Compliance and Valuation Challenges from Recent Stark Law and Anti-Kickback Statute Changes

Taos Health Law Roundtable

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Focus of Presentation

- Recent key changes to Stark Law and the Anti-Kickback Statute that impact valuations and establishing fair market value.
- Compliance challenges for valuators to support fair market value opinions.
- Hypotheticals of healthcare transactions and service agreements.

The Stark Law, 42 U.S.C. 1395nn

- Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies.
- Prohibits the entity from submitting a claim to Medicare (or another individual or payer) for those referred DHS.
- A claim that is made in violation of the Stark Law may make it false or fraudulent, creating liability under the civil False Claims Act.

The Stark Law – Designated Health Services ("DHS")

- Clinical laboratory services.
- Physical therapy services
- Occupational therapy services
- Outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment 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 – Key Compensation Exceptions

- Bona fide employment relationships exception
- Personal Service Arrangements exception
- Fair Market Value Exception
- Indirect Compensation Arrangements
- In-Office Ancillary Services Exception
- Academic Medical Centers
- Isolated Transactions Exception

The above exceptions require compensation to be *consistent with fair market value*, *commercially reasonable*, and not take into account the *volume or value of referrals* or *other business generated* for the entity.

Recent Stark Law Changes

- Modernizing and Clarifying the Physician Self-Referral Regulations (85 Fed. Reg. 77, 492 , December 2, 2020) – Final Rule.
- Effective January 19, 2021, with the exception of the group practice special rules for profit shares and productivity bonuses effective January 1, 2022.
- 2022 Medicare Physician Fee Schedule (86 Fed. Reg 64996, November 19, 2021).

Stark Law – New Exceptions for Value-Based Arrangements

- Three new exceptions for value-based arrangements – apply based on the level of risk:
  - Full Financial Risk
    - Protects remuneration paid under value-based arrangements where a VBE has assumed full financial risk from a payor for patient care services for a target patient population during the entire duration of the value-based arrangement.
  - Value-Based Arrangements with Meaningful Downside Financial Risk to a Physician
    - Protects remuneration paid under value-based arrangements where a physician has taken on meaningful downside financial risk (at risk or forgo 10%) for failure to achieve the value-based purposes of the VBE.
  - Value-Based Arrangements
    - Generally protects remuneration paid under value-based arrangements regardless of the level of risk undertaken by the VBE or any of its VBE Participants as long as specific requirements are met.

The Stark Law – New Exceptions for Value-Based Arrangements

- The 3 new exceptions for value-based arrangements do not include typical Stark Law requirements that compensation be:
  - Fair market value.
  - Not based on the volume or value of referrals or other business generated.
  - Commercially reasonable (however the "no risk" value-based exception requires the arrangement to be commercially reasonable)
- If a value-based exception is satisfied and an employed physician takes on meaningful downside risk, the physician's compensation may no longer be subject to FMV.

The Stark Law Final Rule – Changes to the "Big Three"

- CMS defined "**commercially reasonable**".
- CMS finalized special rules for the **"volume or value"** and **"other business generated"** standards to create *objective tests.*
- CMS finalized 3 separate definitions for **"fair market value"** that will apply to equipment rentals, office space rentals, and to all other arrangements generally.

Stark Law Final Rule – New Definition for "Commercially Reasonable"

- CMS defined "commercially reasonable" as "that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty."
- CMS codified a favorable response to recent court decisions that a "commercially reasonable" arrangement does not need to be profitable.
- Example: Certain hospital call coverages are necessary to keep the hospital open but payment for coverage may exceed the patient fees generated.

Stark Law Final Rule – New Definitions for Fair Market Value

- CMS adopted 3 new definitions for "Fair market value", including a FMV definition for General Services, Rental of Equipment and Rental of office Space.
- Each of the 3 new FMV definitions Includes the condition that the value must be ***consistent with the general market value*** of the subject transaction.
- CMS adopted 3 new definitions for "General Market Value" for *Assets*, *Compensation*, and *Rental of equipment or office space*.
- CMS reiterated the importance of Fair market value determinations not including any downstream revenue or other benefits a certain employer may enjoy for employing a physician.
- In other words, the value of a physician's services should be the same regardless of whether the employing entity is a health system, a private equity firm or a physician-owned entity.

Stark Law Final Rule – New Definitions for Fair Market Value

Fair Market Value means:

1) **General**: The value in an arm's length transaction, consistent with the *general market value* of the subject transaction.

2) **Rental of equipment**: The value in an arms length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the *general market value* of the subject transaction.

3) **Rental of office space**: The value in an arms length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lesser where the lessor is a potential source of referrals to the lessee, and consistent with the *general market value* of the subject transaction.

Stark Law Final Rule – New Definitions for General Market Value

General Market Value means—

1) **Assets**. The price that an asset would bring on the date of acquisition of the asset as a result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.

2) **Compensation**. The compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well informed parties that are not otherwise in a position to generate business for each other.

3) **Rental of equipment or office space.** The price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

Stark Law Final Rule – "Volume or Value of Referrals" and "Other Business Generated" Standards

- Many exceptions to the Stark Law require that compensation not take into account the volume or value of referrals (V/V) or other business generated (OBG) between the parties.
- CMS adopted an "objective test" to determine whether a compensation arrangement is determined in any manner that takes into account the V/V or OBG between the parties.
- **New "Objective Test":** Compensation from an entity furnishing DHS to a physician takes into account the V/V or OBG by the physician only if:
  - the formula used to calculate the compensation includes the physician's referrals to the entity or OBG as a variable; and
  - resulted in an *increase or d*ecrease in the compensation that positively correlates with the number or value of the physician's referrals to, or the OBG for the entity.

Stark Law Final Rule – "Group Practice" Allocation of DHS Profits

- Physician groups must comply with the *in-office ancillary services exception*, which includes restrictions on the allocation of DHS profits.

The Stark Law Final Rule included *several clarifications* to the group practice DHS profit allocation rules including:

- ***No Split Pooling***: Profits from all of the DHS of the group (or a subset of at least 5 physicians in the group) must be aggregated and then distributed). A group practice can not distribute profits from DHS on a service-by-service basis.
- CMS removed the reference to Medicaid from the definition of "overall profits".

Stark Law Final Rule - Establishing FMV for Physician Compensation

Things to consider:

- New definitions for FMV.
- CMS commentary on the new objective "bright line" tests for whether compensation takes into account the value or volume of referrals or other business generated for the entity.
- CMS commentary on different bonus formulas.
- CMS commentary on survey reliance.
- Considerations when paying for quality outcomes.

Stark Law Final Rule – CMS Commentary on Establishing FMV

- In other words, only when the mathematical formula used to calculate the amount of the compensation includes referrals or other business generated as a variable, and the amount of the compensation correlates with the number or value of the physician's referrals to or the physician's generation of other business for the entity, is the compensation considered to take into account the volume or value of referrals or take into account the volume or value of other business generated."

Stark Law Final Rule – CMS Commentary on Establishing FMV

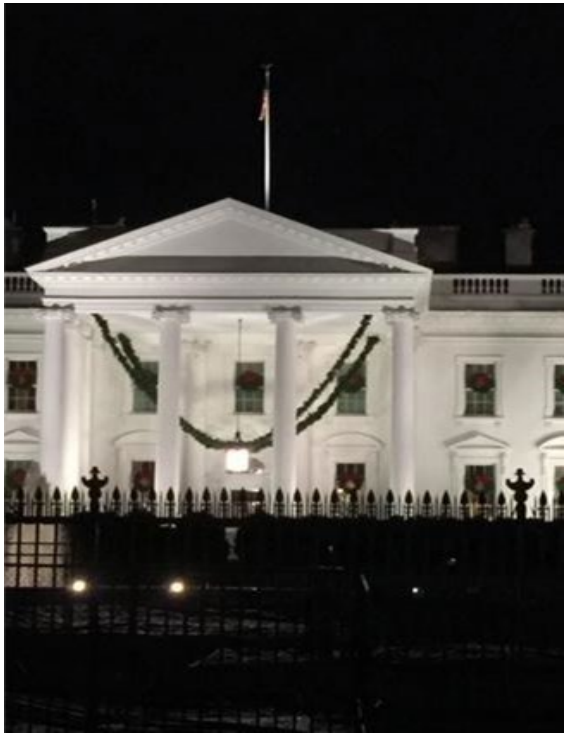
- CMS cautioned against the overreliance on surveys to set physician compensation, stressed case by case basis.
  - "We continue to believe that the general market value of a transaction is based solely on consideration of the economics of the subject transaction"
  - "We continue to believe that the fair market value of a transaction— and particularly, compensation for physician services—may not always align with published valuation data compilations, such as salary surveys"
- CMS did not agree with public comments that "as long as an organization pays its physicians at or below the 75th percentile of the market" then the compensation will be FMV.
- CMS commented that there may be instances where compensation exceeding the 90th percentile may be appropriate, or compensation at the 50th percentile may not be appropriate.

The Anti-Kickback Statute 42 USC 1320a-7b(b)

- Criminal statute that requires intent of an illegal inducement.
- Prohibits the knowing and willful offer, solicitation, payment or receipt of remuneration to induce or reward the referral of business reimbursable under any of the Federal health care programs.
- Also prohibits the payment of remuneration intended to induce or reward the purchasing, leasing or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any service or item reimbursable by any Federal health care program.
- Key safe harbors for physician compensation arrangements:
  - Personal services and management contracts, 42 CFR 1001.952(d)
  - Employment safe harbor, 42 CFR 1001.952(i)

The Anti-Kickback Statute, (cont'd)

- Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (85 Fed. Reg. 77684, Dec. 2, 2020) – OIG Final Rule.
- Final Rule amended and added new safe harbors for value-based arrangements and that protect certain payment practices and business arrangements from sanctions under the Anti-Kickback Statute.
- Effective January 19, 2021.



Anti-Kickback Statute Final Rule, (cont'd)

- The Stark Law and Anti-Kickback Statute Final Rules both adopted 3 new exceptions / safe harbors for value-based arrangements. However, these new Stark Law exceptions and Anti-Kickback Statute safe harbors are not identical.
- The new safe harbors to the Anti-Kickback Statute for value-based arrangements include the same 6 primary definitions as the Stark Law exceptions, with a few exceptions:
  - The Anti-Kickback Statute Final Rule definition for a Value-Based Activity includes the additional requirement that the activity does not include the making of a referral.
  - Value-Based Enterprises (VBEs) cannot be a patient acting in their capacity as a patient.

Anti-Kickback Statute Final Rule – Safe Harbors for Value-Based Arrangements

- The OIG adopted 3 new safe harbors for remuneration exchanged between participants in a value-based arrangement that are intended to foster better coordinated care and managed patient care:
  1) Care coordination to improve quality, health outcomes, and efficiency without requiring the providers to assume risk;
  2) Value-based arrangements with substantial downside financial risk; and
  3) Value-based arrangements with full financial risk.

Anti-Kickback Statute Final Rule – Personal Services and Management Contracts Safe Harbor

- Personal Services and Management Contracts Safe Harbor:
  - OIG replaced the requirement that *aggregate compensation* be *set in advance* with a requirement that the *methodology for determining compensation* be set in advance.
  - OIG eliminated the condition that requires that if an agreement provides for the services of an agent on a periodic, sporadic, or part-time basis, the contract must specify the schedule, length and exact charge for such intervals.
  - The Safe Harbor was also modified to protect certain *outcomes-based payments* as long as certain conditions are met.

U.S. ex rel. Thomas P. Fischer v. Community Health Network, Inc. (S.D. Ind. Oct. 2021)

- 2014: Relator (former CFO) alleged that the Community Health Network violated the Stark Law by paying physicians compensation that exceeded FMV and was based on the volume or value of referrals.
- 01/2020: U.S. intervened and alleged that Community had several employment relationships with physicians that did not meet a Stark Law exception because compensation for several employed physicians was well above FMV and bonuses were conditioned on a minimum target of referral revenues to the Community.

U.S. ex rel. Thomas P. Fischer v. Community Health Network, Inc. (cont'd)

- 10/2021: Court denied Community's motion to dismiss and concluded that the government plausibly alleged that physician compensation was determined in a manner that took into account the V/V of referrals.
- 10/2021: Government's complaint alleged, in part, that Community's valuation consultant opined that in order to be presumptively FMV, physician compensation needed to be ***below the 75th percentile*** of national benchmark data, or the compensation per productivity needed to be ***less than the 60th percentile***.

U.S. ex rel. Allison v. Southwest Orthopedic Specialists, PLLC (W.D. Okla. July 2020)

- **Allegations**: Orthopedic specialty hospital and management company (partial owner of the hospital) paid improper remuneration to an orthopedic physician group for patient referrals in the form of:
  - Free or below-fair market value office space, employees, and supplies;
  - Compensation in excess of fair market value for the services provided by the orthopedic group;
  - Equity buy back provisions and payments for certain physicians in the orthopedic group that exceeded fair market value; and
  - Preferential investment opportunities in connection with the provision of anesthesia services at the specialty hospital.

U.S. ex rel. Allison v. Southwest Orthopedic Specialists, PLLC (cont'd)

- This settlement also resolved issues arising out of the management company's preferential offering of investment opportunities to physicians for surgery facilities in Texas.
- Orthopedic Specialty Hospital and Orthopedic Physician Group settled the case for $72.3 million.
- The management company paid $60.86 million to the U.S., $5 million to the State of Oklahoma, and $206,000 to the State of Texas.

U.S. ex rel. Jennings v. Flower Mound Hospital Partners, LLC (N.D. Tex. Dec. 2021)

- **Allegations**: Physician-owned hospital violated the Stark Law and Anti-Kickback Statute when it repurchased shares from physician-owners aged 63 or older and resold them to younger physicians.
- Government alleged that the hospital impermissibly took into account the volume or value of certain physicians' referrals when it: (1) selected the physicians to whom the shares would be resold; and (2) determined the number of shares each physician would receive.
- Hospital settled for $18.2 million and the relator (physician-owner of the hospital) received approximately $3 million.

U.S. ex rel. McGee and Dewey v. Texas Heart Hospital of the Southwest, LLP (E.D. Tex. Dec. 2020)

- A partially physician-owned hospital and a wholly owned management company subsidiary paid $48 million to resolve claims that the hospital violated the FCA resulting from violations of the Stark Law and the Anti-Kickback Statute.
- Relators alleged (two former physician owners) that the hospital violated the Stark Law and the Anti-Kickback Statute by requiring physician owners to satisfy ***the hospital's yearly 48 patient-contact requirement in order to maintain ownership in the hospital.***
- The two former physician-owner relators collectively were paid $13,920,000 as their share of the recovery.

Hypothetical #1: Inpatient Psychiatry

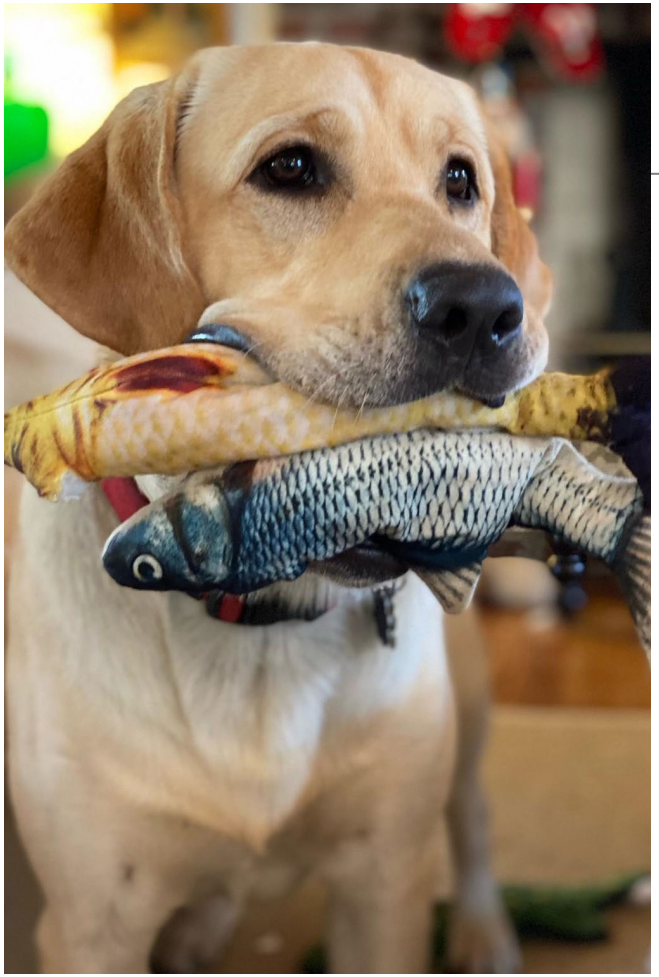
- COVID-19 has exacerbated mental health deficiencies in our healthcare system and the burden of mental health providers.
- A hospital needs to maintain psychiatric coverage for its inpatient psych unit and its existing provider is 70 and wants to retire.
- Locums coverage is very limited, will impact continuity of service and is very expensive.
- Survey data lags current market realities, with 90th percentile psychiatrist comp noted as approximately $425,000, NP/PA at $160,000.
- Physician is willing to stay for 1 year under a PSA for 24/7 coverage serviced by him and two midlevel providers, but desired compensation package would result in total comp well above 90th percentile.
- How do you analyze FMV and CR for the transaction?

Hypothetical #2: Value Based Model

- CMS has new disease specific payment model, that pays under a capitated model that varies based on the level of assumed risk.
- CMS has specified that contracting entity must include physicians and may include other service or product providers.
- Physicians opting into the program will be aligned with patients based on where the patient received majority of their care (but not necessarily their existing provider).
- How do you determine the purchase price for optional participants looking to participate through a JV? Do VBE exceptions apply?

Hypothetical #3: Physician Compensation

- Health system is considering new bonus incentive formulas for employed physicians.
- Employed hospitalists ask whether a bonus of 5% of their salary if the hospital's operating margin is 2% is feasible.



Questions?

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