

## Conditions Of Participation And Payment As Qui Tam Defense



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*Law360, New York (December 07, 2011, 1:28 PM ET)* -- Health care fraud allegations, particularly where they involve a sealed whistleblower suit filed on behalf of the government under the False Claims Act, called a qui tam, can initially appear to be much more serious than they are.

If you routinely defend health care fraud cases, the following scenario is common. An upset hospital CEO calls you, having just received a U.S. Department of Health and Human Services Office of the Inspector General subpoena asking for documents alluding to the physician's billing for medically unnecessary services, billing for services not rendered and upcoding (charging more for services than what was actually rendered) by physicians.

All of the allegations appear to involve related patient hospital stays. Despite two things suggesting the possibility of a qui tam: (1) the use of an OIG subpoena, which allows the government to obtain evidence and more freely share it between criminal and civil investigators and prosecutors, unlike a federal grand jury subpoena where Federal Rules of Criminal Procedure Rule 6(e) limits that disclosure; and (2) the billing for medically unnecessary services, services not rendered and upcoding all could involve a parallel criminal and civil investigation, would more likely be the type of information known to someone who worked for the hospital.

Considering the FCA damages include treble the actual loss plus between \$5,500 and \$11,000 per claim, the hospital has what could become an expensive problem. After speaking with a confident Assistant U.S. Attorney, you find out the case involves a "civil investigation." As you conduct interviews and review soon-to-be-produced documents as part of the internal investigation, you learn the hospital fired its chief financial officer six months ago, he has accepted a position out of state, and that none of the physicians involved in the allegations are hospital employees. You have likely identified the potential whistleblower, called a "relator."

These types of cases are routinely defended and settled prior to the government making a decision whether to intervene (assuming responsibility for the litigation), or declined (leaving it to the relator's

counsel to decide whether to proceed independently) because of the FCA's penalties. Eventually, the government intervenes and litigation begins against our client hospital. While the litigation is often defended by attacking the status of the relator, who has to be the original source of the information contained in the complaint.

To be an original source, the relator must have direct and independent knowledge of the claim by claim allegations and have voluntarily provided them to the government. Under the statute, the issues are jurisdictional in nature. While 9(b) and other defenses are commonly raised, a too infrequently used defense in these types of cases involves the showing the government the distinction between conditions of participation and conditions of payment.

### **Distinguishing Between Conditions of Participation and Conditions of Payment**

Conditions of participation are quality of care standards directed towards an entity's continued ability to participate in the Medicare program rather than a prerequisite to a particular payment. Further, several courts have declined to impose liability under the FCA when alleged false certifications of compliance were not conditions of payment.[1] In fact, conditions of participation are codified in a separate section than of conditions of payment.[2]

In a qui tam action alleging that two health and hospice care providers submitted fraudulent Medicare and Medicaid claims in violation of the FCA, the court recognized that "if merely signing this form converts a condition of participation into a condition of payment, then every hospice provider not fully complying with all conditions of participation may be held liable under the FCA, thus undermining the distinction between conditions of payment and participation, as well as Medicare's internal administrative structure to deal with violations of conditions of participation. To so hold would burden federal courts with what should be administrative determinations of whether medical services were performed in compliance with Medicare statutes and regulations governing participation." [3]

Where a contractor participates in a certain government program in order to perform the services for which payments are eventually made — in this case, Medicare — courts are careful to distinguish between conditions of program participation and conditions of payment.[4] Conditions of participation, as well as a provider's certification that it has complied with those conditions, are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program.[5]

Conditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment.[6] Rather than a denial of payment as to any individual bill, the ultimate sanction for violation of conditions of participation is generally "removal from the government program." [7] Therefore, violation of a regulation that is merely a condition of participation would not, as a matter of law, be material to the government's decision to pay or not pay any individual claim.[8]

The regulations specifically governing Medicare provide for detailed administrative procedures in handling alleged or actual failures of the conditions of participation by a provider.[9] If the state survey

agency determines that a provider has failed to substantially comply with the conditions of participation, the provider is typically permitted to submit a corrective action plan. The corrective action plan is prospective in nature, and the Medicare rules do not provide for recoupment of payments for past noncompliance.

### **Conditions of Participation Do Not Give Rise to Fraud**

The courts have overwhelmingly ruled that conditions of participation are immaterial and unrelated to Medicare's reimbursement rules, routinely refusing to impose liability under the FCA when alleged false certifications of compliance were not conditions of payment.[10]

The Second Circuit has held that assessing quality of care by health care providers would obligate federal courts "to step outside their primary area of competence and apply a qualitative standard measuring the efficacy" of medical procedures.[11] By recognizing the distinctions between federal statutes or regulations that are conditions of participation and conditions of payment, courts have held a failure to meet conditions of participation cannot give rise to a FCA claim.[12]

In reviewing the government's complaint in intervention against the hospital, you realize the allegations fail to take into account four significant things: (1) Medicare does not require hospitals to certify the compliance of nonemployed physicians; (2) Medicare has not specified what constitutes medical necessity; (3) Not only does Medicare give a great deal of deference is given to a physician's independent medical judgment, but so do juries; (4) the government must prove the falsity of each claim which may contradict the "treating physician rule."

#### *1) The Hospital's Responsibility Regarding the Actions of Nonemployed Physicians*

As mentioned earlier, none of the physicians that are the subject of allegations were employees of the hospital. In a case alleging a criminal violation of the Anti-Kickback Statute, the court held that a hospital is not responsible for ensuring the actions that have been certified by nonemployee physicians comply with the Medicare rules and regulations. The court reasoned that Title 42 of the Code of Federal Regulations, which imposes conditions of participation, does not require that hospitals certify physicians compliance with the Anti-Kickback Statute.[13]

The court noted that "nothing in either the statute or the regulation suggests that the hospital is required to certify that every physician who rendered care to patients in the hospital ... did so in compliance with the laws and regulations regarding the provision of health care services." [14]

Though some circuits have not adopted implied certification, which would actually make FCA civil liability in the hospital case even more difficult to prove, the Thomas court agreed "that a hospital's act of submitting a claim for payment to the government impliedly certifies that the hospital has complied with the Anti-Kickback Statute ... but, it is another matter to say that a hospital's act of submitting a claim for payment is implied certification that a person who is not employed by the hospital, is not an agent or subcontractor of the hospital and who does not act under the hospital's control, complied with

the Anti-Kickback Statute."<sup>[15]</sup> It is certainly a defense worth considering in Anti-Kickback cases.

## *2) Medicare Has Not Delineated What Constitutes "Medical Necessity"*

Under the Social Security Act, Medicare only reimburses for services which are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."<sup>[16]</sup> The Centers for Medicare and Medicaid Services, however, "has not delineated what constitutes 'medically indicated' and 'medically necessary' items or services furnished to Medicare patients and the specific documentation required to support medical necessity in individual cases."<sup>[17]</sup>

## *3) Deference is Given to a Physician's Independent Medical Judgment*

Courts have specifically recognized that "only physicians are licensed to diagnose and treat illnesses" and that a hospital's purpose is "to provide physical facilities and equipment to physicians," noting that hospitals separately bill for the services they render.<sup>[18]</sup>

In fact, courts have recognized that "the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations — but rather only those regulations that are a precondition to payment — and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the Act's reach."<sup>[19]</sup>

With regard to medical necessity, courts have also been reluctant to question a physician's medical discretion in best determining a course of treatment for patients. Specifically with regard to medical necessity, courts have accepted what is known as the "treating physician rule" in holding that the judgment of treating physicians caring for patients should be given "extra weight" and should not be rejected unless "a reasoned basis (is offered), in conformity with statutory purposes for declining to do so."<sup>[20]</sup>

## *4) The Government Must Prove the Falsity of Each Claim*

Even when the government can establish that claims are medically unnecessary, it must still prove that the defendant knew that the services rendered were medically unnecessary. To prove the knowledge element, some courts have held that the government must prove more than the FCA's actual knowledge, reckless disregard or deliberate ignorance standards, but that the defendant "lied."<sup>[21]</sup>

"The Second Circuit has adopted the Ninth Circuit's standard that the 'requisite intent is the knowing presentation of what is known to be false' as opposed to negligence or innocent mistake ... 'Known to be false' does not mean scientifically untrue, but 'a lie.'"<sup>[22]</sup> In the Ninth Circuit, the court has held that "the [FCA] is concerned with ferreting out 'wrongdoing,' not scientific errors. What is false as a matter of science is not, by that very fact, wrong as a matter of morals."<sup>[23]</sup>

What initially may appear as a potentially more problematic case may be defensible primarily because

Medicare does not require hospitals to certify the compliance of nonemployed physicians, whose medical judgment is given great deference. Medicare also recognizes the distinction between conditions of participation, which may only involve administrative action, and conditions of payment. They should, however, be more frequently considered as another way to get the government to decline intervention reduce a settlement amount, or at trial.

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[1] U.S. ex rel. Landers, 525 F. Supp. 2d at 978-79 (citing U.S. ex rel. Gross v. AIDS Research Alliance-Chicago, 415 F.3d 601, 604 (7th Cir. 2005) (“A FCA claim premised upon an alleged false certification of compliance ... also requires that the certification of compliance be a condition of or prerequisite to government payment.”); U.S. ex rel. Willard v. Humana Health Plan of Tex. Inc., 336 F.3d 375, 381-83 (5th Cir. 2003); U.S. ex rel. Siewick v. Jamieson Science & Eng'g., 214 F.3d 1372, 1376 (D.C. Cir. 2000); U.S. ex rel. Mikes v. Straus, 274 F.3d 687, 702 (2d Cir. 2001) (payment not expressly conditioned on compliance with conditions of participation set forth in 42 U.S.C. § 1320c-5(a)).

[2] 42 C.F.R. Part 424.

[3] United States, et al. ex rel. Wall v. Vista Hospice Care Inc., et al., 2011 \*6 (N.D. Tex. Mar. 9, 2011) (citing United States ex rel. Conner v. Salina Reg'l Health Ctr. Inc., 543 F.3d 1211, 1219 (10th Cir. 2008). Courts are not the place where such issues are to first be resolved." Id.

[4] United States, et al. ex rel. Blundell v. Dialysis Clinic Inc., 2011 \*15 (N.D. N.Y. Jan. 19, 2011 (citing Conner, 543 F.3d at 1220 (10th Cir. 2008)).

[5] Id.

[6] Id.

[7] Id.

[8] United States ex rel. Sanchez v. AHS Tulsa Regional Med. Ctr., 754 F. Supp. 2d 1270, 1289 (N.D. Ok. 2010) (citing Conner, 543 F.3d at 1219-20)).

[9] See 42 C.F.R § 488.1, et seq.

[10] Conner, 543 F.3d 1211; United States of America, ex rel. Anne F. Landers v. Baptist Memorial Health Care Corp., et al., 525 F. Supp. 2d 972, 978-79 (W.D. Tenn. 2007).

[11] See U.S. ex rel. Mikes, 274 F.3d 687, 702 (2nd Cir. 2001).

[12] U.S. ex rel. Landers, 525 F. Supp. 2d at 978-79 (citing U.S. ex rel. Gross v. AIDS Research Alliance-Chicago, 415 F.3d 601, 604 (7th Cir. 2005); U.S. ex rel. Willard v. Humana Health Plan of Tex. Inc., 336 F.3d 375, 381-83 (5th Cir. 2003); U.S. ex rel. Siewick v. Jamieson Science & Eng'g, 214 F.3d 1372, 1376 (D.C. Cir. 2000); U.S. ex rel. Mikes, 274 F.3d 687, 702 (2nd Cir. 2001) (all declining to impose liability under the FCA when alleged false certifications of compliance were not conditions of payment)).

[13] United States ex rel. Thomas v. Bailey, 2008 (E.D. Ark 2008).

[14] Id. at \*10.

[15] Id. at \*9.

[16] 42 U.S.C. § 1395y (a)(1)(A).

[17] United States v. Prabhu, 442 F. Supp. 2d 1008, 1032 (D. Nev. 2006).; see, e.g., Medicare Program: Criteria and Procedures for making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302, 4304, 4308, 4312 (1989) ("current regulations are general and we have not defined the terms 'reasonable' and necessary,' nor have we described in regulations a process for how these terms must be applied").

[18] United States ex rel. Bailey v. Ector County Hospital, 386 F. Supp. 2d 759, 766 (W.D. Tex. 2004).

[19] United States ex rel. Mikes v. Strauss, 274 F. 3d 687, 699-700 (2d. Cir. 2001). See also United States ex rel. Bailey v. Ector County Hospital, 386 F. Supp. 2d 759 (W.D. Tex. 2004).

[20] State of N.Y. v Sullivan, 927 F.2d 57, 60 (2d Cir 1991); Klememtowski v. Sec'y, 801 F. Supp. 1022, 1026 (W.D.N.Y. 1992); Gartman v. Sec'y, 633 F. Supp 671, 680-682 (E.D.N.Y. 1986) ("the physician is to be the key figure in determining utilization of health services").

[21] In re Cardiac Devices Qui Tam Action, 221 F.R.D. 318, 339 (D. Conn. 2004).

[22] Wang v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir. 1992).

[23] United States ex rel. Anderson v. N. Telecom Inc., 52 F. 3d 810, 815-820 (9th Cir. 1995) (same).