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Over the last decade, the government’s primary enforcement vehicle regarding the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1230a-7b, and the Stark Law, 42 U.S.C. § 1395nn, has been whistleblower actions filed under the False Claims Act (“FCA”).

In one recent case, United States ex rel. Pogue v. Diabetes Treatment Centers of America, Inc., a District Court considered whether the qui tam plaintiff’s action – alleging that defendant paid physicians excess compensation – could proceed to trial even though the defendant’s attorneys had regularly reviewed the physician’s compensation for compliance with law.

In Diabetes Treatment Centers, the court, in denying defendant’s motion for summary judgment, highlighted the potential vulnerabilities that health care companies may confront under the FCA and AKS when they contract with physicians without obtaining a fair market value evaluation and when it appears that the purpose of the contract is to obtain additional revenue.

Diabetes Treatment Centers

In Diabetes Treatment Centers, the court considered whether the relationship between the defendant, Diabetes Treatment Centers of America (“DTCA”), and the physicians with whom it contracted to serve as medical directors at the DTCA in-hospital facilities breached the AKS and the Stark Law and also resulted in an FCA violation.

As to the allegation, the court noted that, to prove a violation, the plaintiff must show that a defendant (1) caused claims to be submitted to the government, (2) sought to induce referrals through payments to physicians and (3) “knew” that such actions violated the AKS. The court’s analysis of the second and third element – i.e., what constitutes “an inducement” to refer health care business and what a company must “know” about the payment to violate the AKS – provides important guidance to defendants regarding what actions may constitute a violation of the AKS or FCA.

First, as to the inducement element, the court pointed out that “[g]iving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient.” The court ruled that the qui tam plaintiff had, for purposes of summary judgment, demonstrated genuine issues of material fact regarding the inducement element by tendering evidence that DTCA paid the physicians more than fair market value, and that DTCA’s business practice was to encourage physicians to refer business to it.

As to the payment in excess of fair market value, the court pointed out that the relator’s expert had opined that defendant paid its medical directors fees far in excess of fair market value. Specifically, the court noted that “[l]egion courts have held that, absent a few exceptions not at issue here, compliance with the AKS requires that a provider pay fair market value to a physician for his services.” The court found that the expert report by itself “constitutes grounds for a reasonable jury to find that a purpose of defendant’s remuneration to its medical directors was to induce referrals to its centers.”

Moreover, the court noted that, although the report alone was sufficient to create a jury issue, the relator also produced other evidence linking the purpose of payments to referrals – evidence ranging from how defendant designed its business model, hired and retained physicians, drafted contracts and compensated physicians:

• Business Model: As to its business model, the court noted that defendant’s business plan “was built chiefly on concerns of census,” and that its profitability analysis identified approaching medical directors “weekly, at their office, to encourage DTCA admissions…” as one method of boosting profits.

• Hiring & Retention: As to its hiring and retention policies, the court noted, based upon DTCA personnel’s deposition testimony, that the company’s negotiations with physicians were influenced by how many admissions physicians could generate. For
example, a DTCA program manager testified that the purpose of hiring medical directors was to “solicit potential admissions.”

- **Contracts**: As to its contracts, the court noted that defendant’s agreements with physicians evaluated them based on census levels. Other contracts listed the physicians’ duties as identifying and developing referral sources. Also significant, DTCA’s contracts with directors often provided for compensation based on a percentage of the annual gross revenue DTCA facilities generated, thus incentivizing physicians to increase revenue – and, thus, their compensation – by referring more patients.

- **Compensation**: Finally, as to compensation, a former medical director at DTCA stated that he understood his role to be to refer patients to the facility and that DTCA “ostensibly paid us for our referrals.” The court concluded that defendant “made clear to its medical directors that their compensation and continuing employment was inextricably linked to the number of patients they provided to the centers and monitored the referrals.”

Second, as to the knowledge element, the court ruled – based upon the allegation of the payment of excess compensation and the encouragement of referrals – that the qui tam plaintiff established sufficient evidence that defendant knowingly violated the AKS to permit the case to proceed to trial. However, the defendant sought to refute the contention by asserting that it reasonably relied upon counsel’s advice regarding its contractual relations with medical directors.

The court recognized that the advice-of-counsel defense is a valid defense under the AKS and FCA, because courts “recognize a good-faith defense to claims pursued under the AKS and FCA.” However, the court rejected defendant’s advice-of-counsel defense for two reasons. First, because the court found that counsel had indeed warned DTCA on several occasions regarding potential noncompliance, it concluded that the defendant actually had not relied on counsel’s advice. Specifically, the court found that the plaintiff’s evidence showed “panoplied warnings from counsel to defendant about potential violations of AKS” and cited a 1989 letter where counsel “bluntly summarized its fears about the company’s business practices”:

> [W]e are receiving an increasing number of requests – several each week – involving different methods of compensating doctors who happen to be the source, or the potential source, of substantial referrals. While some of these proposals are doubtless clean, **some are not** and the mere volume of the transactions casts a shadow even upon those that might otherwise past [sic] muster. Thus we have an increasing concern about your ability to successfully defend all of the arrangements which are now in place and many of the arrangements for which our opinion has been sought. . . . We get the feeling that some of your people who are negotiating contracts may not fully appreciate all of the considerations that go into dealing with this problem.

Moreover, the court pointed out that, although the lawyers cautioned that a “key component of attorneys' advice to defendant centered on the necessity of conducting a fair market value analysis of medical directors’ services in addition to requiring the directors to maintain time logs detailing their work,” defendant elected to “deliberately ignore” the lawyers’ warnings and “continue to carry out its business as usual.” The court also noted that, until 1995, defendant did not even attempt to ascertain fair market value for its medical directors or define their duties, and that, even then, it used “personal judgment” and “rule[s] of thumb.”

Second, the court rejected the defendant’s advice-of-counsel defense because it believed that counsel did not have all relevant facts and that DTCA may have even misled counsel. For example, in response to DTCA’s assertion that, since an attorney never told it with certainty that it would be found liable for an AKS violation, it could not have knowingly violated the law, the court found that the defendant’s lawyers only found that defendant’s acts conformed with law because the attorneys’ analysis had assumed (not found) that the compensation paid was at fair market value and not tied to the volume or value of referrals, and that the attorneys had relied upon DTCA’s statements in this regard. Given that, the court found that –

In view of [plaintiff’s] production of evidence regarding defendant’s conduct during the relevant time period, it seems as though defendant’s counsel may have been misled by the company when analyzing the contracts. Perhaps this was the only reason why most attorneys did not explicitly say that a given contract was patently illegal.

[Plaintiff] has certainly produced sufficient evidence of defendant’s knowledge or reckless disregard of available information about its potential violation of the AKS. The evidence is sufficient for a reasonable jury to find that defendant acted with the requisite level of culpability for imposition of liability under the AKS and FCA.

### Lessons Learned

The decision in Diabetes Treatment Centers illustrates two important lessons. The first is that companies, to minimize the risk of exposure, should seek contemporaneous fair market value evaluations so that courts and qui tam whistleblowers cannot so easily assert that customary business practices result in a violation of the AKS and the FCA. Indeed, the case exemplifies the ease with which a court may stitch together from the loose thread of facts that arguably exist in many health care companies a potential violation of law. For example, most reputable health care businesses have e-mails and documents in their files in which they discuss the need to increase patient volume and encourage physicians to refer patients to them – if for no other reason than that they believe that their business furnishes patients with a higher quality of care than their competitors do. The case demonstrates how easily a whistleblower and a court can convert discussions of increasing volume and the encouragement of referrals into a potential AKS and FCA violation when there are no contemporaneous fair market value opinions.

The second important lesson is that an advice-of-counsel defense in this area is not a panacea unless counsel is provided all essential facts and does not assume that material facts (such as fair market value) exist without evidence. Indeed, as defendant learned in this case, invocation of this defense frequently causes more harm than good because it results in the waiver of the attorney-client privilege, and all caveats and warnings lawyers had provided during this course of the representation – rather than exonerating the company – inculpate the company because these expressed concerns, to the extent not acted upon, are then used against the company to show that it was being recklessly disregardful or deliberately ignorant of its duty to adhere to the law because it ignored its lawyers’ advice.