Legal Opinion Letter

Vol. 24 No. 18 October 9, 2015

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

Court Holds that Defendant's Plausible Interpretation of Ambiguous Regulation Defeats False Claims Act Liability

by Kristin Graham Koehler

A federal district court in Kansas City, Missouri has held that a company that follows a "plausible" interpretation of an ambiguous federal reimbursement regulation cannot be liable for "knowingly" violating the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq*., even if a "more reasonable interpretation" exists. *United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City*, No. 4:12-cv-0876, 2015 WL 3616640, *10 (W.D. Mo. June 9, 2015).

This dispute centered on the Medicare regulations that set reimbursement rates for anesthesia services. The Centers for Medicare and Medicaid Services ("CMS"), the federal agency that administers the Medicare program, reimburse anesthesiologists at different rates, depending on the extent to which they are personally involved in the medical procedure. An anesthesiologist is eligible for reimbursement at the "Medical Direction" rate if he or she oversees nurse anesthetists in up to four procedures concurrently, so long as the anesthesiologist "personally participates in the most demanding aspects of the anesthesia plan," including "emergence," the process during which the anesthesia patient gradually regains consciousness. 42 C.F.R. § 415.110(a)(1). If the anesthesiologist does not personally participate in "emergence" and satisfy other requirements, he or she is reimbursed at a lower rate.

Relator John Donegan—now deceased—filed a *qui tam* suit against his former employer, Anesthesia Associates of Kansas City ("AAKC"). It alleged that anesthesiologists at one of AAKC's medical centers consistently were not present during "emergence," but that AAKC fraudulently billed Medicare at the "Medical Direction" rate based on the false representation that they were present. *Donegan*, 2015 WL 3616640, at *5–6. AAKC denied that allegation, disputing the relator's definition of "emergence." *Ibid.*

According to the relator, "emergence" ends in the operating room, and anesthesiologists must be physically present in that room to qualify for the "Medical Direction" rate. *Id.* at *6. By contrast, AAKC argued that "emergence" is a lengthy and gradual process that continues in the recovery room. AAKC asserted that it complied with the regulation because its anesthesiologists visit the patient either "in the operating room, in the hallway during the patient's transfer to the recovery room, or after the patient arrives in the recovery room." *Id.* at *5.

The district court held that the reimbursement regulation was "ambiguous," and that AAKC's interpretation was "plausible." *Id.* at *10. As the court explained, "CMS has not defined emergence" in the regulation itself or any other guidance document. *Id.* at *5. In addition, the court found no "consensus within the anesthesia community" on when emergence ends. *Id.* at *10. As the court observed, medical literature indicates that the duration of "emergence" can be "different" for "each patient." *Id.* at *5.

Kristin Graham Koehler is a Partner in Sidley Austin LLP's Washington, DC office.

The court further held that AAKC's "plausible" interpretation of the regulation defeated any claim that AAKC violated the FCA. *Id.* at *10. To violate the FCA, a person must act "knowingly"—*i.e.*, with "actual knowledge," "deliberate ignorance," or "reckless disregard of the truth." 31 U.S.C. § 3729(a)(1)(A) & (b). In *United States ex rel. Ketroser v. Mayo Foundation*, 729 F.3d 825 (8th Cir. 2013), the Eighth Circuit held that a defendant's "reasonable interpretation" of an "ambiguous" regulation "belies the scienter necessary" to establish an FCA claim. *Id.* at 832. Relying on that precedent, the district court reasoned that AAKC's plausible reading of "emergence" negated the assertion that it "knowingly" committed fraud. *Id.* at *8–10.

In reaching that decision, the court rejected the position taken by the United States, which had declined to intervene in the case, but filed a Statement of Interest. *See* Statement of Interest, *United States ex rel. Donegan v. AAKC*, No. 12-876 (Feb. 13, 2015) (Doc. No. 272). According to the United States, "the mere fact of ambiguity in federal regulations . . . does not establish an absence of *scienter* . . . , even if defendant can later articulate a reasonable interpretation of those regulations." *Id.* at 3. Instead, the court must conduct a "fact-based assessment" of the defendant's "state of mind." *Id.* at 3–4. If the defendant "recognized an ambiguity" in the regulation at the time it submitted a claim, but "made the decision not to inquire" into other possible interpretations the relevant federal agency "might" favor, liability may be appropriate. *Id.* at 3, 5.

The district court rejected this fact-based standard as foreclosed by Eighth Circuit precedent. Under the district court's analysis, unless there is an "'authoritative contrary interpretation, . . . a defendant does not act with the requisite deliberate indifference or reckless disregard by taking advantage of a disputed legal question.'" *Donegan*, 2015 WL 3616640, at *10 (quoting *United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1190–91 (8th Cir. 2010)) (additional internal quotation marks omitted).

Thus, the court refused to hold AAKC liable even though the relator had "arguably put forth a more reasonable interpretation," and even though AAKC had a "financial motive" for its contrary position. *Id.* at *10. In the district court's view, unless the relator could show that "*no* reasonable interpretation of the law" supported AAKC's position, AAKC could not "knowingly" violate the FCA. *Ibid* (emphasis added). The relator's estate has appealed the decision to the Eighth Circuit, where briefing is underway.

The district court's decision joins a substantial line of authority in which courts have declined to impose FCA liability on defendants who followed a reasonable interpretation of a regulation or contractual provision in good faith. *See*, *e.g.*, *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999); *Hagood v. Sonoma Cnty. Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996).

The decision is particularly notable because it indicates that courts typically can conduct this analysis as a matter of law—*i.e.*, by examining the regulation and relevant guidance documents—without an extensive factual investigation into the defendant's state of mind. This conclusion is sensible: If an FCA defendant's construction of an ambiguous regulation is reasonable as a matter of law, it should be difficult—if not impossible—to demonstrate that the defendant acted with the "actual knowledge," "deliberate indifference," or "reckless disregard" necessary to prove a violation of the FCA. This decision is welcome news to corporate clients, which must regularly interpret complex—and, often ambiguous—regulations.

 ISBN 1056 3059