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## Eighth Circuit Affirms that an Objectively Reasonable Interpretation of an Ambiguous Regulation Defeats Liability Under the False Claims Act

In *United States ex rel. Donegan v. Anesthesia Associates of Kansas City, P.C.*, 833 F.3d 874 (8th Cir. 2016), the Eighth Circuit affirmed that a defendant cannot be liable under the False Claims Act (“FCA”) for claims for payment that allegedly violated an ambiguous regulation if the defendant held a reasonable interpretation of the regulation. The case provides a valuable reminder to potential FCA defendants of the utility of carefully and contemporaneously documenting one’s interpretation of ambiguous government regulations.

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### Background

The Relator, Timothy Donegan, alleged that his former employer, Anesthesia Associates of Kansas City (“AAKC”), violated the FCA by submitting claims for Medicare reimbursement from anesthesia services at the “Medical Direction” rate. According to Donegan, such claims were knowingly false because AAKC anesthesiologists were not present in the operating room during patients’ “emergence” for anesthesia, which was allegedly a condition of payment for submitting claims at the Medical Direction rate. The Medical Direction rate applies when an anesthesiologist directs a qualified individual in up to four concurrent anesthesia cases. The Medicare regulations require the anesthesiologist to complete seven steps, including “personally participat[ing] in the most demanding procedures, including, if applicable, induction and emergence.” *Id.* at 877 (quoting 42 C.F.R. § 415.110). Donegan alleged that AAKC’s anesthesiologists were virtually never present for “emergence” because they did not visit the patient after surgery until they were in the recovery room. Donegan claimed that “the broadest definition of ‘emergence’” ends when the patient is turned over to the recovery room nurse.

The United States declined to intervene in the case. After extensive discovery, the District Court in the Western District of Missouri granted summary judgment to the Defendant because the Relator failed to establish that the Defendant “knowingly submitted false claims.” *Id.* at 877-78. Specifically, the District Court found that the term “emergence” is ambiguous and had not been defined by CMS, and that AAKC’s definition of “emergence” as a process that includes the patient’s recovery time was objectively reasonable. Because AAKC held an objectively reasonable interpretation of the ambiguous regulation, it did not have the scienter necessary to establish a claim of fraud under the FCA. The Eighth Circuit agreed with the District Court’s conclusions on these points of law.

### Eighth Circuit’s Holding

The Eighth Circuit observed that there was no CMS definition or controlling guidance defining the key term “emergence.” Given the term’s “obvious lack of a plain meaning,” it agreed that the regulation was ambiguous. *Id.* at 878. In internal company documents, AAKC, however, had defined emergence in 2001 (before Donegan began his employment) “to include the recovery room.” In addition, both parties’ experts agreed that “emergence” is a process that can extend into the recovery room. On that record, the Eighth Circuit held, as a matter of law, that AAKC’s interpretation was objectively reasonable, even if CMS or a reviewing court could interpret the regulation differently. *Id.* at 879. Accordingly, Donegan’s allegations amounted to “a claim of regulatory noncompliance, not an FCA claim of knowing fraud.” *Id.*

The *Donegan* case is consistent with the Eighth Circuit's earlier ruling in *United States ex rel. Ketroser v. Mayo Foundation*, which held that an FCA defendant's reasonable interpretation of an ambiguous regulation "belies the scienter necessary to establish a claim of fraud under the FCA." 729 F.3d 825, 832 (8th Cir. 2013).

The *Donegan* opinion clarified, however, that an objectively reasonable interpretation does not necessarily or automatically defeat a finding of FCA scienter. According to the Eighth Circuit, summary judgment on the basis of FCA scienter would not be proper if the relator produced sufficient evidence of government guidance that warned against an otherwise reasonable interpretation of an ambiguous regulation. In that circumstance, there would be sufficient evidence that the defendant acted in reckless disregard of the truth or falsity of the claims for payment to defeat summary judgment. *Donegan*, 833 F.3d at 879-80.

### Takeaways

A key takeaway from the *Donegan* ruling for potential FCA defendants is the importance of promptly and clearly documenting any assumptions made about the interpretation and application of government regulations that might be important to claims they submit to government entities for payment. As part of that process, businesses should also confirm what guidance, if any, the relevant agencies have provided about the relevant regulations. Careful review and documentation could save a potential FCA defendant from onerous litigation costs and possible liability.

If you have any questions or would like to discuss the foregoing or any related matter, please contact the Ropes & Gray attorney with whom you regularly work, or an attorney in our [False Claims Act](#) practice.