January 14, 2009

FALSE CLAIMS ACT ALERT

RECENT FALSE CLAIMS ACT CASE LAW DEVELOPMENTS

In November 2008, the Department of Justice (DOJ) announced that it secured more than $1.34 billion in False Claims Act (FCA) recoveries in fiscal year 2008. Almost the full amount of these recoveries—$1.12 billion—stemmed from health care cases.

As DOJ stiffens its resolve to enforce the FCA, it is important to monitor FCA case law developments to evaluate areas that create the greatest risk of exposure to liability for health care companies.

Recently, two significant court decisions shed important light on the potential scope of the FCA. In *United States ex rel. Conner v. Salina Regional Health Center,*[1] the Tenth Circuit considered the extent to which a private *qui tam* plaintiff (known as a "relator") could invoke the FCA when that person, a physician, believed that a hospital did not provide him with adequate staff to perform surgery and violated other conditions of participation with which hospitals must comply to participate in the Medicare program. In *United States ex rel. Pogue v. Diabetes Treatment Centers of America, Inc.*,[2] 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.

The rulings in both cases address potential areas of exposure and important FCA defenses. In *Salina Regional Health Center*, the Tenth Circuit appropriately ruled that a false hospital cost report certification does not breach the FCA, if the false certification did not cause the government to pay additional funds to the hospital. The court's ruling will help to rein in some broader theories that *qui tam* plaintiffs have invoked under the FCA. In *Diabetes Treatment Centers*, the court, in denying defendant's motion for summary judgment, highlighted the potential vulnerabilities that health care companies may confront 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.

SALINA REGIONAL HEALTH CENTER

In *Salina Regional Health Center*, the relator, an ophthalmologist and eye surgeon on the hospital's medical staff, contended that the hospital submitted false claims, because, in

[1] 543 F.3d 1211 (10th Cir. 2008).
[2] 565 F. Supp. 2d 153 (D.D.C. 2008).

its cost report, it certified that it complied with the rules and regulations governing the Medicare program when, in fact, the hospital had failed to comply with a number of Medicare's conditions of participation.[3] For example, the relator claimed that defendant had failed to provide adequate nurses and other personnel; failed to establish a quality assurance program that meets regulatory standards; failed to properly maintain medical records; and dumped patients without proper screening, evaluation and treatment.[4]

Specifically, the relator asserted that, if a hospital knowingly breaches any Medicare rule or regulation (no matter how trivial the violation), then all claims that the hospital submits are actionable under the FCA, because a hospital official certifies in its cost report that he or she is "familiar with the laws and regulations regarding the provision of health care services, and the services identified in this cost report were provided in compliance with such laws and regulations."[5] The basis for the relator's theory is that the government would not have paid any claim if it had known of the false certification.[6] Some courts have concurred with this theory in the context of lawsuits alleging a violation of the FCA stemming from an alleged violation of the Stark Law or the Anti-Kickback Law, or where the alleged breach caused the government to pay more than it would have paid but for the violation.[7]

In *Salina Regional Health Center,* however, the Tenth Circuit rejected the view that a false hospital cost report certification, by itself, triggers FCA liability. Specifically, the court pointed out that the FCA only applies if a false certification "leads the government to make a payment which it would not otherwise have made."[8] The court concluded that a hospital cost report certification does not serve this function. Instead, the court ruled that a hospital certifies compliance with Medicare rules, on the cost report, as a "condition of participation"—not a "condition of payment"—meaning that a hospital certifies compliance to maintain its ability to participate in the Medicare program and not simply to receive payment.[9]

The court based its conclusion on the plain language of the cost report certification; the fact that a false statement by itself (without a false or fraudulent demand for payment) does not create FCA liability; the remedial administrative process regarding participation in the Medicare program; and the policy that expert administrators ought to administer the Medicare program, and not private citizens or courts of law.

First, as to the cost report certification's plain language, the court pointed out that the certification, on its face, does not indicate that any non-compliance with a Medicare rule or regulation would result in denial of payment:

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[3] 543 F.3d at 1214.
[4] *See United States ex rel. Conner v. Salina Regional Health Ctr. Inc*., 459 F. Supp. 2d 1081, 1084 (D. Kan. 2006) (describing allegations), *aff'd in relevant part,* 543 F.3d 1211 (10th Cir. 2008).
[5] 543 F.3d at 1218 (quoting 42 C.F.R. § 413.24(f)(4)(iv)).
[6] *Id.*
[7] *Id.* at 1223.
[8] *Id.* at 1219 (citations omitted).
[9] *Id.* at 1220. Specifically, conditions of participation "are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program." *Id.* (citation omitted). For example, if a condition of participation, such as a staffing requirement, is breached and the violation is identified during a survey, typically the facility is required to institute a corrective action plan and is permitted to continue to receive payment while the deficiency is corrected. Conversely, conditions of payment "are those which, if the government knew they were not being followed, might cause it to actually refuse payment." *Id.* For example, the Medicare statute requires that payment shall only be made for medically necessary items and services, 42 U.S.C. § 1395y(a)(1)(A), and, hence, providing medically necessary services is a condition of payment and not a mere condition of participation.

> Although this certification represents compliance with underlying laws and regulations, it contains only general sweeping language and does not contain language stating that payment is conditioned on perfect compliance with any particular law or regulation. Nor does any underlying Medicare statute or regulation provide that payment is so conditioned. Thus, by arguing that the certification's language is adequate to create an express false certification claim, [the relator] fundamentally contends that *any* failure by [the hospital] to comply with *any* underlying Medicare-reimbursable service renders this certification false, and the resulting payments fraudulent. Lest there be any doubt about the potential impact of this proposed theory, [the relator] estimates that the United States has been damaged by [the hospital] in an amount exceeding $100,000,000 *per year* in reliance on allegedly false certifications.[10]

Second, the court ruled that the cost report certification, standing by itself, was insufficient to create FCA liability because "[l]iability [under the FCA] does not arise merely because a false statement is included within a claim, but rather the claim itself must be false or fraudulent."[11] Thus, according to the court, a false certification did not create FCA exposure, unless that statement caused the government to pay a claim that it would not otherwise have paid.[12] Here, that would not be true unless the government would refuse to pay for a particular item or service because, as the relator alleged, the hospital failed to provide adequate nurses and other personnel; failed to establish a quality assurance program that meets regulatory standards; failed to properly maintain medical records; and dumped patients without proper screening, evaluation, and treatment. The court found that a mere regulatory breach of these regulations would not immediately disqualify the hospital from payment, and, hence, the false cost report certification could not result in FCA liability.[13] As the court noted, "[r]eading the FCA otherwise would undermine the government's own administrative scheme for ensuring that hospitals remain in compliance and for bringing them back into compliance when they fall short of what the Medicare regulations and statutes require."[14] The court also noted that the relator did not cite any regulations or case law showing that the government normally seeks retroactive recovery of Medicare payments for services based upon violations of conditions of participation.[15]

Third, the court believed that Medicare's complex and remedial administrative process supported its ruling that a cost report certification was a condition of participation, not a condition of payment. Specifically, the court noted that, before participation in the Medicare program, hospitals must undergo inspections and are subject to a "validation survey" that ensures ongoing compliance with Medicare conditions.[16] However, if, as a result of the survey, a provider appears noncompliant, the government does not immediately suspend Medicare enrollment or billing privileges. Rather, the relevant regulations permit the provider to create a plan of correction and allow a reasonable period of time—usually 60 days—to address any deficiencies.[17] Only after finding that the provider

[10] *Id.* at 1219.
[11] *Id.* (*quoting United States ex rel. A+ Homecare, Inc. v. Medshares Mgm't Grp., Inc.*, 400 F.3d 428, 443 (6th Cir. 2005)).
[12] *Id.*
[13] *Id.* at 1219-20.
[14] *Id.* at 1220.
[15] *Id.* at 1221.
[16] *Id.* at 1220.
[17] *Id.* at 1220-21 (citing 42 C.F.R. § 488.28(a), (c) & (d)).

has not "substantially" complied may the government, at its discretion, terminate a Medicare participation agreement.[18]

Given this process, the court ruled that the hospital's cost report certification represents the provider's assurance that it continues to comply with the requirements of Medicare participation, because implied in this certification is the recognition that the provider could face consequences through the administrative procedures described above if it falls short of substantial compliance.[19] However, because the court concluded that, in the first instance, *substantial* compliance—and not necessarily *perfect* compliance—was all that was required under the detailed administrative mechanism for managing Medicare participation, the cost report certification did not serve as a condition of payment.[20]

Fourth, the court concluded that policy considerations supported its ruling because, if relators were permitted to institute *qui tam* actions regarding a hospital's compliance with conditions of participation, then relators would be empowered to supplant the Medicare program's carefully crafted administrative review process and inappropriately transfer authority from expert administrators to determine whether Medicare's complex rules have been breached to unaccountable, non-elected private *qui tam* relators and ultimately courts of law:

> [C]onsider if [the relator's] view of the certification were correct. An individual private litigant, ostensibly acting on behalf of the United States, could prevent the government from proceeding deliberately through the carefully crafted remedial process and could demand damages far in excess of the entire value of Medicare services performed by a hospital. If successful, the consequences of such an action would likely be catastrophic for hospitals that provide medical services to the financially disadvantaged and the elderly.... Further, rather than relying on the experience of state agencies to survey compliance, such a broad reading of the FCA and the certification would burden the federal courts with deciding whether medical services were performed in full compliance with a host of Medicare statutes and regulations. As the Second Circuit has cautioned, "courts are not the best forum to resolve medical issues, concerning levels of care." *Mikes*, 274 F.3d at 700. It is therefore with good reason that the agencies of the federal government, rather than the courts, manage Medicare participation in the first instance in cooperation with the states and accreditation organizations. *See id.* ("[P]ermitting qui tam plaintiffs to assert that defendants' quality of care failed to meet medical standards would promote federalization of medical malpractice, as the federal government or the qui tam relator would replace the aggrieved patient as plaintiff.") And when an individual plaintiff is harmed, state tort law remains a powerful incentive for hospital to provide quality care. There is thus no basis in either law or logic to adopt an express

[18] *Id.* at 1221.
[19] *Id.*
[20] *Id.*

false certification theory that turns *every* violation of a Medicare regulation into the subject of an FCA qui tam suit.[21]

DIABETES TREATMENT CENTERS

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 FCA. 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 Anti-Kickback Statute and the Stark Law and also resulted in a violation of the FCA.

As to the AKS 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.[22] 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."[23] The court ruled that the relator 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.[24] 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."[25] 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."[26]

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 one method to boost profits was to approach medical directors "'weekly, at their office, to encourage DTCA admissions'..."[27]

[21] *Id.*
[22] 565 F. Supp. 2d at 160.
[23] *Id.* at 162 (quoting *Polk County v. Peters*, 800 F. Supp. 1451, 1455 (E.D. Tex. 1992)).
[24] *Id.* at 162-63.
[25] *Id.* at 162 (citations omitted).
[26] *Id.* at 163.
[27] *Id.* at 163-166.

- ***Hiring & Retention***: As to its hiring and retention policies, the court noted, based upon DTCA's 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."[28]

- ***Contracts***: As to its contracts, the court noted defendant's agreements with physicians evaluated them based upon census levels. Other contracts listed the physicians' duties as identifying and developing referral sources. Also significant, DTCA 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.[29]

- ***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 stated that DTCA "ostensibly paid us for our referrals."[30] 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."[31]

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 relator 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."[32] However, the court rejected defendant's advice of counsel defense for two reasons. First, the court rejected the defense because, far from relying on counsel's advice, it found that, on most occasions, counsel actually warned DTCA regarding potential non-compliance. Specifically, the court found that relator'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":

> we 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

[28] *Id.* at 164.
[29] *Id.*
[30] *Id.*
[31] *Id.* at 165.
[32] *Id.* at 166-67.

> that some of your people who are negotiating contracts may not fully appreciate all of the considerations that go into dealing with this problem.[33]

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," that defendant elected to "deliberately ignore" the lawyers' warnings and "continue to carry out its business as usual."[34] 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."[35]

Second, the court also 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.[36] Given that, the court found that—

> In view of relator'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.
>
> Relator 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.[37]

[33] *Id.* at 167.
[34] *Id.* at 167-68.
[35] *Id.* at 168.
[36] *Id.* at 169.
[37] *Id.*

CONCLUSION

The court's ruling in *Salina Regional Health Center* offers hope, while the court's ruling in *Diabetes Treatment Centers* identifies potential peril.

The decision in *Salina Regional Health Center* offers hope in that its precedent may chill *qui tam* plaintiffs—and their counsel—from invoking the sledgehammer of the FCA to police every potential technical, non-material violation of law. It also offers hope in that courts will continue to realize that expert health care administrators should evaluate compliance, in the first instance, and not self-interested, financially incentivized private citizens or non-expert courts.

The decision in *Diabetes Treatment Centers* suggests potential peril in how the court stitched 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 will have e-mails and documents in their files where 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. *Diabetes Treatment Centers* illustrates, however, the ease with which a whistleblower and a court can convert discussions of increasing volume and the encouragement of referrals into a potential AKS and FCA violation. The most useful lesson, perhaps, that can be drawn from this case is that companies, to minimize the risk of exposure, should seek contemporaneous fair market value evaluations so that courts and relators cannot so easily assert that customary business practices result in a violation of the AKS and the FCA.

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