What Is FMV/Commercial Reasonableness? Why Should I Care?

David Pursell
Partner
Husch Blackwell LLP

Objectives

- Define and Distinguish FMV, Commercial Reasonableness, VOVOR and OBGBTP
- Delineate the differences between their application under Stark and the Anti-Kickback Statute
- Differentiate between analysis for best practices, self-disclosure and defense
- Review the impact of Tuomey, the Halifax decisions, Borrası and other recent case law on best practices
The Three Hats
For Analyzing Transactions

- Transaction Design and Implementation
  - Best Practices
  - Risk Tolerance
  - Relative Benefits

- Compliance Review
  - Defensible Position
  - Appropriate Corrections

- Litigation Defense
  - Risk Tolerance
  - Reasonable Defenses

Analyzing Risk

- Deal Pressure - We have to make this deal work, whatever it takes!
  - What is Fair Market Value?

- Business Pressure - How did we get here? We can’t afford to pay this much!
  - What is Commercially Reasonable?

- Identify the key compliance issues in each transaction - Every deal is different!
Context

- **Fair Market Value**
  - An explicit requirement of ten exceptions to the Stark Law and three Anti-Kickback Statue Safe Harbors.
  - An implicit requirement to avoid liability under the Anti-Kickback Statue in the absence of a Safe Harbor.
  - An implicit issue in the indirect compensation definition.

- **Volume or value of referrals or other business generated between the parties**
  - Prohibition in all but one of the ten Stark Law exceptions and all three Anti-Kickback Statue Safe Harbors that contain the fair market value requirement. Implicitly includes fair market value as an issue in the prohibition.

- **Commercially Reasonableness**
  - Required for eight of the ten Stark Law exceptions and all three Anti-Kickback Statue Safe Harbors that contain the fair market value requirement.

“Fair Market Value”

- The value in arm's-length transactions, consistent with the general market value

- “General Market Value” - the compensation that would be included in a services agreement as a 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.
Arm’s Length Bargaining

- **U.S. ex rel. Kosenske v. Carlisle HMA, Inc.**, 554 F.3D 88 (3rd Cir. 2009)

- Arm’s-length negotiation between a hospital and a physician will not be bona fide bargaining between parties “who are not otherwise in a position to generate business between the parties.”


- “While the value agreed upon by parties who are in a position to refer business to each other and who take into account anticipated referrals will be a fair value as between the parties, such an arrangement is not “fair market value” under the Stark Act.”

- Generally, 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 price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.  
  42 C.F.R. §411.351
“Safe Harbor” rates based on surveys eliminated in Phase III, but “[r]eference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value.”

“We intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm’s-length transactions who are not in a position to refer to one another.”

“Depending on the circumstances, the ‘volume or value’ restriction will preclude reliance on comparables that involve entities and physicians in a position to refer or generate business.” 66 F.R. at 944

Good faith reliance on an independent valuation may be relevant to intent, but it does not establish the ultimate issue of the accuracy of the valuation figure itself.

72 F.R. at 51015.

- Is the valuation valid?
  - Duty to look behind?
  - Tuomey
  - Bradford
Clinical vs. Administrative Rates

Compensation paid for clinical work must be FMV for clinical work and the rate paid for administrative work must be FMV for administrative work.

- "We note that the fair market value of administrative services may differ from the fair market value of clinical services."
  72 F.R. at 51016

Anti-Kickback Statue

- Does not explicitly impose a fair market value or commercial reasonableness requirement on hospital/physician financial relationships.
  - Implicit element – essential element of an anti-kickback statue violation is a payment for the purpose of inducing referrals. 
    U.S. v. Greber, 760 F. 2d 68, 71 (3rd Cir. 1985).
  - Consequently, if the intent and conduct of the parties is to pay fair market value for services which will be actually rendered and not also for the purpose of inducing referrals, then the arrangement does not violate the statute. See U.S v. Bay State Ambulance and Hospital Rental Service, Inc., 874 F.2d 20, 29-30 (1st Cir. 1989); 64 F.R. 63518, 63519-21 (Nov. 19, 1999)
  - Some courts have held that compliance with the AKS requires that a provider pay fair market value to a physician for his services. See Pogue v. Diabetes Treatment Centers of America, 565 F. Supp.2d 153 162 (D.C.D.C. 2008); Am. Lithotripsy Soc. v. Thompson, 215 F. Supp2d 23, 27 (D.D.C. 2002) (Indeed, “[p]ayment exceeding fair market value is in effect deemed payment for referrals.”).
FMV Issues

Use of Market Data

- **Self-perpetuating**
  - Implication of more physicians being employed each year by hospitals
  - The concept that the median becomes the low point of FMV
  - The mathematical result is the median will continue to rise each year

- **Higher WRVU’s result in lower compensation per WRVU**

- **Development of the DATA point “Comp per WRVU”**

  Mathematical Equation = \( \frac{\text{Compensation}}{\text{WRVU’s}} \)
**Compensation and Compensation per Work RVU by Quartile of Production for Surgery: General**

- **1st Quartile**: $298,155
- **2nd Quartile**: $353,007
- **3rd Quartile**: $403,704
- **4th Quartile**: $529,236
- **Compensation per WRVU**:
  - **1st Quartile**: $70.62
  - **2nd Quartile**: $57.39
  - **3rd Quartile**: $52.19
  - **4th Quartile**: $48.98


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**Fixed Payments**

*U.S. ex rel. Villafane v. Solinger*

- Not determined in a manner that takes into account VOVOR/OBGBTP can mean one of three things in a fixed payment:
  1. A fixed payment never takes into account VOVOR/OBGBTP
  2. A fixed payment takes into account VOVOR/OBGBTP if extrinsic evidence parties did so when structuring the compensation, even if otherwise FMV
  3. A payment takes into account VOVOR/OBGBTP only if, on its face, it is a fixed payment that is above FMV or it varies based on the number of referrals; intent or extrinsic evidence not a factor.

Court adopts third position. 543 F. Supp. 2d 678

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Fixed Payments

U.S. ex rel. Singh v. Bradford Regional Medical Center, 2010 WL 4687739 (W.D. Pa.)

- Defendant hospital, was concerned that two of its largest referring cardiologists would acquire their own nuclear camera, which the hospital estimated could have an adverse impact of roughly $950,000.00 on hospital revenue. The hospital and physicians entered into an agreement providing that the nuclear camera leased by the physicians would be subleased to the hospital.
  - Fair market value assessment prepared that compared the revenue the hospital expected to generate with the sublease in place to the revenue it expected if it did not have the sublease in place, with the expectation that the physicians would refer to the hospital if the sublease was in place and would not in its absence.
  - Court concluded that payments under the sublease for a non-compete agreement given by the physicians took into account the revenue Bradford anticipated receiving from expected physicians referrals.

VOVOR


- Principal Stark Law issue:
  - Does the bona fide employee exception permit a bonus pool that includes non-personally performed DHS revenue, if the pool is allocated based on the proportion of personally performed services of physicians participating in the pool.
  - Held: No; employee exception only permits a bonus to a physician based on his or her own personally performed services.
**DCF Payment for Technical Revenue Stream**

- **Comment:** One commenter asked us to clarify that a valuation of a physician’s practice could include the value of self-generated DHS in the purchase price as long as the purchase agreement was not contingent on future referrals.

- **Response:** For purposes of section 1877 of the Act, the valuation of a physician practice could include the value of DHS in the purchase price if the DHS provided by the selling physician fit into an exception, such as the in-office ancillary services exception, and the purchase agreement (and purchase price) is not contingent on future referrals. Depending on the identity of the purchaser, however, the inclusion of the value of ancillary revenues could implicate the antikickback statute.
  

- **Query:** Why would a hospital pay more than hard asset value instead of buying on open market?

**FMV and the AKS BFE Exception**

*U.S. v. Borrasi,* 639 F.3d 774 (7th Cir. 2011)

- Defendant essentially argued that statutory exception for “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services” protected payments to employees even if in excess of fair market value for the services provided.

- Court held that “one purpose” rule applied in employment context. Court did not otherwise explain the meaning of the statutory language.
**FMV and the AKS BFE Exception**


- In a portion of the non-intervened claims, *qui tam* relator asserted that the claims that were referred by physicians whose compensation arguably exceeded fair market value did not, as a consequence, meet the *bona fide* employment exception to AKS.
- Defendant argued in its motion to dismiss that employed physicians met the definition of a bona fide employee for federal income tax purposes (the definition in the safe harbor regulation, which does not mention FMV), therefore, these claims should be dismissed.
- The Court used the old IRS 20-factor test, determined that the physicians were employees and therefore, dismissed these claims as covered by the exception. Did not discuss the remainder of the exception nor the *Borassi* case.

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**Commercial Reasonableness – Stark Law**

- An arrangement is **commercially reasonable** if it is:
  - A sensible, prudent business arrangement
  - From the perspective of the parties involved,
  - **Even in the absence of potential referrals.**

  69 F.R. at 16093
Commercial Reasonableness - Anti-Kickback Statue

- The purpose must be reasonably calculated to further the business of the lessee or purchaser.

- Space, equipment, or services that the lessee or purchaser needs, intends to utilize, and does utilize in furtherance of its commercially reasonable business objectives.

64 Fed. Reg. 63518, 63525 (Nov. 19, 1999)

Commercial Reasonableness


- Compensation paid at flat annual rate for part-time employment providing principally academic services. Government argued agreement was not commercially reasonable because, even though reasonable on its face, the hospital entered into the agreement with individual who was not qualified and made no effort to ensure the services were actually performed.


- Agreement, standing alone was commercially reasonable, but not commercially reasonable when hospital entered into multiple agreements for the same service with different physicians that, in the aggregate, exceeded the hospital’s need for the service.
Potential Factors

- Is it commercially reasonable in the absence of referrals?
  - Are specific elements of the agreement standing alone commercially reasonable, as well as in conjunction with each other.
    - E.g., length of term becomes a more important factor as more impediments to termination are imposed in the provisions of the agreement.
  - Non-exhaustive list: length of the term; renewal/evergreen provisions; termination for cause provisions; termination without cause provisions; full time/part-time employment; compensation terms- fixed vs. production formula; periodic review of fixed or production formula compensation; ability to adjust compensation/formula; net cost of the agreement to the hospital; eligibility for pension, welfare and fringe benefits; scope of duties; requirements for documentation (administrative vs. clinical time and amount of time expended); duplication of work required. In an equipment or real estate lease: the justification for any terms that are not typical in a commercial real estate or equipment lease.

Determining Commercial Reasonableness

- First step in determination of whether an agreement is commercially reasonable must be: “Is the transaction consistent with fair market value?”
  - Standard definition of FMV addresses many of the issues thought to require a commercial reasonableness assessment
  - Any transaction that fails to be consistent with fair market value is commercially unreasonable
  - If a transaction meets the FMV standard, it may be commercially unreasonable for other reasons
Commercial Reasonableness

Underlying Principles

- All business transactions must aid organizations in accomplishing their strategic, operational, and/or financial objectives
- Assesses the overall arrangement, including qualitative considerations such as strategy and operations, whereas fair market value primarily assesses the financial aspects of the arrangements (range of dollars only)
- Considers the aggregate terms of the overall arrangements and asks the question: "Does this deal make sense?"

Applying Guidance to Assess Commercial Reasonableness

- Healthcare organizations and providers should use several analyses to determine whether an arrangement meets the standard of commercial reasonableness. The analyses include inquiries relating to the specific terms of a proposed arrangement in relation to the transactions:
  1. Business purpose
  2. Provider of service
  3. Appropriateness with regard to the healthcare provider’s facility and patient population
  4. Suitability, considering the human and capital resources of the healthcare entity
- These assessments each address various aspects of potential transactions, including overall economic sense and relationship to the business goals of the organization proposing to enter into a physician arrangement

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Business Purpose Analysis

- Arrangements between physicians and hospitals should be reasonably necessary to effectuate appropriate patient care and commercially reasonable business purpose without inducing prohibited referrals and compensation arrangements - “Legitimate Business Purpose.”

Facility Analysis

- The size and patient population of a particular medical facility should be considered in assessing the reasonableness of a proposed arrangement to which that facility will be a party.
  - Do sound business reasons exist for a specific services arrangement
- Arrangements characterized as unnecessary or those creating overutilization are presumably neither reasonable nor economically sensible.
  - Carefully consider whether physician services are necessary to carry out the purpose of a proposed arrangement or whether non-physician providers can satisfactorily perform the services
  - Whether a certain position requires the services of a physician trained in a particular specialty
  - Does size and patient population justify the specific arrangement
Independence and Oversight Analysis

- In *U.S. v. SCCI Hospital Ventures*, government’s financial expert asserted several specific factors that are critical to a determination of commercial reasonableness related to physician services arrangements. These factors included whether:
  1. The hospital performs regular evaluations of the *actual* duties performed by the physician;
  2. The hospital assesses the effectiveness of the physician’s performance;
  3. There is a sustained, bona fide need for the physician services;
  4. Whether the services were duplicative.

Halifax Again

- Government Expert’s Commercial Reasonableness Factors Included:
  - *Halifax* incurred material financial losses related to the neurosurgeons’ practices
  - Neurosurgeons were favorably treated in comparison to other employed physicians
  - With the exception of medical oncologists, the neurosurgeons were the only employed specialist group who earn compensation above or near the 90th percentile levels.
  - The Number of WRVUs Were Materially Inconsistent Year to Year
  - There were material inconsistencies in the coding of physicians’ services that reflected work at a rate substantially in excess of full-time (3.33 to 4.2 FTE)
Questions?

David B. Pursell
Partner

HUSCH BLACKWELL LLP
4801 Main Street, Suite 1000
Kansas City, MO 64112-2551
Direct: 816.983.8190
Fax: 816.983.8080
david.pursell@huschblackwell.com
huschblackwell.com