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False Claims Act (FCA) and Medical Necessity: Increasingly Tenuous Relationship

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Article By Laura McLane
Rebecca C. Martin
McDermott Will & EmeryFCA Update Blog

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On January 19, 2017, another district court ruled that a mere difference of opinion between physicians is not enough to establish falsity under the ***False Claims Act.*** In **US *ex rel.* *Polukoff v. St. Mark's et al.***, No. 16-cv-00304 (Jan. 17, 2017 D. Utah), the district court dismissed relator's non-intervened *qui tam* complaint with prejudice based on a combination of Rule 9(b) and 12(b)(6) deficiencies. In so doing, the *Polukoff* court joined *US v. AseraCare, Inc.,* 176 F. Supp. 3d 1282, 1283 (N.D. Ala. 2016) and a variety of other courts in rejecting False Claims Act claims premised on lack of medical necessity or other matters of scientific judgment. This decision came just days before statements by Tom Price, President Trump's pick for Secretary of Health and Human Services (HHS), before the Senate Finance Committee in which he suggested that CMS should focus less on reviewing questions medical necessity and more on ferreting out true fraud. Price's statements, as well as decisions like *Polukoff*, are welcome developments for providers, who often confront both audits and FCA actions premised on alleged lack of medical necessity, even in situations where physicians vigorously disagree about the appropriate course of treatment.

In *Polukoff*, the relator alleged that the defendant physician, Dr. Sorensen, performed and billed the government for unnecessary medical procedures (patent formen ovale (PFO) closures). The relator also alleged that two defendant hospitals had billed the government for associated costs. Specifically, the relator alleged that PFO closures were reasonable and medically necessary only in highly limited circumstances, such as where there was a history of stroke. Medicare had not issued a National Coverage Determination (NCD) for PFO closures or otherwise indicated circumstances under which it would pay for such procedures. However, the relator held up medical guidelines issued by the American Heart Association/American Stroke Association (AHA), which, essentially, stated that PFO closures could be considered for patients with "recurring cryptogenic stroke despite taking optimal medical therapy" or other particularized conditions.

The relator alleged that Dr. Sorensen performed more PFO closures than other physicians throughout the country and that part of the reason for this outlier status was that Dr. Sorensen believed that PFO closures could be used as a "preventative measure for patients who had not yet suffered a stroke, but who had an elevated risk of a stroke." Dr. Sorensen was also alleged to perform the procedures to treat chronic migraines. Notably, one defendant hospital (where relator had performed these procedures) was alleged to have disciplined and ultimately revoked the physician's privileges.

The defendants moved to dismiss on various grounds, including failure to satisfy Rule 9(b), as well as Rule 12(b)(6) for failure to plead an objectively false claim submitted to the government. For Rule 9(b), the court ruled that in *US ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163 (10th Cir. 2010), the Tenth Circuit had stepped away from the more stringent pleading standards in *US ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702 (10th Cir. 2006), and no longer required specific allegations regarding the bills submitted to the government, so long as there was an otherwise "adequate basis for a reasonable inference that false claims were submitted." The court then held that relator had met the specificity requirements as to Dr. Sorensen and for one of the defendant hospitals.

Significantly, however, Court ruled that relator had not adequately alleged a fraudulent scheme against the

second hospital. Relator alleged that the hospital had conducted an internal investigation and took action to stop Dr. Sorensen from performing the procedure on pre-stroke patients, which ultimately led to Dr. Sorensen relinquishing his privileges. In language that will ring true to compliance officers everywhere, the court observed that the hospital's "efforts to curb Dr. Sorensen's use of PFO closures is not evidence of a fraudulent scheme." In addition, the court ruled that the relator had otherwise failed to provide sufficiently individualized details regarding "who, what, when, where" about the hospital's knowledge to survive Rule 9(b).

With respect to Rule 12(b)(6), the court dismissed the remainder of the case on the ground that the relator could not establish that an objectively false claim had been submitted to the government. The court further denied a request to amend on the ground that "in the absence of an objective standard created by the government," FCA claims premised on a medical necessity standard must fail.

The court noted that the relator's claim was based on two closely related requirements: (1) that providers must submit a certification with any request for payment from Medicare stating that the "services shown on this form were medically indicated and necessary for the health of the patient" and (2) the Medicare statute provides that "no payment may be made…for any expenses incurred for items or services …which…are not reasonable and necessary" for diagnosis or treatment. The court succinctly boiled this down, stating "Thus Dr. Polukoff's FCA causes of action rest upon his contention that the defendants represented (either explicitly or implicitly) that the PFO closures performed… were medically reasonable and necessary and that this representation was false."

Noting that the FCA requires "proof of an objective falsehood" and that FCA liability "must be predicated on an objectively verifiable fact," the court pointed to the reasoning of *AseraCare*, that a "mere difference of opinion between physicians, *without more*, is not enough to show falsity." The court went on to hold that the relator could not demonstrate that defendants' representations regarding the reasonability and necessity of the PFO closures could "be proven to be objectively false": "Opinions, medical judgments, and 'conclusions about which reasonable minds may differ cannot be false' for the purposes of an FCA claim." The court further held that the relator's assertion that some of the procedures were not reasonable or necessary because they were performed on patients who had not suffered a stroke was a subjective medical opinion that could not be proven objectively.

Significantly, the court expressly found that the AHA medical guidelines proffered by the relator could not be equated with the "medical necessity standard imposed by Medicare," observing that Medicare "does not require compliance with an industry standard as a prerequisite to payment" and thus failure to comply with those standard does not support a claim that the certification of medical necessity is objectively false. Finally, the court observed that the government was free to clarify the conditions under which it will or will not pay for a procedure, but "in the absence of an objective standard created by the government," attempts to prove a violation of the "reasonable and necessary" standard would necessarily rest on evidence of "medical opinions and subjective standards of care rather than objectively false representations."

Polukoff is welcome news for health care providers. In cases where the FCA is used by the government and relators to monitor and attempt to punish allegedly "fraudulent" conduct that, in reality, involves questions of physician judgment, *Polukoff*'s adoption of *AseraCare*'s logic gives added weight to arguments against liability premised on disagreements over clinical decision-making.