

## Deconstructing *Tuomey*: 25 Years on, Is It Time for Congress to Revisit the Stark Law?

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In 1989, Congress enacted the Ethics in Patient Referrals Act. Twenty-five years later, in *United States ex rel. Drakeford v. Tuomey*,<sup>1</sup> the Fourth Circuit upheld the largest False Claims Act (FCA) judgment predicated on Stark Law violations to date: \$237 million. Writing in concurrence, Judge Wynn summarized the situation as “[a]n impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area,” concluding that “even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act.”<sup>2</sup>

The court’s opinion did not quarrel with this assessment: “we do not discount the concerns raised by our concurring colleague regarding the result in this case. But having found no cause to upset the jury’s verdict in this case and no constitutional error, it is for Congress to consider whether changes to the Stark Law’s reach are in order.”<sup>3</sup>

This is not the first time that serious concerns have been raised about the breadth, complexity, and inscrutability of the Stark Law as currently implemented. As part of the Balanced Budget Act (BBA) of 1995, Congress voted to repeal the Stark Law as applied to compensation arrangements, but the BBA was vetoed by President Bill Clinton. More recently, the law’s namesake, former Representative Fortney “Pete” Stark, has urged its repeal.<sup>4</sup>

This article is not intended to summarize all the facts of *Tuomey* or its extended procedural history, which have been recounted elsewhere. Rather, we seek to comment on three key aspects of the case: (1) the defendant’s advice of counsel/*scienter* defense; (2) the court’s application of the “takes into account” prong to *Tuomey*’s physician employment agreements; and (3) certain inherent tensions in the Stark Law that the *Tuomey* odyssey underscores.

### Too Many Cooks: *Tuomey* and Advice of Counsel

The basic allegation in *Tuomey* was that *Tuomey* Regional Medical Center entered into 19 part-time employment agreements with surgeons and gastroenterologists, that those agreements failed to comply with the Stark Law, and that as a result the hospital’s submission of claims for services referred by the employed physicians violated the FCA. The jury in the first *Tuomey* trial found that *Tuomey* violated the Stark Law but not the FCA, concluding that *Tuomey* relied on the advice of its counsel that the agreements complied with Stark, so that the hospital could not have “knowingly” submitted false claims.<sup>5</sup>

The jury in the second *Tuomey* trial rejected that defense, and the Fourth Circuit upheld the jury’s verdict, concluding that “the record here is replete with evidence that *Tuomey* shopped for legal opinions approving of the employment contracts, while ignoring negative assessments.”<sup>6</sup> What are the lessons the health law bar should draw from this? How should a client address negative legal assessments? A brief review of the advice *Tuomey* received from counsel with respect to the employment agreements is instructive.

Timothy Hewson at Nexsen Pruet was *Tuomey*’s longtime counsel, who helped develop the part-time physician employment model at issue in the case. On January 20, 2004, Richard Kusserow, former inspector general for the Department of Health and Human Services (HHS), who is not an attorney, provided *Tuomey* an 11-page “devil’s advocate” evaluation of the employment contracts. The letter stated: “From the limited information provided to us it does not appear as if there are significant Stark issues involved other than meeting the commercially reasonable standard.”<sup>7</sup>

On January 28, 2004, Mr. Hewson provided the *Tuomey* board with an executive summary of the transactions that concluded the arrangements complied with the Stark Law.<sup>8</sup> Mr. Hewson also testified that several of the physicians were represented in their negotiations by a partner at Nelson Mullens, and that both firms approved the final form of the employment agreement.<sup>9</sup> *Tuomey* entered into 19 employment agreements over 2004–2005.

Dr. Michael K. Drakeford, the future relator, was offered an employment agreement and engaged Greg Smith, a partner at Womble Carlyle, to represent him. Mr. Smith voiced concerns to Mr. Hewson that the arrangements were not fair market value or commercially reasonable.<sup>10</sup> At Mr. Smith’s suggestion, in September 2005 Dr. Drakeford and *Tuomey* jointly engaged Kevin McAnaney, former Chief of the Industry Guidance Branch of the Office of Counsel to the HHS Inspector General, to provide a verbal assessment of the proposed employment agreements.<sup>11</sup> The Fourth Circuit summarized Mr. McAnaney’s assessment as follows:

McAnaney warned *Tuomey* that procuring fair market valuations, by itself, was not conclusive of the accuracy of the valuation. He emphasized that it would be very hard to convince the government that a contract that paid physicians “substantially above even their collections, much less their collections minus expenses,” would constitute fair market value. According to McAnaney, compensation arrangements under which

the contracting physicians are paid in excess of their collections were “basically a red flag to the government.” He noted that similar cases had previously been prosecuted before, although all of them ultimately settled.

McAnaney also pointed out that the ten-year term of the contracts, combined with the thirty-mile, two-year noncompete provision would reinforce the government’s view that Tuomey was “paying [the physicians] above fair market value for referrals.” He concluded that the contracts did not pass the “red face test,” and warned that the government would find this “an easy case to prosecute.”<sup>12</sup>

Tuomey did not seek further advice from Mr. McAnaney and did not expand the scope of its engagement letter to include a written assessment. At Mr. Hewson’s recommendation, Tuomey sought and received a formal written opinion from a partner at Hall Render and adjunct health law professor, which concluded that the arrangements complied with the Stark Law. The court disregarded the opinion, however, finding the firm had not been given full disclosure, including being told of Mr. McAnaney’s unfavorable assessment.

The jury assessed damages against Tuomey only for those claims submitted on or after September 2005, when Mr. McAnaney had provided his verbal assessment. The Fourth Circuit found “that a reasonable jury could have concluded that Tuomey was, after September 2005, no longer acting in good faith reliance on the advice of its counsel when it refused to give full consideration to McAnaney’s negative assessment of the part-time employment contracts and terminated his representation.”<sup>13</sup> As others have suggested, this raises a question for practitioners as to whether conflicting opinions create inherent risk, or whether there was simply a requirement to give “full consideration” to Mr. McAnaney’s concerns that Tuomey failed to adequately address.

Of interest, however, later in the opinion the court notes: “Given that a jury found Tuomey possessed the requisite *scienter* under the FCA, *it necessarily also found Tuomey knew that its contracts varied with or took into account referrals.*”<sup>14</sup> But as the description of the various legal assessments above indicates, none of the attorneys (or non-attorney consultants) apparently ever suggested to Tuomey that the arrangements failed to comply with Stark because the compensation “varied with or took into account” referrals. Richard Kusserow stated that the only Stark issue was commercial reasonableness, Greg Smith stated that the arrangement raised fair market value and commercial reasonableness issues, and Kevin McAnaney’s “red flags” all related to fair market value concerns.<sup>15</sup> (Relator’s complaint itself alleges that Tuomey entered into agreements that did not meet the fair market value and commercial reasonableness requirements, but is silent as to any “takes into account” issue.<sup>16</sup>) If, as the court indicates, the jury found

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that Tuomey knew that its contracts varied with or took into account referrals, and did so on the basis articulated by the court, it is hard to see how Tuomey was even put on notice of that issue at any time by any counsel.

Arguably, this is splitting hairs, as Tuomey was told that there were potential fair market value and commercial reasonableness issues, and, therefore, was on notice of a potential violation of the Stark Law. But the FCA liability was predicated on there being, in the first instance, a violation of the Stark Law. Unlike the federal Anti-Kickback Law, where the government only need prove that the defendant knew its conduct was wrongful or illegal, but not necessarily that it specifically violated the statute, here the government bore the burden of proving that Tuomey knew<sup>17</sup> that the compensation to the physicians varied with or took into account the volume or value of the physicians’ referrals to Tuomey. If the court is correct that the jury had to find not that Tuomey “recklessly disregarded” Stark warnings in general, but specifically that *it knew its contracts varied with or took into account referrals*, the record of counsel’s advice is troubling: could the jury have reasonably found that Tuomey had the requisite *scienter* for FCA liability when none of Tuomey’s (or opposing) attorneys flagged a “takes into account” problem?

More broadly, when Stark lawyers advise on compliance with a particular exception, or when they analyze violations, they have commonly divided the various elements of a Stark exception into “substantive” and “technical” criteria, and in the authors’ experience regulators have viewed violations through the same lens. “Technical” elements include the writing, signature, and term requirements, for example, while the “takes into account,” set in advance, fair market value, and commercial reasonableness criteria are generally viewed as “substantive.” Perhaps there is another distinction, however, that should be drawn between the elements of the common Stark exceptions. *Structural* issues as to whether compensation “takes into account” referrals or is set in advance—or whether

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a contract complies with the various technical requirements of the common Stark exceptions—are legal issues for lawyers to advise upon, while *economic* questions of fair market value and commercial reasonableness are arguably outside the lawyer’s expertise. Clearly, advice from reputable counsel that the compensation is structurally deficient—that it takes into account referrals or is not set in advance—must be carefully considered, as these are issues within counsel’s knowledge and expertise, but the same cannot be said for issues of fair market value and commercial reasonableness. We do not mean to suggest that a counsel’s warnings as to fair market value should be ignored, but ultimately the question of fair market value is one for the appropriate experts to determine. Counsel’s role is to review the valuation and “kick the tires” on the assumptions and reasoning, but in a decidedly non-expert role. Similarly, matters of commercial reasonableness are arguably outside of counsel’s area of expertise. While some valuation firms may opine as to commercial reasonableness, perhaps it is the operational folks themselves—and Board members who come from the business world—who are best equipped to evaluate and document the commercial reasonableness of a transaction, albeit guided in that endeavor by counsel.

Based on this distinction between the structural and economic elements of the Stark exceptions, and the fact that attorneys are not qualified to issue fair market value or commercial reasonableness opinions, the *Tuomey* court arguably placed undue weight on McAnaney’s fair market value and commercial reasonableness concerns. This is especially concerning because the threshold issue under the Stark Law was whether Tuomey knew it was paying compensation that varied with or took into account the volume or value of referrals, an issue McAnaney did not even opine on.

## **Referral Madness: *Tuomey*’s Treatment of “Varies with or Takes into Account”**

The facts in *Tuomey* are peculiar. Hospitals, with the express blessing of the Stark regulations, routinely require their employed physicians to refer to the hospital system.<sup>18</sup> Accordingly, the notion that a hospital’s employed physicians would be required to work in the hospital’s facilities is not, on its face, controversial. And physician compensation based on personal productivity, a metric expressly referenced in the employment exception and Centers for Medicare & Medicaid Services (CMS) commentary,<sup>19</sup> could not be viewed as uncommon.

Importantly, however, the 19 *Tuomey* physicians remained in private practices, being part-time employees *only* when performing outpatient surgeries and procedures. Yet, they were required to do all outpatient surgeries—in practice, to refer all outpatient surgeries—to Tuomey.<sup>20</sup> Those referrals were not made in the scope of their employment, but from their private practices. The Fourth Circuit opinion, broadly read, calls into question all productivity bonuses to hospital-employed surgeons and proceduralists, even full-time ones.<sup>21</sup> We believe that such a reading is unwarranted, and that the question of whether the *Tuomey* contracts “varied with or took into account referrals” can be answered in a manner consistent with both the jury verdict and the CMS commentary.

The *Tuomey* physicians were not employed *directly* by Tuomey Healthcare System, Inc., which operated Tuomey Regional Medical Center, but by a Tuomey affiliate. Thus, the government had the initial burden of proving that the hospital company had an *indirect* compensation arrangement with the physicians. To satisfy the regulatory definition of an indirect compensation arrangement, Tuomey had to know<sup>22</sup> that the employment compensation paid by its affiliate *varied with or took into account* the volume or value of the physician’s referrals or other business generated for Tuomey’s hospital (which we sometimes refer to here as the “volume/value” standard). If the government prevailed on the volume/value issue, the burden of proof would shift to Tuomey to prove that the compensation qualified for the indirect compensation arrangement exception, including the fair market value and commercial reasonableness elements thereof. But if Tuomey prevailed on the volume/value issue, it would win *the whole* case, including the FCA allegations, and the fair market value and commercial reasonableness issues would be moot.

The government advanced an expansive interpretation of the volume/value standard, where compensation “takes into account” referrals if the purpose and motive for the compensation was to pay for referrals. The government pointed to evidence that the compensation was intended to function as “phantom stock” in the hospital’s outpatient surgery department and that the hospital’s motive was to deter the physicians from moving their cases to their offices or a competing ambulatory surgery center.<sup>23</sup> The government argued to the Fourth

Circuit that the jury was entitled to conclude that “[t]he real reason for the arrangements was to pay the doctors for their referrals, but to do so indirectly and covertly so as to gloss the relationship with the veneer of legality.”<sup>24</sup> In other words, under the government’s theory, if the *reason* for the compensation is to induce or pay for referrals, then the compensation takes into account the volume or value of referrals.<sup>25</sup>

The government also argued that the compensation failed the volume/value standard because of the one-to-one relationship between the physicians’ compensation and the volume of their referrals for the facility component of outpatient surgeries (sometimes referred to herein as the “Correlation Argument”).<sup>26</sup> According to the Correlation Argument, productivity-based compensation varies with, or takes into account, the volume or value of referrals because, with every personally performed service, there is a referral of a facility component service. Those facility component referrals correlate to the compensation the physician earns under the productivity bonus.

Finally, the government argued that the compensation “took into account” the physicians’ *anticipated referrals*.<sup>27</sup> In support, the government alleged that the compensation consultant used the net present value of the facility component business that the hospital stood to lose if referrals were redirected as a benchmark, and cited evidence of management’s *intent* for the compensation to account for, and thus indirectly take into account, the value of the physician’s outpatient surgery business to Tuomey.<sup>28</sup>

In defense, Tuomey advanced a narrow interpretation of the volume/value standard. Tuomey argued that the trial court committed reversible error by letting the government introduce evidence of Tuomey’s motives or purposes, and for not giving the jury an instruction that it had to decide whether on *the face of the contracts* the compensation varied with or took into account the volume or value of referrals.<sup>29</sup> Tuomey urged that CMS’ express intent to establish “bright-line” rules foreclosed from the volume/value analysis considerations of why or how the compensation was determined; the only relevant consideration was the contractual compensation itself. Because the compensation was paid solely on the basis of each physician’s collections, Tuomey argued, the compensation neither varied with nor took into account the volume or value of the physician’s referrals to Tuomey.<sup>30</sup>

In addressing the Correlation Argument, Tuomey cited a Stark II Phase II preamble statement by CMS as the last word on the issue: “The fact that corresponding hospital services are billed would not invalidate an employed physician’s personally performed work, for which the physician may receive a productivity bonus (subject to the fair market value requirement).”<sup>31</sup> Thus, Tuomey argued, compensation based on personally performed services that *correlate* with hospital referrals cannot be found to *vary with* the volume or value of referrals.

The jury for the second trial was instructed that if it found the employment agreements created an indirect compensation arrangement between Tuomey and the physicians, Tuomey would need to satisfy *either* the indirect compensation exception or the employment exception. Notably, the latter includes an express exception to its volume/value standard that tracks the CMS commentary, expressly permitting “payment of . . . a productivity bonus based on services performed personally by the physician . . . .”<sup>32</sup> The jury, however, did not find that Tuomey’s compensation qualified for the employment exception.

On appeal, Tuomey argued that the CMS commentary was not limited to the employment exception and should control for purposes of determining whether Tuomey violated the volume/value standard. The Fourth Circuit disagreed, concluding that a reasonable jury could find that the compensation to the physicians *varied with* the volume or value of the physician’s actual or anticipated referrals to Tuomey. The court acknowledged that the compensation received by the physicians was “based solely on collections for personally performed professional services,” but because there was a facility component referral with the performance of each surgery or procedure, both the physicians’ base salaries and productivity bonuses varied with the volume or value of the physicians’ referrals, the base salary being adjusted annually based on collections from the prior year.<sup>33</sup>

The court distinguished the CMS commentary on two bases. First, the court noted that the CMS commentary addressed productivity *bonuses*, while Tuomey’s *base salary* also varied based on personally performed services.<sup>34</sup> The court also argued that the CMS commentary was limited in application to the Stark employment exception and could not apply to the volume/value standard in the indirect compensation arrangement definition.<sup>35</sup>

The court’s efforts to distinguish the CMS commentary from the facts in Tuomey are subject to potential criticism. First, the argument that *bonuses* based on personal productivity are permissible but changes to the following year’s *base salary* are not seems suspect as a matter of logic or policy. Would dividing the increased base compensation into an unchanged base and a fixed “bonus” payment in the following year change the outcome? And why should a payment that fluctuates directly with the volume of services be favored over a fixed payment that is unaffected by future services? The argument that the CMS commentary only applies to the employment exception is also troubling, particularly where the compensation is paid under an employment agreement that is part of an unbroken chain of financial relationships between the physician and the hospital. Does the court’s reasoning mean that if the hospital directly employed the physicians, the productivity compensation would not offend the volume/value standard, but employment by a hospital subsidiary renders the standard violated? How does the court’s position square with

# Analysis

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the Stark II Phase II commentary that “all physicians, whether employees, independent contractors, or academic medical center physicians, can be paid productivity bonuses based on work they personally perform”<sup>36</sup>

We would argue that the court’s attempt to reconcile its adoption of the government’s Correlation Argument with the CMS commentary is unconvincing, and that the Correlation Argument is unnecessary to find a violation of the volume/value standard under the *Tuomey* facts.

The physician employment agreement with the gastroenterologists provided: “Physician shall provide outpatient gastroenterology procedures, including outpatient endoscopic procedures, and other related services (the ‘Services’). . . . The Services shall be provided to outpatients at the Hospital or at facilities owned or operated by the Hospital”<sup>37</sup> and “Physician shall not have the right to perform invasive outpatient gastroenterology procedures at the Independent Practice or elsewhere while this Agreement is in effect.”<sup>38</sup> Effectively, then, the agreement required that if the gastroenterologist saw a patient in her private practice and determined that an invasive outpatient gastroenterology procedure was required, the physician had to refer the patient to Tuomey to perform the service.

CMS’ position, adopted in regulation, is that if compensation from an employer or under a personal services contract is conditioned on a requirement to refer to a particular provider, the compensation necessarily “takes into account” referrals unless (among other things) there are written exceptions for patient preference, payer requirements, and the best medical interest of the patient in the physician’s judgment.<sup>39</sup> Tuomey’s contracts did not include these exceptions.<sup>40</sup> More importantly, in mid-2004 CMS amended that regulation to clarify that the required referrals must “relate solely to the physician’s services covered by the scope of the employment or the contract . . . . In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment or contract.”<sup>41</sup> In its commentary, CMS stated:

For example, an entity that employs or contracts with a physician on a part-time basis to provide services to the entity cannot condition the employment or contract—or any compensation under the employment or contract—on referrals of the physician’s private practice business (for example, patients seen by the physician when he or she is not working part-time for the entity).<sup>42</sup>

In Tuomey’s case, the physicians retained their private practices, only working within the scope of their part-time contracts with Tuomey subsidiaries *when performing outpatient surgeries or procedures in Tuomey’s hospital*. Because the part-time contracts required the physicians to refer to Tuomey the physician’s private practice patients, the part-time contracts “varied with or took into account” referrals.

Viewed this way, the problem in Tuomey was not the one-to-one relationship between the physician’s productivity compensation for personally performed services and referrals for hospital facility component services. *Rather, it was that Tuomey conditioned the physicians’ compensation on referrals to Tuomey, referrals that were made by the physicians not as employees but as private practitioners*. Under this approach, a full-time hospital-employed surgeon can be paid productivity-based compensation conditioned on referrals for surgeries to the employer’s facilities,<sup>43</sup> an outcome CMS clearly intended by its commentary and the manner in which it addressed, by regulation, compensation conditioned on referrals to a particular health care provider.

### Complexity and Contradiction in the Stark Law: Where Do We Go from Here?

The words of Judge Wynn that began this article reflect a growing consensus that the Stark Law has strayed far from its initial intent. It is extraordinary to read Representative Stark’s description of the law in 1989, urging Congress to establish rules of conduct that, unlike the federal Anti-Kickback Law, would be clear, easily understood, and self-policed:

What is needed is what lawyers call a bright line rule to give providers and physicians unequivocal guidance as to the arrangements that are prohibited. If the law is clear and the penalties are substantial, we can rely on self-enforcement. Few physicians will knowingly break the law. The Ethics in Patient Referrals Act provides this bright line rule.<sup>44</sup>

There is a sense of reluctance and regret in the *Tuomey* decision. Yet, the Fourth Circuit upholds a \$237 million judgment, noting that “[t]he degree of reprehensibility of the defendant’s conduct is [p]erhaps the most important indicium of the reasonableness of a punitive damages award,” that the “Stark Law expresses Congress’s judgment that all services provided in violation of that law are medically unnecessary,” and that “the Stark Law expresses Congress’s judgment of the reprehensibility of the conduct at issue by deeming services provided in violation of the law worthless.”<sup>45</sup> In our research, nothing in the Congressional Record suggests that Congress deemed

services rendered nonreimbursable by the Stark Law to be “medically unnecessary” or “worthless.” It is hard to imagine how a hospital’s missing signature on a medical directorship agreement, for example, could render the facility component of a surgery performed by that medical director to be “medically unnecessary.”<sup>46</sup> In fact, CMS stated in the Stark II Phase I preamble that “nothing in the statute suggests that the Congress intended to limit the statute’s reach to referrals of medically unnecessary tests or procedures.”<sup>47</sup> This statement cannot be squared with the court’s assertion that services rendered pursuant to Stark-prohibited referrals are inherently medically unnecessary.

Why then does the Fourth Circuit state, without citation, that Stark-infected services are medically unnecessary and worthless? We would suggest that absent such hyperbole, it becomes more difficult to defend the notion that failure to satisfy an inscrutable payment rule constitutes the “reprehensible” conduct needed to defend the fines levied under the Due Process Clause and Excessive Fines Clause of the U.S. Constitution.

The industry today finds itself struggling with ill-defined fair market value and commercial reasonableness standards that allow the government to engage in a “battle of the experts” where the burden of proof is on the defendant. Advice of counsel, which the concurrence notes must be “especially robust in Stark Law cases prosecuted under the False Claims Act,”<sup>48</sup> is dependent on the opinions of outside valuation experts that counsel is ill-suited by training to rigorously evaluate. Moreover, the introduction of intent and motive evidence has the effect of conflating the Stark Law and federal Anti-Kickback Law in the proceedings, moving us ever further from the “bright line” rules Congress believed it was adopting.<sup>49</sup>

The *Tuomey* court concluded its opinion by noting “it is for Congress to consider whether changes to the Stark Law’s reach are in order.”<sup>50</sup> The authors would suggest that a few basic changes could move us away from the “impenetrably complex” “booby trap”<sup>51</sup> decried by the *Tuomey* concurrence: clarifying “takes into account” with an objective test for compliance, creating “safe harbors” the industry can rely upon in establishing fair market value, and limiting “commercial reasonableness” to an inquiry as to whether the transaction advances the DHS entity’s legitimate interests (e.g., no unneeded services). A quarter century later, it may be time for Congress to act. **C**

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## Endnotes

- 1 *United States ex rel. Drakeford v. Tuomey (Tuomey II)*, No. 13-2219, 2015 U.S. App. LEXIS 11460 (4th Cir. July 2, 2015).
- 2 *Id.* at \*56, \*69 (Wynn, J., concurring). The Fourth Circuit previously described the Medicare statute generally as “among the most completely impenetrable texts within human experience.” *Rehab. Ass’n of Va. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994). This commentary was quoted approvingly by the U.S. District Court for the District of Columbia, adding: “Picture a law written by James Joyce [footnoting that the court refers to Joyce’s later work, specifically *Finnegan’s Wake*] and edited by E.E. Cummings.” *Catholic Health Initiatives—Iowa v. Sebelius*, 841 F. Supp. 2d 270, 271 (D.D.C. 2012); cf. DAVID FOSTER WALLACE, *THE PALE KING* 84 (2011) (“one of the great and terrible PR discoveries in modern democracy [] is that if sensitive issues of governance can be made sufficiently dull and arcane, there will be no need for officials to hide or dissemble, because no one not directly involved will pay enough attention to cause trouble. No one will pay attention because no one will be interested, because, more or less *a priori*, of these issues’ monumental dullness.”).
- 3 *Tuomey II*, 2015 U.S. App. LEXIS 11460, at \*55.
- 4 See Joe Carlson, *Stark Law Complicated by “Smart Lawyers” Finding Loopholes*, MODERN HEALTHCARE (Nov. 30, 2013), available at [www.modern-healthcare.com/article/20131130/MAGAZINE/311309955](http://www.modern-healthcare.com/article/20131130/MAGAZINE/311309955); David Whelan, *Stark Regrets: I Shouldn’t Have Written That Law*, FORBES BLOG (Nov. 30, 2007, 1:52 PM), available at <http://blogs.forbes.com/sciencebiz/2007/11/30/stark-regrets-i-shouldnt-have-written-that-law/>.
- 5 See *Tuomey II*, 2015 U.S. App. LEXIS 11460, at \*8–12 (recounting the procedural history of the case).
- 6 *Id.* at \*30.
- 7 Transcript of Record at 278, *United States ex rel. Drakeford v. Tuomey*, 976 F. Supp. 2d 776 (D.S.C. 2013) (No. 3:05-2858) (Kusserow testimony). The Fourth Circuit stated that Mr. Kusserow “hedged considerably” in his assessment by referencing unspecified issues with the compensation at the end of his written analysis. *Tuomey II*, 2015 U.S. App. LEXIS 11460, at \*36. At trial, however, Mr. Kusserow testified: “The only concern I had, reasonably—commercially reasonable standard was that, and woven through the whole thing, was the fair market value issue. Other than that, I did not think to add any more focus on the Stark Law” and “The only two issues I saw that I was concerned about is where it intersected with the Antikickback Statute and with the fair market value, and also the related issue of commercially reasonable services.” Transcript of Record, *supra*, at 278–79. The precise basis for and scope of Mr. Kusserow’s engagement by Tuomey is unclear from trial testimony. He testified that he had not been asked to review Stark issues by Tuomey, only the federal Anti-Kickback Law, but “I kind of fudged on that.” *Id.* at 268, 306–07. His consulting firm, Strategic Management Services, had already been engaged to do a general review of Tuomey’s compliance program, and Tuomey’s compliance officer had reportedly asked the Strategic Management Services consultant for an assessment of federal Anti-Kickback Law risks. *Id.* at 343 (Al Bassett testimony). Neither Mr. Bassett nor the compliance officer is an attorney. Mr. Kusserow, who is also not an attorney, emailed Mr. Hewson that his assessment was “a pro bono effort” for which he would not charge for his time or effort. At trial, when asked “was Tuomey requesting a freebie or was that something that your firm was doing as a sort of marketing effort for Tuomey?,” Mr. Kusserow responded that an associate at his consulting firm had committed him to do the assessment without charge, “and he also said that if we demonstrated we can do good work here maybe we can do more work for them in the future.” *Id.* at 263, 289–90 (Kusserow testimony).

- 8 Transcript of Record, *supra* note 7, at 1776–78 (Timothy Hewson testimony).
- 9 *Id.* at 1778–79.
- 10 *Id.* at 796–97 (Greg Smith testimony).
- 11 In Mr. McAnaney’s engagement letter dated May 6, 2005, he stated: “I will report orally my conclusions as well as an evaluation of any potential compliance issues.” Defendant’s Exhibit 1 (Entry No. 299-2), *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858, 2010 U.S. Dist. LEXIS 143457 (D.S.C. July 13, 2010).
- 12 *Tuomey II*, 2015 U.S. App. LEXIS 11460, at \*22–23 (citations omitted).
- 13 *Id.* at \*33.
- 14 *Id.* at \*39 (emphasis added).
- 15 Notably, even Mr. McAnaney’s cautions to Tuomey regarding fair market value were in the vein of cautions regarding how Tuomey’s valuation and compensation methodology would be viewed by the government, not an independent analysis of how the valuation was flawed or whether the compensation was or was not fair market value. If CMS and OIG are statutorily proscribed from even issuing advisory opinions on fair market value, Mr. McAnaney’s cautions to Tuomey regarding how the government would evaluate the fair market value issue arguably did not go to Tuomey’s “knowledge” that its compensation was not fair market value, but to its “knowledge” of Mr. McAnaney’s assessment of its litigation risk.
- 16 Complaint at 8, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858, 2010 U.S. Dist. LEXIS 143457 (D.S.C. July 13, 2010).
- 17 The terms “knowing” and “knowingly” under the FCA “mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information . . . .” 31 U.S.C. § 3729(b)(1).
- 18 An employer’s requirement that a physician-employee refer patients to a particular provider, supplier, or practitioner must, by Stark regulation, make exceptions for patient preference, payer requirements, and the best medical interests of the patient in the physician’s judgment. 42 C.F.R. § 411.354(d)(4)(iv)(B).
- 19 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c)(4); *see also* 69 Fed. Reg. 16054, 16067 (Mar. 26, 2004).
- 20 *Tuomey II*, No. 13-2219, 2015 U.S. App. LEXIS 11460, at \*6 (4th Cir. July 2, 2015).
- 21 *See id.* at \*27–28.
- 22 That is, Tuomey had to have “actual knowledge of, or act[] in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receive[d] aggregate compensation that varie[d] with, or [took] into account, the volume or value of referrals or other business generated by the referring physician” for Tuomey. 42 C.F.R. § 411.354(c)(2)(iii).
- 23 Brief for Appellee United States of America at 6–7, 10–11, *United States ex rel. Drakeford v. Tuomey Healthcare Sys. (Tuomey I)*, 675 F.3d 394 (4th Cir. 2012) (No. 10-1819), 2011 WL 1209674.
- 24 *Id.* at 12.
- 25 *Id.* at 20 (“The whole purpose of these arrangements was for the hospital to thwart emerging competition by locking up the physicians’ valuable outpatient referrals for a decade or more; the hospital told the physicians this was precisely its goal.”).
- 26 *Id.* at 9, 25–28.
- 27 In the Fourth Circuit’s opinion in Tuomey’s first appeal, the court held that “takes into account” includes compensation that takes into account *anticipated* referrals, not just actual referrals. *Tuomey I*, 675 F.3d at 408–09.
- 28 Brief for Appellee United States of America, *supra* note 23, at 6–8, 15–16, 30–31.
- 29 The Fourth Circuit’s instruction in *Tuomey I* was that the issue for the jury on remand was “whether the contracts, *on their face*, took into account the value or volume of anticipated referrals. . . .” *Tuomey I*, 675 F.3d at 409 (emphasis added).
- 30 Brief of Appellant Tuomey Healthcare System, Inc. at 25–26, *Tuomey I*, 675 F.3d 394 (No. 10-1819), 2011 WL 792205.
- 31 Reply Brief of Appellant Tuomey Healthcare System, Inc. at 7–8, *Tuomey I*, 675 F.3d 394 (No. 10-1819), 2011 WL 792206 (quoting 69 Fed. Reg. 16054, 16089 (Mar. 26, 2004) (sometimes referred to herein as the “CMS commentary”)). CMS was responding to the following comment: “A commenter presented the following scenario. A hospital employs a physician at an outpatient clinic and pays the physician for each patient seen at the clinic. The physician reassigns his or her right to payment to the hospital, and the hospital bills for the Part B physician service (with a site of service reduction). The hospital also bills for the hospital outpatient services, which may include some procedures furnished as ‘incident to’ services in a hospital setting. The commenter’s concern is that the payment to the physician is inevitably linked to a facility fee, which is a designated health service (that is, a hospital service). Accordingly, the commenter wondered whether the payment to the physician would be considered an improper productivity bonus based on a DHS referral (that is, the facility fee).” As indicated above, CMS’ response to this comment was as follows: “The fact that corresponding hospital services are billed would not invalidate an employed physician’s personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement).” 69 Fed. Reg. at 16088–89.
- 32 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c)(4).
- 33 *Tuomey II*, No. 13-2219, 2015 U.S. App. LEXIS 11460, at \*26–28 (4th Cir. July 2, 2015).
- 34 *Id.* at 29 n.10.
- 35 *Id.*
- 36 69 Fed. Reg. at 16067.
- 37 Entry No. 302-16, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858, 2010 U.S. Dist. LEXIS 143457 (D.S.C. July 13, 2010) (Section 1.1 of Physician Employment Agreement).
- 38 *Id.* (Section 6 of Physician Employment Agreement).
- 39 42 C.F.R. § 411.354(d)(4)(iv)(B).
- 40 Steve Pratt of Hall Render advised Tuomey that the contracts should include these exceptions. Second Amended Complaint of the United States at 25–26, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858, 2010 U.S. Dist. LEXIS 143457 (D.S.C. July 13, 2010).
- 41 42 C.F.R. § 411.354(d)(4)(v).
- 42 69 Fed. Reg. 16054, 16069–70 (Mar. 26, 2004).
- 43 Subject to the exceptions set forth in 42 C.F.R. § 411.354(d)(4)(iv)(B) for patient preference, payer requirements, and the best medical interest of the patient in the physician’s judgment.
- 44 135 CONG. REC. H240-01 (daily ed. Feb. 9, 1989) (statement of Rep. Stark).
- 45 *Tuomey II*, No. 13-2219, 2015 U.S. App. LEXIS 11460, at \*47–48, 51 (4th Cir. July 2, 2015) (citations omitted).
- 46 *See* 42 U.S.C. § 1395y(a)(1) (no payment may be made under Medicare for “items or services – (1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”).
- 47 66 Fed. Reg. 856, 896 (Jan. 4, 2001).
- 48 *Tuomey II*, 2015 U.S. App. LEXIS 11460, at \*66–67 (Wynn, J., concurring).
- 49 The government’s approach in *Tuomey* did little to clear up such confusion. For example, the government repeatedly and incorrectly asserted in its questioning of witnesses that the Stark employment exception includes a requirement that the arrangement not violate the federal Anti-Kickback Law. *See, e.g.*, Transcript of Record, *supra* note 7, at 1888 (G. Norman Acker, Assistant U.S. Attorney, cross-examination of Tim Hewson) (“The ones you considered here, the indirect compensation exception and the bona fide employment exception, both require compliance with the Anti-Kickback Statute, isn’t that right?”); *id.* at 2114 (Tracy L. Hilmer, U.S. Department of Justice, cross-examination of Steven H. Pratt) (“And isn’t it true under both of those exceptions [the Stark indirect compensation and employment exceptions] one of the things that—one of the elements of the exceptions is that you haven’t violated the Anti-Kickback Statute?”); *cf. id.* at 37 (G. Norman Acker, Government’s Opening Statement) (“What is the Stark law? . . . The common sense answer is the Stark law says you can’t pay for referrals.”); *id.* at 2400 (G. Norman Acker, Government’s Closing Statement) (“And the Stark Law, as you’ve heard over and over again, one of the basic tenets is you can’t pay for referrals.”). Similarly, while the regulatory definition of “fair market value” in the Stark Law would appear to be an objective one, the government has recently asserted that a determination of “fair market value” must “in the first instance” consider “the parties’ rationale in settling upon certain compensation.” United States’s Response to Defendants’ Joint Motion for Partial Summary Judgment on Volume or Value of Referrals at 12, *United States ex rel. Robinson-Hill v. Nurse’s Registry & Home Health Corp.*, No. 08-145 (E.D. Ky. May 28, 2015).
- 50 *Tuomey II*, 2015 U.S. App. LEXIS 11460, at \*55.
- 51 *Id.* at \*56, \*69 (Wynn, J., concurring).