On March 30, 2012, the United States Court of Appeals for the Fourth Circuit overturned the district court’s $45 million judgment in U.S. ex rel. Drakeford v. Tuomey Healthcare System. Although the decision was based on procedural grounds (violation of 7th Amendment right to jury trial), in its opinion remanding the case for further proceedings, the Fourth Circuit addressed two Stark Law issues which it felt were likely to be raised on remand: (1) whether a “referral” (as defined in the Stark Law) was made by the physicians in question; and (2) whether the contracts with the physicians implicated Stark’s “volume or value” standard by taking into account anticipated referrals. The following article discusses the Fourth Circuit’s holdings and the potential ramifications with respect to the structuring of future hospital-physician arrangements.

Background
At issue in the Tuomey case were a series of part-time employment agreements entered into between wholly-owned subsidiaries of Tuomey Healthcare System (Tuomey) and certain specialist physicians on its medical staff. By way of brief summary, the important facts of the case are as follows:

- Tuomey, faced with increased competition from physicians performing outpatient procedures in their offices and physician-owned surgery centers, offered part-time employment agreements to physicians practicing in a local gastroenterology group, as well as local orthopedists and other specialists. Pursuant to the employment agreements, the physicians would perform their outpatient procedures exclusively at Tuomey for a period of 10 years. The physicians acted in the capacity of employees only when they were performing surgical procedures.

- The agreements further included a 2-year, 30-mile post-termination non-competition provision. The physicians were paid a base salary tied to collections of personally performed services (see below), plus...
a productivity bonus totaling 80% of collections and up to 7% of collections for meeting certain quality measures.

- The base salary involved “tiered” compensation, whereby each physician would earn a base of $5,000 for personally performed collections of up to $185,000, and an additional $5,000 in base compensation for each additional $25,000 of personal collections.

- The employment agreements also included a full-time benefits package for some of the physicians, including health coverage, malpractice insurance, and CME reimbursement.

- In developing a benchmark for physician compensation, Tuomey’s compensation consultant calculated the value of potentially lost referrals with respect to a particular physician practice and divided it by the number of physicians in the practice.

- Tuomey received a fair market value report stating that the compensation paid to the physicians was justifiable so long as it did not exceed 150% of the 90th percentile—a methodology which was rejected at trial by both parties’ experts.

- In tape recorded conversations with physicians, Tuomey executives represented that the payments functioned as “phantom ownership” in Tuomey’s outpatient surgical center and that the hospital wanted to “share revenues with those people who might otherwise, frankly go out and compete with us...” In other conversations, hospital executives explained that it was reasonable for the hospital to lose money on the proposed employment agreements because the “hospital has other sources of revenue.”

- The government argued that Tuomey’s arrangements with the physicians constituted an indirect compensation arrangement under the Stark Law which did not meet the requirements of the indirect compensation arrangement exception, because the compensation paid to the physicians “took into account the volume or value of the physicians’ referrals.”

At trial, the jury sided with the government and found that a Stark violation had occurred; however, the jury found that Tuomey did not violate the Federal False Claims Act (FCA). In July 2010, on a post-trial motion, the district court entered a $45 million judgment against Tuomey for the equitable claims of payment by mistake of fact and unjust enrichment, based on the jury’s finding that Tuomey violated the Stark Law. The district court also set aside the FCA verdict and granted the government’s motion for a new trial on the issue of the FCA violation. Tuomey appealed the district court’s judgment.

The parties’ arguments on appeal
In its brief appealing the district court’s decision, Tuomey argued that the Stark Law does not apply in the first instance to the financial relationship between Tuomey and the employed physicians. Both parties previously acknowledged that the only “financial relationship” under the Stark Law which is potentially applicable to the Tuomey case is an “indirect compensation arrangement.” Under the Stark Law regulations, in order for an “indirect compensation arrangement” to exist, the referring physician must “receive aggregate compensation...that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician.” The Stark Law definition of “referral” excludes any designated health services (DHS) personally performed or provided by the referring physician. Tuomey argued in its brief that the physicians were paid only for their personally performed professional services, and therefore, no indirect compensation arrangement existed.
In response to Tuomey’s arguments, the government argued in its reply brief that the physicians’ compensation varied with the volume and value of their referrals because the physicians only earned money for work (performing surgical procedures) that simultaneously generated a facility fee for the hospital. To advance this argument, the government contended that, despite the fact that the compensation was based on personally performed services, every time the physicians performed a procedure, the cash component of the physicians’ salaries increased, as did the volume of referrals of the technical component of outpatient services to Tuomey. Thus, the government argued that because the physicians’ salaries were expressly determined by the number or value of hospital outpatient procedures performed, the Stark Law was implicated. The government also argued that the arrangements with the physicians “took into account the volume or value” of the physicians’ referrals because the compensation paid to the physicians was designed to exceed their personal collections and included an amount that represented a portion of their anticipated referrals of the technical component of the hospital outpatient services.

The Fourth Circuit’s opinion
On March 30, 2012, the Fourth Circuit overturned the district court’s judgment finding a violation of Tuomey’s 7th Amendment right to a jury trial—because the district court set aside the jury verdict in its entirety, no factual basis existed to sustain the judgment against Tuomey on the equitable claims. The Fourth Circuit ordered a new trial.

Although the case was decided on procedural grounds, the Fourth Circuit’s opinion addressed two Stark Law issues that were raised on appeal that the court felt were likely to recur on remand: (1) whether a “referral” was made by the physicians; and (2) whether the contracts with the physicians implicated Stark’s “volume or value” standard by taking into account anticipated referrals.

Was a referral made?
This issue goes to the crux of Tuomey’s threshold argument that the Stark Law is not implicated in the first place, because the physicians were paid for their personally performed services (i.e., the professional component of surgical procedures), which do not constitute “referrals” under the Stark Law. The Fourth Circuit, citing the preambles to the Stark Law, held that, in the context of inpatient and outpatient hospital services, personally performed professional services still generate a “referral” of the technical component of hospital services. Thus, the “facility” or “technical” component of a physician’s personally performed services constitutes a referral and the Stark Law is implicated.

Was the volume or value standard implicated?
The Fourth Circuit stated that contracts that take into account anticipated referrals implicate Stark’s volume or value standard. Although the court undertook a somewhat tortured analysis of the Stark definition of fair market value and various regulatory preambles, the Court ultimately determined that physicians should be compensated for the services they actually perform and not for their ability to generate referrals. Thus, the Fourth Circuit stated that on remand the jury must consider: (1) whether the contracts on their face took in account the volume or value of referrals; and (2) whether the arrangement violates the fair market value standard by taking into account anticipated referrals in computing physician compensation. If either of these factors is present, then the arrangement constitutes an indirect compensation arrangement under the Stark Law and must meet an exception. Further, the Fourth Circuit agreed with
the court in *U.S. ex rel Villafane v. Solinger,*1 that “intent alone does not create a violation” of the Stark Law.

**Implications of the Circuit Court’s opinion**

The Fourth Circuit Court’s decision provides clarity in respect to several issues. First, the fact that an arrangement involves only the provision of personally performed services does not mean that the Stark Law can be ignored. In the case of inpatient or outpatient hospital services, a Stark analysis will always be necessary, because the personally performed services will automatically generate a “referral” of DHS. Further, it is clear that when establishing compensation methodologies, a hospital cannot compensate physicians for their anticipated referrals; rather, the compensation must reflect only the fair market value of the services actually being provided by the physicians.

However, the court’s analysis also leaves several important questions unanswered. First, the court did not address whether an agreement for personally performed services that generate a corresponding technical component referral will always be considered to vary based on the volume or value of referrals. Arguably, a compensation arrangement could involve the provision of services that generate technical component referrals, but not necessarily vary based on the volume or value of such referrals—such as where a physician receives fair market value compensation based on work relative value units (wRVUs) or professional fee collections for personally performed services. In other words, it is not clear whether an arrangement involving a physician who is a bona fide full-time employee, with a substantial office-based practice and only a subset of services that are provided at the hospital, would be distinguishable from the arrangement in *Tuomey* where the physicians were part-time employees only when providing surgery at the hospital.

Moreover, it does not appear that the Court properly assessed if an “independent compensation arrangement” existed in the first place. The Court seemed to read a fair market value standard into the definition of an independent compensation arrangement where none exists in the regulatory wording of such definition.

Furthermore, the court did not address the government’s assertion that an arrangement where a physician’s compensation exceeds collections will necessarily implicate the volume or value standard, leading to continued ambiguity with respect to certain arguably bona fide arrangements, such as arrangements that involve the provision of a large amount of uncompensated care. Additionally, the court did not consider whether a fair market value compensation arrangement could still be deemed to take into account anticipated referrals by virtue of the hospital’s general strategic objectives in entering into the arrangement.

These unanswered questions perpetuate the complexities of structuring hospital-physician arrangements in the wake of the *Tuomey* case and result in continued uncertainty in the context of indirect compensation arrangements between hospitals and physicians. @

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