

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

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CLAY J. COUNTRYMAN, J.D.
PARTNER
BREAZEALE, SACHSE & WILSON, LLP
CLAY.COUNTRYMAN@BSWLLP.COM

RUD BLUMENTRITT, CPA/ABV, CVA
PARTNER
HORNE
RUD.BLUMENTRITT@HORNE.COM



BREAZEALE, SACHSE & WILSON, L.L.P. | ATTORNEYS AT LAW



Focus of Presentation

- Discuss recent key changes to Stark Law and the Anti-Kickback Statute
- Impact of recent changes on establishing fair market value physician compensation
- New compliance challenges in supporting fair market value
- Recent Stark Law and Anti-Kickback statute cases.

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.



Stark Final Rule Changes

- 3 New “Fair Market Value” Definitions: (1) General Application (2) Space Rental (3) Equipment
- 3 New “General Market Value” Definitions: (1) compensation for services (2) purchase of assets (3) rental of equipment or space
- Created a definition for Commercial Reasonableness
- Created a New Volume or Value Special Rule “Objective Test”



New Stark Definitions of FMV

Key FMV changes:

- Definitions are much more specific and concise (before we had an extremely long and wordy definition)
- Removes the volume or value standard from the definition of general market value
- CMS reiterated the importance that FMV compensation determinations not include any downstream revenue or other benefits that a specific employer may enjoy
- Clarifies that FMV is a stand alone concept
- Adds clarity and is closer to the statutory intent than some courts have strayed

What CMS did not do:

- Did not establish safe harbors or rebuttable presumptions with respect to physician compensation so that compensation within specified survey data ranges could be presumed to be at fair market value.

Definition of Commercial Reasonableness

- Not previously defined in the regulations (previously only described in the 1998 commentary)

New regulatory definition:

Commercially reasonable means 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. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Key Points:

- Addresses the widespread misconception on the nexus between the commercial reasonableness of an arrangement and its profitability
- CMS commentary – CR Is NOT a question of valuation – separate and distinct
- CMS did not clarify what constitutes a "legitimate business purpose"
- Caution! – it may continue to be tempting for Whistleblowers and Courts to view losses as evidence of an absence of commercial reasonableness

New Volume or Value Standard

- Considered a “special rule,” rather than a definition
- Prior framework focused on what DID NOT violate the prohibition
- New rule focuses on formulas that DO violate the standard using an “objective test”:
 - Does the formula used to calculate compensation include the physician’s referrals as a variable?
AND
 - Results in an *increase or decrease* in the compensation that positively correlates with the number or value of the physician’s referrals?

Key Points:

- Results in a “bright-line” test for determining if an arrangement violates the Volume or Value or “other business generated” requirement
- If the compensation method falls outside of the defined circumstances, then “the compensation will not be considered to “take into account” the volume or value of referrals
- CMS reaffirmed that compensation based on wRVUs (unit-based compensation) does NOT take into account the volume or value of referrals
- CMS declined to comment on instances where fixed compensation arrangements could take into account the volume or value of referrals

New Conditions for Directed Referrals

If remuneration to the physician is conditioned on referrals to a particular provider (**directed referrals**), then:

The requirement must be in writing and signed

No directed referrals if:

- Patient chooses different provider
- The payor determines the provider
- Referral is not in the patient's best medical interest

Key Changes:

Most of the requirements for directed referrals existed under the former rules however, the new rules added the following two conditions:

1. Compensation must be set in advance
2. Compensation is not contingent on the number or value of the physician's referrals

New Guidance on Using Physician Salary Surveys

Important new CMS commentary on using physician salary survey data:

- Survey data may not align with specific circumstances
- Specific circumstances may justify compensation above or below the survey range
- CMS does not have a policy around the 75th Percentile (See recent court ruling in the Community Health Network case)
- Surveys are “just a starting point”
- Must consider all the other factors that impact FMV:
 - Physician-specific factors (experience, training, skills, etc.)
 - Location-specific factors (size, competition, payor mix, etc.)
 - Task-specific factors (specialty, acuity, volume, hours, coverage)
 - Situational factors (background facts, problems to be solved, etc.)

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.



Stark Final Rule Changes – Takeaways

- Commercial Reasonableness definition alone is reason to cheer
- FMV Definition is “cleaner” but still somewhat complex
- Decoupling Volume or Value from General Market Value is helpful
- Comments on salary surveys were helpful but may imply more work
- Volume or Value will be interesting to see if it has the desired impact
- Value-based framework may make some of these changes less relevant long-term
- Will whistleblowers, DOJ, and courts struggle any less to understand the regulations?
- Changes probably create greater flexibility, but are still complex

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.



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.



Questions?

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