



# Above the Fold: What We Can Learn from Enforcement Actions

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## OVERVIEW

- **Stark Act, Physician Compensation**
- **Conflicts of Interest and Reputational Risk**
- **How to Avoid Creating a Whistleblower**

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## Stark Act and Physician Compensation

- Section 1877 of the Social Security Act (the Act):
  - If a physician (or an immediate family member of such physician)
  - has a financial relationship with an entity . . . ,
  - then the physician may not make a referral to the entity for the furnishing of
  - Designated health services for which payment otherwise may be made under Medicare.

(The DHS entity is also prohibited from submitting claims.)

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## Stark Act and Physician Compensation

- Key Questions
  - What is a referral?
  - What is DHS?
  - What is a financial relationship?

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## Stark Act and Physician Compensation

- Key Provisions in Stark Regulations
  - Indirect Compensation Arrangements 42 CFR §411.354(c)(2), and §411.357(p)
  - Bona Fide Employment Relationship 42 CFR §411.357(c)
  - Personal Service Arrangements 42 CFR §411.357(d)

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## Stark Act and Physician Compensation

- Key Concepts in these Provisions
  - Volume and Value of Referrals
  - Fair Market Value
  - Commercial Reasonableness

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## Stark Act and Physician Compensation – Important Case Law

- *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.* (2015)
  - Surgeons paid annual base salary adjusted each year for all services rendered the previous year
  - Productivity bonus equal to 80% of their collections for that year
  - Other non-salary comp.
  - Required to conduct all surgeries at Tuomey
  - 4<sup>th</sup> Circuit upheld jury verdict and award of over \$237 million in damages and penalties

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## Stark Act and Physician Compensation – Important Case Law

- *United States ex rel. Bookwalter v. University of Pittsburgh Medical Center, et al.* (2019)
  - Neurosurgeon Compensation was base salary plus bonus based on number of WRVUs
  - Surgeon earned WRVU and hospital billed facility fee each time surgery conducted
  - District court dismissed case, 3<sup>rd</sup> Circuit overturned district court and remanded

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## Stark Act and Physician Compensation -- NPRM Changes Affecting Physicians Compensation

- We are not addressing value-based payment structures
- Definition of Fair Market Value (FMV)
- Definition of Taking Account of Volume and Value
- Definition of Commercial Reasonableness

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## Stark Act and Physician Compensation -- NPRM Changes Affecting Physicians Compensation

- Definition of Fair Market Value
  - FMV is an important part of the Stark regulations
  - Key Requirement in many exceptions (Employment relationship, PSA, lease arrangements, one-time transactions, etc.)
  - Current Definition "Fair market value means the value in arm's-length transactions, consistent with the general market value. "General market value" means the ... 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... at the time of the service agreement. Usually, the fair market price is ... the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the... compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

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## Stark Act and Physician Compensation -- NPRM Changes Affecting Physicians Compensation

- NPRM Changes to Definition of FMV
  - No longer specifically addresses compensation.
  - No longer has any mention of volume or value of referrals between entities involved in the transaction or compensation arrangement.
  - Does this mean entities are now free to consider volume and value to establish FMV? But what about the prohibition on "taking into account" volume and value.

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## Stark Act and Physician Compensation -- NPRM Changes Affecting Physicians Compensation

- Volume and Value of Referrals
- Key terms in multiple Stark provision (Indirect compensation arrangement, employment arrangements exception, PSA exception, lease agreements exception, etc)
- Current regulations include the terms "varies with" and "takes into account," the volume and value of referrals. Current regulations have no definition of what "taking into account" the volume or value of referrals means

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## Stark Act and Physician Compensation -- NPRM Changes Affecting Physicians Compensation

- NPRM Changes to Volume and Value Include:
  - Deleting references to "varies with" volume and value of referrals (Indirect compensation arrangements)
  - Includes a rule explaining when compensation is considered to take into account the volume and value of referrals or other business generated (proposed section 42 CFR §411.354(d)).
    - The formula used to calculate compensation includes physician's referrals or other business generated to the entity as a variable
    - Predetermined direct correlation between prior referrals or other business generated to entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined

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## Stark Act and Physician Compensation -- NPRM Changes Affecting Physicians Compensation

- Commercial Reasonableness
  - No definition of Commercial Reasonableness in the current regulations
  - NPRM Definition of Commercial Reasonableness:
    - "Commercial Reasonableness means that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."

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CONFLICTS OF INTEREST AND REPUTATIONAL RISK

- Open Payments



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CONFLICTS OF INTEREST AND REPUTATIONAL RISK

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## Conflicts of Interest and Reputational Risk

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interest**

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## How to Avoid Creating a Whistleblower

- Whistleblower Characteristics
- Compliance Program
- Clear Policies
- Responsiveness to Complaints
- Management Problem lead to whistleblower problems
- Exit Interviews
- Hotlines and follow-up

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