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Tenth Circuit Revives FCA Claim Based on Alleged Lack of Medical Necessity

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The Tenth Circuit Court of Appeals has issued a significant decision, finding that a physician's medical judgment about the medical necessity of heart procedures can be "false or fraudulent" under the federal False Claims Act (FCA). *United States ex rel. Polukoff v. St. Mark's Hosp., et al.*, No. 17-4014 (10th Cir. Jul. 9, 2018). The district court previously had dismissed the FCA case on a motion to dismiss, a development my colleagues discussed in detail in a prior post. The Tenth Circuit's ruling not only revived relator's *qui tam* FCA case, but also may open the door to more FCA lawsuits based on allegations that claims for treatments or services reimbursed by federal health care programs are "false" because they are not "medically necessary."

The Relator's Allegations in the FCA Complaint

The physician-relator is a former colleague of defendant Dr. Sherman Sorensen, who

provided cardiology services at two hospitals, both of which are also defendants in the FCA lawsuit: Intermountain Medical Center (Intermountain) and St. Mark's Hospital.

Relator alleged that Dr. Sorensen performed medically unnecessary heart surgeries, which were reimbursed by federal health care programs. Specifically, relator contended that Dr. Sorensen performed unnecessary patent foramen ovale (PFO) closure procedures to close a hole in the patient's heart, allegedly to cure migraines and to prevent strokes in patients with an elevated stroke risk. According to relator's complaint, Dr. Sorensen performed an unusually high number of PFO closures: during a time period when the Cleveland Clinic performed 37 PFO closures, Dr. Sorensen performed 861 PFO closures.

The circumstances under which PFO closures are necessary and reimbursable by Medicare were not addressed by any national coverage determination (NCD) or local coverage determination (LCD). Relator thus pointed to guidance from the American Heart Association and American Stroke Association (AHA/ASA) on PFO closures, and Intermountain's internal guidelines for PFO closures that mirrored AHA/ASA guidance. According to relator, the relevant AHA/ASA guidance showed that "there has long been general agreement in the medical community that PFO closure is not medically necessary," except in limited circumstances.

Allegedly False Certifications of Medical Necessity

Because the PFO closures were purportedly not medically necessary, relators alleged that defendants' representation to the government that the PFO closures performed by Dr. Sorensen were medically reasonable and necessary were "objectively false." As to Dr. Sorensen, he allegedly submitted express false certifications by certifying on the CMS-1500 form that the PFO closure procedures were "medically indicated and necessary for the health of the patient." Dr. Sorensen purportedly knew that Medicare would not reimburse for PFO closures to treat migraines, so he represented that he performed PFO closures according to AHA/ASA guidelines. As to the defendant hospitals, they allegedly requested reimbursements for the PFO closures by submitting annual hospital cost reports in which they certified that the services identified in the cost report were provided in compliance with relevant laws and regulations.

The District Court and Tenth Circuit Decisions

The district court dismissed relator's FCA claims on a motion to dismiss and found that representations about the medical necessity of procedures could not be proven to be "objectively false" because "opinions, medical judgments, and 'conclusions about which reasonable minds may differ cannot be false' for the purposes of an FCA claim." Relator appealed the decision.

The Department of Justice (DOJ), which declined to intervene in relator's FCA lawsuit, filed an amicus brief in the appeal. DOJ argued, among other things, that a certification of medical necessity can be false where the claim is not reimbursable. DOJ also disputed the district court's conclusion that medical judgments cannot be proven "objectively false" and argued instead that a factfinder can assess the truth

or falsity of a statement of medical necessity by reference to clinical information and medical documentation, relevant policies and standards, and expert and other witness testimony. DOJ further contended that a reasonable disagreement about the medical necessity of a medical procedure is relevant to "knowledge" under the FCA, rather than "falsity."

While the appeal remained pending, on June 28, 2018, DOJ submitted a letter to the Tenth Circuit, citing the Sixth Circuit Court of Appeal's recent decision in *United States v. Paulus*, No. 17-5410 (6th Cir. June 25, 2018). DOJ argued that the Sixth Circuit "squarely rejected the district court's conclusion in this case that statements involving medical analysis cannot be 'false,'" as well as the district court's finding that "a statement of opinion cannot be false."

The Tenth Circuit found that "[i]t is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA for at least three reasons":

- The Tenth Circuit reads the FCA broadly;
- The fact that an allegedly false statement constitutes a speaker's opinion does not disqualify it from forming the basis of FCA liability; and
- Claims for medically unnecessary treatment are actionable under the FCA.

The court adopted the argument from DOJ's amicus brief that a "Medicare claim is false if it is not reimbursable, and a Medicare claim is not reimbursable if the services provided were not medically necessary." In the absence of any applicable NCD or LCD, the court found that for a claim to be reimbursable, it must meet the government's definition of "reasonable and necessary" as found in the Medicare Program Integrity Manual, including if the procedures were done in accordance with standards of acceptable medical practice. The court thus went on to hold that a "doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary **under the government's definition of the phrase**."

The court acknowledged that its "broad definition of 'false or fraudulent' might expose doctors to more liability under the FCA." But the Tenth Circuit concluded that the United States Supreme Court addressed this concern in *Universal Health Servs. v. United States ex rel. Escobar*, 136 S.Ct. 1989 (2016) through strict enforcement of the FCA's "rigorous" materiality and scienter (i.e., "knowledge") requirements.

Takeaways

The Tenth Circuit's decision may result in more FCA cases based on a purported lack of medical necessity, particularly claims based on alleged departures from industry guidance. The court's decision muddied the waters regarding the test for "reasonable and necessary" (and thus "falsity") by stating the standard is the "government's definition of the phrase." Without a directly relevant NCD or LCD, it is difficult to know under what circumstances the government considered PFO closures medically necessary and reimbursable by federal health programs.

Because the Tenth Circuit adopted a broad definition of "false and fraudulent," the decision may also shift the inquiry in FCA cases based on medical necessity from "falsity" to two other elements of the FCA: knowledge and materiality.

In practice, the lawsuit also suggests that hospitals should monitor compliance with their internal standards and keep an eye out for physicians who perform an unusually high number of certain procedures.