Bloomberg BNA

BNA's
Health Care Fraud Report™

Health-Care Industry Adapts to the Stark Reality of a Post-Tuomey World

The $237.5 million amended judgment leveled against Tuomey Healthcare System has served as a wake-up call to hospitals, physicians and health care attorneys around the country who deal with physician employment contracts, making sure they don't run afoul of the federal physician self-referral law, or ''Stark law,'' according to health care fraud attorneys interviewed by Bloomberg BNA (17 HFRA 883, 10/2/13).

It is clear that hospitals and practitioners alike will have to re-evaluate their physician hiring and compensation practices in light of the government's interpretation of the Stark law as argued in the case and take steps to ensure that their exposure to a lawsuit similar to *Tuomey* (*United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, D.S.C., No. 3:05-cv-2858, *amended judgment* 10/2/13) is minimized, according to the attorneys.

The litigation, which is continuing thanks to an Oct. 3 appeal by Tuomey to the U.S. Court of Appeals for the Fourth Circuit (17 HFRA 924, 10/16/13, understandably drew attention partly due to the massive damage award, which was reduced from a prior $277 million judgment following a jury trial.

But the broad arguments advanced by the government in the case in relation to the Stark law have caused a great deal of discussion in the health-care bar apart from the judgment and verdict.

Those arguments include the government's theory on the boundaries of ''commercial reasonableness'' of physician compensation under the Stark law, and the appropriate methods of investigation for a hospital's board of directors and executives in determining the proper level of compensation for a physician or practice group the hospital wishes to employ.

Five health-care fraud attorneys discussed those issues and their implications on the industry, practice and future possible litigation with Bloomberg BNA. They gave their insights into what went wrong for Tuomey, based in Sumter, S.C., and identified a number of areas where health-care fraud attorneys need to focus their attention to steer hospital clients away from the situation in which Tuomey now finds itself.

A spokeswoman for Tuomey Healthcare System told Bloomberg BNA Nov. 15 the center would not comment on the case or its potential impact because the litigation is pending appeal.

Tuomey Contracts, Board Actions. The lawsuit was the product of a False Claims Act whistleblower lawsuit filed by Michael Drakeford, in which the federal government later intervened.

Tuomey originally was found guilty of Stark violations, but not guilty on FCA charges, in March 2010 (14 HFRA 335, 4/21/10). The trial court vacated that verdict and granted the government's motion for a new trial, which the Fourth Circuit refused to reverse in October 2010 (14 HFRA 889, 11/3/10). The Fourth Circuit reversed the trial court's order for Tuomey to pay $44.9 million in equitable damages based on the vacated jury verdict (16 HFRA 283, 4/18/12).

At the retrial, Tuomey was found guilty May 8 of violating the Stark law and the False Claims Act (17 HFRA 450, 5/15/13). The trial court ordered Tuomey to pay nearly $277 million (22 HLR 1486, 10/3/13) but entered an amended judgment Oct. 2 reducing the penalty by nearly $40 million (22 HLR 1518, 10/10/13). Attorneys for the hospital system have requested review by the Fourth Circuit.

Drakeford alleged that Tuomey contracted with a group of specialist physicians to conduct outpatient procedures only at Tuomey's hospital facility and assign all of the Medicare and Medicaid reimbursements to the hospital. Drakeford was one of the physicians approached by Tuomey to take part in this business plan.

The term "commercial reasonableness" "has a meaning that is broad enough to permit a hospital to operate a practice group at a loss."

JOHN T. BRENNAN JR., CROWELL & MORING LLP

The part-time employment contract terms offered to the specialist physicians by Tuomey represented a large increase in their overall pay and included certain productivity bonus provisions that the government alleged took overall hospital referrals into account. The 10–year term of the contracts also was quite lengthy and gave the physicians full-time employee benefits, although they were only part-time employees.

 ISSN 1092-1079

The Tuomey hospital board commissioned a fair market value study on the contracts to validate the overall compensation packages offered. According to the appraisals, the pay packages were at market rate, although it was apparent from the appraisals that Tuomey would be losing money on the physicians' compensation judged against their expected personal service billings alone. (14 HFRA 335, 4/21/10)

The Tuomey board was aware of the potential Stark implications of its proposed pay packages and asked for an opinion on the issue from outside counsel Kevin G. McAnaney, McAnaney told Bloomberg BNA.

McAnaney, now with the Law Offices of Kevin G. McAnaney, in Washington, told the Tuomey board there may have been problems with the contracts, according to deposition testimony he gave during the litigation.

Despite legal advice from McAnaney, a former chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General, Department of Health and Human Services, McAnaney told Bloomberg BNA that Tuomey decided to continue with the contracts, some of which had been signed already.

Government Arguments at Trial. Physician compensation contracts don't violate the Stark law if the compensation is in line with the fair market value, doesn't take into account the volume or value of referrals by the physician and ''the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer'' (42 U.S.C. § 1395nn(e)(2)).

The government made several arguments at trial as to why Tuomey's contracts with the specialist physicians violated the Stark law and the FCA, as well.

One particular argument that several industry experts have noted was that the compensation packages Tuomey offered the specialist physicians were ''commercially unreasonable'' because Tuomey would lose money on the contracts based purely on the expected billings of the physicians. McAnaney said that the government argued that a physician contract in which the hospital loses money on the contract is per se commercially unreasonable and, therefore, violated the Stark law.

The government also raised the specter of intent on the part of the Tuomey board, with regard to the solicitation and then dismissal of McAnaney's outside opinion concerning the physician employment contracts. The implication of the dismissal was that Tuomey was aware the contracts ran afoul of the Stark law but proceeded, anyway.

Further, the government presented evidence that part of Tuomey's motivation in hiring the physicians was to prevent competition from other providers, or the physicians themselves, in the future.

The jury's verdict only indicated that it found Tuomey guilty of violating the Stark law and the FCA, so it is unclear exactly which parts of the government's argument the jury found convincing. But the overall course of the litigation provided valuable perspectives on the government's view of the Stark law and lessons for attorneys in the health-care industry.

Commercial Reasonableness of Subsidizing Practices. John T. Brennan Jr., with Crowell & Moring LLP, Washington, told Bloomberg BNA that the term ''commercial reasonableness'' ''has a meaning that is broad enough to permit a hospital to operate a practice group at a loss.'' Brennan said that ''commercial reasonableness means that a hospital can take into account what is commercially reasonable in the broader scope for the hospital.''

Brennan said the fact that a hospital operates a practice group at a loss, or employs a physician at a compensation level greater than their personal billings, ''doesn't mean that the hospital is paying for referrals.''

Indeed, Brennan noted that there are a variety of reasons that hospitals might, and indeed do, employ physicians at a loss without counting their referral billings. These include maintaining its mission to serve the community, or to better integrate patient care, as the government has increasingly encouraged.

McAnaney echoed Brennan's thoughts on the government's interpretation of commercial reasonableness in the Stark law. McAnaney said that declaring the compensation of any physician practice that loses money for a hospital as commercially unreasonable is ''legally wrong.''

McAnaney stated that a physician or practice group bringing in less money for the hospital than their compensation level is legally permissible under the Stark law as long as the compensation is at fair market value. ''[I]f it's fair market value, it doesn't matter if [hospitals] are subsidizing [a practice group],'' he said. ''You are entitled to pay them that much.''

McAnaney said that the government's interpretation of the Stark compensation rules was ''virtually impossible to comply with.'' McAnaney said that there were ''very few physician compensation arrangements that would pass muster'' under the government's interpretation of the Stark law, putting health systems hiring physicians at risk.

Linda A. Baumann, with Arent Fox LLP, Washington, told Bloomberg BNA that ''it is wrong to say that it's not commercially reasonable to employ a group practice at a loss. She said ''it is very commonly the case that primary care physicians, in particular, are hired at a loss.''

Baumann said hospitals are legally obligated to treat indigent and uninsured patients, and ''you can't always make a profit'' in some instances. She also said some hospitals take on additional physicians or practice groups because ''they've had bad patient results or complaints because they didn't have sufficient coverage by a certain specialty.''

''[V]ery few physician compensation arrangements . . . would pass muster'' under the government's interpretation of the Stark law, putting health systems hiring physicians at risk.

KEVIN G. MCANANEY, LAW OFFICES OF KEVIN G. MCANANEY

Lewis Morris, an attorney with LeClairRyan in Annapolis, Md., and former chief counsel to the HHS Office of Inspector General, told Bloomberg BNA that the idea that a physician group losing money is per se evidence that the hospital is taking referrals into account

  HFRA ISSN 1092-1079

''shows an unsophisticated understanding of how hospitals go about meeting their mission.''

Morris added, ''There are going to be practices which are not money makers but are critical to servicing the community.''

Stark Law Is a Strict Liability Statute. Health-care attorneys also took issue with the presentation of certain evidence in the Tuomey trial by the government that seemed geared to show that Tuomey knew the specialist physician contracts violated the Stark law, suggesting an element of intent on the part of Tuomey's board. The Stark law is a strict liability statute, and intent on the part of the alleged violator is not an explicit element the prosecution is required to show.

''Stark is meant to be a strict liability statute. You are either in an exception or you are not,'' Morris told Bloomberg BNA. ''[W]hat the government appears to have done in this case is point to a lot of evidence of intent on the part of [Tuomey]. So suddenly you get this question of, 'Is intent relevant? Is that a new element? ' ''

Referring to McAnaney's sought-after opinion on Tuomey's proposed physician contracts, Baumann said that ''sometimes [hospitals] consult more than one'' attorney, ''and you can draw a negative inference from that.''

But, she said, simply because an attorney gives legal advice that doesn't comport with other legal advice a hospital board already has received, or raises red flags, doesn't mean that a considered action is illegal.

''It's disconcerting to me that a red flag is now being equated with being illegal,'' Baumann said, but added that ''you have to be wary of the fact that people can read a negative inference into that.''

Baumann said an intent on the part of Tuomey to prevent the formation of a competing physician entity is not necessarily illegal under Stark, ''so long as they don't pay the physician in a manner that reflects their referrals.''

'Group Think' at Play. Another problem that may have tripped up the Tuomey board was an insular mindset in conceiving and valuing the physician compensation packages, Morris said. ''[W]hat this case also seems to suggest is maybe more questions need to be asked about who are the parties'' crafting physician compensation arrangements.

Morris said there could be ''a risk of group think'' if a hospital board uses the same team to come up with a strategic plan, finds a particular physician practice group that fits the plan and then values the plan.

He noted that it was not inappropriate for the Tuomey board to use their own local counsel throughout the process of hiring the specialist physicians but said another ''important takeaway'' from the litigation outcome was that ''that someone on the board has to take on the role of being the devil's advocate.''

Joseph E.B. White, with Nolan & Auerbach PA, Philadelphia, who focuses on FCA plaintiff litigation, told Bloomberg BNA that it appeared from evidence at trial that the Tuomey board was ''put on notice that they were possibly crossing the line and decided to go for it anyway.'' White said that ''there were some very compelling facts that [Tuomey's board] may have known'' that they were doing something wrong.

Baumann said that while there were ''red flags'' in Tuomey's negotiations with the specialist physician group, she believed that Tuomey was making an effort to ''operate consistent with the law.''

Baumann said Tuomey's situation showed that ''there is no bright line; there's a danger zone.'' She added, ''The only really safe thing to do, it seems to me, is to take such a conservative position that there are no red flags'' in the physician employment process.

Don't Enter 'Danger Zone.' Morris said it appeared the government was holding the Tuomey board ''to a standard of heightened skepticism.''

He said there was evidence at trial that ''the board was engaged, it was an active participant in a strategic planning for the institution, it was getting status reports, it was getting assurances about the propriety of the engagement, and the fair market value of it, asking all the right questions, and relying on competent counsel.''

Morris said the outcome of the trial ''does give you pause if you are counsel to a board or a board member about what [] standard [of care] you are going to be held to'' in regard to the board's fiduciary duty. He said the litigation ''seems to suggest that boards are held to a fairly high level of skepticism when presented with financial deals with physicians that look very lucrative.''

McAnaney said that a big mistake the Tuomey board made was ''not unwinding the contracts when they realized they were under investigation.''That might have been a politically unappetizing path for the Tuomey board at the time, he said, because it might have ''alienated a good part of the physician community in their area.''

McAnaney said the Tuomey board didn't appreciate the potential damages, but ''a hospital in Tuomey's position, and a board in Tuomey's position, would think very differently about it [now], given what happened.''

White told Bloomberg BNA that hospital boards need to take to heart the lesson that ''you simply cannot take into account what that [physician] is going to send to the hospital in terms of referrals.''

He said any analysis of the impact a physician's employment will have on the larger hospital business, including referrals, ''needs to be siloed,'' adding, ''If that requires bringing in additional consultants to make sure that happens before you put pen to paper, it's probably wise to do that.''

Dangerous for Boards to Ask Compensation Questions. Indeed, several attorneys remarked on how dangerous it can be for a hospital board to openly contemplate the impact of hiring a physician or practice group on the hospital's overall finances beyond the physician's expected personal service billings.

''[E]very hospital system in this country has, today, Stark problems.''

—LEWIS MORRIS, LECLAIRRYAN

Morris said that ''[t]here seems to be an open question'' as to whether a hospital administrator or board can ask ''how are we going to afford'' a physician at a fair market compensation rate ''in a way that doesn't leave open the implication that you are talking about referrals.''

''That is what is causing lots of hospital executives and their counsel sleepless nights,'' he said.

Morris said questions like those ''get dangerously close to saying, 'What's my return on investment,' '' and insinuating that referrals are part of the consideration. ''At this point, the alarms start going off.''

Brennan shared Morris's concern for whether it is appropriate ''for a hospital administrator to consider whether or not the employment or purchase of a practice group would be helpful to the hospital's mission'' or if engaging in a particular business relationship would benefit the hospital ''through more referrals or a larger service area.''

Brennan said an administrator can make that assessment as long as he doesn't allow it ''to influence the fair market value compensation of that physician. Hospitals are entitled to make reasonable business decisions.''

Make Hiring Decisions Transparent, Legal. To avoid the appearance of impropriety, Baumann said that hospitals considering hiring physicians or a practice group need to be able to clearly demonstrate the reason for making the move was for commercially reasonable reasons unrelated to potential referrals.

''It's always good to have an independent appraisal of whether the terms of the agreement are commercially reasonable, as well as fair market value'' to support a proposed employment agreement, she said.

Morris agreed, stating that hospitals hiring physicians ''need to be able to articulate at the time this happens'' the corporate goal in bringing those physicians on board. He added that the reasons for hiring physicians have to ''not only be transparent, [they] have to be defensible'' under the Stark law.

Morris said that two legally defensible reasons would be to replace physicians lost through retirement or to respond to a community need. A stated goal of making up lost revenue ''by the referrals they generate for ancillary services'' wouldn't be legally defensible, he said.

Stark Problems Prevalent. In the wake of the *Tuomey* verdict, one might think that it would go without saying that a hospital cannot explicitly state that it is hiring a practice group for its anticipated referrals, but White said it does happen.

There are instances where a ''negotiation includes charts that show the [return on investment] of both the medical group and the hospital system,'' sometimes including charts ''based on anticipated referrals,'' White said, and ''that type of evidence can be ''smoking guns in our cases.''

While not all hospitals have the ''smoking gun'' evidence of a Stark violation lurking in a hospital administrator's e-mail account or a server backup tape, Morris said ''every hospital system in this country has, today, Stark problems.''

Morris said that even ''innocuous technical violations'' such as a physician practice lease that is commercially reasonable and at fair market value, but is expired, constitutes ''a Stark violation.''

Even a small technical violation means that ''all the services provided during the expired lease are subject to recoupment and under some circumstances, if identified and not repaid, are subject to the False Claims Act,'' Morris said.

Tips for Facing Potential Stark Liability

If a hospital reviewing the *Tuomey* litigation suspects that it might have a Stark violation, or discovers one, health care attorneys outlined several steps that the hospital can take to mitigate any damage:

- Any suspect physician compensation contracts should be reviewed by competent Stark counsel;
- If a hospital discovers an unsigned physician employment contract, it should first check with the practice to see if it has a contract signed in its possession;
- If further review of an arrangement reveals red flags (no appraisal, unsigned contracts, e-mails referencing referrals) the hospital's compliance officer and general counsel need to inform the corporate executives and the board of directors of the issue;
- Assure those alerting the compliance officer of possible Stark violations that their concern is being taken seriously so they don't become a whistleblower; and
- If legitimate Stark violations are uncovered, the hospital should prepare to use the Stark self-disclosure protocol and try to head off a future whistleblower action.

Stark Worries: Review, Self-Disclosure. On the topic of self-disclosure, Baumann agreed that if a hospital discovers a Stark violation, ''some form of self-disclosure is called for.'' She said that hospitals might not be entirely satisfied with the Stark self-disclosure protocol in practice, however.

''[It's] one potential option, it's just not a speedy one,'' Baumann said, adding that disclosing parties aren't promised ''a whole lot of benefits,'' and it's difficult to tell ''how advantageous'' the self-disclosure protocol was to past disclosing parties.

Morris was more enthusiastic about the benefits of using the Stark self-disclosure protocol. ''It would stop the clock for purposes of repayment of the overpayment, which is likely to be identified,'' he said. ''It would also signal to the government that you are an institution that has integrity.''

He said ''[the Centers for Medicare & Medicaid Services] has also demonstrated that those who successfully navigate its disclosure protocol are getting a good financial deal'' and pay much less than ''what their full Stark exposure would be.''

Hospitals that honestly disclose Stark violations ''save the government a lot of time and a lot of resources,'' Morris said, adding that the government ''sees the advantage of rewarding those who participate in a sincere fashion.''

'Siren Call' to Whistleblowers. However, Morris said that participation in the self-disclosure protocol and cooperation with the government won't absolve a hospital

  HFRA ISSN 1092-1079

of its liability under the FCA and the threat of a whistleblower lawsuit.

White said that ''a direct response to *Tuomey*'' is that everyone in the medical community ''is dusting off the arrangements they have with hospitals and looking over them with a fine tooth comb.'' Prior to *Tuomey*, he said, many people were unaware that physician compensation contracts that took into account the volume and value of referrals were illegal under the Stark law.

White said that any time the government intervenes in an FCA case, as it did in *Tuomey*, ''it's an invitation for the qui tam bar to bring more cases like this.'' He said, ''I have no doubt that [a] case—perhaps even more egregious than *Tuomey*—is currently in the litigation pipeline, and it's sitting on the desk of a Department of Justice official right now.''

McAnaney agreed that *Tuomey* was ''a wake-up call for hospitals, and it's a siren call to the government and whistleblowers'' simply from the size of the judgment award. ''[H]opefully, it's going to make hospital people aware of the exposure under Stark, which is something I don't think people really appreciated'' prior to the verdict.

Baumann said that similar qui tam cases were probably ''already under seal, [and] some of them are probably unsealed.''

Tension Between Stark, Hospitals. Baumann cited an increase in Stark enforcement in recent years. ''There is a natural tendency on the government's part to push [Stark] as far as it will go,'' especially once the government ''realized what a powerful tool it was, particularly in combination with the False Claims Act,'' she said.

McAnaney said that ''the problem with *Tuomey* as a legal matter is that the government threw all these things against the wall [at trial], they got this big verdict, and now they think all of those things are the law.'' He said the *Tuomey* judgment demonstrated ''the fundamental unfairness of the False Claims Act applied in the health care setting. No one can actually afford to try these cases because, if they lose, they are out of business.''

McAnaney further stated that ''[t]he government has unfairly demonized [] Tuomey'' in referring to the alleged illegal physician compensation arrangements ''as 'kickbacks,' which is wrong as a matter of law. McAnaney said they are ''technical violations of a payment policy.''

White agreed with McAnaney's assessment that similar FCA cases like *Tuomey* will be too financially risky for hospitals to bring to trial. White said the increased Stark pressure on hospitals was the result of the government starting to take greater action against contracts that were always illegal, rather than a sea change in the interpretation of the Stark law.

''[T]he health care system doesn't operate like other businesses,'' White said. ''When operating with government health care dollars, you must turn square corners.''

He acknowledged the tension between the reality of the hospital business today and the Stark law but said that tension has ''always been there, and the government is just now increasingly trying to enforce some of those regulations.''

New Legislation, Regulation Unlikely. Increased statutory enforcement and pushback from an industry as important as health care can generate pressure on the government to make some accommodations for industry realities.

But Baumann said she believed any legislative or regulatory change in the Stark law was ''not very likely just because the [enforcement] money is so good.'' She said the government needs to preserve the flow of enforcement dollars ''to keep Medicare afloat. They need it to balance the budget, and it's so politically popular to get on a soap box and talk about the fraudsters.''

Brennan said ''either a legislative or regulatory remedy on some of these issues would be helpful.'' He said that ''some coordination between HHS and CMS and DOJ would be helpful as well, adding that ''I think that DOJ's interpretations here are not consistent with what the law was intended to do.''

''I have no doubt that [a] case [] perhaps even more egregious than *Tuomey* is currently in the litigation pipeline, and it's sitting on the desk of a Department of Justice official right now.''

—JOSEPH E.B. WHITE, NOLAN & AUERBACH PA

McAnaney concurred that some type of legislative remedy would be best but said it is unlikely to occur. He said the Stark law should be repealed, ''at least with respect to the compensation piece,'' because the public policy benefits of that portion of the law are outweighed by the technical burdens of compliance.

In addition, McAnaney chastised the Centers for Medicare & Medicaid Services for ''abdicating its role in interpreting its own statute'' and leaving interpretation of the Stark law to the DOJ. ''CMS should clarify what the statute means in a way that people know what it is, in advance,'' he said.

He said the problem with the CMS addressing that issue is that, referring to difficulties with the Affordable Care Act, ''obviously, they have other things on their plate right now.''

White disagreed with those who said Congress or CMS should act to change the Stark law, saying calls for legislative or regulatory fixes to hospitals' Stark woes were uncalled for, even after *Tuomey*.

''There's a little bit of uncertainty in the provider community,'' White said, ''but I think all that is going to work out as people realize that *Tuomey* was possibly the most egregious perfect storm possible. The government has limited time, money, and resources, and they only go after those cases that have egregious patterns of fraud.''

BY ERIC TOPOR

To contact the reporter on this story: Eric Topor in Washington at etopor@bna.com

To contact the editor responsible for this story: Ward Pimley at wpimley@bna.com