"Caveat Confirmator": Legally False Claims And the Federal False Claims Act

By John M. O'Connor

False claims recoveries in the health care field are a growth area. In the 2003 fiscal year, the government collected $1.48 *billion* in suits initiated by whistleblowers under the federal False Claims Act. Most of that was obtained in the health care industry.

The Federal False Claims Act provides for penalties against those who file false claims with the government and gives a portion of the government's recovery to qualifying individuals who have provided the information on which the government's recovery is based. (These whistleblower suits are also called *"qui tam"* actions, a Latin shorthand for "one who brings the action for himself as well as the king.")

Large amounts of money are involved and health care entities are especially vulnerable. Health care entities, such as hospitals, laboratories, nursing homes, and physician practice groups submit a high volume of claims to the government. A false claim is punishable by a penalty of $5,000 to $10,000 *per claim*. Even more formidable is the prospect of facing damages for claims that may have spanned several years—and then having those damages multiplied by three, as provided in the False Claims Act.

Range of Damages

For example, $641 million was recovered from HCA Inc. (formerly Columbia/HCA) to settle claims of overbilling and kickbacks. The whistleblowers' combined take was $154 million. A California hospital system paid $51 million to settle allegations that unnecessary cardiac procedures were performed. SmithKline Beecham Clinical Laboratories paid $325 million based on allegations that lab tests were either not needed or not performed.

A health care provider's first reaction to the prospect of mega-damages under the False Claims Act might easily be, "That can't happen here." Assuming that most health care entities view themselves as law abiding, there may be a tendency to believe that the False Claims Act will only ensnare those who specifically set out to defraud the government and "We don't do that here." This reaction is understandable—but very dangerous.[1]

First, although the statute exacts penalties only where the false claim is submitted "knowingly," the definition of "knowing" includes "reckless disregard of truth or falsity" and "acts in deliberate ignorance of truth or falsity." In other words, even if a health care entity did not intentionally sit down and decide to defraud the government, a court or jury might later decide that it had been reckless or culpably ignorant.

Second, claims can be considered "false" in ways that are not obvious. For example, courts have recognized a "certification theory" of liability under the False Claims Act. If payment is conditioned upon a certification or representation by a health care provider that it has complied with certain federal statutes or regulations, or with certain contractual terms, and it is later proven that these provisions were not complied with, then the prior representation may be held false, subjecting the entity to the treble damages and penalties provided in the False Claims Act. Since such false certifications may have occurred over a period of several years involving numerous claims, the potential exposure can be daunting.

The Second Circuit's Decision in *Mikes*

In the Second Circuit, the leading case on this "false certification" liability is *Mikes v. Straus*, 274 F. 3d 687 (2d Cir. 2001) ("*Mikes*"). In *Mikes*, the Second Circuit held that a false certification that applicable laws and regulations had been complied with could be a violation of the False Claims Act ("FCA"), but not every law or regulation would lead to FCA liability.[2]

The Second Circuit noted that a claim could be "factually false" or "legally false." As one might expect, a factually false claim "involves an incorrect description of goods or services provided or a request for goods and services never provided."[3] The legally false claim involves a "false representation of compliance with a federal statute or regulation or a prescribed contractual term."[4]

"Legally False" Claims

The legally false claim may be based upon an express false certification or an implied false certification. "An express false certification is, as the term sug-

gests, a claim that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment."[5] An implied false certification is based upon the act of submitting a claim for payment from the United States where compliance with certain governing federal rules is a precondition for payment.

The Second Circuit held that a claim under the FCA is legally false only if a party certifies compliance with a statute or regulation that is a condition to governmental payment.[6] In other words, it is not every false certification or representation of compliance with a statute or regulation that will be a false claim within the meaning of the FCA. The United States must have conditioned compliance with the statute or regulation as a requirement for payment.

The facts in the *Mikes* case, and the Court's analysis of those facts, illustrate the application of this distinction. The plaintiff in *Mikes* was an individual whistleblower, not the government. The plaintiff, a pulmonologist, sued her former employer, a partnership of physicians. She alleged that spirometers had not been properly calibrated, that spirometry procedures were performed by medical assistants who had not been properly trained by the employer, and that these practices violated government regulations.[7]

The plaintiff claimed that there was an express false certification and an implied false certification. The defendants submitted their claims on the forms designated by the Health Care Finance Administration ("HCFA"). The form, HCFA-1500, stated:

> I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate supervision.[8]

The Court agreed that in signing and submitting this form, the defendants expressly certified that they would comply with the terms on the form and that such compliance was a precondition of government payment.[9]

The plaintiff Mikes argued that guidelines published by the American Thoracic Society ("ATS"), a division of the American Lung Association, set out the generally accepted standards for spirometry and that the defendants had violated those standards, including the recommendation that the spirometers be calibrated daily. The Second Circuit held that non-compliance with the ATS standards did not implicate the defendants' statements in the certification, *i.e.*, that the services were "medically indicated and necessary." The Court held that the plaintiff Mikes challenged only the "quality of defendants' spirometry tests and not the decisions to order this procedure for patients."[10] The Court pointed out that the medical necessity for a procedure and the quality of that procedure "are distinct considerations."[11]

So, even if adherence to the ATS guidelines were required, and even if the defendants violated those guidelines, it still could not be said that the express certification in the HCFA-1500 form was false.

Mikes also claimed that the defendants had made implied false certifications. While the Second Circuit approved the theory of implied false certification as a basis for a false claim under the FCA under certain circumstances, it held that Mikes' allegations were insufficient to state such a claim. The Court held that by submitting a claim for payment, the defendants had impliedly certified that they had complied with the following section of the Medicare Act:

> [N]o payment may be made under [the Medicare statute] for any expenses incurred for items or services 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.[12]

Since this section "*expressly* prohibits payment if a provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision."[13]

Again, however, there was no false certification within the meaning of the FCA because Mikes' claims went to the *quality* of the spirometry tests and not to whether they were reasonable and necessary.

The Court acknowledged that Mikes had cited a statute that mandated a qualitative standard of care.[14] However, the Court held that the statute Mikes cited was not an explicit condition of receiving *payment* on a claim; it was a condition of the health care practitioner's *participation* in the Medicare program. The remedy for violation was not refusal to pay a claim but sanctions for the practitioner.

Worthless Services

Although the government has not conditioned payment on the quality of the services performed, the Second Circuit recognized that a claim for payment for

services that are so deficient as to be worthless would be a violation of the FCA that was independent of any certification made by the claimant, whether express or implied.[15] The Court viewed a claim for worthless services as akin to seeking reimbursement for a service not provided and therefore derivative of a factually false claim. "In a worthless service claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all."[16]

However, in *Mikes*, the Court held that plaintiff's allegations could not succeed on a "worthless services" basis because there was no showing that the defendants "knowingly," as that term is defined in the FCA, submitted a claim for worthless services.[17]

District Court Decisions

Three District Court decisions within the Second Circuit have further delineated the elements of a "legally false" claim under the FCA.

The District of Connecticut tackled false certification issues in the medical device context in *In re Cardiac Devices Qui Tam Litigation*, 221 F.R.D. 318 (D. Conn. 2004). The action was initiated by a whistleblower and the government eventually intervened. The complaint alleged that the defendant hospitals had submitted false claims in that they sought and received payment from the government for services performed using medical devices that had not been approved for marketing by the FDA. The complaint alleged that the manufacturers of the cardiac devices in question provided the devices to the hospital defendants pursuant to an "Investigational Device Exception," which restricted their use to "carefully monitored clinical trials, the purpose of which was to gather evidence of the safety and effectiveness of the devices."[18] None of the devices had been approved for marketing by the FDA and the Medicare manual stated that: "Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not considered reasonable and necessary."[19]

The defendants argued that the government was, in effect, alleging a *per se* fraud theory, *i.e.*, "equating fraud with an alleged violation in a 1000-page manual."[20] However, citing *Mikes*, the District Court held that the Medicare statute expressly conditions payment by the government on procedures being "reasonable and necessary," and that the complaint stated a cause of action for legally false certification of compliance with the "reasonable and necessary" statutory pre-requisite to payment.

What Is "Knowingly"?

The hospital defendants' "*per* se" argument resurfaced in another context in connection with the FCA's requirement that a false claim must be made "knowingly" to incur FCA liability. As the Court pointed out, the FCA defines "knowingly" in three ways: (1) actual knowledge that the claim is false; (2) acting in deliberate ignorance as to whether the claim is true or false; or (3) acting in reckless disregard as to whether the claim is true or false.[21] No proof of specific intent to defraud is required. At the other end of the spectrum, negligence or innocent mistake does not constitute a false claim.

Although rejecting the defendants' contention that the government was equating a failure to adhere to a Medicare Manual provision with fraud, the Court held the defendant hospitals to a standard that, as a practical matter, can be viewed as approaching a *per se* rule.

Government's "Catch 22"

The District Court first held that, "'Participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment.'"[22] The government then parlayed an allegation that the defendant hospitals did not follow a requirement in the Medicare Manual, into an allegation that the defendants acted "knowingly" within the meaning of the FCA by constructing what might be viewed as a "Catch 22" argument. The government first pointed out that each of the defendant hospitals had been provided with a copy of the Medicare Manual and that there was a duty on the part of hospitals to familiarize themselves with the provisions. According to the government, if the hospitals actually reviewed the Medicare Manual, they had actual knowledge of the provisions in question and so the claims were knowingly false. On the other hand, if the hospitals did not actively and regularly review the Medicare Manual, then they acted with "reckless disregard" of their compliance with Medicare rules and instructions. Under this theory, it would seem that once the hospitals have the Medicare Manual in hand, at least at the pleading stage, it will be very difficult to avoid the conclusion that they acted knowingly within the meaning of the FCA.[23]

Anti-Kickback and the FCA

In *United States ex rel. Barmak v. Sutter Corp.*, No. 95 Civ. 7637 KTD RLE, 2002 WL 987109 (S.D.N.Y. May 14, 2002), the operative allegation for present purposes was that the defendants had fraudulently obtained Medicare overpayments by paying kickbacks to hospitals and doctors for patient referrals.[24]

With respect to the kickback allegations, the Court held that those violations of the federal anti-kickback statute could not form the basis for a claim under the FCA. The District Court reasoned that the anti-kickback statute was a federal criminal statute, that no private cause of action was created, and that the Court had no reason to believe that Congress intended to "subvert the Department of Justice's exclusive jurisdiction over the anti-kickback statute by grafting the FCA's *qui tam* provisions onto it."[25] The District Court recognized that the Fifth Circuit had come to the opposite conclusion and had ruled that violation of the anti-kickback provisions could form the basis for an FCA claim. The Second Circuit had not yet addressed this issue and the District Court noted that the question was a "hotly disputed and controversial area of the law."[26] The Court also stated that a violation of the anti-kickback statute would not, in any event, be an *ipso facto* violation of the FCA.

Bidding

In *United States ex rel. Taylor v. Gabelli*, 03 Civ. 8762 (SAS), 2004 WL 1719357 (S.D.N.Y. July 29, 2004), the District Court addressed allegations that bidders for licenses issued by the Federal Communication Commission violated the FCA by falsely certifying that they met the government's definitions of "small" or "very small" business for purposes of obtaining a discount in connection with the auction of licenses for the use of a spectrum, or range, of radio frequencies.

With respect to the unsuccessful bidders, the Court held that the allegedly false certifications were not false claims within the meaning of the FCA. The Court applied the principle set forth in *Mikes*, that to constitute a legally false certification under the FCA, the statute or regulation not complied with must be a prerequisite to a payment by the government. Where the defendant's non-compliance with a statute or regulation "'would not have influenced the Government's decision to pay,' the failure to comport with the regulations cannot serve as a basis for an FCA claim."[27] In *Gabelli*, the Court held that, "A bid, by its very nature, does not request or demand monetary compensation."[28] Accordingly, even if unsuccessful bidders had falsely certified compliance with regulations on their bids, there was not a false claim under the FCA.

With respect to successful bidders, the Court's conclusion was different. A potential bidder was required to file an application "certifying, among other items, the applicant's eligibility for a federal discount and status as a qualified entry."[29] There were a series of auctions and qualifying "small" and "very small" business were entitled to discounts of percentages that varied by the auction; for example, in one auction, very small businesses were entitled to a 25 percent discount and small businesses were entitled to a 15 percent discount. The plaintiff whistleblower, an attorney specializing in federal administrative and telecommunications law, alleged, among other things, that the defendants that were successful bidders had falsely certified that they met the government definitions of "small" and "very small" businesses, and as a result received discounts to which they were not entitled.[30]

The defendants argued that plaintiff's allegations amounted to a disagreement with the defendants' "legal determination" as to whether they qualified for "small" or "very small" bidding status and that there were no "false or fraudulent statements.[31]

The *Gabelli* court held that the complaint stated a cause of action under the FCA against the successful bidders. The complaint alleged that the successful bidders had deliberately and falsely certified that they were small or very small businesses, entitled to federal discounts ("bidding credits"), and that such false certifications, if proven and knowingly made, sought "payment from the federal treasury (bidding credits)."[32]

"Reverse False Claim"

The plaintiff whistleblower in *Gabelli* also invoked the concept of "reverse false claims." In most false claims cases, the false claim seeks to have the government pay out money to which the claimant is not entitled. In a "reverse false claim," the defendant seeks to avoid paying money owed the government.[33] The whistleblower argued that once a bid was successful, the obligation to pay the full non-discounted amount of the bid attached. Since the successful bidders were required to file a more complete application following the bid, the whistleblower argued that a false certification in the post-bid application (stating that the defendants were entitled to a discount as small or very small businesses) was an attempt to avoid or decrease a preexisting obligation to pay money to the government—a "reverse false claim." The Court did not rule as to whether the complaint stated a cause of action under this theory. Instead, it held that the plaintiff, in effect, was alleging two theories of false certification, *i.e.*, that the defendants sought to: "(1) receive federal monies and (2) decrease their contractual obligations."[34] The Court held that these two theories were "two ways of describing the same transaction." The "reverse false claims" theory was dismissed, the Court stating it was "redundant."[35]

For health care providers, the *Gabelli* decision again illustrates the application of the *Mikes* holding that a claim can be "legally false" if it falsely certifies that statutory or regulatory requirements have been complied with and the statute or regulation in question is a condition for payment from the government. Although the District Court viewed the "reverse false claim" presented in *Gabelli* as "redundant" in light of the circumstances in that case, the discussion of this theory is a reminder that the false certification theory will also be applicable if the effect is not to obtain payment from the government, but rather to reduce or avoid an obligation to pay the government.

Conclusion

Since claims submitted for payment of federal monies can be "legally false," express or implied certifications must be taken seriously, including representations contained in standard forms, statutes, and regulations. For example, the standard form in *Mikes* required the physicians requesting payment for the medical procedures to certify that the services were: (1) medically indicated and necessary for the health of the patient; (2) furnished either (a) personally by the signing physician or (b) by an employee of the signing physician under the signing physician's "immediate supervision" and "incident to my professional service." (The person certifying should break down the language in this fashion because that is what government counsel will do to determine whether there has been a violation.) If any of the statements certified are incorrect, and are later held to have been "knowingly" made, heavy liability under the False Claims Act awaits.

A "legally false" certification can also be triggered by the mere submission of a claim even if there are no express representations made. The very presentation of the claim is an implied certification that there has been compliance with certain statutory and regulatory requirements. The requirements that have been impliedly certified are those on which the government has conditioned eligibility for payment; not all false certifications create liability under the False Claims Act. As demonstrated by the *Mikes* decision, where Medicare payment is sought, one such implied certification is that all services and items for which payment is sought are: (a) "reasonable and necessary"; and (b) for the purpose of either the diagnosis and treatment of illness of injury, or to improve the functioning of a malformed body member.

The *Cardiac Devices* case demonstrates that the government can define the meaning of "reasonable and necessary" in its manuals and that the very presentation of a claim is an implied certification that the procedures are "reasonable and necessary" as defined in the manual. Accordingly, in order to know exactly what is being certified by presenting a claim, the person presenting must know what provisions in the regulations or applicable manual affect the meaning of "reasonable and necessary." The implied certification will be that these provisions, as well as any other provisions on which the government has conditioned payment, have been complied with. If there has been no such compliance, the presentation of the claim may be held "legally false."

For False Claims Act liability, the false claim must be made "knowingly" and innocent mistakes or negligence do not create liability. However, the statutory definition of "knowingly" includes reckless disregard of the requirements on which federal payment is conditioned, and courts have held that participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment. The result is that, even if the claim was presented without any conscious knowledge that it was legally false, there may nevertheless be liability under the False Claims Act if it is later held that the circumstances evidence a reckless disregard of the requirements for proper payment. Since the government has argued that failure to actively and regularly review the applicable Medicare manual constitutes reckless disregard, and since the False Claims Act provides for treble damages and penalties per claim, those persons who are certifiers, including those causing certifications to be made by others, must proceed with caution: caveat confirmator.

Endnotes

1. According to press releases from the United States Attorney's Office for the Southern District of New York, in 2004 alone two prestigious New York hospitals, two insurance companies, and a billing company settled False Claims Act cases for an aggregate total of over $36 million. Press releases, United States Attorney, Southern District of New York (March 11, 2004; August 12, 2004; August 13, 2004; September 23, 2004) (on file with the author).

   The complaints against one hospital involved allegations that claims were submitted under the names of doctors when in fact the services (newborn deliveries) were performed by midwives and other doctors, including residents, who were not eligible for Medicaid reimbursement. The complaint against the other hospital involved allegations that it had improperly retained payments received from Medicare for graduate medical education expenses.

   The two insurance companies settled allegations that the cost reports they submitted to the government misrepresented their compliance with previously approved budgets in order to obtain performance incentive payments and greater reimbursement. The billing company was alleged to have submitted claims for reimbursement to Medicare and Medicaid on behalf

of health care providers and to have used "default" diagnosis codes that were false and bore no relationship to the actual diagnosis given to patients or the actual procedure performed. The government also alleged that this caused it to pay for abortion services that were not covered by federal law.

Medicaid is provided by states with the United States paying a portion of state Medicaid costs.

2. The elements of liability under the FCA are submitting: (1) a claim; (2) to the United States government; (3) that is false or fraudulent; (4) knowing of its falsity; and (5) seeking payment from the federal treasury. *Mikes*, 274 F.3d at 695.
3. *Id.* at 697.
4. *Id.* at 696.
5. *Id.* at 697-98.
6. The Court noted that in so holding it was joining the Fourth, Fifth, Ninth, and District of Columbia Circuits. *Id.* at 697.
7. Spirometry is a diagnostic pulmonary function test. With the type of spirometers used by the defendants, the patient blows into a mouthpiece to measure volume and speed of exhale. *Id.* at 694.
8. *Id.* at 698. The form also stated "No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations." *Id.* at 699. The Court noted that the Medicare regulations stated that certification is a prerequisite to Medicare payment.
9. *Id.*
10. *Id.*
11. *Id.* at 699.
12. 42 U.S.C. § 1395y(a)(1)(A) (2005); *Id.* at 701.
13. *Id.* (emphasis in original).
14. Section 1320c-5(a) of 42 U.S.C. (2005) provides that health care practitioners must assure, to the extent of their authority, that "services or items ordered or provided by such practitioner . . . will be of a quality which meets professionally recognized standards of health care . . . ."
15. The *Mikes* court cited with approval *SmithKline Beecham, Inc.*, 245 F.3d 1048 (9th Cir. 2001) (allegation that falsification of laboratory test data, when test results fell outside of acceptable standard of error, states worthless services claim).
16. *Id.* at 703.
17. The Court stated that the defendants had produced "overwhelming" evidence of their genuine belief that the spirometry procedures they performed had medical value. The defendants stated they relied on the instruction manual for the machines and their former chief medical assistant, a non-party, gave testimony that the Court concluded supported their claim that they had held a good faith belief in the medical value of the procedures they performed. *Id.*
18. 221 F.R.D. at 329.
19. *Id.* at 335.
20. *Id.* at 334.
21. 31 U.S.C. § 3729(b).
22. *Id.* at *339. The District Court in *Cardiac Devices* quoted *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001) (quoting *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 63 (1984)).
23. With respect to some, but not all, of the hospital defendants, the government alleged additional facts regarding actual knowledge. As to these defendants, the government made an additional claim of common law fraud. *Id.* at *340-41, *331.
24. 2002 WL 987109 at *1. The whistleblower plaintiff had brought a prior FCA complaint and the government had intervened in part. That earlier complaint, which alleged, among other things, that the defendants had violated the FCA by waiving co-payments for sales of medical equipment, had been settled. Promptly after the settlement, the plaintiff whistleblower brought a second action. The Court dismissed the other claims in the second complaint on grounds of *res judicata* and failure to properly plead fraud.
25. *Id. at* *6.
26. *Id.* at *5.
27. *Id.* at *12, quoting *Mikes.*
28. *Id.*
29. *Id.* at *2.
30. *Id.* at *5.
31. *Id.* at *13.
32. *Id.*
33. *Id.* at *10. There is liability under the FCA if a person "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7)(2005).
34. *Id.* at *14.
35. The Court did not address the rationale for dismissing a claim because it was an alternative theory of liability. Litigants frequently proceed on alternative legal theories, which, of course, can become very significant if one theory is later found deficient for some reason on appeal. Also, the "reverse false claim" theory was arguably the theory that was better suited to the allegations of the complaint, since the alleged false certification apparently reduced the amount that the successful bidders would otherwise have had to pay the government.

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