FEBRUARY 13, 2013

THE FALSE CLAIMS ACT AND QUALITY OF CARE

Can the False Claims Act be used by the government or whistleblowers in quality of care cases? The Department of Justice seems to think so, based in significant part on the retention of overpayments amendments to the FCA by FERA and the PPACA. For more please read Retention of Overpayments under FERA and the PPACA.If they are right, the ramifications for health care providers, and the attorneys who advise them, are legion, the consequences significant.

Recently a DOJ attorney, during a presentation about the False Claims Act, said "we are starting to look at quality of care cases as potential FCA cases." He explained that every claim to a federally funded health care program impliedly certifies that the services provided meet the standard of care; therefore, services that fail to meet the standard of care are false. When challenged that such application would mean federalization of third-party claims for malpractice, he begged to differ. The government expects that it purchased services of a certain quality, he explained, and when it does not receive that quality, the claim is false. It is not different, he posited, from a fighter jet the government is assured goes Mach 2 when, in fact, it only goes Mach 1. The obvious argument that the Mach 2 claim comes from testing the manufacturer claims to have performed, rather than pure outcome-based evaluation, was considered unpersausive. He went on to assure the audience that the FCA would not be applied to individual cases with bad outcomes but would, rather, be used as a tool when there was a pattern of poor quality. An example, he suggested, would be a peer review case - if a hospital, as a result of peer review, determined that a physician consistently provided services below the acceptable standard of care, permitting the doctor to continue billing for services at the hospital, or failing to repay claims identified as inadequate, could be a False Claims Act violation. Rest assured, he promised, the Government would only bring such cases in the most egregious examples - there was no interest in federalizing simple medical malpractice cases.

QUALITY OF CARE CASES BEFORE FERA/PPACA

Whistleblowers have been trying to shoehorn quality of care cases into the False Claims Act for well over a decade.(see, e.g., *U.S. ex rel. Swan v. Covenant Care, Inc*., 279 F.Supp.2d 1212 (E.D.Cal. 2002); *U.S. ex rel. Phillips v. Permian Residential Care Center*, 386 F.Supp.2d 879 (W.D.Tex. 2005); *Chesbrough v. VPA, P.C.*, 655 F.3d 461 (C.A. 6 2011)).In the seminal case on the issue, *U.S. ex rel. Mikes v. Straus*, (274 F.3d 687 (C.A.2 001)) the Second Circuit Court of Appeals refused to allow a whistleblower to proceed in a case based upon the allegation that the health care provided was not up to acceptable medical standards. The Court explained in a pair of sentences destined to be quoted by courts around the nation in the ensuing years:

Moreover, permitting 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. Beyond that, we observe that the courts are not the best forum to resolve medical issues concerning levels of care. State, local or private medical agencies, boards and societies are better suited to monitor quality of care issues.(274 F.3d 700)

FERA/PPACA

The Fraud Enforcement Recovery Act of 2009 (“FERA”) was enacted on May 20, 2009. FERA created an entirely new type of “false claim,” improper retention. Previously, the False Claims Act required proof of an actual claim that was knowingly false at the time of its submission.(*U.S. ex rel. Aflatooni v. Kitsap Physician Services*, 314 F.3d 995, 1002 (9th Cir. 2002)) Under FERA, though, knowingly failing to repay an overpayment to the government, even if it was not known to be an overpayment when originally billed, is a false claim. The Patient Protection and Affordable Care Act of 2010 (PPACA), which went into effect on March 23, 2010, clarified the improper retention claim, stating such retention would become a false claim if not repaid within 60 days of knowledge of the overpayment. The new improper retention false claim is the mechanism the Government seems to believe makes quality of care matters viable FCA cases. However, it is not clear the Government has considered the ramifications of such a theory.

PEER REVIEW

In medical peer review a committee of physicians reviews the work of a peer to determine whether it met the appropriate standards of care. By its very definition, the peer review process addresses the same standard the Government might consider in quality of care FCA cases, the

standard of care for the applicable medical care and procedures. Based upon the improper retention theory, once a hospital, through its peer review committee, determines a course of treatment for a Medicare or Medicaid patient fell below the standard of care, it might at that point have identified an overpayment. Peer review committees often review several of a physician's cases, not just the treatment of an individual patient. It is not clear, should the Government begin to actively pursue quality of care cases, how many cases create a critical mass sufficient to trigger a False Claims Act suit. Additionally, should the Government pursue quality of care cases in the same manner it prosecutes other FCA cases, it is likely it will argue that notice of that critical mass is sufficient to put the hospital on notice that all of a physician's claims are suspect. In such a case, failure to fully investigate the physician's entire body of work could fall under the "deliberate ignorance" or "reckless disregard" definitions of "knowledge" under the FCA, greatly expanding potential liability.

The chilling effect on peer review should be obvious. Health care providers will be hesitant to investigate whether a course of treatment met the appropriate standards of care if such a determination could lead to False Claims Act litigation. With its treble damages and penalties of $5,500 to $11,000 per claim, as well as potential decertification as a Medicare or Medicaid provider, the risk could outweigh the benefit of honest, aggressive peer review. Health care providers' peer review procedures are controlled by bylaws, individual state statutes and regulations, accreditation requirements, and more. It is difficult, perhaps even impossible, to significantly change how peer review is performed. However, with the specter of the False Claims Act looming over every peer review determination, providers should approach such activities with a new sense of caution and knowledge of the increased risks and requirements.

MALPRACTICE

Malpractice lawsuits are controlled, in general, by individual State statutes. Patients alleging injuries due to a provider's failure to meet the applicable standards of care can file a lawsuit to be compensated for their injuries. Turning the FCA into a mechanism for policing quality of care creates obvious problems with malpractice cases.

First, anybody can be a whistleblower in a False Claims Act case, where the real party in interest is the United States of America, not the injured patient. A whistleblower could bring such a case, even if it is contrary to the interests of the injured patient. The patient would have no control over the FCA action. The whistleblower, and perhaps the government, could conduct discovery and prosecute the case in a way contrary to the patient's wishes. It could even bring the suit when the patient has no interest in taking any action.

Second, the FCA could be used by injured patients to federalize their cases, circumventing State efforts at tort reform and limits on medical malpractice claims. An ancillary problem is one of insurance - medical malpractice insurance covers claims for negligence, but it does not provide coverage for FCA violations. Providers previously offered some protection by state laws and malpractice insurance would suddenly find themselves practicing in an entirely new, undefined, and unprotected environment. These are not likely risks doctors and hospitals are willing to accept. Their predictable response at a time when there is already a dearth of providers will be to flee the practice of medicine.

Third, how might such claims effect malpractice litigation? A finding of malpractice could lead to an overpayment obligation or potential FCA liability. Would a provider be required to consider repayment and additional potential liability in considering settlement? When would the provider have knowledge of the obligation - at the time the case was filed, at the time a panel or expert witness finds the standard of care was not met, or only upon an affirmative finding by a judge or jury? The time is crucial, for the sixty days to repay the federal health care program runs from the moment of knowledge, though that moment is not actually anywhere defined. If the potential moment of knowledge predates completion of the litigation can repayment be used against the provider as evidence of malpractice? Potential FCA liability creates an new arena of risk, one that requires that a Medicare or Medicaid provider facing malpractice allegations approach them from a new point of view and increased caution.

WHISTLEBLOWERS

The Government offers reassurances that any use of the FCA to police quality of care would be cautious, focused only upon the most egregious of practices. However, such assurances offer no limitations on the actions of whistleblowers. While the Government may refuse to intervene in such cases, it has shown absolutely no proclivity to move to dismiss even the most baseless FCA cases over whistleblowers' objections.The only exceptions are to be found in defense contracting cases in which the Government moves to dismiss based upon threats to national security and classified information during discovery.Whistleblowers would be free to ignore the Government's reassurances and bring FCA cases based upon peer review, malpractice cases, and even the slightest allegations of failure to meet standards of care. Given that a medical standard of care can be quite fluid, and is ultimately based upon experts' opinions of what was appropriate, these are not even cases that could be easily defeated at the motion to dismiss or summary judgment stage, but rather would require fact-based determinations that could only be made by a jury.

CONCLUSION

The FCA, as amended by FERA and the PPACA, is the Government's most powerful tool to combat fraud and overbilling in federal health care programs. The addition of the improper retention claim to the FCA makes it ever more powerful. The limitations on improper retention claims are not clear from the statute and promised regulations have yet to be written. Should the Government decide to add quality of care to its FCA repertoire, or should whistleblowers begin to explore the viability of FCA malpractice cases in federal courts, the ensuing confusion, chilling effects on the practice of medicine, and invasion of patients' own malpractice claims would be just the beginning of an explosion of unintended consequences that would echo through the entire health care industry.

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Should you have any questions, please contact your regular Hall Render attorney.