Stark Law Overhaul

An In-Depth Series on CMS's New Final Rule

Webinar 4

Key Standards (Part II): "Fair Market Value" and "Commercial Reasonableness" Standards, and Indirect Compensation Arrangements

Stark Law Overhaul Series

Date	Topic
March 18	Rolling Up Our Sleeves: A Stark Law Refresher (and Clearing the Brush)
April 1	Separating the Wheat From the Chaff: Technical Requirements, Low-Dollar Violations, and Payment Discrepancies
April 15	Key Standards (Part I): The 'Volume or Value' Standard
April 29	**Key Standards (Part II): The 'Fair Market Value' and 'Commercial Reasonableness' Standards, and Indirect Compensation Arrangements**
May 13	New Wine in Old Bottles: Providing Greater Flexibility Under Existing Exceptions
May 27	What's Past is Prologue: Technology Subsidies Part Deux
June 10	The Problem of the Square Peg and the Round Hole: When FFS and Managed Care Collide

Agenda

- Fair Market Value (FMV) Standard
- Commercial Reasonableness Standard
- Indirect Compensation Arrangements (ICAs)
- Q&A

Fair Market Value Standard

Where is the FMV Standard?

Stark Law Exceptions

- 12 exceptions for compensation arrangements (covering, for example, rental of office space, rental of equipment, bona fide employment relationships, personal service arrangements, and indirect compensation arrangements)
- Exception for services provided by an academic medical center

Special Rules

- Unit-Based Special Rules (retired effective January 19, 2021)
- Required Referrals Special Rule

New ICA Definition

- Effective January 19, 2021

Reorganization of Definitions

Fair Market Value means . . .

- ***General***. The value in an arm's-length transaction, consistent with the general market value of the subject transaction.
- ***Rental of equipment***. With respect to the rental of equipment, the value in an arm's-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.
- ***Rental of office space***. With respect to the rental of office space, the value in an arm's-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 lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction

Reorganization of Definitions

***General Market Value* means . . .**

- ***Assets***. With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the 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.
- ***Compensation***. With respect to compensation for services, 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.
- ***Rental of equipment or office space***. With respect to the rental of equipment or the rental of 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.

Intermingling of FMV and Volume/Value Standards by CMS

- **Required Referrals Special Rule** (2001 Phase I Regulations)
  - Special rule to protect arrangements pursuant to which physician is required to refer patients to a particular provider as a condition of payment, provided certain safeguards are implemented.
  - As long as the conditions of the Required Referrals Special Rule were met, HCFA (and later, CMS) would not consider compensation conditioned on referrals to implicate the Volume/Value Standard.
  - Required that physician's compensation be "consistent with *fair market value* for services performed *(that is, the payment does not take into account the volume or value of anticipated or required referrals)*."
- **Definition of "Fair Market Value"** (2004 Phase II Regulations)
  - "Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, *where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals*."

Intermingling of FMV and Volume/Value Standards by Courts

- *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162 (3d. Cir. 2019) ("***Bookwalter II***")
  - Concerned compensation paid to neurosurgeons employed by affiliates of the University of Pittsburgh Medical Center ("UPMC").
  - Key inquiry: Did relators' complaint plead sufficient facts to satisfy ICA Definition?
    - At the time (i.e., 2019), *prong two* of the ICA Definition (**ICA Volume/Value Standard**) required that the "aggregate compensation" provided for in the compensation arrangement closest to the referring physician (in this case, the employment compensation paid to the neurosurgeons under their employment agreements) **"varies with, or takes into account"** the volume or value of the physician's referrals to, or other business generated for, the DHS Entity (here, UPMC).
    - ICA Definition did not include FMV standard at this time.
  - Third Circuit concluded that the relators' complaint plausibly alleged that the *ICA Volume/Value Standard was met* because relators had alleged that "the surgeons' pay *far exceeded their fair market value*," and "*aggregate compensation that far exceeds fair market value . . . suggests that the compensation takes referrals into account*."
  - In 2004 Phase II Regulations, CMS took position that an excessive or inflated fixed flat compensation amount could trigger the Volume/Value Standard.

Disentangling FMV and Volume/Value Standards

- Changes made by Final Rule (2020)
  - **Required Referrals Special Rule**
    - "The compensation is consistent with the fair market value of the physician's services ~~*(that is, the payment does not take into account the volume or value of anticipated or required referrals)*~~."
  - **Definition of "Fair Market Value"**
    - ~~"Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, *where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals*."~~

The Myth of Market Survey Data

- U.S. Department of Justice (DOJ), relators, and courts frequently have treated market survey data as a key indicator of whether physician compensation is consistent with FMV.
  - ***Bookwalter II***
    - Third Circuit concluded that relators had alleged that neurosurgeons' employment compensation "far exceeded" FMV because, among things, several of the physicians were *paid above the 90th percentile* as compared to neurosurgeons nationwide.
  - FCA settlements
    - Common allegation is that the amount of physician compensation violated the FMV Standard of an applicable Stark Law exception because the compensation exceeded a certain percentile (typically the 90th) in a market survey.
    - For example:
      - **North Broward Hospital District**, Case No. 10-60590 (S.D. Fla. 2010): **$69.5 million settlement**.
      - **Adventist Health System**, Case No. 3:13-cv-00217 (W.D.N.C. 2013): **$115 million settlement**.

The Myth of Market Survey Data (cont'd)

- FMV Safe Harbors (2004 Phase II Regulations)

FMV Safe Harbor #1	FMV Safe Harbor #2
• Hourly payment rate for physician services deemed FMV if it was "less than or equal to the *average hourly rate for emergency room physician services in the relevant physician market*, provided there are at least three hospitals providing emergency room services in the market."	• Hourly payment rate for physician services deemed FMV if it was determined by (i) "*averaging the 50th percentile national compensation level* for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice)" in at least four of six specified surveys, and (ii) dividing that average compensation amount by 2,000 hours.

- Safe harbors eliminated in 2007. But CMS cautioned that "[r]eference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value."

The Myth Debunked: Final Rule (2020)

- ***"It is not CMS policy that salary surveys necessarily provide an accurate determination of fair market value in all cases."***
  - "Parties do not necessarily fail to satisfy the fair market value requirement simply because the compensation *exceeds a particular percentile* in a salary schedule."
  - Nor "are parties required to pay a physician what is shown in a salary schedule if the specific circumstances do not warrant that level of compensation."
- "[T]he rate of compensation set forth in a salary survey may not always be identical to the worth of a *particular* physician's services."
- The circumstances unique to a *particular* arrangement may "dictate" that the parties "to an arm's length transaction veer from values identified in salary surveys and other valuation data compilations that are not specific to the *actual* parties to the subject transaction." E.g., due to:
  - **Quality of physician's services** - See example in white paper.
  - **Compelling need for the physician's services** - See example in white paper.

Commercial Reasonableness Standard

Where is the Commercial Reasonableness Standard?

Statutory Exceptions

- Space Rental
- Equipment Rental
- Employment
- Pre-1989 Hospital-Group Arrangements

Regulatory Exceptions

- Space Rental
- Equipment Rental
- Employment
- Pre-1989 Hospital-Group Arrangements
- Isolated Transactions
- FMV Compensation
- Indirect Compensation Arrangements
- Timeshare Arrangements
- Limited Remuneration to Physician
- Value-Based Arrangements

What is the Commercial Reasonableness Standard?

- Standard + No Referrals (9 Exceptions)
  - Space Rental: "The lease arrangement would be [1] **commercially reasonable** [2] even if **no referrals were made** between the lessee and the lessor."
  - Employment: "The remuneration is provided under an arrangement that would be [1] **commercially reasonable** [2] even if **no referrals were made** to the employer.
- Standard Only (1 Exception)
  - Value-Based Arrangements: "The arrangement is **commercially reasonable.**"

No Definition in Regulations Pre-Final Rule

1998 Preamble to Proposed Rule:

> Commercially reasonable "mean[s] that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals."

Why Define the Commercial Reasonableness Standard Now?

- Hypothetical
  - Hospital employs Physician at a salary of $250,000 per year.
  - Compensation does not violate Volume/Value Standard (i.e., compensation does not "take[] into account the volume or value of referrals by" Physician to Hospital).
  - Compensation meets FMV Standard (i.e., compensation is "[c]onsistent with the fair market value of the services.")
  - However, Hospital's total **costs** to employ physician (salary + non-salary overhead, etc.) are greater than **revenues** generated by Hospital based on Physician's personally performed services.
- FCA whistleblowers have argued that, under these circumstances, the arrangement is not "commercially reasonable even if no referrals were made [by Physician] to [Hospital]."
- Why? Because it is not "reasonable" from a "commercial" standpoint for a DHS Entity to enter into an arrangement pursuant to which it knows it is going to lose money.

Proposed Rule (2019)

- CMS rejects whistleblower position:
  - "It is apparent… that there is a widespread misconception about our position on the nexus between the commercial reasonableness of an arrangement and its profitability."
  - The "determination of commercial reasonableness is not one of valuation."
  - "Nor does the determination that an arrangement is commercially reasonable turn on whether the arrangement is profitable."

Non-Exclusive List of Reasons for Entering Into Unprofitable Arrangements

- Community need.
- Timely access to health care services.
- Fulfillment of licensure or regulatory obligations (e.g., EMTALA).
- Provision of charity care.
- Improvement of quality and health outcomes.

Final Rule (2020)

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.**

- An arrangement's profitability is not "completely irrelevant" or "always unrelated" to "a determination of its commercial reasonableness, for instance, in a case where the parties enter into an arrangement aware of its certain unprofitability and there exists no **identifiable need or justification**—other than to capture the physician's referrals—for the arrangement."
- Arrangements "that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely **duplicate other facially legitimate arrangements**."

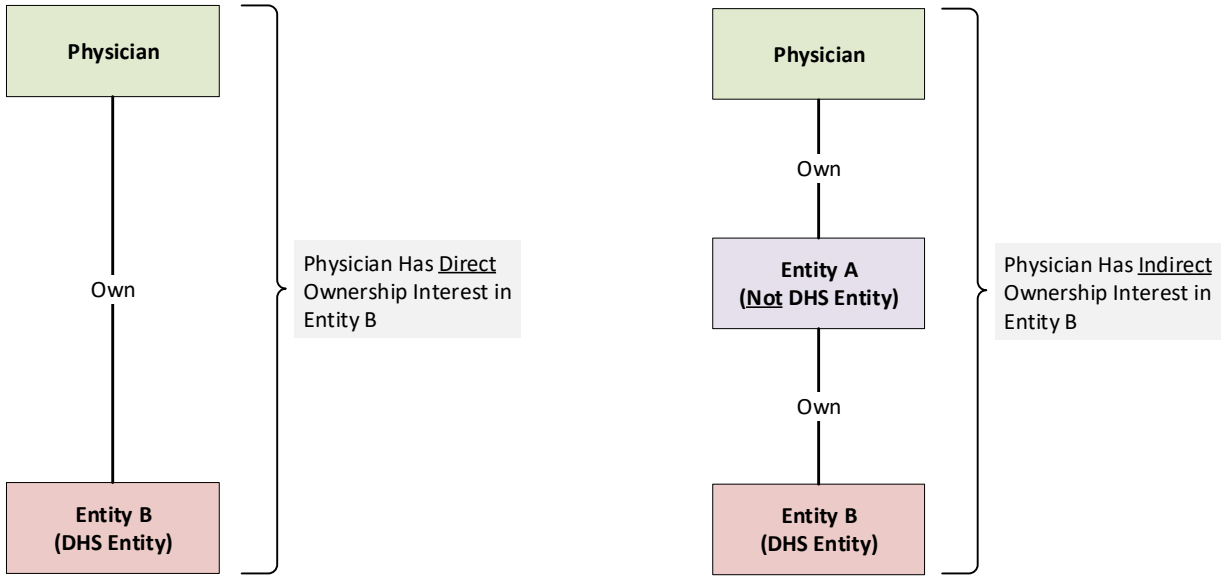
Final Rule (2020) (cont.)

- "An arrangement whose purpose is to attract a physician's business . . . would not be commercially reasonable in the absence of the physician's referrals" and, as such, "would not satisfy" the Commercial Reasonableness Standard.
- This is **not true**. While the "purpose" of an arrangement may be relevant for AKS purposes, it is not relevant to determining whether the Commercial Reasonableness Standard is satisfied for Stark Law purposes:
- Assume for example that (i) Hospital is considering extending an offer of employment to a community Physician, and (ii) the compensation would be a flat $250,000 per year irrespective of whether or the extent to which Physician refers patients to Hospital. Under these circumstances, both of these can be true statements:
  - Hospital hopes and even expects that if Physician accepts Hospital's offer and becomes a Hospital employee, Physician will refer patients requiring inpatient and outpatient services to Hospital.
  - The amount that Hospital pays Physician under their employment agreement is commercially reasonable even if Physician refers no patients to Hospital

Indirect Compensation Arrangements

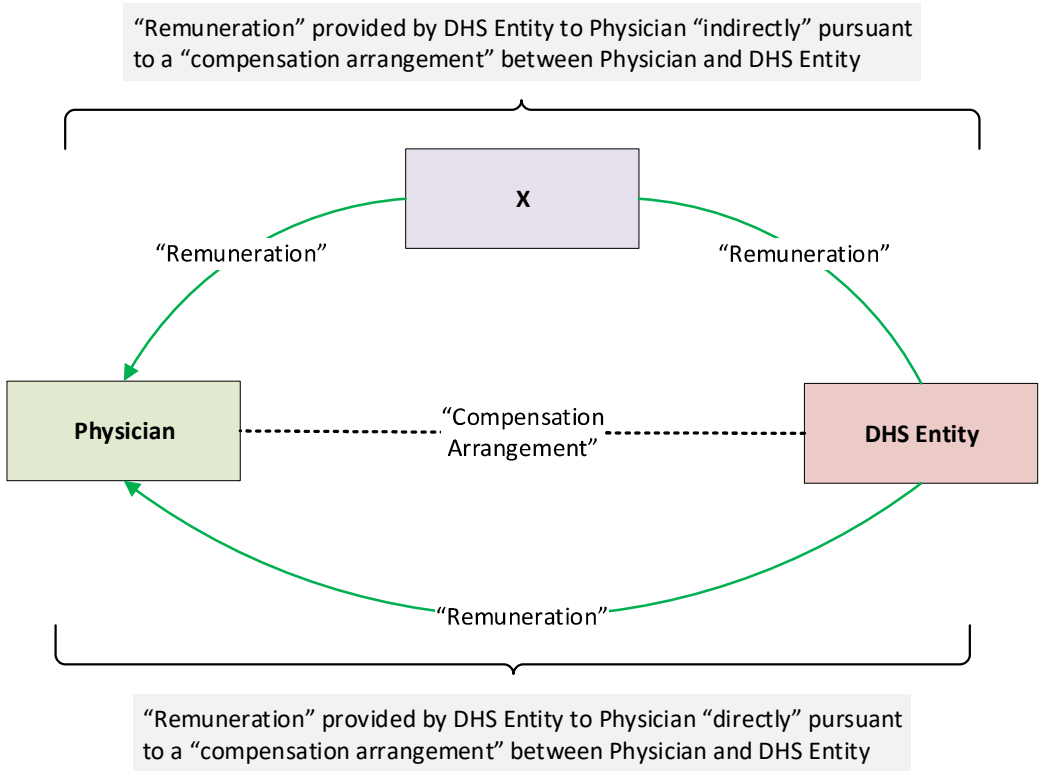
Stark Law Statute

- Stark Law statute expressly provides that an **ownership interest** may be *indirect*:
  - "An ownership or investment interest . . . includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service."



Stark Law Statute

- On the other hand, the Stark Law statute defines **compensation arrangements** as follows:
  - "The term 'compensation arrangement' means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity" (subject to certain exceptions).
  - "The term '**remuneration**' includes any remuneration, *directly or indirectly*, overtly or covertly, in cash or in kind."



Regulatory ICA Definition (2001)

- An ICA exists if the following three conditions are met:

Prong One	• There is an unbroken chain of *at least two* financial relationships between the referring physician and the DHS Entity.
Prong Two	• The *aggregate* compensation the referring physician receives from the person in the chain with whom the physician has a "direct financial relationship" *varies with or otherwise reflects* the volume or value of the referring physician's *referrals* to or *other business generated* for the DHS Entity (**ICA Volume/Value Standard**).
Prong Three	• The DHS Entity has *actual knowledge* of, or acts in *reckless disregard or deliberate ignorance* of, the fact that the aggregate compensation (in the compensation arrangement identified in Prong Two) triggers the ICA Volume/Value Standard.

Prong One: Agents

Hypothetical

- Physician employed by Medical Practice.
- Lab (a DHS Entity) enters into arrangement with Medical Practice, pursuant to which the latter agrees to make Physician available to Lab for purposes of furnishing medical directorship services.
- Because Medical Practice routinely sends a courier to Lab to deliver specimen, Lab (with Physician's consent) sends her monthly compensation to the attention of the Medical Practice Administrator, who agrees to accept Lab's check on Physician's behalf and deliver it to her.

- **Phase I (2001)**: An **agent** *does not* qualify as an intervening person or entity for purposes of applying Prong One of the ICA Definition.
  - Lab → Administrator/Physician (Link 1)
  - Because there is only one financial relationship between Lab and Physician, *Prong One is not met*.
    - So this can't be an ICA. But it is a *direct* compensation arrangement between Lab and Physician.
- **Phase II (2004)**: CMS reverses course. An **agent** *does* qualify as an intervening person or entity.
  - Lab → Administrator (Link 1) and Administrator → Physician A (Link 2)
  - Because there is an unbroken chain of two financial relationships between Lab and Physician, *Prong One is met*.

Prong One: Stand In the Shoes

Hypothetical

- Physician A owns Medical Practice
- Physician B employed by Medical Practice.
- Lab (DHS Entity) enters into arrangement with Medical Practice, pursuant to which Medical Practice agrees to make Physician B available to Lab for purposes of furnishing medical directorship services.

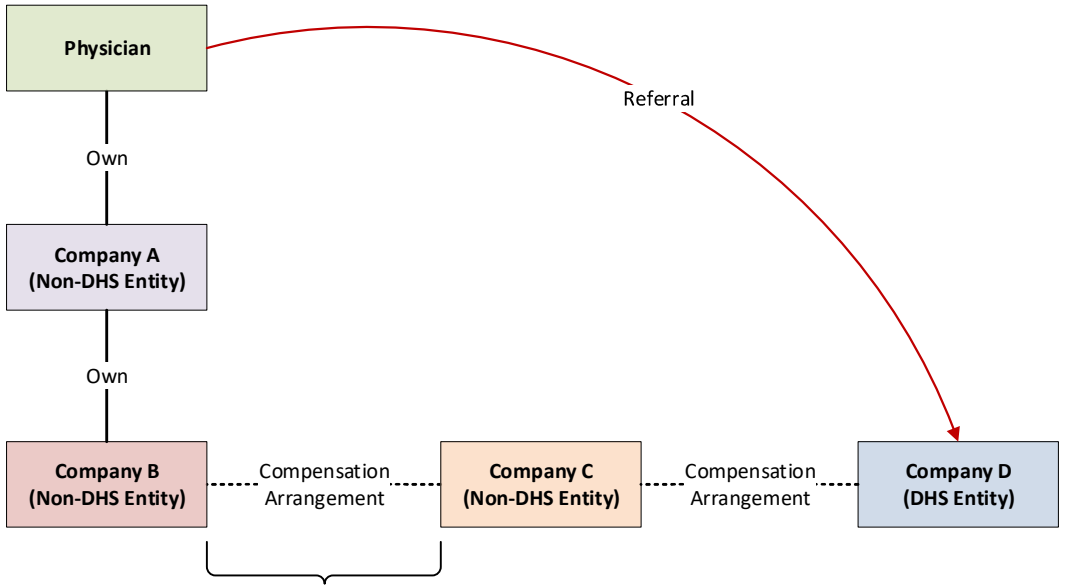
- **Prior to Phase III (2007)**: A physician organization qualifies as an intervening entity.
  - Lab → Medical Practice (Link 1) and Medical Practice → Physician A (Link 2)
  - Lab → Medical Practice (Link 1) and Medical Practice → Physician B (Link 2)
- **Phase III (2007)**: A physician "stands in the shoes" of their physician organization, such that it does not serve as an intervening entity.
  - Lab → Medical Practice/Physician A (Link 1)
  - Lab → Medical Practice/Physician B (Link 1)
- **2008**: CMS limits "stand in the shoes" rule to physician-owners (excluding titular owners).
  - Lab → Medical Practice/Physician A (Link 1)
  - Lab → Medical Practice (Link 1) and Medical Practice → Physician B (Link 2)

Prong Three: State of Mind

- What does it mean for the DHS Entity to have "*actual knowledge*" or act "*in reckless disregard or deliberate ignorance of*," the fact that the Prong Two Compensation Arrangement triggers the ICA Volume/Value Standard?
- Prong Three generally imposes a "**duty of reasonable inquiry**" on DHS Entities.
  - DHS Entity "in possession of facts that would lead a reasonable person to suspect the existence of an indirect financial relationship" must "take reasonable steps to determine whether such a financial relationship exists."
- Absent information that would "put a reasonable person on alert," there is "**no affirmative duty to inquire or investigate**."
- Same as scienter requirement in False Claims Act and Civil Monetary Penalty Law.
- "Red flag" test.

Prong Two Prior to Final Rule

- Two-step process:
  - Identify the "direct financial relationship" in the unbroken chain of financial relationships that is (i) closest to the referring physician, and (ii) takes the form of a compensation arrangement (**Prong Two Compensation Arrangement**).
  - Ascertain whether the aggregate compensation in that financial relationship meets the ICA Volume/Value Standard.



This is the "Prong Two Compensation Arrangement" (i.e., it is the compensation arrangement closest to the referring physician in the unbroken chain of financial relationships between Physician and DHS Entity (i.e. Company D).

ICA Volume/Value Standard (Prior to Final Rule)

Phase I (2001)

- The aggregate compensation in the Prong Two Compensation Arrangement "*varies with or otherwise reflects*" the volume or value of the referring physician's referrals to or other business generated for the DHS Entity.

Phase III (2007)

- The aggregate compensation in the Prong Two Compensation Arrangement "*varies with, or takes into account*," the volume or value of the referring physician's referrals to or other business generated for the DHS Entity.

Proposed Rule (2019)

- The aggregate compensation in the Prong Two Compensation Arrangement "*takes into account*" the volume or value of the referring physician's referrals to or other business generated for the DHS Entity.

Final Rule (2020): Prong Two

- Two-step process:
  - Identify **Prong Two Compensation Arrangement** (still the "direct financial relationship" in the unbroken chain of financial relationships that is closest to the referring physician)
  - Apply new two-part test (**New Prong Two Test**)

New Prong Two Test

Part One

Similar (But Not Identical) to Historic ICA Volume/Value Standard

- The **aggregate compensation** in the Prong Two Compensation Arrangement "**varies with**" the volume or value of the referring physician's *referrals* to or *other business generated* for the DHS Entity.

Part Two

Incorporates Retired Unit-Based Special Rules

- The **individual unit of compensation** in the Prong Two Compensation Arrangement meets any *one* of the following three criteria:
  - the individual unit of compensation is "not **fair market value** for items or services actually provided"; or
  - the individual unit of compensation is calculated using a formula that includes the physician's **referrals** to the DHS Entity as a "*variable*," resulting in an increase or decrease in the physician's compensation that "*positively correlates*" with the number or value of the physician's referrals to the DHS Entity; or
  - the individual unit of compensation is calculated using a formula that includes the physician's **other business generated** to the DHS Entity as a "*variable*," resulting in an increase or decrease in the physician's compensation that "*positively correlates*" with the physician's generation of other business for the DHS Entity.

Applying New Prong Two Test

Hypothetical

- Health System (non-profit) is sole member of two wholly-controlled, non-profit subsidiaries: Hospital and Physician Organization.
- Hospital transfers funds to Physician Organization in ordinary course—both directly and through Health System—to help Physician Organization meet its financial obligations, including payroll.
- Physician Organization employs Physician, pursuant to which Physician furnishes services at, and orders various diagnostic tests and other DHS from, Hospital.
- Physician Organization compensates Physician $240,000 per year.

- **Prong One met.**
  - Hospital → Physician Organization (Link 1) and Physician Organization → Physician (Link 2)
- **Prong Two analysis.**
  - Prong Two Compensation Arrangement is Link 2 (Physician Organization → Physician).
  - That compensation arrangement *does not satisfy part one* of New Prong Two Test.
    - Physician's aggregate compensation (i.e., $240,000 per year) does not vary at all, let alone with Physician's referrals to or other business generated for Hospital.
    - Because part one of New Prong Two Test is not satisfied, **there is no ICA**.

Applying New Prong Two Test (cont'd)

Hypothetical

- Same but in addition to base salary of $240,000 per year, Physician Organization agrees to pay Physician a bonus of $5 for each clinical diagnostic lab test Physician orders from Hospital's outpatient diagnostic laboratory.

- Prong Two Compensation Arrangement (Physician Organization → Physician) now *satisfies part one* of the New Prong Two Test.
  - Due to unit-based component ($5 per lab test), Physician's aggregate compensation now *varies with* (i.e., is positively correlated to) the volume of Physician's referrals of DHS (i.e., the number of clinical lab tests ordered by Physician for Medicare patients) and the volume of other business generated by Physician (i.e., the number of clinical lab tests ordered by Physician for non-Medicare patients).
- As for *part two* of the New Prong Two Test:
  - The unit of compensation ($5) does not change during the course of the parties' arrangement, so second and third criteria not met.
  - But *first criterion is met*: In Final Rule, CMS made clear that **"referrals" are not "items or services,"** so the unit of compensation ($5) cannot be "fair market value" for "items or services actually provided."
- **Because both parts of Test are met, Prong Two is met.**

Q&A

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