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Increasing Scrutiny of Healthcare Fraud and Abuse Laws

The first installment of this three-part Health Capital Topics series discussed the framework of current healthcare fraud and abuse laws – namely, (1) the *Anti-Kickback Statute* (AKS); (2) the *Stark Law* (Stark); and, (3) the *False Claims Act* (FCA), as well as the regulatory thresholds of *Fair Market Value* (FMV) and *Commercial Reasonableness* (CR) – within the current era of healthcare reform in the United States. The second installment of this three-part series briefly discussed the more notable fraud and abuse violations prosecuted by the federal government. This final segment of the series will examine how the *Department of Justice* (DOJ) and *Office of Inspector General* (OIG) continue to prosecute increasingly complex violations of healthcare fraud and abuse laws, and how these prosecutions affect the level of compensation deemed to be consistent with *FMV*.

The fraud and abuse lawsuits identified in part two of this series focused on the more blatant violations of healthcare fraud and abuse laws where healthcare providers compensated physicians "*practicing in similar…settings located in similar environments,*"[1] in excess of the 90th percentile of physician compensation. However, recent prosecutions of healthcare fraud and abuse laws have demonstrated that the level of physician compensation deemed to be consistent with *FMV*, as required by many *Stark* exceptions,[2] has dramatically decreased. Indeed, courts seem to have abandoned their initial reasoning that "*any definition of fair market value that would automatically deem anything over the median or indeed anything at the 80th percentile, as necessarily not being fair market value would seem illogical.*"[3] In addition to this recent trend toward lowering the physician compensation percentile considered to be within *FMV*, the *DOJ* and *OIG* have demonstrated an increased willingness to prosecute more complex healthcare fraud and abuse violations, i.e., schemes that involve physician compensation and complicated referral arrangements.

In *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.* (Tuomey), Michael Drakeford, M.D. alleged that Tuomey, a private, non-profit community hospital in South Carolina, violated *Stark* and *AKS* when it entered into more than fifteen employment agreements, all of which were designed to induce and maintain referral relationships.[4] Tuomey entered into Employment Agreements with area physicians, conferring salary and benefits to those physicians in excess of the net collections received from their professional practices.[5] Tuomey would then generate two billings to Medicare, one for the professional services rendered and a second "*facility fee*" assessed because Tuomey provided the space, nurses, equipment, and other items for the physicians' practices.[6] The court found that the facility component of the physicians' personally performed services and the resulting fee constituted a "*referral*" as defined by *Stark* and its regulations.[7] In doing so, the court relied on the *OIG's* official commentary, which stated:

> *"We have concluded that when a physician initiates a designated health service and personally performs it him or herself, that action would not constitute a referral of the service to an entity…However, in the context of inpatient and outpatient hospital services, there would still be a referral of any hospital service, technical component, or facility fee billed by the hospital in connection with the personally performed service. Thus, for example, in the case of an inpatient surgery, there would be a referral of the technical component of the surgical service, even though the referring physician personally performs the service."*[8]

This lawsuit *seems to indicate* a shift in the *DOJ* and *OIG's* focus for several key reasons. The court in *Tuomey* established physician compensation in the 75th percentile as the benchmark for *Stark* scrutiny, likely responding to the case's expert reports, which noted that that the 75th percentile was at the high end of what was considered to be *FMV* for physician compensation.[9] Additionally, failure by a physician (with whom the hospital has a financial relationship) to *personally perform* the technical (facility) components of treating a patient for which Medicare is subsequently billed constitutes a non-compliant referral under the *Personal Services Arrangement* (PSA) exception to *Stark,* because "*the personal services exception does not extend to a facility fee a hospital bills for a facility component resulting from a personal performed service*."[10] Together, these two elements significantly expand the scope of physician contracts that could be subject to *Stark* scrutiny.

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In 2010, four former members of Bradford Regional Medical Center's (BRMC) medical staff brought a *qui tam* action entitled *United States ex rel. Singh et al. v. Bradford Regional Medical Center et al.* The relators' complaint alleged that BRMC, a Pennsylvania-based non-profit hospital, and V&S Medical Associates (V&S), a private internal medicine practice formed by former BRMC employees Kamran Saleh, M.D. and Peter Vaccaro, M.D.,[11] engaged in a lease arrangement designed so that BRMC could obtain patient referrals in exchange for payments made to V&S, allegedly for the use of their Nuclear Camera.[12] The lease agreement regarding V&S's camera included a covenant not to compete and a ten percent collections fee, which together were found to constitute a financial relationship between BRMC and V&S.[13]

Defendants argued they qualified for Stark immunity under the *Indirect Compensation Exception*; the *Personal Services Safe Harbor*; the *Equipment Rental Exception*; and, the corresponding *AKS Safe Harbor* for Equipment Rentals. However, the additional monthly payments exchanged for the covenant not to compete in the sublease agreement took into account the amount of business BRMC would receive from V&S, because BRMC, analyzed the benefits and drawbacks of the covenant not to compete, "*based on the assumption that the Physicians would likely refer this business to the Hospital in the absence of a financial interest in their own facilities or services, although they are not required to do so by virtue of any of the covenants contained in the Agreements or otherwise.*"[14] In addition to the covenant not to compete, the ten percent collections fee inherently varied with the volume of referrals, because "*as more referrals for tests on the GE camera were performed, more money was collected for the services*."[15] Because these arrangements were deemed to not be *FMV*, they did not qualify under any of the proposed exceptions or *Safe Harbors*.[16] Additionally, the court found that the defendants lacked the necessary written agreement to afford protection under the relevant *Stark* exceptions and *AKS Safe Harbors*.[17]

This case similarly indicates increased government scrutiny because, despite the fact that the financial terms were effectively equal to *FMV* (the relators did not assert that the financial terms exceeded FMV, and did not engage an expert to render an opinion on the matter),[18] the court found that *any* compensation that takes into account *potential referrals* cannot be *FMV*. Additionally, the *Bradford* case lacked the traditional employment relationship found in typical healthcare fraud and abuse cases, instead centering on an indirect compensation agreement consisting of rental fees for equipment that took into account the amount of referrals that would or would not have been made using the equipment.[19]

Shortly thereafter, in *United States v. Campbell*, the federal government prosecuted Joseph Campbell, M.D., a New Jersey cardiologist, alleging that the physician received *illegal remuneration* (i.e., *kickbacks*) for referrals made from his private cardiology practice to University of Medicine and Dentistry of New Jersey's (UMDNJ) University Hospital (UH).[20] In addition to his private cardiology practice, Dr. Campbell was employed as a Clinical Assistant Professor (CAP) at UMDNJ for an annual salary of approximately $75,000.[21] In return for this salary, Dr. Campbell agreed to dedicate 48% of his time (almost 20 hours per week) performing teaching, research, and patient care services for UMDNJ.[22] In reality, however, UMDNJ did not require Dr. Campbell to perform any of these services, but compensated him $70,000 nonetheless. The primary service Dr. Campbell provided was to refer his patients to UH for inpatient and outpatient hospital services.[23] Dr. Campbell claimed he did not violate *Stark* because he personally saw the patients he referred to UMDNJ himself, and, in the alternative, that he had a legitimate employment contract under *Stark's Bona Fide Employment Agreement Exception* and the corresponding *AKS Safe Harbor*.[24] To prove he had a viable *Employment Contract*, Dr. Campbell produced an *expert report* stating his salary as a CAP was consistent with *FMV*. The court nonetheless found Dr. Campbell in violation of *Stark* because, although he performed the professional component of the referral, he did not perform the technical component for which payment was billed to Medicaid, and thus, the employment relationship was required to meet an exception.[25] Further, the court stated that even if Dr. Campbell believed he was entering into a *legitimate employment contract*, and his salary was *FMV* for the services enumerated in the agreement, he did not meet the requirements of that contract during his *employment*. Therefore, the $70,000 payment he received from UMDNJ for *services* could not be considered *CR* or *FMV*.[26]

The *Campbell* case demonstrates that healthcare providers can be billed for the *technical component* of a referral, despite the fact that the physician provides the *professional component* of the referral himself. Additionally, the court acknowledged that although compensation is within the *FMV* range for services specified in a contract, the failure to perform those required services makes the compensation *commercially unreasonable* and not *FMV*.

In *United States ex rel. Kunz v. Halifax Hospital Medical Center*, Elin Baklid-Kunz, the Director of Physician Services of Halifax Medical Center (Halifax), a 764-bed hospital in East Central Florida, brought a *qui tam* suit against Halifax and Halifax Staffing, Inc. (Halifax Staffing), a non-profit corporation providing staffing personnel to Halifax Hospital.[27] The complaint alleged violations of *Stark*, *AKS*, and *FCA* when Halifax unlawfully paid incentives to medical oncologists and overpaid three neurosurgeons. Halifax provided bonuses to the oncologists and neurosurgeons from an "*incentive compensation pool*" (comprised of 15% of the oncology program's margin)[28], in a manner which varied with physician referrals, and the pool itself was based on services the physicians did not personally perform (e.g.,

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outpatient medical oncology services, physician services, and related outpatient oncology pharmacy charges).[29]

Additionally, Halifax partially compensated three neurosurgeons on staff with a bonus equal to 100% of collections based on their professional services.[30] Halifax also paid all expenses of the physicians' practice.[31] Based on the testimony of the expert witness for the government, this bonus payment placed the neurosurgeons' compensation, in some years, at more than double the compensation that neurosurgeons at the 90th percentile earned, despite productivity levels of the Halifax neurosurgeons falling well below that rank.[32] Consequently, the court found that the neurosurgeons' compensation greatly exceeded *FMV* and triggered genuine issues of material fact involving nearly every requirement of the *Bona Fide Employee Stark exception*.[33]

The *OIG* and *DOJ* are increasingly analyzing technical compliance with *Stark* exceptions. Based on the court's decision, and in light of the expert testimony, *Halifax* seems to indicate that benchmark for *FMV* determination is trending downward toward the median (50th percentile) – a standard that may drastically increase the number of physician contracts, and the amount of provider compensation, that would fall within regulatory scrutiny.

Generally, these foregoing four cases reflect a trend of *increased scrutiny* on behalf of the *DOJ* and *OIG* in determining who to pursue for violations of *Stark*, *AKS*, and *FCA*, by decreasing the benchmark threshold for physician compensation considered to be within *FMV* from the 90th percentile to the 50th to 75th percentiles. This *increased scrutiny* has been financially profitable for the government, with a record $4.33 billion recovered from fraud and abuse judgments and settlements in fiscal year 2013.[34] The high *return on investment* (ROI) on the federal government's fraud and abuse enforcement over the last three years was recently noted in *OIG*'s "*Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2013*," citing that $8.1 was recovered for every one dollar invested in enforcing healthcare fraud and abuse laws and prosecuting violations of those laws.[35] The financial gains associated with this trend of *increased scrutiny* may continue to motivate the federal government's prosecution of smaller healthcare systems and individual defendants; the examination of potential healthcare fraud and abuse violations outside the traditional employment relationship; and, the pursuit of increasingly complex fact patterns in combating violations of healthcare fraud and abuse laws.

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[1] "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which they have Financial Relationships" Federal Register Vol. 66, No. 3, (January 4, 2001), p. 916.
[2] *Ibid*, p. 944; "Limitations on certain physician referrals" 42 U.S.C. §1395nn(b)-(e); "General exceptions to the referral prohibition related to both ownership/investment and compensation" 42 C.F.R. § 411.355(a)-(i); "Exceptions to the referral prohibition related to ownership or investment interests" 42 C.F.R. § 411.356(a)-(c); "Exceptions to the referral prohibition related to compensation arrangements" 42 C.F.R. § 411.357(a)-(p).
[3] "United States ex rel. Villafane v. Solinger, Memorandum Opinion", No. 3:03-cv-519, (W.D. Ky. April 8, 2008), ECF No. 177, p. 21.
[4] "United States ex rel. Drakeford v. Tuomey, Amended Complaint", No. 3:05-CR-2858-MJP (D. S.C. Oct, 4 2005), ECF No. 1, p. 8-11.
[5] *Ibid*, p. 4-5.
[6] "United States ex rel. Drakeford v. Tuomey, Appellate Opinion", 675 F.3d 394 (4th Cir. 2012), p. 399.
[7] *Ibid*, p. 406.
[8] *Ibid*, 66 Federal Register (January 4, 2001), p. at 941.
[9] "U.S. ex rel. Drakeford v. Tuomey Healthcare Systems, Inc., Kathleen McNamara Expert Report", No. 3:05-cv-02858 (D. S.C. 2010), ECF No. 358-3, p. 9; "U.S. ex rel. Drakeford v. Tuomey Healthcare Systems, Inc., Steve Rice Expert Report" No. 3:05-cv-02858 (D. S.C. 2010), ECF No. 302-47, p. 31.
[10] "United States ex rel. Drakeford v. Tuomey, Appellate Opinion," 675 F.3d 394 (4th Cir. 2012), p. 406.
[11] "United States ex rel. Singh et al. v. Bradford Regional Medical Center et al., Opinion", No. 04-186 Erie, (W.D. Pa. Nov. 10 2010), ECF No. 145, p. 2.
[12] *Ibid*, p. 16.
[13] *Ibid*, p. 24.
[14] *Ibid*, p. 32.
[15] *Ibid*, p. 51.
[16] *Ibid*, p. 49, 51.
[17] *Ibid*, p. 58.
[18] *Ibid*, p. 47-49.
[19] *Ibid*, p. 32, 35.
[20] "United States v. Campbell, Amended Complaint", No. 08-1951(SDW-ES), (D. N.J. Sept. 19, 2008), ECF No. 26, p. 19.
[21] *Ibid*, p. 10.
[22] *Ibid*.
[23] *Ibid*, p. 11.
[24] *Ibid*, p. 6.
[25] *Ibid*.
[26] *Ibid*, p. 8.
[27] "U.S. ex rel. Kunz v. Halifax Hospital Medical Center, Amended Complaint", No. 6-09-CV-1002 (M.D. Fla. Dec. 23, 2009), ECF No. 2, p. 37; "U.S. ex rel. Kunz v. Halifax Hospital Medical Center, Order", No. 6-09-CV-1002 (M.D. Fla. Nov. 13, 2013), ECF No. 396, p. 16.
[28] *Ibid* (M.D. Fla. Nov. 13, 2013), p. 4.
[29] *Ibid* (M.D. Fla. Dec. 23, 2009), p. 37; *Ibid* (M.D. Fla. Nov. 13, 2013), p. 16.
[30] *Ibid* (M.D. Fla. Nov. 13, 2013), p. 25.
[31] *Ibid*.
[32] "U.S. ex rel. Kunz v. Halifax Hospital Medical Center, Order", No. 6-09-CV-1002 (M.D. Fla. Nov. 18, 2013), ECF No. 399, p. 10-11.
[33] *Ibid*, p. 10.
[34] "The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2013," U.S. Department of Health & Human Services Office of Inspector General, February 2014, p. 8.
[35] *Ibid*.

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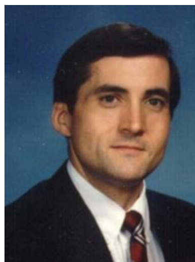

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