


AN A.S. PRATT PUBLICATION

FEBRUARY 2016

VOL. 2 • NO. 2



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**GOVERNMENT
CONTRACTING
LAW**
REPORT



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Library of Congress Card Number:

ISBN: 978-1-6328-2705-0 (print)

Cite this publication as:

[author name], [article title], [vol. no.] PRATT’S GOVERNMENT CONTRACTING LAW REPORT [page number] (LexisNexis A.S. Pratt);

Michelle E. Litteken, GAO Holds NASA Exceeded Its Discretion in Protest of FSS Task Order, 1 PRATT’S GOVERNMENT CONTRACTING LAW REPORT 30 (LexisNexis A.S. Pratt)

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An A.S. Pratt® Publication

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Minimizing Exposure to Stark Law Liability in False Claims Act Cases by Isolating Those Who Determine Fair Market Value from Those Who Measure Contribution Margin or Other Similar Operational Data

*By Robert S. Salcido**

The government and relators have collected several hundred million dollars in False Claims Act (“FCA”) judgments or settlements in cases alleging an FCA violation based upon an alleged Stark Law violation. The author of this article discusses the issue and suggests steps health care companies can take to measure whether their financial relationships with physicians are profitable while minimizing exposure to liability under the FCA and Stark Law.

Many recent False Claims Act/Stark law lawsuits and settlements have targeted health care companies’ analysis of “contribution margin,” downstream revenue or similar operational data measuring the value of physician referrals in filing FCA lawsuits.

There are steps health care companies can take to measure whether financial relationships with physicians are profitable (and hence viable) while minimizing exposure to liability under the FCA and Stark Law.

STARK LAW AND FALSE CLAIMS ACT

The FCA has become the primary enforcement vehicle for the Ethics in Patient Referrals Act, better known as the Stark Law. There are now more than 150 public cases citing to both the Stark Law and the FCA.¹ The government and relators have collected several hundred million dollars in FCA judgments or settlements in cases alleging an FCA violation based upon an alleged Stark Law violation.²

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¹ As of October 12, 2015, a simple Lexis search of the phrases “Stark Law” and “False Claims Act” generated 155 cases that used both phrases in the court’s decision.

² For example, in *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 792 F.3d 364

The Stark Law prohibits certain types of health care referrals for designated health services (“DHS”) when a health care entity has a financial relationship with a physician. Services a physician personally performs are not referrals for purposes of the Stark Law. Personally performed professional services are acts that the doctor does for the patient directly, such as performing surgery for which the doctor bills a professional fee. This is distinguished from ancillary services that the physician may refer to the hospital for which the hospital separately bills a facility fee or technical component.

Critical to compliance with the Stark Law is that the payment to the physician be at fair market value (“FMV”). FMV under the Stark Law means that the payment is consistent with “general market value,” which is defined as “compensation that would be included . . . 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.*”³

In addition to FMV, several Stark Law exceptions require that the arrangement be “commercially reasonable.” The government has stated that “an arrangement will be considered ‘commercially reasonable’ in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician . . . of similar scope of specialty even if there were no potential for DHS referrals.”⁴

THE CHALLENGE THE STARK LAW PRESENTS TO THOSE SETTING FMV

To determine FMV and be consistent with the Stark Law’s mandate that market value is determined without reference to other business the physician generated, typically, hospitals compare the physician’s personally performed, professional fee revenue to the expenses associated with providing those services. When measured in this constricted fashion, the analysis typically shows that the health care entity lost money by employing the physician.

(4th Cir. 2015), the 4th Circuit affirmed the district court’s FCA judgment awarding plaintiffs \$237,454,195 (which later settled for more than \$72 million, purportedly based upon Tuomey’s ability to pay). Also, Halifax Hospital Medical Center and Halifax Staffing agreed to pay \$85 million to resolve allegations that they violated the FCA and Stark Law after long-standing litigation construing several provisions of the Stark Law. More recently, the government has consummated other FCA/Stark Law settlements, including one with North Broward Hospital District (“Broward Health”), a special taxing district in Florida, which operates hospitals, for \$69.5 million.

³ See 42 C.F.R. § 411.351(emphasis supplied).

⁴ 69 Fed. Reg. 16,054, 16,093 (Mar. 26, 2004).

Thus, to obtain a more realistic gauge regarding whether the hospital satisfies its costs by entering into a financial relationship with the physician, some hospitals will measure the physician's "contribution margin" by comparing the full amount of revenue obtained by all the services and items the physician referred—that is, revenue stemming from the physician's "downstream activity," such as inpatient admissions, outpatient visits and the provision of ancillary services—that results from the physician's management of the patient revenue to the direct costs associated with these services. Indeed, sophisticated modules exist in the marketplace that purport to measure a physician's contribution margin based upon downstream referrals by integrating hospital and ambulatory data at the patient level. The modules can also measure "leakage," that is, the downstream referrals and associated revenue the physician sends to the hospital's competitors, rather than referring back to the health care entity with which the physician has a financial relationship.

The existence of this data presents a potential problem for the hospital related to Stark Law (and ultimately FCA) compliance, especially regarding highly compensated physicians. This is because the determination of FMV is an art, not a science, and there is a wide range of variation regarding what any physician in any medical specialty should arguably receive as compensation. Compounding this problem is the fact that the government has refused to establish an approved methodology to determine FMV⁵ or commercial reasonableness.⁶

⁵ During Phase II of Stark Law rulemaking, the Center for Medicare and Medicaid Services' ("CMS") Final Rule added to the FMV definition a provision deeming hourly compensation for a physician's personal services to be FMV if the payment is established using either of two specified methodologies. In Phase III, however, CMS eliminated the FMV safe harbor. *See* 72 Fed. Reg. 51,012, 51,015 (Sept. 5, 2007). Although CMS, in the notice and comment rulemaking context, has refused to establish a bright-line methodology to determine FMV, the Department of Justice ("DOJ"), in a litigation context when prosecuting an FCA case based upon an alleged violation of the Stark Law—and seeking treble damages and substantial civil penalties—is not shy about retaining an expert witness who will opine about what is a "correct" methodology to set FMV for purposes of the Stark Law. *See, e.g., in United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No. 6:09-cv-1002 (M.D. Fla.), government expert Kathy McNamara opining that the "correlation between physician pay and physician production" is "essential in determining fair market value" and that there "should be a direct correlation between a physician's work effort and earned cash compensation Therefore, in order to determine the FMV of a physician's compensation, a valuator must analyze the physician's production information, specifically net collections and total [work relative value units] and compare the physician's production to the physician's total cash compensation earned." *See* Expert Report of Kathy McNamara at ECF. No. 310-3 at 12.

⁶ Similarly, like FMV, although CMS, in the notice and comment rulemaking context, has not furnished a methodology to determine what it considers to be commercially reasonable, the

Thus, when hospital officials have in their files two sets of data—one showing that, just based upon the physician’s personally performed services, the hospital loses money, and a second showing that, if the physician’s downstream referrals are taken into account, the hospital makes money—an FCA plaintiff may contend that the hospital violated the Stark Law, because the compensation it paid to the physician was influenced by the very data the official has in its files—namely, that the hospital would make money based upon the volume and value of the physician’s downstream referrals.

Set forth below is a description of some recent cases and settlements where FCA plaintiffs have sought to establish this type of allegation, and steps a hospital can undertake to reduce the risk of confronting FCA liability when it measures the value of a physician’s downstream revenue.

FCA CASES AND SETTLEMENTS QUESTIONING THE MANNER IN WHICH A HEALTH CARE ENTITY SETS FMV

FCA Cases Addressing Contribution Margin and Financial Losses in the Context of Alleged Stark Law Violations

The alleged facts in *United States ex rel. Schaengold v. Memorial Health, Inc.*,⁷ demonstrate how a person setting or negotiating physician compensation and having data related to contribution margin can result in an FCA action. This is especially true when the government, as is common in FCA actions, combs

DOJ, in a litigation context when prosecuting an FCA case based upon an alleged violation of the Stark Law, has not been reticent about opining on what is commercially reasonable. For example, in the *Tuomey* litigation, the government’s expert opined:

Our findings demonstrate that the terms of the physician employment agreements were not commercially reasonable for all groups because:

- The term of the physician employment agreement is 10 years without provisions to change the physicians’ compensation methodology.
- The physicians’ net outpatient collections are not required to exceed their practice overhead and their base salary before bonuses are earned.
- Combined with the cost of billing fees, each physician’s compensation and benefits paid materially exceed his or her Tuomey outpatient collections.
- Since their inception, Toumey’s physician practices have incurred material financial losses.

See Expert Report of Kathy McNamara at ECF. No. 358-3 at 12 in *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, No. 3:05CV-02858 (D.S.C.). As a result, under the Stark Law, the factors to take into account to determine commercial reasonableness and FMV are likely to be ultimately established by the government’s expert witnesses’ reports in FCA litigation (where the government is seeking treble damages and substantial civil penalties) rather than by notice and comment rulemaking by the specialized agency charged with developing the regulations.

⁷ No. 4:11-cv-58, 2014 U.S. Dist. LEXIS 169555 (Dec. 8, 2014) (“*Schaengold I*”).

through all emails and correspondence related to the financial transaction prior to filing or intervening in the FCA lawsuit. In *Schaengold I*, the government asserted:

- Board minutes reflected that the health system sought to expand the employed primary care physician base to engender “loyalty” in its markets to “move” its “economic engine.” Health system leadership identified another problem of “Specialists . . . not getting any referrals from [health system’s] primary care” doctors and as a result resolved to look into keeping “[r]eferrals within . . . family.”⁸
- Certain physician groups were identified to increase volume and to deprive competitors of volume.
- One group that the health system targeted had a “projected contribution margin of \$3.5–5 million per year.”⁹
- The salaries paid to one group of physicians “were well in excess of the 90th percentile of market benchmarks” under the Medical Group Management Association (“MGMA”).¹⁰
- Based upon the payment of these salaries, the health system estimated that, in the six-month period of 2008 during which the physicians worked for the health system, the system sustained losses “in excess of \$199,000 per physician, or \$597,000 overall.” During 2009, these “losses were in excess of \$369,000 per physician, or \$1.1 million overall.” In 2010, the health system’s losses “were in excess of \$474,000 per physician, or \$1.4 million overall.” And, finally, during January and February 2011, these “losses were in excess of \$130,000 per physician, or \$392,000 overall.”¹¹
- Minutes of a personnel and compensation committee meeting show that the health system was judging the effectiveness of the physicians’ compensation arrangement by reference to patient volume. Additionally, the chairman of the finance committee in 2008, who approved the physicians’ employment contracts, stated that the health system “went after a [physician] heavily for several years because aof [sic] volume.”¹²
- The court concluded that, for purposes of Fed. R. Civ. P. 12(b)(6), the

⁸ *Id.* at *12.

⁹ *Id.* at *13–14.

¹⁰ *Id.* at *15.

¹¹ *Id.* at *15–16.

¹² *Id.* at *18–19.

government stated a cause of action.

Similarly, in *United States ex rel. Schaengold v. Mem'l Health, Inc.*,¹³ the court covered the separate allegations of the relator, a former chief executive officer and president of the health system. The relator, like the government, alleged that FMV determinations were tainted by data reflecting downstream volume. Specifically, the relator alleged:

- “Management included in the FY 2011 budget a downstream volume and revenue negative impact of \$80 million in gross charges, which translated to a reduction of \$12 million in Net Revenue or a loss of \$800,000 in Net Revenue per physician if the . . . physician groups’ compensation was reduced to reflect fair market value, as a result, physicians left the health system.”¹⁴
- “The Board demanded the downstream income and patient referrals be calculated and included in the . . . budget process.” Board members also allegedly “insisted that downstream income and patient referrals be considered in negotiating a new compensation model for the Community-based physicians.”¹⁵
- The 2009 audited financials were released in April 2010 and reported an \$18.6 million loss from physician contracts.¹⁶
- The relator contended that the relevant physicians received approximately \$1.8 million each year in excess compensation when compared to the 75th percentile of total compensation as calculated by MGMA.¹⁷
- In particular, the relator informed the chairman of the board’s strategic planning committee that one physician group received compensation at or above the 90th percentile of the MGMA.¹⁸
- Due to possible losses in downstream revenue and patient referrals, the board rejected the proposed compensation reduction that the relator requested in order to set compensation at fair market value.¹⁹
- The court ruled, that, where the relator pleaded that objective

¹³ No. 4:11-cv-58, 2014 U. S. Dist. LEXIS 174977 (Dec. 18, 2014).

¹⁴ *Id.* at *16–17.

¹⁵ *Id.* at *16.

¹⁶ *Id.* at *13.

¹⁷ *Id.*

¹⁸ *Id.* at *14.

¹⁹ *Id.* at *16–17.

benchmarks of compensation were exceeded—compensation that exceeded the 75th percentile and the 90th percentile of MGMA—sufficient facts were pleaded to state a cause of action, and, presumably discovery would proceed.²⁰

In other cases, the government and relators have similarly made arguments that payment to physicians exceeded FMV, because either the hospital lost money on the physician (measured by comparing the physician’s professional revenue with the practice’s costs) or the physician was paid at the higher end of the scale, and the hospital was aware of the value of downstream revenue. For example, in *United States ex rel. Parikh v. Citizens Med. Ctr.*,²¹ the court found that, even if the cardiologists were making less than the national median salary for their profession, given the relator’s allegations that the cardiologists’ income more than doubled after they joined the defendant hospital even while their own practices were costing the hospital between \$400,000 and \$1 million per year in net losses, those allegations are sufficient to allow an inference that they were receiving improper remuneration. The court noted that this inference is particularly strong, given that it would make “little apparent economic sense for the hospital to employ the cardiologists at a loss unless it were doing so for some ulterior motive—a motive relators identify as a desire to . . . induce referrals.”

FCA Settlements Addressing Contribution Margin and Financial Losses in the Context of Alleged Stark Law Violations

Moreover, the government’s recent FCA/Stark Law settlements further illustrate how relators and the government piece together two facts: (1) the hospital loses money on physician employment if you look at revenue stemming from the physician’s personally performed services compared to related costs; and (2) the hospital will make money if the physician’s contribution margin is calculated by including the value of downstream referrals to attempt to prove an FCA and Stark Law violation.

Specifically, from these two facts, FCA plaintiffs conclude that the hospital must have paid excessive compensation (explaining the losses on personally performed services) to obtain the profits stemming from downstream referrals

²⁰ *Id.* at *29–30. See also the government expert’s report in *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No. 6:09-cv-1002 (M.D. Fla.), in which the government expert asserted that the hospital paid neurosurgeons in excess of FMV because, among other things, the hospital’s own documents showed its “direct practice losses to total nearly \$2 million”; however, once it factored in “the neurosurgeons’ referrals, the overall contribution margin increased to a projected profit of more than \$6.5 million.” See Expert Report of Kathy McNamara at ECF. No. 310-3 at 29.

²¹ 6:10-CV-64, 2013 U.S. Dist. LEXIS 134693, at *35 (S.D. Tex. Sept. 20, 2013).

and that this practice violates the Stark Law. Although the conclusion does not logically follow—just because the hospital loses money regarding its employment of the physician does not necessarily mean that the physician received excessive, above-market compensation, and just because the hospital measures contribution margin does not necessarily mean that it paid excessive compensation to the physician to obtain downstream referrals—this narrative clearly has become an attractive one for the government and relators to pursue in FCA actions.

The government's recent FCA settlement with Broward Health reflects the government's interest in reviewing arrangements where the health care facility measures contribution margin and downstream referrals. In Broward Health, the relator, an orthopedic surgeon who had staff privileges at defendant's hospitals, alleged the following facts:

- If physician referrals to the hospitals were not considered, Broward Health compensated its physicians to generate losses in excess of approximately \$160 million over the eight years relevant to the complaint.²²
- However the relator contends that Broward Health was not concerned about these losses, because Broward Health tracked and monitored the value and volume of referrals from each physician in secretive "Contribution Margin Reports."²³ Specifically, the relator asserted that Broward Health deliberately planned and budgeted for massive net operating losses from the overcompensation of employed physicians while secretly tracking profits from referrals by these physicians to Broward Health hospitals and clinics.²⁴
- For example, the relator asserts that, midway through fiscal year 2011, Broward Health calculated the year-to-date "net losses from operations for its employed physicians to be \$10,501,373."²⁵ However, once the contribution margin for inpatient and outpatient referrals for these physicians was calculated, it showed a net gain of \$5,929,288.²⁶
- Additionally, the relator contended that, for physicians with high numbers of referrals, Broward Health permitted these physicians to

²² See Relator's Compl., *United States ex rel. Reilly v. N. Broward Hosp. et al.*, No. 10-60590, ¶ 11 (S.D. Fla. Sept. 16, 2015), ECF No. 75.

²³ *Id.*, ¶ 70.

²⁴ *Id.* ¶ 77.

²⁵ *Id.*, ¶ 183.

²⁶ *Id.*, ¶ 188.

inflate their relative value unit (“RVU”) numbers to increase their compensation. The relator asserted that this practice allowed Broward Health to appear to pay physicians based on RVU production, but, in reality, Broward Health knowingly entered into numerous physician employment contracts based, in part, on excessive compensation rates per RVU and then knowingly permitted certain physicians to escalate their compensation even higher with inflated numbers of RVUs while Broward Health tracked and monitored offsetting referral profits. Specifically, the relator asserted that the RVUs had been inflated because Broward Health failed to apply the multiple procedure reduction rule in calculating RVUs for outpatient and inpatient services and procedures, which is contrary to the MGMA method of calculating physician work RVUs.²⁷

Thus, what these cases and settlements illustrate is that, if the health care entity has in its files a detailed paper trail where downstream revenue and contribution margin are mentioned and the physician is paid at the higher end of the pay scale, or the physicians are employed and compensated at a higher rate than private practice and the hospital documents substantial losses stemming from the physician’s employment, an FCA plaintiff can cobble these facts together to attempt to assert that there was not only a Stark Law violation, but also an FCA violation, because the health care entity “knowingly” violated the Stark Law.

STEPS TO MINIMIZE EXPOSURE TO LIABILITY

Hospitals, and other health care entities, must be aware that courts have ruled that they ultimately bear the burden of proof to establish that they have complied with a Stark Law exception or the Anti-Kickback Law’s safe harbors.²⁸

²⁷ *Id.* ¶¶ 154–58.

²⁸ See, e.g., *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 792 F.3d 364, 374 (4th Cir. 2015) (pointing out that, once a relator or the government has established the elements of a Stark Law violation, it becomes the defendant’s burden to show that a Stark Law exception applies); *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009) (“Once the plaintiff or the government has established proof of each element of a violation under the [Stark] Act, the burden shifts to the defendant to establish that the conduct was protected by an exception”) (citation omitted); *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No. 6:09-cv-1002, 2013 U.S. Dist. LEXIS 161718 at *16–*17 (M.D. Fla. 2013) (“Once the government has demonstrated proof of each element of a violation of the Stark Statute, the burden shifts to the defendant to establish that his conduct was protected by a safe harbor or exception. The government need not prove, as an element of its case, that a defendant’s conduct does not fit within a safe harbor or exception”); *United States ex rel. Parikh v. Citizens Med. Ctr.*,

Thus, in light of developing case law, any health care entity using contribution margin-like data or tracking physician losses should have robust methods to prove that an arrangement satisfies FMV without reference to downstream referrals or leakage and should validate that the payment is commercially reasonable.

As to FMV, a health care entity should either retain external reviewers or assign internal reviewers who have not been exposed to contribution margin data to confirm that the arrangement is FMV, using reliable survey data demonstrating that the arrangement would be FMV without reference to the volume or value of any referrals.

As to commercial reasonableness, there are a number of reasons that a hospital may study contribution margin data and leakage and employ a physician at a loss measured by direct physician revenue and physician cost. For example, studying contribution margin and leakage data is useful in (1) improving care coordination and avoiding needless duplication of services; for example, by learning whether care stays “in-house,” a facility can ensure that patients, especially those with chronic conditions, get the right care at the right time while avoiding medical errors and unnecessary duplication of services; (2) improving quality of patient care by learning whether physicians are referring patients outside the facility because physicians believe patients are better served by physicians or hospitals outside the facility and undertake corrective action; and (3) identifying whether patients are being referred elsewhere because the patients require services that are not readily available through the hospital.

Contribution margin data can appropriately be used as a tool at the hospital to measure whether the hospital can satisfy its costs and thus continue to discharge its mission of serving its community.

The best route for accommodating the legitimate need to take into account the full financial picture stemming from a relationship with a physician and avoiding potentially harmful, negative facts in an FCA proceeding is for the hospital to separate and isolate those responsible for determination of FMV and commercial reasonableness from any access to, or knowledge of, the contribution margin data.

If this approach is followed, your FCA defense lawyer, if the transaction is

977 F. Supp. 2d 654, 668 (S.D. Tex. 2013) (“Relators correctly argue . . . that Anti-Kickback Statute and Stark employment exemptions are affirmative defenses on which [the hospital] has the burden of proof”) (citations omitted); *United States ex rel. Singh v. Bradford Reg’l Med. Ctr.*, 752 F. Supp. 2d 602, 634 (W.D. Pa. 2010) (“Once it has been determined that a financial relationship exists, the burden shifts to defendants to establish the applicability of an exception”) (citations omitted).

investigated or litigated, will be able to produce testifying witnesses who can aver that FMV and commercial reasonableness were determined without regard to the volume or value of the physicians downstream referrals.