full time benefits for minimal hours per week
  - Cejka showed that certain physicians, across the country, received between 49% and 63% of net collections, but Tuomey paid, on average, 131% of net collections
  - Non-Compete Agreement locked in referrals
  - Reactive to competing ambulatory surgery center and physician groups informing Tuomey they may perform surgeries in their own offices rather than at Tuomey.

U.S. ex rel. Drakeford v. Tuomey Healthcare System

Top 6 Lessons from Tuomey

- Fair Market Value and Commercially Reasonable Opinions Must be Defensible
- Seek Expert Fair Market Value and Commercially Reasonable Advice
- Compliance and Legal Departments Should Evaluate all Physician Financial Arrangements at the Commencement of the Arrangement for Fair Market Value and Commercial Reasonableness
- Stark is a Strict Liability Law
- Be Proactive and Implement an Effective Compliance and Monitoring Program for Physician Financial Arrangements
- If the Arrangement is Fair Market Value and Commercially Reasonable, then a Covenant may be Defensible

Infirmary Health and Diagnostic Physicians Group

- **Allegations:**
  - Lawsuit brought by local cardiologist alleging that contracts between Infirmary and two clinics violated the Stark law and other relevant Medicare laws.
  - Allegations that Infirmary had agreements with the physicians groups that paid the group a percentage of Medicare payments for tests and procedures that were DHS referred by physicians but not personally performed.
  - Estimated $522 million in reimbursements impacted.
- **Settlement:**
  - July 2014 - $24.5 million settlement between Infirmary Health and the physician group.

Infirmary Health and Diagnostic Physicians Group

- **Arrangement:**
  - The arrangement allegedly focused on the hospital offering physician groups below market office space and other bonuses in return for referrals implicating the Anti-kickback Statute.
  - Further, it was alleged the hospital offered bonuses that were based upon referrals and ordered tests in violation of the Stark Law.

Infirmary Health Learning Points

- Review Arrangements with Newly Acquired Physicians groups
  - Infirmary Health acquired some of the physician groups at issue and allegedly failed to review arrangements post-acquisition.
- DOJ is Focusing on Physician Group Involvement
  - Infirmary Health is one of multiple settlements under the Stark Law that have specifically included the involved physician groups. Physicians entering into arrangements should be aware of these increased risks.
- Make sure the arrangement operates as indicated in the written documentation.
  - Ensure that necessary changes to compensation methodology are made post-practice acquisition.

Varying Based Upon Volume or Value: What does this mean?

- Two standards: i) cannot ***vary*** with the volume or value, and ii) cannot be ***based upon*** volume or value.
- Four levels of volume and value:
  i. Paying a doctor for each referral of designated health services. ***Clearly prohibited***.
  ii. Creation of a bonus pool that varies with either the gross revenue or net margin of a service line. Division of bonus pool based upon each physician's referrals of DHS. ***Clearly prohibited***.
  iii. Creation of a bonus pool that varies with either the gross revenue or net margin of a service line. Division of bonus pool based upon percentage of work RVUs in comparison with aggregate wRVUs of all applicable physicians. ***Halifax case, but unlitigated***.
  iv. Fixed bonus pool or bonus based upon overall success of AMC, both financially and based upon quality metrics. ***Unlitigated***.

Possible Stark Law Strategies

- Payments by a Physician
- Employment (no contract needed)
- Delayed signature (30 vs. 90 days)
- Temporary noncompliance
- No referrals
- Nonmonetary compensation
- Fair market value
- Commercial reasonableness
- Indirect compensation definition/exception
- Arrangements with physician organizations / stand in the shoes
- No DHS entity
- Multiple written documents signed by the parties
- 6 month holdover

2015 Physician Self-referral Updates

- Clarification of the writing requirement in various exceptions related to compensation arrangements
  - A collection of documents, including "contemporaneous documents evidencing the course of conduct between the parties," may satisfy the writing requirement. 80 Fed. Reg. 41686, 41915 (July 15, 2015).
  - "To satisfy the writing requirement, the facts and circumstances of the [compensation] arrangement must be sufficiently documented to permit the government to verify compliance with the applicable exception." Id.

2015 Physician Self-referral Updates

- Clarification of the 1-Year Term Requirement (§§ 411.357(a), 411.357(b), and 411.357(d))
  - Arrangements that last as a matter of fact for at least one year satisfy the requirement. 80 Fed. Reg. 41686, 41916-17 (July 15, 2015).
  - A formal "term" provision in a contract is not required to establish that the arrangement satisfied the 1-year term requirement; a collection of contemporaneous documents may be sufficient.

Self-referral Disclosure Protocol

Overview of the SRDP Protocol

- Introduction and Discussion of Protocol
- Cooperation with OIG and the Department of Justice
- Instructions Regarding Submission
- Verification
- Payments
- Cooperation and Removal and Timeliness of Disclosure
- Factors Considered in Reducing Amounts Owed

Self-referral Disclosure Protocol

Why use the SRDP?

- Suspected Whistleblower
- Sale/Purchase Transaction
- Revenue Integrity
- Change in Management
- Financing Requirement
- Governance Requirement
- Overpayment Has Been Identified
  - Consider other compliance options?

Self-referral Disclosure Protocol

Introduction and Discussion of Protocol

- Purpose is to resolve actual or potential violations of the physician self-referral law
- Separate from the advisory opinion process - **MUST ADMIT A VIOLATION HAS OCCURRED**
- Disclosure must be made in good faith
- Cannot appeal settlement
- Application of Reopening Rules

Self-referral Disclosure Protocol

Cooperation with the OIG & DOJ

- Physician Self-referral Law only violations or potential violations to CMS.
- Physician Self-referral Law and additional violations or potential violations of other criminal, civil, and administrative laws to OIG.
- The same conduct should not be disclosed under both SRDP and OIG's Self-Disclosure Protocol.
- Coordination with Law Enforcement.
- Corporate Integrity Agreements.

Self-referral Disclosure Protocol

Instructions Regarding Submission

- Special instructions for physician-owned hospitals that failed to disclose ownership in public advertisements or websites, available on the CMS website
- Required information related to the matter disclosed for all other disclosures:
  - Description of Actual or Potential Violation(s)
  - Financial Analysis

Self-referral Disclosure Protocol

Instructions Regarding Submission

- Description of Actual or Potential Violation(s)
  - Identifying Information
  - Description of the nature of the matter being disclosed
  - Duration of violation
  - Disclosing party's legal analysis of how the matter is a violation
  - Circumstances under which the matter was discovered and measures taken to address the issue and prevent future abuses
  - Statement identifying a history of similar conduct or enforcement action
  - Description of the pre-existing compliance program
  - If applicable, a description of appropriate notices provided to other government agencies
  - Whether the matter is under current inquiry by the government

Self-referral Disclosure Protocol

Instructions Regarding Submission

- Financial Analysis
  - "Look Back" Period
  - Total amount actually or potentially due and owing
  - Description of the methodology used including estimates
  - Summary of auditing activity and documents used

Required Repayments

- The SRDP is needed because ACA/Health Reform requires prompt repayment of overpayments
- Section 6402 of the ACA requires that all overpayments be reported and returned by the later of:
  - (i) sixty (60) days after the date on which the overpayment was identified; or
  - (ii) the date any corresponding cost report is due
- When a disclosure is made according to the SRDP repayment obligations are suspended until a settlement agreement is reached or a disclosing entity is removed (or removes itself) from the SRDP

Quantification of Potential Overpayment

Providers need to:

- Determine commencement and ending of period of time during which financial relationship fell out of compliance
- Utilize the 6-month holdover period, where applicable (personal services arrangements and rental of space and equipment exceptions)
- If financial arrangement was with a group practice, identify each physician in the group practice
- Determine when any applicable physician "referred" to the DHS entity during the period of disallowance
  - Referring physician
  - Admitting physician
  - Attending physician
  - Consulting physician
- Especially for the consulting category, determine if items or services ordered by "tainted" physician impacted the reimbursement received

Quantification of Potential Overpayment

Assuming provider diligently quantifies the potential overpayment during the "lookback" period with due diligence, 60-day reporting period does not commence until the amount of the overpayment has been ***identified***.

Factors Considered, Reducing Penalty and Repayment Amounts

CMS may consider the following factors in reducing the amount due:

- Nature and extent of the improper or illegal practice
- Timeliness of the self-disclosure
- Cooperation in providing additional information
- Litigation risk
- Financial position of the disclosing party
- Effectiveness of compliance program, especially if compliance program resulted in discovery of potential Stark infraction

Nature and Extent of Improper / Illegal Practice

Some of the sub-factors CMS will weigh include:

- Commercially reasonable? Fair market value?
- Takes into account volume or value of referrals?
- History of program abuse?
- Set in advance?
- Presence, strength of preexisting compliance program?
- Length, pervasiveness of noncompliance?
- Steps taken to correct noncompliance?

Self-referral Disclosure Protocol (SRDP): Recent Developments

- As of September 17, 2015, there were 697 self-disclosures filed, of which 150 have been resolved through settlement or withdrawal from the SRDP. Very little reported information exists regarding how the settlements were determined.
- As of December 2014, all disclosures should be submitted in electronic form ONLY.
  - Signed certifications must still be submitted in hardcopy.
- August 2014 approval from OMB for CMS to establish an "expedited review track" for SRDP disclosures.
  - No indication when the "expedited track" will be available to disclosing entities.
- On the CMS SRDP Q&A webpage, CMS has stated that the "lookback period" for financial analysis under the SRDP is the four-year reopening period for Medicare Claims. The four-year period is determined from the date of the submission to the SRDP.
  - CMS "overpayment" rule, which would affect the duration of the "lookback period," has not yet been published in final.
  - Proposed rule "expires" on February 16, 2015.

Questions