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Stark Law: Back to Basics

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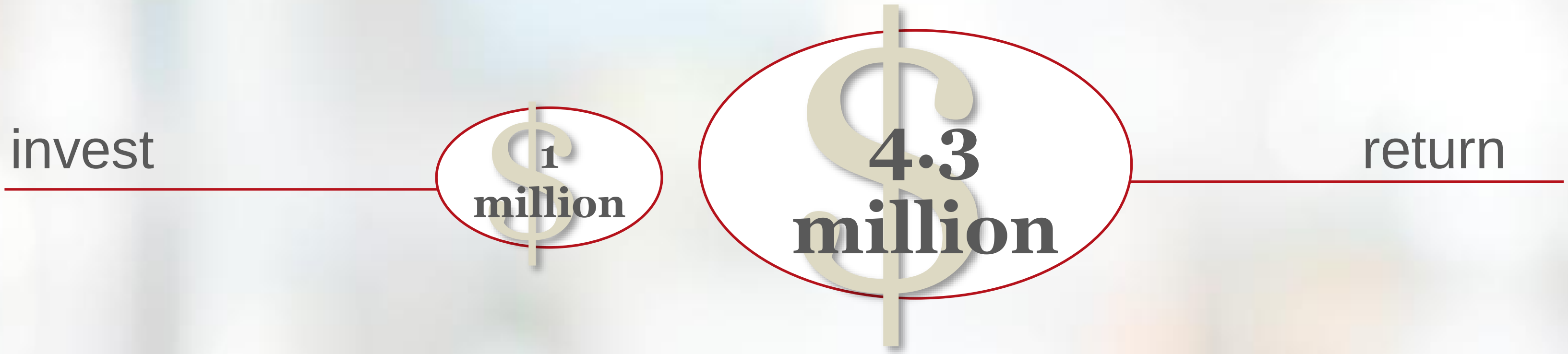
Agenda

- Background – Enforcement Environment
- Stark Law Basics
  - Key Definitions
  - Exceptions
  - Group Practice
- "The Big Three"
  - Fair Market Value
  - Commercial Reasonableness
  - Volume/Value Standard
- Case Law Developments and Trends

Why do we care? – Enforcement Landscape

Prosecuting 'fraud' is good business



In July 2021, an HHS report stated that for every $1 invested in OIG, DOJ and FBI investigations related to health care fraud in the past three years, $4.30 was returned.

Why do we care? – Potentially Steep Penalties

Violations of Stark, even if minor technical violations, can lead to:

- Required refunds to Federal health care programs
- Sanctions from CMS
  - Financial penalties
  - Potential exclusion from Federal health care programs
- Potential False Claims Act Liability
  - Stark violations can serve as basis for qui tam or government initiated FCA liability
  - Even steeper financial penalties – per claim fines + treble damages

The Stark Law - Overview

The Stark Law makes it a civil offense for:

A physician or immediate family member → **To have a financial relationship with an entity** → **And refer to that entity** → **For designated health services possibly paid for by Medicare**

…unless the financial relationship meets a specified exception to the Stark Law.

The Stark Law is strict liability

- No intent required
- Prohibited relationship is *per se* improper
- Highly technical

Core Definitions

Definitions - Physician

A physician or immediate family member → To have a financial relationship with an entity → And refer to that entity → For designated health services possibly paid for by Medicare

- What is a **Physician**?
  - M.D., D.O., Dentists and oral surgeons, Podiatrists, Optometrists, Chiropractors
- What is an **Immediate Family Member**?
  - Husband, wife, natural & adoptive parent, child, sibling, step-relatives, in-laws, grandparent, grandchild, spouse of grandparent or grandchild

Definitions – Financial Relationship

A physician or immediate family member

To have a financial relationship with an entity

And refer to that entity

For designated health services possibly paid for by Medicare

- What is a **Financial Relationship**?
  - A direct or indirect;
  - Ownership or investment interest or compensation arrangement;
  - In or with an entity providing DHS.

Definitions - Referral

A physician or immediate family member → To have a financial relationship with an entity → **And refer to that entity** → For designated health services possibly paid for by Medicare

- **<u>Remember</u>** – ultimate intent of Stark Law is to prohibit overutilization and the generation of “extra referrals” by physicians for financial gain.

- So, for Stark Law to apply, we need both:
  - A financial relationship; and
  - One or more referrals

  between the physician and the entity providing DHS.

Definitions – Referral (cont.)

- What is a referral ?
  - Very Broad – The request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B (and Medicaid)
  - Radiologists, pathologists, and radiation oncologists are not deemed referring physicians under certain circumstances:
    - Pursuant to a request for consultation
      - Document request in medical record
      - Written report prepared and provided to the physician who request the consultation
  - Does *not* include DHS personally performed by the referring/ordering physician

Definitions – Designated Health Services

A physician or immediate family member → To have a financial relationship with an entity → And refer to that entity → **For designated health services possibly paid for by Medicare**

What are Designated Health Services (DHS)?

- 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 (DME) 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 Law - Overview

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Stark Exceptions

- How do exceptions to Stark work?
  - Stark has numerous exceptions based on the type of financial relationship
  - Exceptions are in three categories:
    - <u>Both</u> an ownership interest and compensation arrangement
    - <u>Only</u> an ownership interest
    - <u>Only</u> a compensation arrangement
  - It is imperative to ensure each element of the applicable exception is satisfied in order to ensure the arrangement's compliance with the Stark Law

Stark Exceptions

When applying a Stark exception, you *must* meet each of the criteria of the applicable exception, or the activity will not fall under the exception.

Remember

Each and every financial relationship with a referring physician must meet an exception to Stark Law (ownership, compensation or both) in order to avoid violations and penalties

Common Elements of Many Stark Exceptions

- Agreement is set out in writing
- Agreement is signed by all parties (signatures should be obtained before the effective date)
- Agreement describes the specific items/services to be provided
- Amount of remuneration is consistent with fair market value
- Remuneration does not take into account the volume or value of any referrals by the referring physician/entity
- Terms of the agreement are commercially reasonable

Exceptions for Ownership Interests <u>Only</u>

- Publicly Traded Securities
- Mutual Funds
- Specific Providers
  - Rural Providers
  - Ownership in a Whole Hospital (significantly limited by ACA)

Exceptions for Compensation Arrangements <u>Only</u>

- Rental of Office Space
- Rental of Equipment
- Bona Fide Employment Relationships
- Personal Service Arrangements
- Physician Recruitment
- Isolated Transactions
- Certain Arrangements with Hospitals Unrelated to DHS
- Group Practice Arrangements with a Hospital
- Payments by Physician for Items and Services
- Obstetrical Malpractice Insurance Subsidies
- Charitable Donations
- Non-monetary Compensation (currently up to $452 annually)
- Fair Market Value Compensation
- Medical Staff Incidental Benefits (currently up to $39 per occurrence)
- Risk Sharing Agreements
- Compliance Training

Exceptions for Compensation Arrangements <u>Only</u> (cont.)

- Indirect Compensation Arrangements
- Referral Services
- Professional Courtesy
- Retention Payments in Underserved Areas
- Community Wide Health Information Systems
- Electronic Prescribing/Health Records
- Limited Remuneration to a Physician
- Assistance to Compensate a Nonphysician Practitioner
- Timeshare Agreements
- Value Based Arrangements
- Cybersecurity Technology and Related Services

Exceptions for Ownership Interests and Compensation Arrangements

- Physician Services (Group Practice)
- In-Office Ancillary Services (Group Practice)
- Academic Medical Centers
- Implants furnished by an ASC
- Preventive Screening Tests, Immunizations, and Vaccines
- Eyeglasses and Contact Lenses Following Cataract Surgery
- Intra-Family Rural Referrals

Stark Group Practice Standards

- **Group Practice:**
  - Certain Stark exceptions require that a physician practice qualify as a "group practice" under Stark in order for the exception to apply
    - Qualifying as a "group practice" requires the practice entity to adhere to certain legal business structure requirements

Stark – Group Practice Standards

- **Group Practice Requirements:**
  - Single legal entity
  - At least two physician employees or owners
  - full range of care requirement
  - Services furnished by members through the group practice
  - Distribution of expenses and income
  - Unified business
  - With <u>limited exception</u>, no compensation based on volume or value of referrals
    - i.e. productivity bonuses based on "incident-to" services
  - Physician-patient encounters requirements
  - Adherence to special profit sharing and productivity bonuses rules

Stark Law Concepts – The "Big 3"

The "Big 3" - Fair Market Value, Commercially Reasonable and Volume/Value

- **#1 - Fair Market Value** –
  - Compensation must be fair market value for items or services actually furnished
  - General application, rental of equipment, rental of office space provisions
  - General Market Value – *bona fide* bargaining – separate provisions for assets, compensation, space/equipment leases

Stark Law Concepts – The "Big 3"

The "Big 3" **- Fair Market Value, Commercially Reasonable and Volume/Value**

- **#2 - Commercially Reasonable** –
  - Need legitimate business purpose
  - Sensible, considering the characteristics of the parties, including their size, type, scope, and specialty
  - Does not have to "result in profit"

Stark Law Concepts – The "Big 3"

The "Big 3" - Fair Market Value, Commercially Reasonable and Volume/Value

- **#3 - Volume/Value Standard**
  - Compensation may not be determined in a manner that takes into account the volume or value of the physician's referrals to the entity
  - **New Special Rules on Compensation -** Stark issue if formula includes the physician's referrals to the entity as a variable
    - Compensation must positively or negatively correlate with the number or value of the physician's referrals to the entity
    - Also applies to the "Other business generated" standard
  - **New Directed Referral Rule –** Prohibits making the existence of a compensation arrangement or the amount of compensation contingent on the number or value of referrals.
    - But can condition on a percentage or ratio of referrals

Case Law Developments and Trends

Setting the Stage

- Most Stark Law violations are settled outside of court and do not result in formal litigation
  - Self Referral Disclosure Protocol (SRDP)
    - To date CMS has reported 369 SRDP settlements
    - Long backlog at CMS
    - CMS released settlements ranging from $33 to $1.2M: most are below $150,000
    - Technical violations include lack of written agreements, nonmonetary compensation, per-click rent, compensation not set in advance, etc.

False Claims Act – The Vehicle for Litigation

submit a false claim;
or
cause a false claim to be submitted;
or
retain an overpayment

WITH

actual knowledge
or
deliberate ignorance,
or
reckless disregard

VIOLATION

$11,803 to $23,607 per Claim + Treble Damages

United States v. Bradford Regional Medical Center (2010)

U.S. v. Bradford: Background

- **The *Qui Tam* Relators**: Four Physicians practicing in the community
- **The Defendants**: Bradford Regional Medical Center, a Pennsylvania nonprofit corporation and two internists who jointly owned a physician group LLC
- Group purchased a GE nuclear imaging camera for its office (referrals from Group = over 40% of the Hospital's nuclear imaging revenues)
- Hospital alleged Physicians violated internal policy against conflicting financial interests; threatened to revoke privileges
- Hospital <u>subleased</u> GE camera from the Group
- Group then entered into a lease for a new camera that included a "buy out" obligation for amounts Group owed on the original GE lease (which Hospital guaranteed)
- This subsequent arrangement <u>was never documented</u> in a formal written lease or agreement

U.S. v. Bradford: Fair Market Valuation and Outcome

- Fair Market Valuation
  - Hospital requested an accountant prepare a fair market value assessment of the sublease. Accountant concluded:
    - Amounts to be paid were reasonable based on:
    - *Hospital revenues expected with sublease vs. Hospital revenues expected without sublease*
  - Revenue projections assume Physicians will refer imaging
  - Hospital Board approved sublease arrangement
- Outcome
  - Bradford Regional Medical Center settled with the government for $2.75 million
  - The District Court ordered Bradford to pay Relator's attorneys fees and expenses, totaling an additional $600,000

U.S. v. Bradford: Summary

- Technical Analysis:
  - No formal documentation
- Intent Analysis:
  - Hospital threatened to revoke privileges
  - Fair market value opinion accounted for referral business
  - Hospital guaranteed lease secured by Physicians in their individual capacities

United States v. Tuomey Regional Medical Center (2010 and 2015)

U.S. v. Tuomey: Background

- **The *Qui Tam* Relator**: Orthopedic surgeon at Tuomey
- **The Defendants**: Tuomey Healthcare System, Inc.; Tuomey Regional Medical Center is a 301-bed hospital located in a MUA
- Physicians were employed on a part-time basis with a non-compete clause and a use requirement
- Some Physicians' compensation exceeded collections
- Agreement contained a 10-year term
- Physicians' compensation based on: base salary; % of collections; and up to 7% productivity bonus
- Lawsuit alleged physician agreements violated Stark and FCA for being above fair market value by taking into account the volume or value of referrals

U.S. v. Tuomey: Outcomes

- First Trial:
  - The court held that an indirect compensation arrangement was created and that the Stark Law (but not the FCA) was violated
  - Tuomey ordered to repay the government $45 million plus interest
- Appeal:
  - Fourth Circuit vacated the decision and sent the case back for retrial
- Second Trial:
  - Jury found Tuomey in violation of the Stark Law and FCA
  - Stark violations totaled $39.3 million; verdict against Tuomey for $237.5 million (DOJ agreed to settlement of $72.4 million)
- Tuomey's second appeal was unsuccessful
- Former Tuomey CEO personally paid $1 million settlement and was excluded from federal healthcare program participation for 4 years

U.S. v. Tuomey: Summary

- Technical Analysis:
  - Agreements were professional productivity agreements
  - Total compensation alleged to exceed fair market value and to not be commercially reasonable (unless referrals were considered)
- Intent Analysis:
  - Recordings of Board meeting minutes in which management and Board members made comments regarding the intent and strategy surrounding the contracts

United States v. Halifax Hospital Medical Center (2013)

U.S. v. Halifax: Background

- **The *Qui Tam* Relator**: Director of Physician Services
- **The Defendants**: Halifax Hospital Medical Center
- The government alleges that Halifax committed years of Stark violations concerning the employment of referring physicians based on compensation that:
  - Was not fair market value;
  - Was not commercially reasonable; and/or
  - Took into account the volume or value of referrals or other business generated by the referring physician

U.S. v. Halifax: Outcome

- November 2013:
  - The court determined, in summary judgment, that Halifax's oncology bonus compensation payments violated the Stark Law
- March 2014:
  - Before jury selection started for trial, Halifax announced an $85 million settlement with the Department of Justice
  - This settlement is notable because of its size. Given the possibility of treble damages and civil penalties, Halifax faced a possible damage award in excess of $1.1 billion
- July 2014:
  - All remaining claims settled for $1 million

U.S. v. Halifax: Summary

- Technical Analysis:
  - The medical oncologists' incentive bonuses were based on the operating margin of the medical oncology program, and this revenue included fees for designated health services (DHS) that were not personally performed
  - As a result, the medical oncologists' remuneration varied based on referrals for DHS
- Intent Analysis:
  - Internal communications
  - Halifax tracked referrals generated by each medical oncologist

United States v. All Children's Health System, Inc. (2013)

U.S. v. All Children's: Background

- **The *Qui Tam* Relator**: Former Director of Operations
- **The Defendants**: All Children's Health System, Inc.
- The government alleged that All Children's committed Stark and False Claims Act violations relating to physician compensation. Allegations were based on:
  - Lack of fair market value;
  - Management's aggressive physician recruiting; and
  - Failure to follow All Children's compensation plan
- Court ruled that as a threshold matter, the **<u>Stark Law applies to Medicaid</u>**

U.S. v. All Children's: Outcome

- April 2013
  - The DOJ declined to intervene in the case, and federal judge granted All Children's motion to dismiss the complaint on the basis that the relator failed to specify with particularity the circumstances constituting the fraud
  - The relator then amended the complaint and set forth the alleged violations in greater detail
  - The court denied All Children's motion to dismiss the amended complaint, and scheduled a trial for April 2015

- April 2014
  - All Children's settled with the federal government, the State of Florida, and the relator for $7 million
  - Note that although the DOJ previously declined to intervene in the case, the relator was able to proceed on their own to navigate the initial procedural challenge
  - Government issued a statement of interest concluding that Stark Law applies to both Medicare and state Medicaid

U.S. v. All Children's: Summary

- Technical Analysis:
  - Relator created a competitive physician salary range by developing a fair market value for physician salaries from three nationwide surveys. The plan disallowed physician compensation to exceed the 75th percentile of the survey data
  - Allegedly, one-third of physicians were paid above this salary range and at least 18 physicians' compensation exceeded the 90th percentile of the salary data
- Intent Analysis:
  - Defendants began "aggressively recruiting" physicians and pediatric groups before Relator's compensation plan was completed or approved
  - Relator advised Vice President that salaries he had contracted far exceeded FMV and would cause the company to lose money; VP told Relator to proceed as directed

Questions?

For more information on these topics visit hallrender.com.

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