

# Valuation of Physician Contracts and Structuring Physician Compensation—Insights from Recent Judicial Precedent

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*Health care reform continues to motivate health care service providers to establish relationships that enhance or expand medical service capabilities and capacity. Many times, the relationships established include transactions that result in service contracts between physicians and health systems. When the relationships are established, the contracting parties should be sure that the arrangements comply with federal regulations, including the federal Anti-Kickback Statute and the federal Self-Referral Law (i.e., Stark Law). Judicial decisions provided in the matters of Singh, M.D. v. Bradford Regional Medical Center and Drakeford, M.D. v. Tuomey Healthcare System, Incorporated, provide insights with regard to establishing acceptable compensation arrangements between health systems and physicians.*

## INTRODUCTION

Health care providers must structure compensation arrangements with referring parties so that these arrangements do not violate the federal Anti-Kickback Statute and the federal Self-Referral Law (the Stark Law).

The federal Anti-Kickback Statute prohibits individuals or entities from knowingly and willfully offering, paying, or receiving remuneration to induce referrals of items or services covered by Medicare, Medicaid, or any other federally funded program.

The federal Self-Referral Law prohibits a physician from referring patients for certain health services to an entity with which the physician or physician's immediate family member has a financial relationship. In addition, the Stark Law prohibits any entity from billing any individual, Medicare, or other payor for designated health services furnished pursuant to a prohibited referral.

Almost any financial arrangement between referring parties requires an analysis by a qualified advis-

er to ensure that it is not in violation of the federal Anti-Kickback Statute or the federal Self-Referral Law. Violations of the federal Anti-Kickback Statute may result in civil and criminal fines, imprisonment, and exclusion from Medicare. Violations of the federal Self-Referral Law may result in civil fines and exclusion from Medicare.

This discussion presents a summary of: (1) the federal Anti-Kickback Statute, (2) the federal Self-Referral Law, and (3) two recent judicial decisions that deal with violations of the federal Anti-Kickback Statute and the federal Self-Referral Law.

## FEDERAL ANTI-KICKBACK STATUTE 42 U.S.C. SECTION 1320A- 7(B) AND 42 C.F.R. SECTION 1001.952

The federal Anti-Kickback Statute prohibits individuals or entities from knowingly and willfully offering, paying, or receiving remuneration to

induce referrals of items or services covered by Medicare, Medicaid, or any other federally funded program.

According to the federal Anti-Kickback Statute, 42 U.S.C. Section 1320a-7b(b), it is illegal to

1. knowingly and willfully solicit or receive any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind
  - a. in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or
  - b. in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program.
2. knowingly and willfully offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person
  - a. to refer an individual to a person for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or
  - b. to purchase, lease, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program.

Based on the broad definition of the federal Anti-Kickback Statute, almost any financial arrangement between referring parties requires an analysis by a qualified adviser to ensure that it is not in violation of the federal Anti-Kickback Statute.

Health care providers should ensure that investment and compensation arrangements between referring parties are properly structured

1. to avoid paying greater than fair market value for services or items and
2. to avoid the inference that the payment for services or items is for referrals.

Violations of the federal Anti-Kickback Statute may result in both civil and criminal fines, imprisonment, and exclusion from Medicare reimbursement, unless the transaction fits within a regulatory safe harbor.

## **FEDERAL SELF-REFERRAL LAW 42 U.S.C. SECTION 1395NN AND 42 C.F.R. SECTION 411.351 ET SEQ.**

The federal Self-Referral Law prohibits a physician from referring patients for certain health services to an entity with which the physician or physician's immediate family member has a financial relationship. In addition, the Stark Law prohibits any entity from billing any individual, Medicare, or other payor for designated health services furnished pursuant to a prohibited referral.

According to the federal Self-Referral Law, 42 U.S.C. Section 1395nn,

1. if a physician (or an immediate family member of such physician) has a financial relationship with an entity,<sup>1</sup> the physician may not make a referral to the entity for the furnishing of designated health services, and
2. the entity may not bill any individual, third-party payor, or other entity for designated health care services furnished pursuant to a referral prohibited above.

The federal Self-Referral Law generally requires that remuneration under any compensation arrangement with a referring physician be (1) set in advance, (2) consistent with fair market value, and (3) not determined in a way that takes into account the volume or value of referrals or other business generated.

Fair market value is defined as compensation that "has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals."<sup>2</sup>

Violations of the federal Self-Referral Law may result in civil fines and exclusion from Medicare reimbursement unless the transaction fits within a regulatory safe harbor.

## RECENT JUDICIAL PRECEDENT

### *Singh, M.D. v. Bradford Regional Medical Center*

#### Introduction

In *Singh, M.D. v. Bradford Regional Medical Center*,<sup>3</sup> the plaintiffs brought a qui tam action under the False Claims Act against Bradford Regional Medical Center (BRMC), two physicians who made referrals to BRMC, and the physician's limited liability company. The plaintiffs claimed that the defendants presented false claims to Medicare in violation of the Stark Act and the Anti-Kickback Act.

#### The Facts of the Case

The defendant BRMC was a nonprofit corporation that owned and operated a hospital in Bradford, Pennsylvania. The hospital provided inpatient and outpatient hospital services to residents of McKean County and the surrounding areas.

Defendants Drs. Saleh and Vaccaro specialized in the practice of internal medicine in Bradford, Pennsylvania. Prior to April 2000, Drs. Vaccaro and Saleh were employed by BRMC. In April 2000, the physicians purchased their practice from BRMC and formed V & S Medical Associates, LLC (V&S).

Defendant V&S is a limited liability company, owned equally by Drs. Saleh and Vaccaro. Drs. Saleh and Vaccaro were also members of the medical staff of BRMC.

The plaintiffs included Drs. Singh, Kirsch, Nadella, and Jacobs. These plaintiffs were all physicians who practiced in Bradford, Pennsylvania, and were members of the medical staff of BRMC. And, these plaintiffs provided the same or similar services as Drs. Saleh and Vaccaro.

Before 2001, Drs. Vaccaro and Saleh referred a significant number of patients to BRMC, including patients who received inpatient and outpatient diagnostic procedures performed on a nuclear imaging camera located at BRMC.

In early 2001, V&S developed a plan to obtain a nuclear imaging camera and install it in its office to allow the company to perform nuclear imaging tests in-house instead of referring the tests to BRMC.

The BRMC chief executive officer learned of these plans in March 2001 and asked his staff to investigate what the financial impact on BRMC would be if this occurred.

The CEO learned (1) that V&S ordered 42.5 percent of the hospital's nuclear studies and (2) that the annual BRMC gross nuclear medicine revenue was approximately \$2.8 million.

Because V&S was such a major referral source to the hospital, the CEO was concerned that if V&S acquired a nuclear camera, this would have a very detrimental impact on the BRMC attempt to establish a cardiology service.

This is because if cardiology diagnostic services were offered in the offices of internal medicine physicians such as V&S, these services would not be available to support the work that cardiologists would perform at the hospital.

Between April 3, 2001, and June 1, 2001, the CEO met with Drs. Vacaro and Saleh and discussed the possibility of entering into a joint venture within the Safe Harbor exceptions to the Stark Law. However, despite these negotiations, V&S decided to proceed with the plan to acquire a nuclear imaging camera.

In May 2001, BRMC adopted a policy providing that if a physician had a financial relationship with a competing health care entity that may have a significant impact on the hospital, that physician would be ineligible for hospital privileges.

In June 2001, V&S entered into a 63-month lease with General Electric (GE) for a nuclear camera. The camera was located at the V&S offices, and Drs. Vacaro and Saleh personally guaranteed the lease.

BRMC threatened Drs. Vacaro and Saleh with the loss of medical staff privileges, alleging that the acquisition of a nuclear camera violated its policy on physicians with competing financial interests.

In the course of discussions regarding possible solutions to the dispute and the enforceability of



the BRMC policy on physicians with competing financial interests, BRMC and V&S resolved the differences by entering into a sublease arrangement.

On April 16, 2003, the parties entered into an agreement providing that the parties would enter into a sublease agreement for the nuclear camera. The sublease agreement provided that BRMC would sublease the GE equipment from V&S, and then use the GE equipment to provide diagnostic tests for BRMC patients.

V&S would also enter into a covenant not to compete agreement with the provision of nuclear cardiology services by BRMC for the sublease agreement term.

Before entering into the final sublease agreement, BRMC obtained a report prepared by an accountant to determine whether BRMC was paying fair market value under the proposed sublease arrangement. The accountant concluded that the amounts to be paid under the sublease were reasonable.

In performing his analysis, the accountant compared (1) the revenue that BRMC expected to receive with the sublease in place to (2) the revenue BRMC expected to receive without the sublease in place.

The revenue projections were based on the expectation that V&S would refer such business to the hospital if the sublease arrangement was approved.

Effective October 1, 2003, BRMC and V&S entered into an equipment sublease for a five-year term expiring on September 30, 2008. The sublease called for BRMC to pay V&S \$6,545 per month. This represented the amount due from V&S to GE for the GE nuclear camera under the V&S lease with GE.

The equipment sublease also called for BRMC to pay V&S \$23,655 per month for all other rights under the equipment sublease, including the covenant not to compete.

Although the sublease stated that the GE camera would be delivered to BRMC, the camera remained at the V&S offices. BRMC paid V&S \$2,500 per month in rent, as well as payments for secretarial and other administrative expenses to keep the camera at the V&S office.

In addition, BRMC paid V&S a billing fee equal to 10 percent of all collections for tests performed on the GE camera. The GE camera was used for four or five months, after which it was not used to perform nuclear tests.

On April 6, 2004, V&S entered into a five-year lease with Phillips Medical Capital LLC (“Phillips”) for a new nuclear camera. In connection with the new lease, Phillips paid approximately \$200,000 to GE as an early termination fee to buy out the GE lease.

V&S agreed to repay this amount in 60 monthly installments of \$3,958.13. BRMC guaranteed the V&S obligation to repay the buyout fee. BRMC and V&S did not sign a formal written lease or agreement reflecting these terms regarding the Phillips nuclear camera.

## The Court’s Opinion

The plaintiffs alleged that the defendants submitted claims to Medicare in violation of the Stark Act and the Anti-Kickback Act.

Both the Stark Act and the Anti-Kickback Act prohibit a health care entity from submitting claims to Medicare based on referrals from physicians who have a financial relationship with the entity, unless a statutory or regulatory exception applies.

The plaintiffs alleged that BRMC sought to gain substantial patient referrals for diagnostic nuclear imaging from V&S and Drs. Vacaro and Saleh. Drs. Vacaro and Saleh had a history of referring patients to BRMC for nuclear imaging until they purchased the nuclear camera. With their own nuclear camera, they no longer needed to refer patients to BRMC for imaging.

The plaintiffs claimed that the sublease agreement was designed so that BRMC would obtain patient referrals from V&S and Drs. Vacaro and Saleh in return for payments in violation of the law.

The defendants denied that their arrangement was unlawful. The defendants explained that their arrangements were a reasonable and fair resolution to the dispute, and they did not require Drs. Vacaro and Saleh to refer patients to BRMC.

The defendants contended that the sublease did not meet the definition of a prohibited direct or indirect financial relationship as defined in 42 C.F.R. Section 411.354(c)(2).

The plaintiffs alleged that the compensation paid by BRMC to V&S took into account patient referrals. In consideration of this argument, the court analyzed the accountant’s report.

In the report, the accountant noted that BRMC wanted a covenant not to compete associated with the sublease to protect three revenue streams:

1. CT and MRI revenue
2. Inpatient net revenue
3. Outpatient net revenue

In the valuation of the covenant not to compete, the accountant presented an exhibit comparing the expected BRMC revenue with the covenant not to compete and the expected BRMC revenue without the covenant not to compete.

In the report, the accountant noted that the data was based on the assumption that the physicians likely would refer these patients to BRMC in the absence of a financial interest in their own facilities or services, although they were not required to do so.

Therefore, the court concluded that the accountant's report was based, in part, on anticipated patient referrals from Drs. Vacaro and Saleh. In addition, BRMC management confirmed in trial testimony that the accountant's report evaluated expected revenue based on the assumption that the defendants would likely refer the business to BRMC.

The BRMC CEO testified that "the purpose of the non-compete . . . was to make sure that [Drs. Vacaro and Saleh] didn't have a financial incentive to refer away from the hospital."

The court also noted that the amount of the monthly noncompete payments was equal to the V&S anticipated profits from the operation of the nuclear camera. Therefore, the starting point for the negotiations between BRMC and V&S was the amount of business V&S thought it could generate for BRMC.

And, the only way the proposed amount of business could be generated by BRMC was if V&S referred the business to BRMC after BRMC leased the GE camera.

The defendants alleged, among other things, that the compensation from the arrangement did not vary or take into account the volume or value of referrals from Drs. Vacaro and Saleh.

In addition, the defendants argued that even if the arrangement did meet the definition of a "financial relationship," it is still permitted since it falls within a statutory or regulatory exception.

The defendants argued that, despite this evidence, the compensation under the sublease agreement met the "bright-line" rule<sup>4</sup> for determining whether compensation takes into account referrals under the Stark Law.

In addition, the defendants submitted an expert report that concluded that the compensation amounts of the noncompete payments was approximately equal to the amount of business the doctors would refer to BRMC. Therefore, the expert concluded that the amounts exchanged by the parties reflected the fair market value.

The court analyzed the "bright-line" rule and found that it did not provide a "bright line" with respect to establishing fair market value. The court concluded that the compensation arrangement between BRMC and Drs. Vacaro and Saleh was inflated to compensate for the doctors' ability to generate other revenue for BRMC.

Specifically, the court found that the amount of the compensation arrangement was derived by taking into account the anticipated referrals from Drs. Vacaro and Saleh. Therefore, the court concluded that the compensation arrangement between BRMC and Drs. Vacaro and Saleh was not fair market value under the Stark Act.

The court also ruled that (1) the 10 percent collection fee arrangement between BRMC and V&S varied with the volume or value of the referrals generated by Drs. Vacaro and Saleh for BRMC and (2) BRMC was aware of the fact that the 10 percent fee it paid to V&S varied with the amount of the referrals.

Therefore, the 10 percent billing fee arrangement constituted an indirect compensation arrangement between the parties.

The defendants also argued that their compensation arrangements (1) qualify for protection under the indirect compensation arrangement exception and (2) fit within a safe harbor provision of the Anti-Kickback Act.

However, the court found that direct compensation arrangements existed between BRMC and Drs. Vacaro and Saleh because

1. the physicians personally signed the sublease agreement with BRMC,
2. in connection with the GE lease buyout, BRMC guaranteed the payments for which the physicians had a personal liability, and
3. BRMC paid \$200,000 for the GE lease buyout.

The court stated that BRMC relieved the physicians of a personal liability, and that this was a substantial benefit that qualified as remuneration to the physicians under the Stark Law.

In addition, the court found that the compensation arrangements did not fit within a safe harbor provision of the Anti-Kickback Act. This is because

1. compensation was determined in a manner that took into account the volume or value of referrals, and therefore, was not fair market value, and
2. some of the actual arrangements between the parties (e.g., the GE nuclear camera was operated out of the V&S office) were not formalized in writing.



The court also stated that, as a matter of law, it could not determine whether the defendants acted with the requisite intent for purposes of determining whether Anti-Kickback Statute and False Claims Act violations occurred. Therefore, the court deferred ruling on damages until a later date.

## *Drakeford, M.D. v. Tuomey Healthcare System, Incorporated*

### **Introduction**

In *Drakeford, M.D. v. Tuomey Healthcare System, Incorporated*,<sup>5</sup> Drakeford filed a qui tam lawsuit in October 2005, alleging that compensation arrangements between a hospital and certain physicians violated the Stark Law.

In 2007, the United States intervened and sought relief under the False Claims Act as to the issue of whether the hospital submitted false claims as a result of the physician contracts. In a March 2010 jury trial, the jury found that the hospital violated the Stark Law but did not violate the False Claims Act.

On July 13, 2010, the District Court found that the hospital violated the Stark Law and entered a judgment indicating that the United States should recover substantial damages. On July 16, 2010, the hospital filed an appeal.

### **The Facts of the Case**

Tuomey Healthcare System, Inc. (Tuomey) was a private, nonprofit South Carolina corporation. It owned and operated Tuomey Hospital, located in Sumter County, South Carolina. Tuomey Hospital provided inpatient and outpatient health care services.

A majority of the physicians who provided medical services at Tuomey Hospital were not employed

by Tuomey Hospital. Rather, they practiced medicine through specialty physician groups organized as professional corporations.

Members of the Sumter County's gastroenterology specialty group informed Tuomey Hospital in early 2003 that they were considering performing outpatient surgical procedures in their offices, as opposed to at Tuomey Hospital. In addition, other specialty physician groups that performed outpatient procedures at Tuomey Hospital were also considering whether to relocate these procedures.

The loss of these procedures would result in serious financial problems for Tuomey Hospital. Therefore, Tuomey Hospital began negotiations with several specialist physicians in 2004 and 2005 to perform outpatient procedures solely at Tuomey Hospital.

One of these physicians was Dr. Michael Drakeford (Drakeford), an orthopedic surgeon with whom negotiations unsuccessfully ended in 2005.

From 2005 to 2006, Tuomey Hospital entered into compensation contracts with 19 specialist physicians. All 19 contracts generally included the same terms. Each contract specified that the physicians were required to perform outpatient procedures only at Tuomey facilities.

In addition, the contracts (1) specified that Tuomey was responsible for billing and collections from patient and third-party payers, and (2) reassigned to Tuomey all benefits payable to the physicians by third-party payers (including Medicare and Medicaid).

Tuomey agreed to pay the physicians the following:

1. Annual base salaries that fluctuated based on Tuomey's outpatient procedure net cash collections
2. Productivity bonuses equal to 80 percent of the net cash collections
3. Incentive bonuses that could total up to 7 percent of the productivity bonuses

Each contract had a ten-year term and provided that the specialist physicians would not compete with Tuomey during the contract term and for two years after the contract ended.

After entering into the compensation agreements, the specialist physicians performed outpatient procedures at Tuomey facilities. These procedures generated two billings:

1. A professional fee for the physician for his or her services (the professional component)

2. A facility fee for Tuomey providing the space, the nurses, the equipment, etc. (the facilities or technical component)

After the procedures were completed, Tuomey submitted claims for reimbursement for both the professional and facilities component to third-party payers, including Medicare and Medicaid.

In October 2005, Drakeford filed a *qui tam* lawsuit alleging that these compensation arrangements violated the Stark Law. In 2007, the United States intervened and sought relief under the False Claims Act as to the issue of whether Tuomey submitted false claims as a result of the physician contracts.

In a March 2010 jury trial, the jury found that Tuomey violated the Stark Law but did not violate the False Claims Act. Subsequent to the jury's verdict, the parties made several post-verdict motions.

On July 13, 2010, the District Court granted the U.S. government's motion for a new trial on the issue of liability under the False Claims Act. And, the District Court judge found that Tuomey violated the Stark Law and entered a judgment indicating that the United States should recover \$44.9 million from Tuomey plus pre-and post-judgment interest regarding counts IV and V of its complaint.

On July 16, 2010, Tuomey filed an appeal contending that the District Court violated its 7th Amendment rights by basing its judgment with respect to the equitable claims on the jury's interrogatory answer regarding the Stark Law, even though the District Court had already set aside the jury's verdict in its entirety.

## The Fourth Circuit Court of Appeals Opinion

In its March 30, 2012, opinion, the Fourth Circuit Court vacated the District Court's July 13, 2010, judgment, and remanded the case to the District Court for a new jury trial. The Fourth Circuit Court concluded that the District Court's judgment in favor of the United States violated Tuomey's 7th Amendment right to a jury trial because the verdict had been set aside.

In arriving at its decision, the Fourth Circuit Court (1) addressed whether the facility component of the services performed by the physicians constituted a referral within the meaning of the Stark Law and (2) examined whether the contracts implicated the volume or value standard under the Stark Law.

The Fourth Circuit Court concluded that the facility component of the services performed by the physicians constituted a referral under the Stark Law.

Therefore, the claims for facility fees based on patient referrals were prohibited under the Stark Law.

Next, the Fourth Circuit Court examined the question of whether the contracts implicated the Stark Law volume or value standard. The regulatory definition of indirect compensation arrangement requires that the aggregate compensation received by the physician varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician.

The U.S. government contended that Tuomey's conduct fit within this definition because it included a portion of the value of the anticipated facility component referrals in the physicians' fixed compensation.

The Fourth Circuit Court began its analysis of this issue by citing the regulatory definition of fair market value, noting that this definition requires that compensation "has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals."<sup>6</sup>

The Fourth Circuit Court concluded that compensation based on the volume or value of anticipated referrals implicates the volume or value standard.

The Stark Law seeks to ensure that hospitals and other health care providers compensate physicians only for the work or services they actually perform, not for their ability to generate other revenue for the provider through referrals.

The Fourth Circuit Court stated that if a hospital provides fixed compensation to a physician that is not based solely on the value of services the physician is expected to perform, but also takes into account additional revenue the hospital anticipates will result from the physician's referrals, that this compensation takes into account the volume or value of these referrals.

These arrangements, though, do not necessarily violate the Stark Law, provided that certain conditions are met (one of which is that the physician's compensation must not take into account the volume or value of anticipated referrals).

Therefore, the Fourth Circuit Court vacated the District Court's judgment, and remanded the case to the District Court for a new jury trial. The Fourth Circuit Court stated that the question that should be put before the jury is whether the physician contracts took into account the value or volume of anticipated referrals.

As the Stark Law indicates, compensation arrangements that take into account anticipated referrals do not meet the fair market value standard. Therefore, the jury must determine whether the physician contracts violated the fair market value standard by taking into account anticipated referrals in computing the physicians' compensation.

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## “Compensation should . . . be equal to the amount that the health care provider would pay to an entity that is not in a position to provide patient referrals.”

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### SUMMARY AND CONCLUSION

This discussion presented a summary of the following:

1. The federal Anti-Kickback Statute
2. The federal Self-Referral Law
3. Two recent judicial decisions that have dealt with violations of the federal Anti-Kickback Statute and the federal Self-Referral Law

Insights from the *Bradford* decision include the following:

1. Any valuation report regarding the valuation of a compensation arrangement between health care providers and referring parties that considers anticipated referrals in arriving at its valuation conclusion may be subject to challenge.

In the *Bradford* decision, the court was critical of the expert report presenting the fair market value of the covenant not to compete. This is because the expert report conclusion was based, in part, on anticipated patient referrals from Drs. Vacaro and Saleh.

2. Any valuation report prepared in connection with a compensation relationship between health care providers and referring parties should be prepared based on the definition of fair market value under the Stark Law.

Fair market value is defined in the Stark Law as compensation that “has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.”<sup>7</sup>

Compensation should therefore be equal to the amount that the health care provider would pay to an entity that is not in a position to provide patient referrals.

3. The details of compensation arrangements between health care providers and referring parties should be documented in writing.

The court in *Bradford* concluded that the compensation arrangements did not fit within a safe harbor provision of the Anti-Kickback Act because some of the actual arrangements were not formalized in writing.

Insights from the *Tuomey* decision include the following:

1. Even compensation arrangements between health care providers and referring parties that involve only the provision of personally performed inpatient or outpatient services should be analyzed by qualified advisers to ensure that the arrangements do not violate the Stark Law.

This is because, as the Fourth Circuit Court noted in *Toumey*, although personally performed services do not constitute “referrals” under the Stark Law, these personally performed professional services generate a “referral” of the technical component of hospital services (providing the facility space, nurses, equipment, etc.).

2. In structuring compensation arrangements, compensation arrangements between health care providers and referring parties must be based on the fair market value of the services actually being provided by the referring parties.

In addition, health care entities may not compensate referring parties for the volume or value of anticipated referrals.

#### Notes:

1. A financial relationship is defined in the Stark Law as (1) an ownership or investment interest in the entity (through equity, debt, or other means, including an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service), or (2) a compensation arrangement between the physician (or immediate family member) and the entity.
2. 42 C.F.R. § 411.351.
3. *Singh, M.D. v. Bradford Regional Medical Center*, 752 F.Supp.2d 602 (W.D. Penn. 2010).
4. The “bright-line” rule states that “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.” 66 Fed. Reg. 877-878.
5. *Drakeford, M.D. v. Tuomey Healthcare System, Incorporated*, 675 F.3d 394 (4th Cir. 2012), vac’g. and rem’g *Drakeford, M.D. v. Tuomey*, No. 3:05—CV—02858—MJP, 2010 WL4000188 (D.S.C. July 13, 2010).
6. 42 C.F.R. § 411.351.
7. *Ibid.*

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