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The Bradford Regional Medical Center Decision Implications for FMV and other Considerations For Stark and Anti-Kickback January 26, 2011

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Background: Physician Self-Referral (“Stark”) Concepts Discussed in Bradford

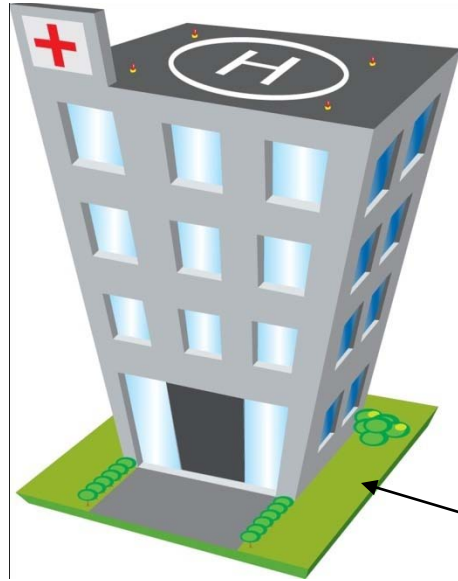


Stark Statute

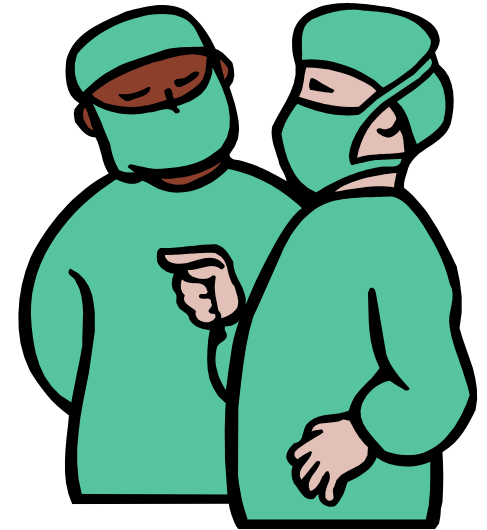
“Indirect Compensation Arrangement” Definition

- **Unbroken Chain” of any number of entities between physician and entity**
- **Aggregate compensation to physician from closest link in chain varies with, or otherwise reflects, volume or value of referrals to entity providing DHS**
- **Entity providing DHS has actual knowledge or acts in reckless disregard of existence of such relationship**
- **Note: Does not apply to physician owners of a “physician organization”**
 - owners “stand in the shoes” of their physician organizations and have a direct compensation arrangement with the same persons and entities with which their physician organizations have a direct compensation arrangement

Indirect Compensation Arrangement



Group Practice has contract with Hosp. to perform and supervise procedures



Physician Refers patients to Hosp for surgery

Hospital knows details of comp arrangement between Physician and Group

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Physician is paid flat fee by Group for each procedure he performs or supervises



Physician is an employee (non-owner) of Group

FMV Requirements in Stark Exceptions

- **Stark Statute definition of FMV (section 1877(h) of the SS Act)**
- **The term “fair market value” means the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted 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.**

FMV and Commercial Reasonableness Requirements in Stark Exceptions

- **FMV defined in §411.351:**
***Fair Market Value* means the value in arm's-length transactions, consistent with the general market value.**
 - “General market value” means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or 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, on the date of acquisition of the asset or at the time of the service agreement.

FMV Definition (cont'd)

- **“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.”**

FMV Definition – Special Rule for Space Leases

- **FMV is the value of rental property for general commercial purposes (not taking into account its intended use)**
 - In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.
 - A rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

Commercial Reasonableness

- **No definition of “commercial reasonableness” *per se***
- **But term is used in conjunction with absence of referrals**
 - Arrangement must be “commercially reasonable” even if no referrals. were made between the parties

Stark Exceptions with FMV and Commercial Reasonableness Requirements, and Prohibition on Taking Into Account the Volume or Value of Referrals

- **Academic Medical Centers (§411.355(e))**
- **Space Leases (§411.357(a))**
- **Equipment Leases (§411.357(b))**
- **Employment (§411.357(c))**
- **Personal Services (§411.357(d))**
 - No commercial reasonableness requirement per se, but the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

Stark Exceptions with FMV and Commercial Reasonableness Requirements, and Prohibition on Taking Into Account the Volume or Value of Referrals (cont'd)

- **Isolated Transactions (§411.357(f))**
- **Group practice arrangements w/hospital (§411.357(h))**
- **Payments by a Physician (§411.357(i))**
 - No commercial reasonableness requirement
 - Statutory exception
- **Fair Market Value (§411.357(l))**
- **Indirect Compensation (§411.357(p))**

Additional Stark Exceptions with Prohibition on Taking Into Account the Volume or Value of Referrals

The following exceptions have a prohibition on taking into account the volume or value of referrals (without a FMV or commercial reasonableness requirement):

- **Physician Recruitment (§411.357(f))**
- **Remuneration provided by a hospital not related to DHS (§411.357(g))**
- **Charitable Donations by a Physician (§411.357(j))**
- **Non-monetary Compensation (§411.357(k))**
- **Medical Staff Incidental Benefits (§411.357(m))**
- **Obstetrical Malpractice Insurance Subsidies (§411.357(r))**
- **Professional courtesy (§411.357(s))**
- **Physician Retention payments (§411.357(t))**
- **Electronic Prescribing and Electronic Health Records (§§411.357(v) and (w))**

Volume or Value for Purposes of the Exception for Indirect Compensation Arrangements

- The exception for indirect compensation arrangements requires that the compensation not be determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.
- But the exception protects only indirect compensation arrangements, and in order to have an “indirect compensation arrangement,” as defined at (§411.354(c), the referring physician (or immediate family member) must receive aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, the compensation.

Volume or Value for Purposes of the Exception for Indirect Compensation Arrangements (cont'd)

- How do the two requirements fit together?
- The volume or value language in the exception for indirect compensation arrangements cannot mean the same thing as in the definition for indirect compensation arrangements, or otherwise the exception would never be available when it is needed.
- The requirement in the exception means that the amount of the compensation cannot change over the course of the arrangement based on the volume or value of referrals or other business generated by the referring physician.
 - e.g., a per-click fee of \$x for surgeries 1-20 performed by referring physician and a per-click fee of \$x+ for surgeries 21-40
 - But some fixed-fee arrangements can impermissibly take into account the volume or value of referrals.

Compensation Background

- **Many Stark exceptions for compensation arrangements require compensation to be “set in advance”.**
- **“Set in Advance” compensation includes:**
 - Flat amount of aggregate compensation; or
 - Amount based on unit-of-time or unit-of-service (“per click”); or
 - Specific formula for calculating the compensation.
 - Formula must be in sufficient detail so that it can be objectively verified.
 - Includes “percentage compensation” formula
 - May not be modified during the course of the agreement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician

False Claims Act case based on alleged knowing Stark violations and Anti-Kickback Statute violations



United States ex rel. Singh v. Bradford Regional Medical Center

The Players

- **Bradford Regional Medical Center – a non-profit hospital serving McKean County in Western PA**
- **V&S Medical Associates – a group practice owned by Drs. Vaccaro and Saleh**
- **Drs. Singh, Kirsch, Nadella and Jacobs – whistleblowers**

United States ex rel. Singh v. Bradford Regional Medical Center

The Facts

- Prior to 2001, Drs. Vaccaro and Saleh were a significant source of referrals to Hospital, including referrals for imaging performed on Hospital's nuclear camera.
- In 2001 Drs. V&S explore idea of obtaining nuclear and installing it in their office.
- Hospital becomes concerned about potential negative effect on Hospital's financial position and on Hospital's ability to recruit cardiologist.

United States ex rel. Singh v. Bradford Regional Medical Center

The Facts (cont'd)

- Hospital meets several times with Drs. V&S and discusses idea of a Joint Venture. Drs. V&S decide to go ahead with obtaining nuclear camera.
- June 2001 – Drs. V&S, through their GP, V&S Medical Associates, LLC, enter into a 63-month lease with GE for a nuclear camera. Drs. V&S give GE personal guarantees.
- Meanwhile, Hospital adopts Policy on Physicians with Competing Financial Interests – physician with financial interest in a competing entity that might have significant impact on Hospital would be ineligible for staff privileges at the Hospital.

United States ex rel. Singh v. Bradford Regional Medical Center

The Facts (cont'd)

- Upon acquiring nuclear camera, Drs. V&S stop referring to Hospital for nuclear imaging – do not change their referral practices to Hospital for inpatients and other outpatient procedures.
- In May 2002 Hospital informs Drs. V&S that by operating their own nuclear camera they have significant competing interest and could lose their staff privileges
- June 2002, Hospital proposes “under arrangements” JV. The JV is offered to all physicians on medical staff, whereby diagnostic center would perform nuclear imaging, and other procedures such as CT, MRI, and Hospital would bill for them. Hospital would pay diagnostic center a fixed fee per procedure.

United States ex rel. Singh v. Bradford Regional Medical Center

The Facts (cont'd)

- In early 2003 parties begin discussing an alternative to the under arrangements JV, namely, a sublease by Hospital of the nuclear camera leased by Drs. V&S from GE.
- In April 2003 parties enter into an Agreement to enter into a sublease. Under sublease agreement, Hospital would sublease the GE camera from V&S Medical Associates, LLC (Group Practice or GP) to provide tests to patients of Hospital. Group Practice, LLC would agree to a covenant not to compete for the term of the sublease agreement.
- April – Sept 2003 parties negotiate final terms of sublease agreement. Group Practice provides Hospital with data on use of GE nuclear camera.

United States ex rel. Singh v. Bradford Regional Medical Center

The Facts (cont'd)

- Before entering into sublease agreement, Hospital has FMV analysis performed by accountant, Charles Day. To perform FMV analysis, Mr. Day compared Hospital's expected revenues with sublease in place to expected revenues without sublease in place. Hospital estimated that it would generate \$402,000 in profit from referrals from Group Practice if parties entered into sublease.
- October 1, 2003 –parties enter into Sublease Agreement. Hospital to pay Group Practice \$6,545 per month for camera (the amount Group Practice owes GE under Lease Agreement). Hospital also agrees to pay Group Practice \$23,655 per month for all other rights under Sublease including covenant not to compete.

United States ex rel. Singh v. Bradford Regional Medical Center

The Facts (cont'd)

- Sublease Agreement provides that if the “under arrangements” JV is implemented, the Sublease would automatically terminate. Sublease provides that Drs. V&S would not own or operate competing nuclear imaging equipment w/in 30 miles of Hospital, and would not provide other outpatient diagnostic imaging w/in 30 miles of Hospital while proposed JV is under consideration.
- Hospital executive says he would not have entered into Sublease if he knew that Hospital would not receive any referrals from Drs. V&S.
- Sublease provides that GE camera would be delivered to Hospital, but camera stayed in Group Practice space. Hospital paid \$2500 month rent , and payments for secretarial and other admin. expenses. Hospital also paid billing fee of 10% of collections.

United States ex rel. Singh v. Bradford Regional Medical Center

The Facts (cont'd)

- April 2004 – GP enters into a 5-year lease with Philips Medical for a nuclear camera. Philips buys out GE lease for \$200,000. Group Practice agrees to pay Philips for the buyout in 60 monthly installments. Lease specifies that camera will be located at Hospital. Hospital executes a guaranty of Group Practice's obligation under the lease. Hospital reimburses Group Practice for Group Practice's payments under the Philips lease, and for Group Practice's payments to Philips for buyout of GE lease, and Hospital also pays Group Practice \$2,300 per month for a Philips service agreement.

United States ex rel. Singh v. Bradford Regional Medical Center

Steps in Court's Analysis

1. Is there a Direct Compensation Arrangement? (Yes, says the court)
2. Is there an Indirect Compensation Arrangement? (Yes, says the court)
3. Does an Exception Apply? (No, says the court – Not FMV, No written agreement)
4. Is Stark Violated? (Yes, say the court)
5. Is Stark Knowingly Violated? (Maybe, says the court – sets the issue for trial)
6. Is the Anti-Kickback Statute Violated? (Maybe, says the court – sets the issue for trial)
7. Is the False Claims Act Violated (Maybe, says the court – sets the issue for trial)

United States ex rel. Singh v. Bradford Regional Medical Center

Court's Stark Analysis

1. Is there a Direct Compensation Arrangement?
(Yes, says the court)
 - Drs. V&S signed the sublease in their individual capacities and benefited significantly from the arrangement.
 - “Stand in the shoes doctrine” applies to sublease arrangement as of 12/07 and arrangement does not qualify for the grandfathering provision.
 - Relators fail to show that personal service contracts created a direct compensation arrangement.
 - “Mere fact that the doctors had separate personal service contracts with the hospital is insufficient to show a direct financial relationship that would fall within the Stark Act” (!!)

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2. Is there an Indirect Compensation Arrangement? (Yes, says the court)

- Generally, in order for there to be an “indirect compensation arrangement,” as defined at §411.354, the physician must receive aggregate compensation from the person or entity with which the physician has a direct compensation relationship that varies with, or otherwise reflects, volume or value of referrals to entity providing DHS.
- Physician ----- Group Practice ----- DHS Entity

United States ex rel. Singh v. Bradford Regional Medical Center

Definition of Indirect Compensation

- Because Drs. Vaccaro and Saleh had ownership interest in V&S, court believes certain language in definition of indirect compensation arrangement is implicated.
- “If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member.)”
§411.354(c)

United States ex rel. Singh v. Bradford Regional Medical Center

Definition of Indirect Compensation

- Based on its reading of the definition, the court looks at the compensation relationship between V&S and the Hospital.
- It chooses this relationship over the compensation relationship between Drs. Vacarro and Saleh and their group practice, V&S.
 - Court's either/or approach is incorrect but makes no difference in this case.

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Indirect Compensation Analysis (cont'd)

- Court addresses question of whether compensation to GP under Sublease did in fact take into account or reflect anticipated referrals.
- Court agreed with Relators that anticipated referrals is a proper basis for satisfying this requirement.
 - Court looked at how appraiser Day valued the covenant not to compete in his FMV analysis of the Sublease. Day indicated his analysis was based on assumption that Drs. V&S would likely refer to the Hospital in the absence of a financial interest in their own facilities, even though the Sublease did not require referrals to Hospital. Court noted Hospital relied on the Day appraisal. Hospital exec testified that purpose of non-compete was to make sure Drs. V&S did not have financial incentive to refer away from Hospital.

United States ex rel. Singh v. Bradford Regional Medical Center

Indirect Compensation Analysis (cont'd)

- Court focused on non-compete clause rather than rental payments and other compensation.

“It is clear that the hospital and the doctors entered into an agreement that was fair for each party. The significant exchange here is the non-compete payments that would require the doctors to not engage in the nuclear camera business. [FMV] to the doctors to get out of the nuclear camera business was roughly the amount of money they would make by staying in the business and referring their patients to their own camera. Similarly, to the hospital [FMV] to pay the doctors to get out of the nuclear camera business was roughly the amount of money they would expect to gain from the doctors no longer referring their patients to their own camera; which amount, unsurprisingly, is in the neighborhood of the business that would potentially be generated by the doctors referring their patients to the hospital for nuclear camera work.

While Defendants argue that there was a back and forth negotiation and that the non-compete agreement does not require the doctors to refer to BRMC, the amount of the non-compete payments took into account, in the common sense understanding of that phrase, the amount of referrals the hospital expected to gain from the doctors. There really is no dispute that the amount of the non-compete payments was arrived at by considering the amount of business BRMC would receive from the doctors. “

**Instead of wrapping up its Indirect
Compensation Arrangement
Analysis, the Court takes a wrong
turn and keeps on going . . .**

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Indirect Compensation Analysis (cont'd)

- Court introduces FMV analysis into question of whether compensation takes into account volume or value of referrals.
- First, the court says “Defendants’ primary response to Relators’ argument [that the compensation arrangement took into account the volume or value of referrals] is that Relators have failed to show . . . that the compensation arrangement is not fair market value.”
 - QUESTION: How does fact that compensation is or is not FMV show that compensation did or did not take into account or otherwise reflect volume or value of referrals or other business generated between the parties?

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Indirect Compensation Analysis (cont'd)

- Hospital and Drs. V&S argued there is a “bright line rule” for when compensation does not take into account volume or value of referrals:

“A compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the arrangement in any manner that takes into account referrals or other business generated.”

Phase I, 66 Fed. Reg. at 877-88.

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Indirect Compensation Analysis (cont'd)

- What does fixed in advance have to do with V or V of referrals?
- What does FMV have to do with V or V of referrals?
- Does the “rule” deem certain fixed compensation arrangements to not take into account volume or value of referrals regardless of intent, and does it have legal force?

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Indirect Compensation Analysis (cont'd)

“Bright line rule”

- Example 1 - GP has been renting space in an MOB owned by Hospital for years, and the lease calls for a 3% increase each year. The present rent is \$22 per square foot. GP persuades Hospital that, in consideration of their long relationship and the fact that GP refers most of its patients to Hospital instead of Hospital's competitor, rent should stay the same; in fact, after thinking it over further, GP persuades Hospital to reduce the rent to \$20 per square foot. Hospital agrees and the parties enter into a new lease for \$20 per square foot. Unbeknownst to the parties, due to poor economic times and a glut of space on the market, the FMV of space in the MOB is between \$19 - \$21 per square foot, and the experts agree this is not likely to change anytime soon.
- Is comp set in advance? Is comp FMV?
- Does comp take into account V or V of referrals?

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Indirect Compensation Analysis (cont'd)

“Bright line rule”

- Example 2 - Hospital and GP enter into a lease transaction. Parties agree that the price per square foot will be between \$15 and \$20 for the entire term, that the beginning rent will be \$18 per sq ft and that as soon as they can get an appraisal they will make any necessary adjustments. Two months after signing the lease the parties get the results of an appraisal, which (correctly) is that FMV is between \$21 and \$24 per sq ft. Parties don't take appraiser's advice and set the sq ft rental amount at \$20. The rental amount stays fixed at \$20 sq ft, and GP's referral patterns (which historically has been to send 30% of its patients to Hospital and the other 70% to two other local hospitals, has not changed.
- Is comp set in advance? Is comp FMV?
- Does comp take into account V or V of referrals?

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Indirect Compensation Analysis (cont'd)

- The Relators argued that (1) FMV should not be addressed until the analysis turns to whether an exception applies and (2) the Hospital and the Drs. V&S had the burden of proving an exception applies.
- Despite saying that the statute and regulations suggest that the Relators are correct that the issue of whether a compensation arrangement is FMV is not considered until the exception stage of the analysis, it proceeded to delve into a FMV analysis.
- Court concluded that the defendants bore the burden of proving an exception applied, based on *Kosenske* (3d Cir) case.
 - Is *Kosenske* at odds with language of False Claims Act that says plaintiff must prove all essential elements of cause of action?

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Indirect Compensation Analysis (cont'd)

- **The court quotes the definition of FMV at 42 CFR 411.351 and concludes that an arrangement that takes into account the volume or value of referrals necessarily is not fair market value**
 - “[W]e find that the amount of the compensation arrangement was arrived at by taking into account the anticipated referrals from the doctors. *We therefore conclude that the compensation arrangement . . . is not fair market value.*”
 - “a compensation arrangement that takes into account anticipated referrals will necessarily be greater than what would be paid by parties who are not in a position to refer business to each other.”

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Indirect Compensation Analysis (cont'd)

- The court concludes that an arrangement that takes into account the volume or value of referrals necessarily is not FMV, but does it also conclude that an arrangement that is not FMV takes into account the volume or value of referrals?
- “In conclusion, we find that Relators have established that the aggregate compensation received by the doctors takes into account the volume or value of anticipated referrals generated by the doctors for BRMC.”
 - Is that conclusion based only on the court’s discussion of the reason for the non-compete or is it also based on the court’s conclusion that the compensation was not FMV???

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3. Does an Exception Apply to the Sublease Arrangement?

- No, says the court, because the arrangement was not FMV.
- No, says the court, because each of the exceptions has a writing requirement that was not satisfied.
 - Court does not buy Hospital's argument that the October 2, 2003 letter was a sufficient writing signed by the parties.
 - Disconnect between the October 2 letter and subsequent October statement

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4. Is Stark Violated?

- **Yes, says the court because claims were submitted.**
 - Court declines to make any finding on damages, but issues a separate briefing schedule to address the damages issue.
 - What damages? There is no private right of action for the enforcement of Stark. There are potentially damages under the False Claims Act, which *does* have a private right of enforcement. Is this what the court is referring to? If so, why does the court set the issue of whether there is a knowing Stark violation for trial (see below) but set a briefing schedule (presumably in advance of the trial) for damages?

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5. Is Stark Knowingly Violated?

- Maybe, says the court and refers to its Anti-Kickback Statute analysis.

6. Is the Anti-Kickback Statute Violated?

- Maybe, says the court.
 - “While we have found that the record evidence establishes that Defendants ‘took into account’ the value or volume of referrals for purposes of the Stark Act, we are unable to conclude as a matter of law that Defendants ‘knowingly and willfully’ paid and received remuneration under the sublease and other arrangements for referrals of services.”
 - an arrangement by itself does not establish an AKS violation
 - “A fact finder viewing this evidence could conclude that Dr. Vaccaro and Dr. Saleh did not knowingly and willfully solicit or receive remuneration from BRMC for referrals and that BRMC did not knowingly and willfully offer or pay remuneration to the doctors for referrals.”
 - “In light of the record evidence, Defendants will have a difficult challenge to prove to the fact-finder that they did not have the requisite intent.”

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7. Is the False Claims Act Violated?

- **Maybe, says the court**

- “[A] fact-finder could . . . believe that Defendants could not have acted ‘knowingly’ based on the fact that they carefully sought to avoid requiring referrals and attempted to make a business decision based on the fair market value assessment of the arrangements.”
- “[T]he record evidence is not strongly in favor of Defendants as it tends to show that Defendants entered into the Equipment Sublease fully aware that the arrangement, which had at its core a non-compete payment roughly equal to the referral business BRMC would gain from the doctors and the business V&S would lose from abandoning its own camera, may not be permitted under the Stark Act and Anti-Kickback Act.”

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- **What does *Bradford* mean for future cases involving FMV issues?**
 - As a district court decision, it has no precedential value *per se*, but as there are few Stark decisions it may be relied upon by other courts (and not just those in Pennsylvania).
 - May have an effect on future decisions involving non-competes and economic credentialing.
 - Does Bradford, regardless of the errors in the court's decision, provide a good indication of how other courts would approach arrangements that may appear to take into account volume or value of referrals?

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- **What does *Bradford* mean for sales of physician practices?**
 - In arriving at a FMV analysis of the worth of the practice, can one ignore the past referral history?
- **What does *Bradford* mean for physician recruitment arrangements?**
 - Hospitals hope and expect to get referrals from recruited physicians.
 - Some recruitment agreements forbid recruited physician from competing with the hospital.

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- **Valuation reports:**
- **Charles T. Day, CPA** – Prepared a valuation report as of the inception of the arrangement
- **James H. Jordon, CFA, ASA (Deloitte)** – Retained expert for the defendants
- **Sal Barbera** – Retained expert for the plaintiffs

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Observations regarding Mr. Day's report:

- 18 pages in length
- The vast majority of the report is “narrative,” with ½ of one page devoted to financial analysis supporting the FMV of the non-compete (of \$284,000 per year).
- The non-compete analysis encompassed a “with and without competition” financial analysis.
- Components of this analysis included consideration of CT/MRI revenues/expenses, as well as inpatient and outpatient revenues.

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- **Observations regarding Mr. Day's report (cont):**
- At the inception of the agreement, V&S did not provide CT/MRI services, but were *considering* such services.
- The report has a significant emphasis on Mr. Day's perception of IRS guidance related to valuations.
- There is no apparent consideration given to the valuation implications of healthcare regulations.
- Mr. Day utilizes an 18% discount rate "as would be required by the Internal Revenue Service..."

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- **Observations regarding Mr. Jordon’s report:**
- Mr. Jordon also utilizes a “with and without competition” approach.
- Of the revenues considered by Mr. Jordon, 60% relate to services areas not currently offered by V&S (*i.e.*, CT and MRI).
- Mr. Jordon characterizes the odds of V&S competing in CT and MRI as 100% (since they were already competing with respect to nuclear medicine).
- The valuation issues were complex, consisting of an equipment lease, a space lease, management services, costs of equipment relocation, payment for a non-compete, a first right of refusal, and considerations for an under arrangement.